



EMORY  
UNIVERSITY

Institutional Review Board

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Emory University IRB

# STANDARD OPERATING PROCEDURES

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## ADMINISTRATIVE

<b>SOP Title:</b>	SOP Portfolio Modifications
<b>SOP Category:</b>	Administrative
<b>Established:</b>	8/29/2013
<b>Last Revision:</b>	4/22/2022

### PURPOSE

The purpose of this document is to describe the process of adding or modifying approved SOPs, Guidance, and Policies ('IRB documents') into the designated H drive area.

### SCOPE OF SOP

The SOP applies to the SOPs, Guidance, and Policies affecting the Emory IRB.

### RESPONSIBILITIES

- **IRB Designated SOP Manager:** Add approved IRB documents to the designated H drive area.
- **IRB Director:** Gives final approval of any new SOP in the designated H drive area.
- **IRB SOP Sub-committee:** Identifies the need for the creation or modification of existing IRB documents.
- **Huron:** periodically, the eIRB system vendor (Huron) will send updates to improve the electronic system. These updates may include updates based on changes in the guidance or policies affecting human subjects' research. These changes will come in the form of updates to the electronic system and the Huron Toolkit.

### PROCEDURE

*Note: The official SOP Portfolio is a pdf document that is uploaded to our website documents folder. There's no link to it from our website itself to keep the document accessible only to the IRB staff. The direct link to the portfolio is: <http://www.irb.emory.edu/documents/SOP%20Portfolio.pdf>*

#### After Huron updates

1. Periodically, Huron will update the electronic system and Toolkit. The Toolkit is the group of regulatory documents Huron created to be used with the electronic system. At Emory, we are only implementing a selection of the checklists and worksheets from the Toolkit.
2. When a Huron update affects our SOPs, P&Ps, checklist, and worksheets, we will update these documents in the next 30 business days, if required.

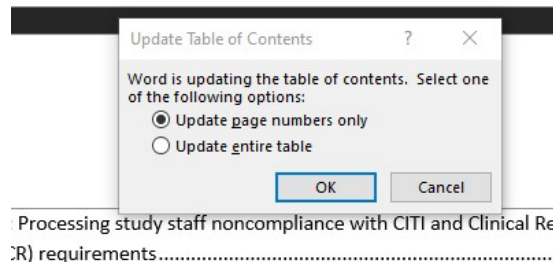
#### For SOP portfolio suggestions (staff)

1. To suggest changes to an SOP, copy the SOP from the SOP portfolio document in word.
2. Track changes and alert the IRB Designated SOP Manager. Save copy under H:\General\Admin IRB Documents\SOP Portfolio\SOPs in process\_Pre Approval Not Ready to Add in to the Portfolio Yet\In progress
3. Ask a member of the staff leadership team to review the change. For a new SOP, the IRB Director should approve it before adding it to the SOP portfolio.
4. After the Director or staff leadership member, as applicable, approve the new or changes to an existing SOP, move the document to the folder entitled H:\General\Admin IRB Documents\SOP

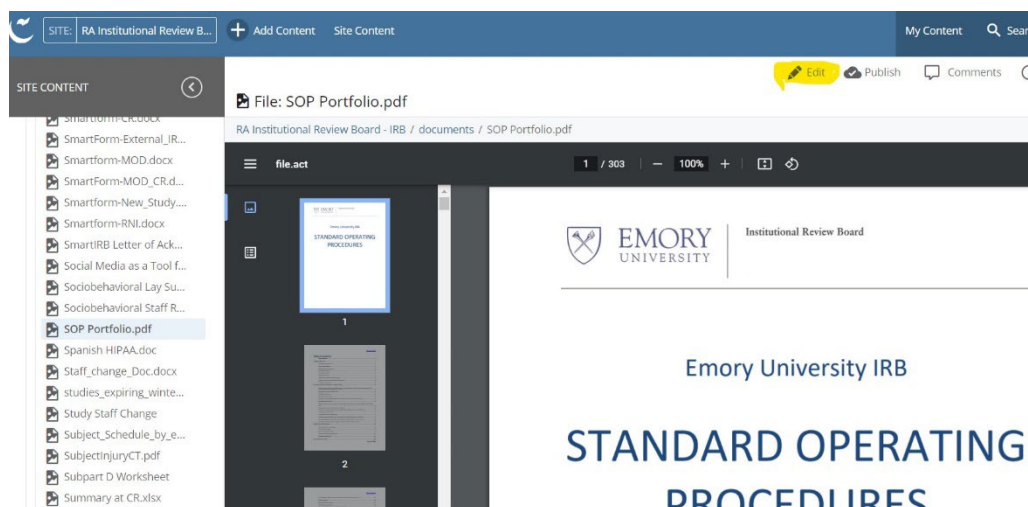
Portfolio\SOP Portfolio Source Files & Where TLs track in ready to go live changes\Revised SOPs Already Approved and Ready to track in to the SOP and go live

Instructions for the SOP Portfolio manager

1. Track and make the approved changes to the Word document portfolio (<H:\General\Admin IRB Documents\SOP Portfolio\SOP Portfolio Source Files\SOP Portfolio.docx>)
  - a. Some changes could have been made to the clean copy, 'clean copy for future tracked changes' of the current portfolio located at H:\General\Admin IRB Documents\SOP Portfolio\SOP Portfolio Source Files
  - b. For other changes located under the "Ready for Add to Portfolio" folder, copy and paste just the body text of the new/revised SOP into the main portfolio; copying the header and the log of changes often led to formatting issues.
  - c. Add a new version date on the SOP that should be the date of the release of the SOP to the staff.
  - d. Under "Log of Significant changes" add the date of the portfolio revisions (same as the date on c) and describe the changes. Be as descriptive but succinct as possible.
  - e. After all the changes are made, remember to update the table of contents so that the page numbers are accurate. This is done automatically by simply right-clicking on the table of contents, click on "update field, and then on "Update entire table"



- f. Review the table of contents and delete any subheaders.
    - g. Keep a copy of the tracked version, and create a new, clean version. PDF the clean version.
2. Update the online SOP portfolio with the revised, clean PDF version:
  - a. Log in to Cascade: <https://cascade.emory.edu>
  - b. Select "RE Institutional Review Board – IRB" from the dropdown menu at the very top of the first window
  - c. From the left-hand menu, navigate to Base Folder/documents/SOP Portfolio.pdf
  - d. Go to the "Edit" tab
  - e. Select the revised PDF version of the portfolio, then click Submit



- f. After replacing with the new version, click on “Publish”.
3. After about a minute or so, check the online SOP link to make sure that the most recent version was successfully uploaded. You may need to press your browser’s refresh button to clear the cache (force it to “forget” the old version)
4. Email or note in teams channel chat the IRB staff, letting them know about the changes, with a copy of the tracked SOP portfolio. Direct the Pod leaders to review these changes at their next meeting and add them to the next IRB staff meeting for in-depth review if needed.

See below an example of such an email/teams chat notification:

**Subject:** Changes to SOP Portfolio: November 1, 2018

Hi everyone,

Please, review the [latest changes for the SOP portfolio](#), to keep up-to-date with new processes, as applicable.

**Remember to refresh your browser in case you do not see the changes.**

**Sr. RPAs: PLEASE SAVE THIS IN THE IMPORTANT NEWS TAB OF YOUR POD REPORT TO REVIEW DURING THE NEXT POD MEETING. FEEL FREE TO REVIEW ONLY THE SOPS AFFECTING YOUR TEAM.**

See the attached document for additional details on these changes. The following SOPs were modified, added, or deleted:

**Changes to SOPs (see changes in attached tracked changes document)**

- SOP Portfolio Modifications- Updating to reflect current practice
- Meeting Facilitation Responsibilities- Added that Meeting Materials be added as supporting documents to the Submit RNI Committee Review activity for RNIs.
- Modifications- Processing from Preliminary Analysis through Approval- Changes in the process to review contingency reviews.
- eIRB Processing of New Study Applications- Preliminary Analysis through Approval- Changes in the process to review contingency reviews.

- Certificate of Confidentiality Process in non-federal studies- Updated to follow new Online Certificate of Confidentiality System User Guide dated 06/25/2020.
- Continuing Review Processing-Preliminary Analysis through Approval- Changes in the contingency review process

**New SOP**

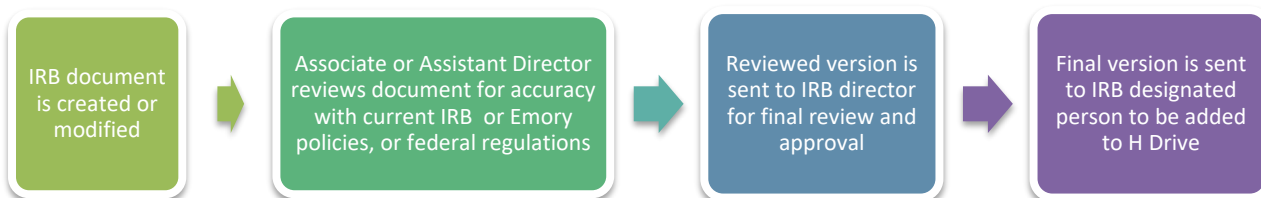
- Advarra Study Processing from Submission to Approval

Let me know if you have any questions,

NAME

5. Save a copy of the email or teams chat notification sent to the staff under H:\General\Admin IRB Documents\SOP Portfolio\Emails or Notifications sent to staff about portfolio changes
6. Save the tracked and PDF versions of the SOP in the archived portfolios folder located at H:\General\Admin IRB Documents\SOP Portfolio\Archived Portfolios

**PROCESS FLOW**



**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
5/5/2021	Updating to reflect current practice
5/24/2021	Added more details in this process, updating graphics
1/21/2022	Removed section about SOP subcommittee & archived log of changes over a year old & updated folder location for archived portfolios
4/22/2022	Updated based on current practice

<b>SOP Title:</b>	Listserv Responsibilities
<b>SOP Category:</b>	Administrative
<b>Established:</b>	9/4/2013
<b>Last Revision:</b>	9/11/2023

**NOTE:** Listserv responses **MUST** be given the same day or at the latest the next day, with no exceptions. If you can't fully respond, at least email to say that you are working on it (or have passed it on to someone, see "Required Procedures for Handling Listserv" below). Listserv day starts at 4 pm the day before the assigned day. The shift ends at 3:59 pm on the assigned day. For example, for someone with a Wednesday assigned day, the shift will start at 4 pm on Tuesday and end at 3:59 pm on Wednesday.

<b>Required Procedures for Handling Listserv</b>	
If you send a response to a listserv email	<u>Not required but preferred practice:</u> Bcc yourself on the response and then save the blind copy to your "Listserv Duties" folder to more easily keep track of what you have done and can let other IRB staff know what has been done if they have questions. Alternatively, save the sent email into your Listserv duties folder.
If you forward the email to another analyst	ALWAYS do so by clicking "Reply" and CC'ing the analyst. The reply should let the sender know you've received their email and are sending it to [analyst] to handle it. That way the sender knows who's responsible for their inquiry.
If you cannot cover listserv due to illness or vacation	Communicate with another listserv staff member to ensure coverage (e.g. switch days for that week) and inform one of the Directors (or direct supervisor)
CITI Completion Reports	Just move to your "CITI Completion Reports" folder under inbox (best to set up a "Rule" so Outlook does this automatically)
If you handle listserv on a University Holiday	Complete tasks from your assigned day when you return to the office.
If designated person [see <a href="#">contact grid</a> ] from Emory Admin Assistant is unavailable during your listserv day	Complete Emory Admin Assistant Designated Person's tasks.

<b>Types of Emails</b>	<b>How to respond/Action taken</b>
Complaints from participants	Forward to Team Q (Shara Karlebach); cc Director

Compliance or UP-related	Send it to Team Q (Shara Karlebach, Jessica Blackburn, Jackson Parker, Briana Rotterman). If a specific study is mentioned, CC the owner of the study.
Contact IRB Staff Activity	<p>Emails with this Subject line are generated when someone logs a comment in a study before the study is assigned to an analyst.</p> <p>If the comment is informational and not at all time-sensitive – someone will see it once it has been assigned – you don’t need to do anything about this type of email – Bcc yourself to indicate that no response was made and save to your “Listserv duties” folder.</p> <p>If the comment is a question or request for assistance that requires a response, you will need to 1) either send an email as a response, 2) refer the issue to someone else, or 3) respond via logged comment. Remember to Bcc yourself to keep track of what was done.</p>
Corp_IRB_Options.xls from ORA-IT or OSP	The subject line is “Corp_IRB_Options – Records Found.” Note: Proposal ID is NOT the IRB file number. Listserv person is not expected to do anything with this email.
PRMC approvals (*)	<p>Forward to the designated person (<a href="#">see contact grid</a>). The designated person will upload as a comment in eIRB. In addition, the designated person will upload DSMB plans, when submitted via listserv.</p> <p>The comment should include whether a study was approved, pending, or disapproved. Distinguish between DSMB plans and PRMC approval.</p>
DSMC Plan approvals	Disregard any that are received.
eIRB account requests	Direct to the IRB Website: <a href="http://www.irb.emory.edu/eirb/index.html">http://www.irb.emory.edu/eirb/index.html</a>
Emails containing identifiable health information, like the name of the study subject.	Delete the email from all folders (including the "Trash") and send an email to all IRB staff (do NOT include the PHI) and request that they do the same (identify the email by sender or subject).
Fee/Cost Questions	<p>Refer them to OCR’s memo on research fees located here: <a href="http://www.ocr.emory.edu/policies/index.html">http://www.ocr.emory.edu/policies/index.html</a> (pull-down ‘Research fees’). Otherwise, Sheila O’Neal, the finance supervisor for OCR, has offered to answer any questions about IRB fees or fee schedules.</p>
FWA, IRB registration questions	First check the IRB website for the answer (or direct the questioner): <a href="http://www.irb.emory.edu/about/overview.html">http://www.irb.emory.edu/about/overview.html</a> . If still unclear, forward to IRB Director.
IRB authorization agreements, collaborating with other institutions	Forward to Julie Martin

Membership List Requests/Roster Requests	The IRB does not provide rosters generally. Sponsors may use the <a href="#">compliance letter</a> to confirm that no conflicted members take part in IRB reviews. Refer to Contact Us section on the IRB website for a partial roster (IRB Members): <a href="http://www.irb.emory.edu/about/staff.html">http://www.irb.emory.edu/about/staff.html</a> If a pdf is requested, they can copy and paste the information from the website into Word.
Need a copy of CITI completion report	Give them the web address of the CITI website. If they then say they still can't access their report, we can send it to them. You can also assure them that our analysts check completions when we screen studies, and we don't need the certificate. You can also request a reset on the CITI website for the member to get a temporary password sent to their email.
Emails stating Costs option chosen for a particular study (*)	Forward to the designated person ( <a href="#">see contact grid</a> ). The designated person will copy the attachment to their personal computer. The designated person should open the corresponding study in eIRB and log a comment like "CTA Cost Option is #___ per attached" and attach the file.
CHOA In Case of Injury (ICOI) and Cost Options	Forward to the designated person ( <a href="#">see contact grid</a> ). The designated person will copy the attachment to their personal computer. The designated person should open the corresponding study in eIRB and log a comment like "ICOI Option is #___ per attached" and attach the file.
PowerChart access inquiries from Emory Healthcare IT"Personnel Verifications" (*)	No longer doing. If you receive an email about power chart verification, reply stating: "The Emory IRB is no longer providing Power Chart verifications. Please contact your leadership for more information."
Research Match emails	Forward to IRB Director
Removal from or addition to IRB listserv ("blast") requests	Forward to Briana Rotterman (Team Q)
Request for an in-person consultation	Take the first one, and then email office about additional requests during the day. If the request is regarding reliance, send to the reliance Assistant Director.
Study staff change questions	Forward to student workers; CC Associate or Assistant Directors and/or Director
Study-related questions	Forward to the analyst who owns the submission. If the analyst isn't available on the day you are monitoring listserv, forward to Associate or Assistant Director.
WCG IRB questions, notifications, and forms	Do nothing if they come directly from WCG IRB. If they are emails from a study team, please forward it to WIRB Listserv. Also, please forward any WCG IRB emails regarding Cost, ICOI, or OoQ.
Other	If unsure how to handle requests that are not noted in this chart, forward to Staff leadership and request assistance. Depending on the situation, you may



	need to reply to the sender to acknowledge receipt and let them know that it is being considered.
Emails from OIT about security reviews	An email will contain a report that should be uploaded under the study history. If there are issues with finding an IRB number, please contact Shara Karlebach for help. If the report indicates any critical issues, indicate that in the comment as the study cannot be approved if still planning to use the software or app.
Voicemails from IRB general number received via email	The person covering the Emory listserv is in charge of calling/emailing people back. The listserv may forward the message to another person as done for emails received in the listserv inbox, including inquiries about studies.
Sponsor not in the list in eIRB	Review the <a href="#">Compass Sponsor list</a> . If the requested sponsor is not on the Compass Sponsor list, <a href="#">fill this form</a> to request the sponsor to be added to the system. Note that you will need the following information <b>about the sponsor organization</b> to complete the form: legal name, address, phone number, and URL. Let the study team know that after ORA IT receives this request, they will need confirmation from OSP. If the requested sponsor is on the Compass Sponsor List, fill out <a href="#">the form</a> - can make hyperlink or use the same hyperlink in the form. "In #1 enter 'yes,' then enter the customer number, which is in the first column of the Compass Sponsor list next to the sponsor in question."
Reliance/Single IRB Questions	Provide them a link to the Collaborative Research page on our website and copy reliance Assistant Director and <a href="mailto:irb.reliance@emory.edu">irb.reliance@emory.edu</a>
<b>Not Research/ Not-Human-Subjects/Not-Human-Subjects-Research/Not-Engaged</b>	See the SOP, <i>Not Research/ Not-Human-Subjects/Not-Human-Subjects-Research/Not-Engaged</i>

(\*) If the designated person is out of the office, the listserver is responsible for those tasks.

#### LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
9/11/2023	Replacing Enid Sullivan with link to contact grid. Archiving logs older then on year of significant changes & clarification on what 'analyst isn't available' means

<b>SOP Title:</b>	Mass Email Listserv Management
<b>SOP Category:</b>	Administrative
<b>Established:</b>	11/6/2015
<b>Last Revision:</b>	10/14/2021

## PURPOSE

Provides steps generate a list of recipients for a mass email from the IRB, formatting of the email, and management of the listserv online system.

## SCOPE

Applies only to IRBResearch-L listserv, not for IRB-L listserv (associated with [irb@emory.edu](mailto:irb@emory.edu)).

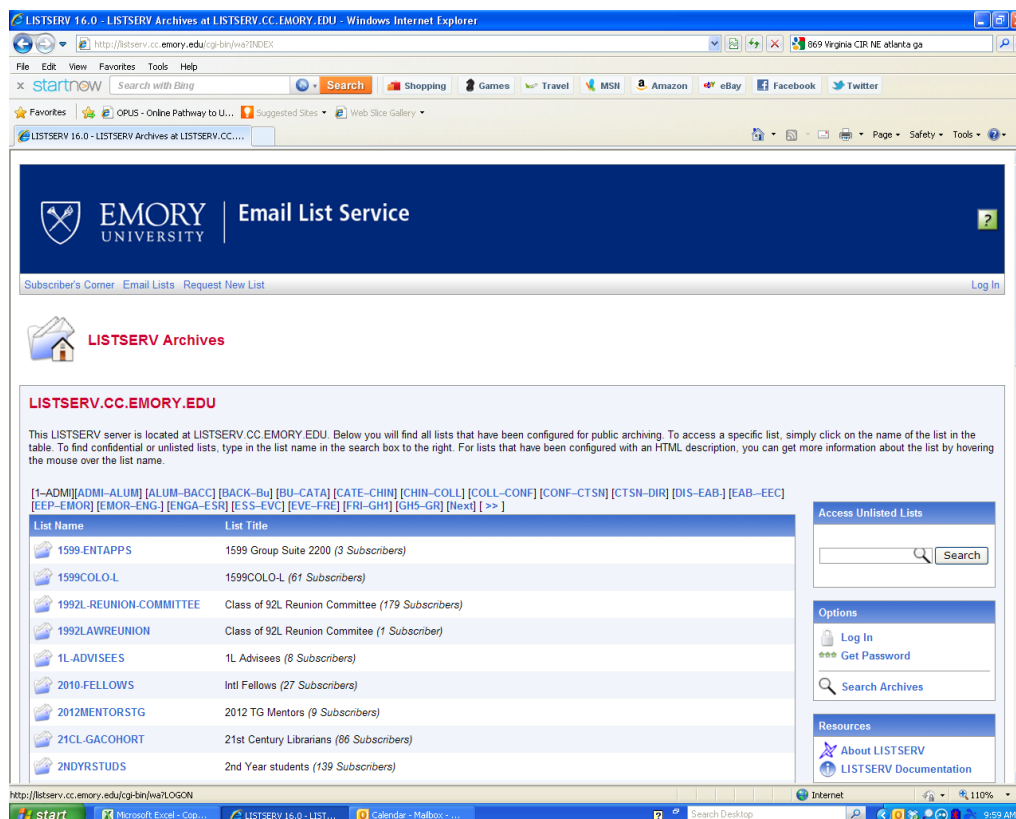
## DEFINITIONS

- **Blast:** the email sent to all subscribers to the IRBResearch-L listserv.

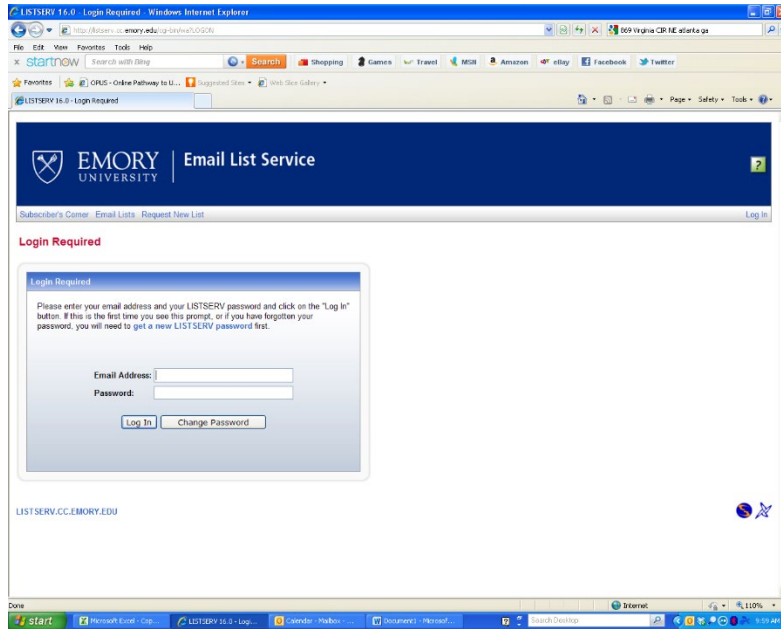
## PROCEDURES

### Logging in for the first time

1. Go to <http://listserv.cc.emory.edu/cgi-bin/wa?INDEX>

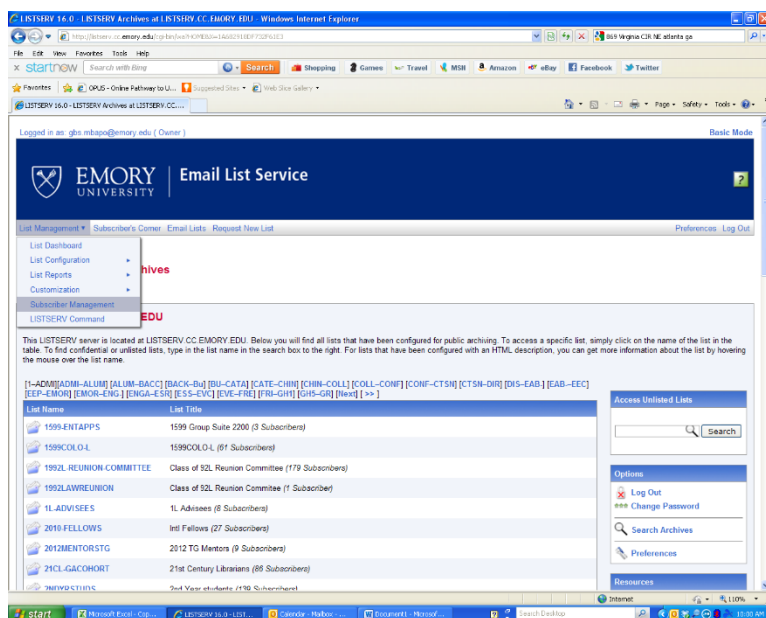


2. If this is your first time – click on the blue text: get a new LISERSV password.



### Creating Email List

1. Run the custom [ORAIT All emails for mass mailing](#) and export results
  - a. This pulls the emails of all eIRB accounts
  - b. eIRB does not remove old/expired accounts; there will be redundancies, but they are irrelevant to the Blast process
2. Remove all columns except Emails
3. Save as Text (Tab delimited) to the E-mail blasts folder on H
  - a. General/QA Working Files/E-mail blasts/YEAR/MONTH
4. Go to the Emory Email List Service website
  - a. <http://listserv.cc.emory.edu/>
  - b. [You should use SSO log in](#)
5. From the top-left drop-down menu, select Subscriber Management



6. Select the Bulk Operations tab
7. Select the Add/Do Not Remove option and choose the exported data as the Input File
8. Import the file, checking for any error messages
9. Open the Remove from listserv spreadsheet in the Email Blasts folder
10. Remove all columns except emails and save as Text (Tab delimited) in /YEAR/MONTH folder
11. Return to the listserv website and select the Remove/Do Not Add option and import the new Remove spreadsheet
12. Open the Add to listserv spreadsheet in the Email Blasts folder
13. Remove all columns except emails and save as Text (Tab delimited) in /YEAR/MONTH folder
14. Return to the listserv website and select the Add/Do Not Remove option and import the new Add spreadsheet

### Writing the Blast

1. Solicit topics from IRB staff
2. Use a previous blast or the blast template as a guide
3. Draft the blast in a Word document so that revisions can be more easily tracked
  - a. Formatting Components (for reference):
    - i. Title: Emory IRB Update at Cambria 26, Date at Cambria 12
    - ii. Table of Contents: Linking to individual sections; Title at Cambria 13 and Items at Calibri 11
    - iii. Content: Titles linking back to TOC; Titles at Cambria 13, Body Text at Calibri 11
    - iv. Contact us: Includes IRB email, phone number, website, and physical office; Title at Cambria 16, Body Text at Calibri 11
    - v. Unsubscribe instructions: Send unsubscribe email to listserv or request to IRB email; Calibri Italic 10
  - b. TOC title link to sections
    - i. Highlight section title
    - ii. Right-click and select Hyperlink...

- iii. Select Place in this Document
    - iv. Select the appropriate Heading
4. Content headings link back to the TOC
  - a. As above
  - b. Select the Things to Know heading
  - c. Repeat for each heading
5. To create new headings
  - a. Go to the View Tab
  - b. Select Outline view
  - c. Add desired text
  - d. Set as Level 2
6. Once the blast draft is ready, send it as an attachment to all the TLs for their input and revisions.

#### Unsubscribing instructions

1. Users can unsubscribe via two methods:
  - a. Send an email to [listserv@listserv.cc.emory.edu](mailto:listserv@listserv.cc.emory.edu) and type **UNSUBSCRIBE IRBRESEARCH-L** in the body of the email, the subject should be left blank
    - i. This automatically removes them from the list and generates an email to [irb@emory.edu](mailto:irb@emory.edu) and to the listserv manager(s)
  - b. Send a request to [irb@emory.edu](mailto:irb@emory.edu). Please include the email address you wish to have removed
2. Add emails of individuals unsubscribing from listserv (via any method) to the master Remove from listserv spreadsheet
  - a. If individuals still have eIRB accounts, their emails will be included in the original export file, even if they have unsubscribed. This is why you must continuously update this list, so that the unsubscription is saved.

#### Sending the Blast

1. Paste the drafted blast into an email. Make sure the banner image is centered in the email.
2. Ensure HTML is enabled
3. Double check that all links work correctly.
4. Send the email to [irbresearch-l@listserv.emory.edu](mailto:irbresearch-l@listserv.emory.edu)

#### Adding/Removing List Owners

1. Log in to the Emory Email List Service
2. From the List Management drop-down, select List Configuration, List Configuration Wizard, then the List Maintenance tab
3. Add/Remove the relevant email from an Owner line
  - a. Be sure to use the [netid@emory.edu](mailto:netid@emory.edu) email address
4. Save

#### Archiving the Blast\* on the IRB Website

\*Only for news-related blasts. Webinar or other education-related blasts don't need to be archived.

1. Log in to Cascade
2. Navigate to the Education, Past News and Email Blasts, Past Email Blasts page
3. Copy and paste the information in a new section of the page. You will have to adjust formatting a lot. You should remove all links except for links within blast news items to helpful documents.
4. You don't need to include the Helpful Links or Unsubscribe information.
5. Title the new section according to the blast title.

#### **LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
7/2/21	Updated report name for SaaS and log in instructions for SSO
10/14/21	Revised direction of drop down menu reference & archived log of updates over 1 year old

<b>SOP Title:</b>	IRB Staff Study Checklists/Worksheets/Other documents Updates
<b>SOP Category:</b>	Administrative
<b>Established:</b>	5/24/2021
<b>Last Revision:</b>	5/24/2021

**PURPOSE**

This SOP will detail the process of updating information in the IRB Staff study checklist and worksheets.

**RESPONSIBILITIES**

- **IRB Director/Team Lead:** makes changes to the checklists, worksheets or other documents and informs the IRB Staff.

**PROCEDURES**

- These changes can only be made by team leads. The documents are [stored here](#) (IRB-Leadership/Documents/Linked docs-do not move or touch).
- To make changes to the documents, click on the ellipsis.
- Click on “open” and then “open in app”
- Save a local copy before making any changes.
- Click on “Review” and then “Track Changes”. Save a clean and tracked version of the document. Make sure you update the document version in the footer. The clean version should have the same name as the one in the one drive folder.
- Drag and drop the new, clean version of the folder in the one drive folder to replace the document. Make sure the name of the document is the same as the one saved in the folder, so the document is replaced.
- Announce the changes in Teams, under “IRB-Staff-To Remember”. Attached the tracked version of the document.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	Onboarding New IRB Staff
<b>SOP Category:</b>	Administrative
<b>Established:</b>	5/13/2015
<b>Last Revision:</b>	09/11/2023

## PURPOSE

Newly hired employees at the Emory IRB will be trained through a structured training program described in this SOP. This program will not only require the participation from the new hire but also current staff members of the IRB. All of the resources for this program can be found on the training program website ([http://www.irb.emory.edu/staff\\_training/](http://www.irb.emory.edu/staff_training/))

## SCOPE

This SOP applies to all new staff that will be involved significantly in IRB issues. This SOP does NOT apply to Temporary Student Workers

## RESPONSIBILITIES

- IRB new hire training coordinator (“Coordinator”) – IRB staff member who is coordinating the New Hire Training Program, commonly the new staff member supervisor
- Go-To-Staff Member: IRB staff member who is responsible for training the new hire on the designated day.
- IRB Director: Consult on questions or concerns that arise during the training and approve updates to the content of the training program as needed.

## PROCEDURE

The hiring of the new employee will be announced to study staff as well as the start date of the new employee.

### Pre-Hire Preparations

- Before the start date of the new employee, the Coordinator will ensure that ORA has arranged for provision of computer and monitors for the new employee.
- Before the start date of the new employee, the Coordinator will prepare the Go-To-Staff Training Sign-up Sheet and send out to the rest of the staff helping with the training so that they can sign-up for the specific days to train the new employee. Only staff leadership or Sr. RPAs should help with this task, unless specifically delegated.

### New Employee Training Program

- The training program will begin on the start date of the new employee. The training modules can be found on the training website. These will be completed according the new staff role and following the google document.
- On the first day of training, the Coordinator will show the new employee where to find the checklists, omnibus forms, processing flowcharts, and all of the new hire documents on the H Drive (H:\General\Admin IRB Documents\New Hire Documents\Documents for New Hire).



- Each day of training, the Go-To-Staff Member will review the relevant training content and ensure that the employee is aware of tasks to complete that day.
- Each day during the training, the Coordinator will check on both the new employee and the designated Go-To-Staff Member for that day to make sure that the training is going as planned and to address any issues with the training program.
- Staff who volunteered for a certain day are responsible for finding substitutes if they have a foreseen absence; if they are unexpectedly absent, the Coordinator will ask for volunteers to substitute.
- The IRB Director should be contacted with any questions or concerns about the training process.
- The contents of the new staff training program will be updated as needed by the Director in collaboration with the Coordinator and Associate or Assistant Directors.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
09/11/2023	Updated references to training flow and terms & archiving log over 1 year

<b>SOP Title:</b>	IRB Department Travel
<b>SOP Category:</b>	Administrative
<b>Established:</b>	11/1/2017
<b>Last Revision:</b>	11/1/2017

#### **PURPOSE**

The purpose of this document is to provide Emory's Travel policies and rules related to travel. This SOP provides additional information than what is provided under the current Emory Policy as applicable to IRB staff.

#### **SCOPE**

The review process and requirements for planning travel covered by the Emory IRB.

#### **PROCEDURE**

Booking travel: It is preferred that all travel be booked/reserved on an Emory issued a corporate credit card. If this is not possible, review the travel plan with TL or supervisor to determine whether expenses can be placed on an existing account. In the event that travel fees are incurred on a TL or supervisor's card, the employee is responsible for complying with any policies referenced below, including submission of expense reports.

#### Travel Receipts

You are required to keep all receipts while traveling for proof of purchase. Keep the receipts until the report is approved for payment. Check the following document, so you are aware of Emory requirements involving keeping receipts during travel:

<https://www.finance.emory.edu/home/travel/receipt%20requirements%20effective%20d21413.pdf>

Additional information can be found at <http://policies.emory.edu/2.94>

#### Air Transportation

Trips should be arranged through [BCD travel](#). This is an external site, which requires a unique login and password. All air travel is billed directly to the SmartKey. Follow Emory IRB policies when booking flights, as there are restrictions. For details, read this policy: <http://policies.emory.edu/2.95>

#### Ground Transportation

For ground transportation needs, go to the [Emory Finance](#) webpage for information about renting a car during a trip. The Emory IRB will not compensate for rentals if the convention is adjacent to the hotel. Please contact your TL before you book or rent a car for business purposes.

If you choose to use your car for a trip done for business purposes, check the same page for current mileage reimbursement.

For additional information about ground transportation requirements, please go to <http://policies.emory.edu/2.98>

#### Lodging

If an employee uses a personal credit card for booking the hotel, a hold will be placed on the card that is generally equal to the amount of a day of stay. This hold is released once the final payment is made to the hotel.

In addition, the hotel will ask for a credit card upon check-in to cover incidentals. If you do not have a corporate card and providing a personal card is an issue, please make plans in advance to have a TL or supervisor provide their card information to the hotel shortly after check-in, or provide your personal credit card, which will be reimbursed after the trip is completed and the expense report is approved.

Please review the Emory policy about hotel bookings at <http://policies.emory.edu/2.97>

### Meals

Personal meals are defined as meal expenses incurred when traveling on business and should only be considered for the days and hours of the actual business trip. Please note the following items from the Emory policy worth repeating:

- Only in rare circumstances should an individual traveler's full day's travel meals, taxes and tips exceed \$100. Tips should be at or under 20%
- When multiple employees are involved, the highest-ranking employee of the hosting organization should incur the expense and submit it for reimbursement.
- When personal funds are used for individual meals, each separate expense and receipt must be listed individually on the expense report with the merchant name, date and proper receipt attached. No bundling or totaling of individual meals into one lump sum for the day or trip.

For more information, please read <http://policies.emory.edu/2.100>

### Non-Reimbursable Expenses

Please see list of Non-Reimbursable or Payable Items under this policy:

<http://policies.emory.edu/2.104>

### Expense Reimbursement

Gather all related receipts, group them as personal or corporate card expenses, and tape them onto one 8-1/2 x 11 sheet:

- Label individual receipts as personal expense [pers] or corporate card [cc].
- Note type of expense on receipt (e.g., taxi, parking, shuttle, tolls, subway, etc.)
- Place asterisk [\*] by alcohol expenses.
- Indicate meals as individuals or a group.
- If a group meal for 10 or fewer people list first and last names.
- If a group meal for more than 10 people indicate the number served.

- If a receipt is missing or lost, list the amount, type, date, and purpose of expense on one 8-1/2 x 11 sheet.
- Complete [form](#) located at [http://ora.emory.edu/docs/orabo\\_travel\\_form.pdf](http://ora.emory.edu/docs/orabo_travel_form.pdf)
- Deliver documents to ORA Business Operations (ORABO) in 1599 Building, 4th floor, Northwest Corner.

**LOG OF SIGNIFICANT CHANGES**

DATE	

<b>Title:</b>	Evaluating IRB Staff Performance
<b>Guidance Category:</b>	Administrative
<b>Established:</b>	8/27/2009
<b>Last Revision:</b>	09/11/2023

The turnaround times are listed in **business days**. Study team contributions listed below are considered the best-case scenario; the IRB cannot control additional delays on their part. Therefore, the overall “total days” are also a best-case scenario. The IRB staff should stay within our targets each time the study team responds to our requests for clarification or changes. Check WIRB/External IRB SOPs for TAT for those studies.

**Note: The times below should be decreased if needed due to urgency – discuss with the Director or Associate or Assistant Director if not sure we should act on the request for urgent handling.**

**Note: Staff must respond to study team calls or log comments within two business days**

### Performance Quotient Expectations

#### New studies

1. Biomed new study analysts:
  - 130-150 new studies per year, ~32-38 per quarter: No more than 5% PQ
2. Socio-behavioral new study analysts
  - 120-150 studies, ~30-38 per quarter: No more than 6% PQ
3. Hybrid new study analysts:
  - 130-150 studies, ~32-38 per quarter: between 5 and 6% PQ

#### Modifications

- 90-110 Modifications per quarter: less than 1% PQ

#### Reportable new information submissions

- 36 to 40 cases per quarter: no more than 5% PQ

Turnaround times and performance quotients are based on getting ~35 new studies per quarter, and ~100 Modifications per quarter, while reassigning all Continuing Reviews to an AA.

Variations from the above numbers due to understaffing or changes in submission volume will be considered when evaluating performance.

For AAs processing Continuing Reviews, the targets are based on office requirements and alerting Associate or Assistant Director if other tasks need to be adjusted in order to accomplish this.

For reportable new information submissions, these numbers will not apply if team Q is assisting the office with other tasks, or has not a full team to work on cases.

Type of Work	Initial Staff Screening	Omnibus Form Deadline and Pinging Schedule	F/up ltr out	Goal
FB New	Triage upon receipt or within 3-7 d of assignment depending on prioritization	Monday before the meeting (Friday for Tuesday meetings)	2 d of MTG	the aim is less than 1 calendar month or less
FB Mod	Triage upon receipt; 3-6 d depending on prioritization	Monday before the weekend (Friday for Tuesday meetings)	2 d of MTG	the aim is 3wks or less; <b>PRIORITIZE based on relevance to subject safety</b>
FB CR (once 45d or less pre-exp date)	Screen <b>no later</b> than 3 weeks from expiration (4 is better); <b>earlier</b> if Grady study; later if submitted less than 30 days before the expiration	Monday before the weekend (Friday for Tuesday meetings)	2 d of MTG but lower priority than New and Mod – UNLESS Grady, expiring, or study team needs for other reason	The ideal is IRB FB review at least 2 weeks prior to expiration, but 1 week if not possible
FB Post-Deferral Resubmission	3d – have Chair weigh in on adequacy of response before sending back to Full Board	Monday before the weekend (Friday for Tuesday meetings)	2 d of MTG	Send to the same panel if not urgent or submitted near that meeting; if urgent discuss with TL or Director as to whether we can send it to a different panel.
Post-Pending Response	2d of receipt		2 d of final approval	If the pending response is acceptable, aim for <6d; otherwise, the aim is 2wks or less
Type of Work	Initial Staff Screening	Pinging schedule	F/up ltr out	Goal
Simple Expedited New	Triage upon receipt or within 3-7 d of assignment depending on prioritization		2 d of decision	the aim is 3 wks or less
Complex Expedited New	Triage upon receipt or within 3-7 d of assignment depending on prioritization		2 d of decision	the aim is 4 wks or less: <b>USE PHONE OR EMAIL to resolve issues whenever possible to avoid delays (log notes in the study too)</b>
Expedited Mod by Staff	Triage upon receipt; 3-5 d depending on prioritization		same day as approval	the aim is 1wk or less

Expedited Mod by DR	Triage upon receipt; 3-6 d depending on prioritization		2 d of decision	the aim is 3wks or less
Expedited CR (once 45d or less pre-exp date)	Screen <b>no later</b> than 3 weeks from expiration (4 is better); <b>earlier</b> if Grady study; later if submitted less than 30 days before the expiration		2d of decision	The aim is IRB DR review no later than 1 week prior to expiration (more is better) when study team submits at least 30 days before the expiration
HSR Determination	Acknowledge immediately; 3d of assignment to screen. For each subsequent response, the IRB staff should reply within 2 days.		same day as determination	the aim is < 1wk (*) – we do not wish to hold up projects that do not require any IRB oversight.
Exempt	Triage upon receipt or within 3-7 d of assignment depending on prioritization		2 d of decision	the aim is 3 wks or less
RE case: SNC or CNC	Triage within 1 to 2 days. Sent to CoRE within one week or sooner if having all required case information (**)	If applicable, the omnibus form should be added one week before the meeting	If SCN or CNC: Friday or Monday after CMTE Q. If NC or not NC, 2 to 3 days	The aim is 4 weeks or less
RNI case: UP	Associate or Assistant Director will log a comment indicating this is a potential UP case. Send to CoRe within 1 to 2 days	If going to Q, one week before the meeting. If going to other committees, follow meeting deadlines.	If the case went to FB, one day after meeting if involves a safety issue that needs to be addressed with an Mod. If not, 1 to 2 days	The aim is for 4 weeks or less
RNI case: Not a UP, NC	Triage within 1 to 2 days. Sent to CoRE within one week or sooner if having all required case information, if applicable (**)	N/A	If expedited: 5 days If CoRE: 2 to 3 days	The aim is for 2 weeks or less

(\*) There is often a lot of discussion with study teams so these determinations usually take longer to review, although we should aim to stay in our targets.

(\*\*) Considering that there is some back and forth with the study team, it is acceptable to wait a week to send a case to CoRE. If the analyst has all the information, it is expected the case to be sent to CoRE sooner

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
9/11/2023	Revised title, archived log of changes over 1 year old



<b>SOP Title:</b>	Inquiries & Complaints received about IRB submissions
<b>SOP Category:</b>	Administrative
<b>Established:</b>	7/25/2018
<b>Last Revision:</b>	7/25/2018

## **PURPOSE**

The purpose of this document is to explain the review process for inquiries or complaints from study teams about studies that were processed or are being processed by an IRB analyst.

## **SCOPE**

The SOP applies to inquiries and complaints received by Associate or Assistant Directors, IRB Director, or other staff regarding items handled by an IRB analyst.

## **RESPONSIBILITIES**

- IRB analyst (IA) – receives questions/complaints or addresses them when prompted by IRB Associate or Assistant Director or Director.
- IRB Associate or Assistant Director (ADs)- receives questions/complaints and checks with staff managing study to submit a final response for a team when applicable. The term TL is used in this SOP referring to ADs.
- IRB Director (ID)- receives questions/complaints and checks with Associate or Assistant Director and staff member before providing a final response to a team when applicable
- Team Q personnel!- received questions/complaints and responds only if the response indicates the IA is following procedure. If not, it will forward questions to IA and TL.

## **PROCEDURE**

Note: Often, the TL, Team Q personnel or ID receive calls, emails with questions or complaints about studies being reviewed by the IRB. Even if the complaint is unfounded, we are required to provide a response, and for that reason, the above-personnel will contact IA who owns the item, and/or their TL (or, if unavailable, another TL) for more information. There are some points to remember during this process:

- If there is enough information from the submission/emails to confirm that the IA has followed current procedure and turnaround times, the complaint recipient can respond directly to the study team, copying the IA and his/her TL
- In any response given to the study team, the IA and TL will be copied, to keep them in the loop about this question/complaint. Copying the TL is important so that the TL can help the IA with follow-up if any. The TL can also provide feedback to the IA if needed.
- The IRB leadership understands that mistakes will be made by IAs just because we are all human beings. Complaints will only lead to performance feedback if there is a pattern of making the same mistake multiple times (including not following turn-around-times) or there is a lack of responsiveness from the IA's part with no justification (e.g. sick or vacation leave).

### **If question/complaint is received by IA directly**

- The IA should review the email with the question/complaint in the next two business days. When responding to a question, the TL does not need to be included. If this is a complaint, the IA should copy their TL.

- If the study team is emailing/calling the IA about the same issue multiple times in a two-day period, and the review is following approved turn-around-times, the IA may reply to the study team, copying his/her TL, letting them know that the request/question was received and that we are working as fast as possible to resolve it.
  - If there are extenuating circumstances, the TL may offer to take ownership of the submission or other matter, for special handling and to avoid burdening the IA. This will be the exception in cases where there is a real need, and TL should remind the study team of this.
- If the study team is raising their voice, being unreasonable about their request, and despite using crucial conversation tactics, the study team is not cooperative, the IA will forward their question/concern to the TL to address.

**If question/complaint is received by a Team Q personnel**

- If there is enough information from the submission/emails to confirm that the IA has followed current procedure and turnaround times, the Team Q person can respond directly to the study team, copying the IA and his/her TL (if not self)
- If there is not enough information to show that the IA is following the procedure, the request will be forwarded to the IA and his/her TL.

**If question/complaint is received by IRB Associate or Assistant Director**

- If there is enough information from the submission/emails to confirm that the IA has followed current procedure and turnaround times, the question/complaint recipient can respond directly to the study team, copying the IA and his/her TL (if not self)
- If there is not enough information to show that the IA is following the procedure, the TL will copy the staff member in their response letting them know that the email was received and that the matter is being reviewed.
- The TL will contact the IA and their TL (if not self) to look into the matter.
  - If the issue was a lack of documentation, the IA will add to their record their communication with the team. The original TL (if available – otherwise the IA or their TL) will then answer, letting them know that the information was reviewed and that the procedure was followed, copying all parties.
  - If during the review of the question the IA's TL and IA found that an error was made, the IA will work with the TL on resolving the issue, and the IA will email the study team letting them know about the correction of the human error.

**If question/complaint is received by IRB Director)**

- If there is enough information from the submission/emails to confirm that the IA has followed current procedure and turnaround times, the ID can respond directly to the study team, copying the IA and his/her TL
- If there is not enough information to show that the IA is following the procedure, the request will be forwarded to the IA and his/her TL, and the ID will email the study team back letting them know that the email was received and that the information is being reviewed by the TL and IA.
  - If the issue was lack of documentation, the IA will add to their record their communication with the team. The original TL (if available – otherwise the IA or their TL) will then answer, letting them know that the information was reviewed and that the procedure was followed. Copy all parties.

- If during the review of the question the IA's TL and IA found that an error was made, the IA will work with the TL on resolving the issue and the IA will email the study team letting them know about the correction of the human error
- The TL will provide an update to the ID when the matter is resolved if ID requests.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	Staff Continuing Education
<b>SOP Category:</b>	Administrative
<b>Established:</b>	10/19/2019
<b>Last Revision:</b>	10/19/2019

**PURPOSE**

To explain the attendance expectations when a webinar or other IRB continuing education event is offered to the IRB staff.

**SCOPE**

The SOP applies to all the Emory IRB Staff.

**RESPONSIBILITIES**

- IRB analyst – responsible to attend the continuing education opportunity or justify their absence with their team leads
- IRB Team Lead- takes track of their supervisees attendance to continuing education opportunities

**PROCEDURE**

- When a new IRB continuing education opportunity is available, the staff will receive a communication via email or teams. The communication will let the staff know if the education event is mandatory or elective
- If the event is mandatory, the staff is required to attend via zoom (if working from home) or in person.
- If the staff member is unable to attend, the staff member needs to justify their absence with their team lead.
- In the case of a webinar, when the recording of the event is available, the staff member should reserve time to view the recording and email their team lead to confirm completion
- If there are no recordings available or the format of the presentation is not a video, the staff member is responsible for reviewing slides or publications available after the presentation. After this is completed, the staff member should email their team lead to confirm completion
- The team lead will reach out their supervisees if the staff member misses a continuing education opportunity and this absence was not explained in advance.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	IRB Staff Meeting Facilitation
<b>SOP Category:</b>	Administrative
<b>Established:</b>	02/24/2023
<b>Last Revision:</b>	

**PURPOSE**

This SOP details the process of facilitating an IRB staff meeting.

**PROCEDURES**

1. The IRB staff member designated to facilitate an IRB staff meeting is responsible for requesting agenda items from the IRB staff one week prior to the staff meeting and compiling them into a word document that will serve as the agenda and eventually the recap for the meeting.
2. No later than close of business Thursday before the scheduled staff meeting, save the document in the folder located here: H:\General\IRB Org and Management\1-Staff Meeting Recaps and email it to the Director and ADs.
3. During the meeting, record the discussion of each item in the word document and save changes. This document will be saved for future reference for IRB staff.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

## COLLABORATIVE RESEARCH / CENTRAL IRBS

<b>SOP Title:</b>	External Collaborators Included in Initial Submissions or in Modifications to Approved Non-Exempt Research
<b>SOP Category:</b>	Collaborative Research / Central IRBs
<b>Established:</b>	9/20/2012
<b>Last Revision:</b>	7/5/2022

### PURPOSE

The purpose of this SOP is to outline the process an analyst uses when an external collaborator is included in an initial submission or is being added via a modification to an approved Emory study. This SOP does not apply to exempt research or to studies where Emory has agreed to serve as the single IRB of record for multiple enrolling sites. For new reliance agreements covering groups of studies (e.g. for a research network), consult with the reliance AD.

For more information, please review the following guidance documents:

- OHRP Guidance on Engagement: <http://www.hhs.gov/ohrp/policy/engage08.html>
- OHRP Guidance on IIAs: <http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.html>

### DEFINITIONS

- **Reliance Agreement** – Documentation that an institution or individual engaged in human subjects research has delegated institutional review board (IRB) review to an independent IRB or an IRB of another institution.
- **IAA** – IRB Authorization Agreement
- **IIA** – Individual Investigator Agreement

### RESPONSIBILITIES

- **IRB Analyst (RPA)** – Recognizes when another institution or individual is collaborating in research with Emory. This is often discovered when an external collaborator is listed in the smart form or on the first page of the protocol. The RPA communicates with the study team and the reliance team to complete the reliance process.
- **Institutional Official (IO)/IRB Director** – Reviews and signs all proposed reliance agreements (Director signs if not federally-funded or if IO is not available within a reasonable timeframe).

### CONSIDERATIONS

Reliance only applies to **non-exempt** human subjects research. If a study has been determined to be exempt, a reliance agreement is not applicable. External researchers that have access to an IRB, such as those at other academic institutions, should consult with their IRB as to whether they need to submit to their local IRB for an exempt determination. If they do not have access to an IRB, the external researcher may remain in the smart form and Emory's determination will be understood to cover the external researcher.

In general, Emory is open to **reviewing** for another institution or individual investigator when:

- The other institution is **not** a separate site in a multisite *clinical* study (i.e. not when the other site is enrolling and performing the protocol interventions on their own patients/subjects)
- Use of a single IRB is required by the regulations.
- The other institutions or individual investigator's activities are minimal risk.
- Local context is not expected to be a significant factor.
- The individual investigator has no institutional affiliation and therefore no other possible IRB (note: Community Physicians may not conduct research at EHC facilities without Emory faculty collaborating and assuming responsibility for the study as PI.)

When in question, contact the reliance team.

## PROCEDURES

For **AVAMC** studies, consult with IRB-VA liaison prior to proceeding.

1. Request that the study team complete our [External Study Team Members template](#) and upload in external study team member section of the smart form.
2. Review [OHRPs Guidance on Engagement](#) to determine if the external collaborator is engaged in human subjects research. You may need to ask for additional clarification from the Emory PI to make this determination. If the external collaborator is NOT engaged, then no reliance is required, and the person should be removed from the smart form. If the collaborator is engaged, then confirm the collaborator is acting as an agent of the collaborator's institution.
3. If use of a single IRB is **not** required by the sponsor or by the regulations or the research has been determined to be exempt, the external collaborator should obtain IRB approval/determination from his/her IRB. Log a comment to the study team telling them this.
4. If the research is non-exempt, the external collaborator is engaged in human subjects research and is located within the U.S., have the study team upload the completed external study team member list template in the smartform.
5. Contact the Reliance AD via email with the following information:
  - External Study Team Member list provided by the study team
  - Brief description of the study and role of the external collaborator(s)
  - Link to the study
  - Funding source
6. The Reliance AD will obtain the necessary signatures on the reliance documents (reliance agreement and local context review form) and upload them with a comment in the history tab of the study. If the study or modification is in the clarifications requested state, the IRB analyst will upload the executed reliance agreement and completed local context review form into the smart form in the external team member section. Otherwise, the IRB analyst will request clarifications so the documents can be uploaded in the smart form.
7. For external collaborators who are covered by an existing master reliance agreement between Emory and the external collaborator's home institution, provide the local context review form to the study team with the header information filled in and ask that the external collaborator have it completed by their home institution's IRB. Once it is completed and signed by the relying institution's IRB, instruct the study team to upload it in the external team member section of the smartform.
8. Continue processing the Modification to add the external collaborator(s).

9. Once the study or modification including the external collaborator(s) is approved, log the comment below in the study workspace and include this sentence in the approval letter “*A reliance agreement has been executed for INSTITUTION/INVESTIGATOR to rely on Emory's continued review and oversight of this protocol.*”

*Dear Study Team,*

*A reliance agreement has been executed for INSTITUTION/INVESTIGATOR to rely on Emory's continued review and oversight of this protocol. Please provide a copy of this approval letter to the relying institution's IRB.*

#### **LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
8/30/2021	Minor edits for clarity of the process, added need to approve modification and archived changes logged over 1 year
1/12/2022	Revised process so Reliance AD handles all IAAs and IIAs.
4/28/2022	Edits for clarity
7/5/2022	revised to include new study submissions and added detail regarding local context review form



<b>SOP Title:</b>	Obtaining Access to WIRB and NCI CIRB
<b>SOP Category:</b>	Collaborative Research / Central IRBs
<b>Established:</b>	11/8/2016
<b>Last Revision:</b>	01/07/2022

## PURPOSE

The purpose of this SOP is to outline the steps necessary to provide IRB staff with access to accounts with WCG IRB and NCI CIRB.

## SCOPE

The SOP applies to Emory IRB staff that will be processing studies that will be reviewed by WCG IRB and the NCI CIRB.

## PROCEDURE

### WCG IRB Studies: (see WCG IRB Study Processing SOP for more information)

- To gain access to the Emory WIRB Listserv: Send an email to Julie Martin asking to be added to the WIRB listserv. Julie will log into listserv.cc.emory.edu and add the IRB staff as a subscriber to the WIRB Listserv.

To gain access to WCG Connexus, use the login wirb-l@listserv.cc.emory.edu and the most recent password which can be found in the AA One Note page.

### NCI CIRB Studies: (see NCI CIRB SOP for more information)

- To gain access to the NCI CIRB IRB Manager: Request a new account from NCI CIRB IRB Manager – <https://eapps-ctep.nci.nih.gov/iam/index.jsp>.
- Request that the Director or designee email [ncicirbcontact@emmes.com](mailto:ncicirbcontact@emmes.com) to update the roster to reflect the IRB staff as an Institutional Contact
- To gain access to CTSU Registered Member Website: The analyst must register with the [CTEP-IAM registration system](#).

## LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
8/30/2021	Revised WIRB instructions and archived log of updates over 1 year old
01/07/2022	Replaced Rebecca with Julie Martin as point of contact for Listserv additions

<b>SOP Title:</b>	WCG Listserv Duties
<b>SOP Category:</b>	Collaborative Research / Central IRBs
<b>Established:</b>	12/9/2014
<b>Last Revision:</b>	7/6/2023

## PURPOSE

The purpose of this document is to outline the steps to address emails in the WCG Listserv.

## DEFINITIONS

- **Form A** – the initial form submitted to the IRB as a notice that a study team has a study that they believe qualifies for submission to WCG IRB.
- **Institutional Sign-Off** – The process step for which WCG IRB does not process a study until WCG IRB receives an email communication from Emory to verify local Emory requirements have been met.
- **Institutional Hold** – The process step in which WCG IRB holds the approval and consent form documents from the study team until WCG IRB receives an email communication from Emory to release the Institutional Hold.
- **Owner**– the Analyst that is assigned to the study
- **WIRB Listserv Monitor** – The person assigned to manage the WIRB listserv on a given day

## WIRB Listserv Monitor Duties/Deviations/Institutional Sign-Off

WIRB Listserv is copied on communications between WCG IRB, the study team and the Emory IRB.

Emails with “Site Pre-Review” and “Sponsor/CRO Pre-Review” do not require action by the Emory IRB because they are requesting input from the study team or the sponsor/CRO.

- a) The AA assigned to the WIRB listserv will scan WIRB listserv emails briefly to make sure there is not an issue that we can help with. Issues that Emory IRB needs to respond to include deviations, requests for Institutional Sign-off, study closeouts and initial approvals.
- **Deviations** –
    - Emails from WCG IRB regarding deviations from the external IRB consent checklist should contain wording similar to “Institutional Pre-Review” or “Institutional Sign-Off” in the subject line. Review the body of emails to determine if the Emory IRB is being asked to provide information.
    - Emory is concerned about deviations from Emory’s ICOI, Cost, Medical record, “How will my drug be provided,” and HIPAA language.
    - If the email is for a deviation, navigate to the study in eIRB and log a comment to the owner/AA that there is a deviation for them to process. Forward the listserv email to the owner/AA.
    - The owner/AA is responsible for resolving the deviation following the steps below.
      - If not already provided, ask the WCG IRB analyst for a tracked changes version of the consent and a list of the sections that contain deviating language.
      - The owner/AA will email the reliance Assistant Director to review the changes. If changes are minimal, include the exact text that is being changed within the body of the email, highlighting or striking-out text to make the deviations clear.

Otherwise include a track-changes copy of the consent(s) and point out the pages that contain the deviations.

- If the deviations are acceptable, respond to the listserv email with “These deviations are acceptable to Emory,” and send to WCG IRB client services, copying the study team. Save a copy of the approval email from the reliance Assistant Director as a private comment in the study space.
- If the deviations are not acceptable, send a response to WCG IRB letting them know the deviations are not accepted and why.
- **Request for Institutional Sign-Off –**
  - The WIRB listserv monitor will navigate to the study in eIRB and log a private comment to the owner/AA regarding the request for Institutional Sign-Off.
  - Forward the listserv email to the owner/AA.
  - The owner/AA will check to see if Institutional Sign-Off was already issued or if there are pending items.
  - If Institutional Sign-Off was already issued, the owner/AA will forward it to WCG IRB.
  - If Institutional Sign-Off was not issued, the owner/AA will either issue Institutional Sign-Off or notify WCG IRB that there are pending issues preventing us from issuing Institutional Sign-Off.

#### **Checking the Status of WCG IRB Studies that have already been Submitted to WCG IRB:**

1. The owner/AA will check the status of their studies that are pending sIRB review weekly.
  - a) Search the WIRB listserv for any updates on the approval.
  - b) Check the status of the study on WCG IRB’s spreadsheet of all Emory studies that shows their current status. This spreadsheet is sent via email to the AAs each week.
  - c) Check the status electronically via [connexus.wirb.com](http://connexus.wirb.com):
    - Login to WCG IRB site [connexus.wirb.com](http://connexus.wirb.com)
    - Select *Workspace Sites*
    - Sort columns by field you are looking for
    - Click on the study to view information.
  - d) Contact WCG IRB study analyst (if known).
  - e) Call Client Services at 800-562-4789.

#### **Post WCG IRB Approval Processing:**

##### **Saving the Regulatory Email and Uploading Docs into eIRB**

Once the study is approved by WCG IRB, WCG IRB sends an email containing approval documents to the listserv with “*Regulatory Documents*” in the subject line.

1. The WIRB listserv monitor will open the email and click on the link to go to the documents in Connexus.
2. Check **each** regulatory document email (including “Change in Research,” “Continuing Review” and “Closeout”) to determine if it is for an initial approval, study closeout or a change in PI. If the Connexus link contains the document “Initial Review Notice,” it is an initial approval. If the documents under “Initial Review” Connexus link mention “Conditional Approval,” no action is needed. Forward the regulatory documents (for initial approval and closeouts) to the owner/AA for them to process.

3. The owner/AA will continue processing the study **from this point forward** and save the clean versions of the attachments with the PI's name next to them in the WIRB Study Document folder at (H:\External IRB Relationships 6.3.2020\03. Current Umbrella IAAs\WIRB\WIRB Study Documents). If there is not a folder with the Study ID, create a new folder.
4. Review the SOP titled "Cost Option for Clinical Trial Agreements and ICFs" to determine the correct cost option.
5. Confirm that the ICOI Option in the approved consent matched the OSP determinations found in the Institutional Sign-Off.
6. Read every word of the Cost and Injury sections and compare to our [consent checklist](#) for the appropriate option number determined for the study.
7. Review the HIPAA language in the consent to ensure that it is the Emory HIPAA language, and that it includes all the required elements from our template.
  - a) Ensure that there are no remaining incomplete template placeholders left in the text.
  - b) Confirm these required sections are present:
    - PHI that Will be Used/Disclosed
    - Purposes for Which Your PHI Will be Used/Disclosed
    - Use and Disclosure of Your Information That is Required by Law
    - Authorization to Use PHI is Required to Participate
    - People Who will Use/Disclose Your PHI
    - Expiration of Your Authorization
    - Revoking Your Authorization
    - Other Items You Should Know about Your Privacy
  - c) If the study has an optional study, confirm the following are included:
    - Brief description of sub study or "Storage of (Data and/or Specimens) for Future Research
    - Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study and Additional People Who Will Use/Disclose Your PHI for Optional Study
8. If St. Joseph's or John's Creek are sites do the following:
  - a) Review the St. Joseph and John's Creek SOP to determine if the SJHC local context review (Ethical and Religious Directives (ERD) and credentialing) is required.
  - b) If it is required, follow the steps in the SOP to send the consent forms and protocol to Rebecca Heitkam.
  - c) Notify the study team that "No research-related activities may begin at the [St. Joseph's/Johns Creek] site(s) until the site ERD approval is received from Rebecca Heitkam or her designee. Any changes required by the site must be submitted to WCG IRB via a Modification."
  - d) Once ERD approval is received, log the information as a comment to the study team.
9. If there are administrative errors such as template language without study specific details, formatting issues, typos, etc., these can be corrected by WCG IRB without additional input from Emory IRB and are not considered "deviations." Go to the "Removing Institutional Hold" section of this SOP.
10. If the deviations have not been previously approved, the owner/AA will follow the steps in this SOP for "Deviations."
  - a) If we can accept the deviation, go to "Remove Institutional Hold" section of this SOP.
  - b) If we cannot accept the deviation, the owner/AA will do the following:
    - Send "Need to revise WCG IRB consents..." email (found at H:\General\External IRB Relationships 6.3.2020\WIRB\Email Templates) to the study team. Copy the WIRB listserv

and PI, instructing them to not consent anyone until they amend their consent forms to reflect the negotiated options.

- Log a Private Comment in eIRB with the approval documents (so study team cannot access them yet).
- Log a comment to the study team in eIRB with text of the email, noting the same message has also been emailed.
- Set a “Rule” in Outlook to move any future emails containing the Sponsor’s protocol number/ID in the Subject line to a special folder for this type of Modification notification so that you will see it immediately.
- Set a reminder to check in on the study team weekly to ensure they submit the Modification to WCG IRB. Copy the PI, Study Coordinator(s), and WIRB listserv on all reminders. Log comments to Study Team in eIRB when reminders are sent.
- Upon second weekly reminder to submit Modification, CC IRB Director and Q Associate or Assistant Director.
- Once the Modification approval notification appears in that Outlook folder, review the revised ICFs to ensure they are now correct. Proceed with the next steps from removing institutional hold forward.
- Remove the Outlook rule (leave the folder for future use)

#### **Removing Institutional Hold:**

1. Once WCG IRB transmits final approved regulatory documents that match Emory IRB language, the owner/AA replies to the regulatory documents email with “Please remove institutional hold” and copies the WIRB listserv, WCG IRB client services and the study team. If administrative issues were uncovered as defined above, add a comment to the email informing both WCG IRB and the study team that the correction can reviewed by WCG IRB with no additional review required by Emory IRB.

#### **Beyond Initial Approval:**

##### **Modifications**

1. WIRB Listserv is copied on all changes to research and on all approved regulatory documents.
2. Check each regulatory document email to confirm it is not an initial approval. There is no need to save or upload approved Consent/HIPAA forms for already approved studies.
3. Study teams are responsible for notifying the Emory IRB of the following changes to an ongoing study:
  - Addition of local study sites
  - Change to PI or addition of study team member that needs immediate access to eIRB
  - Updates requiring a new ancillary review (e.g.; Procedures involving radiation, cancer-related aims added, new conflict of interest, etc.)

Depending on the study status (“Active” vs “External IRB”), the study team may report changes by submitting a modification (that we **approve**) or will use the “update study” function (that we **accept**). We prefer study teams to use the modification function if they have it. If they do not have that option, the study team will need to use the update study activity. Be aware that study teams are able to accept site updates themselves. They should not do this, and AAs are still responsible for reviewing updates.

Review the WCG IRB approval letter and confirm the changes being reported to the Emory IRB match what is noted in the WCG IRB approval letter.

#### **Changes Reported using a Modification**

1. For modifications to add or remove Emory study personnel, follow the SOP “Adding/Removing Study Personnel.” AAs can approve these modifications.
2. For modifications indicating increased risk, follow the SOP titled “Modifications: Mods indicating increased risk.”
3. For modifications that require new ancillary reviews such as a new COI, change to radiation procedures, infectious agents, etc., consult an Assistant Director for guidance.

#### **Changes Reported using Update Study activity**

1. When the study team uses the “update study” function the owner/AA receives an email. Review each update.
2. When updates are finalized, the owner/AA will receive an email “Emory eIRB Notification of Finalize Updates.” The owner/AA needs to look at each one to confirm the study team has not finalized the update themselves.
3. Review the changes reported and finalize the update. The owner/AA can approve modifications for study staff changes.
4. Click “Accept Site Updates”

#### **Consent Deviations Post Approval**

1. WCG IRB sends an email to the WIRB listserv if there are deviations to Emory-required institutional language after documents are approved.
2. The listserv monitor will route deviations as noted above in this SOP.

#### **Continuing Reviews**

- Study teams are expected to report CR data to the Emory IRB. The report should be made upon receipt of the CR approval letter provided by WCG IRB. If the PI is not available to report the data, it may come in via logged comment.
- If the data comes via logged comment, confirm that the IRB renewal letter is for the correct study and the CR Workbook is attached.
- If relevant documents are attached, click “Report Continuing Review data” on the left menu. A new window will open.
- In #4, upload the IRB approval letter and CR Workbook and click OK.

**1. Specify enrollment totals at this investigator's sites:**

**2. Specify enrollment totals at this investigator's sites since last approval:**

**3. Check the items that are true for this site since the last IRB approval:** (initial review or last continuing review)

- NO subjects experienced unexpected harm
- Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- NO subjects withdrew from the study
- NO unanticipated problems involving risks to subjects or others
- NO complaints about the study
- NO publications in the literature relevant to risks or potential benefits
- NO interim findings
- NO multi-center trial reports
- NO data safety monitoring reports
- NO regulatory actions that could affect safety and risk assessments
- NO other relevant information regarding this study, especially information about risks
- In the opinion of the PI, the risks and potential benefits are unchanged
- All modifications to the protocol have been submitted to the IRB
- All problems that require prompt reporting to the IRB have been submitted

**4. Supporting documents:** (include an explanation of each item left unchecked above)

Name
There are no items to display

**5. Comments:**

- Click "Return to Post-Review" on left menu.
- Click the box to the right of question #3.
- Click OK.
- Click "Edit sIRB Decision."
  - Enter the new effective date of local site. (Do not change initial approval or initial effective dates.)
  - Enter the last day of study approval period.
  - Enter last day of local site approval period.
  - Upload the CR approval letter in #3.
  - Click OK.
  - Confirm the dates entered are correct on the main study page. If not, click "Return to Post-Review" and complete the process again.

**Active**

Entered IRB: 8/12/2020 1:03 AM  
Initial approval: 1/4/2020  
Initial effective: 1/5/2020  
Effective: 1/7/2021  
Approval end: 1/7/2022  
Last updated: 2/22/2021 12:31 PM

- The study team is also be expected to update their study personnel list at this time. Specifically, they need to add any team members that were added during the prior approval period. If you do not see a corresponding update with the report of CR data, please request. Once the personnel are added, training should be confirmed per the SOP entitled “Training Verification.”
- The WIRB listserv is copied on WCG IRB expiration notices to study teams. No action is needed by the IRB analyst for these emails.

### **Reportable New Information (RNIs)**

Study teams are required to report local adverse events directly to WCG IRB if they meet WCG IRB’s reporting criteria. They are also required to report events to the Emory IRB per the guidance posted on the Emory IRB website. Once WCG IRB receives a report from a study team, WCG IRB copies the WIRB listserv on emails to the study team and/or the Emory IRB in regard to these reports.

1. The WIRB listserv monitor reviews these emails to determine if WCG IRB is requesting information from the IRB and notifies the Director or Associate Director of email communications regarding Serious or Continuing Noncompliance, Unanticipated Problems involving Risks to Human Subjects or Others. WCG IRB posts its reporting criteria on the WCG IRB website for study teams to reference.
2. If an Emory audit/inspection reveals compliance issues with our local site, then the “institution” must report those findings to WCG IRB per their reporting guidelines. IRB’s Team Q would be involved in those decisions.
3. Save all emails related to RNIs and Unanticipated Problems under the WCG IRB Study Document folder (H:\General\External IRB Relationships 6.3.2020\WIRB\WIRB Study Documents W0000XXX) after notifying the Q team.
4. Follow the SOP entitled “[Reportable New Information \(RNI\) Submission Notification Process for External IRB Studies](#)” for additional steps.

### **WCG IRB Close-outs in SaaS system:**

WCG IRB close-outs are sent by email to the WIRB listserv.

1. The WIRB listserv monitor navigates to the specific WCG IRB study workspace in eIRB and logs a comment that the study has been closed by WCG IRB and attaches the WCG IRB closure letter.
2. Click “Assign Coordinator” and take ownership of the submission.
3. Click “close site”
4. Once the closeout is finalized, email the WCG IRB close-out letter to OCR and the WIRB listserv using the “Emailing W0000 Close-out” email template (found at H:\General\External IRB Relationships 6.3.2020\WIRB\Email Templates).
  - Add WCG IRB # to the subject line.
  - Attach close-out letter
  - In the body of the email, add in the study title, WCG IRB #, and PI.
  - Add signature and hit send

### ***Helpful tips:***

- When you forward emails, place the WCG IRB number in your subject line.
- Copy the WIRB listserv on ALL email correspondence



- Copy WCG IRB client services on ALL correspondence that is going to WCG IRB and copy the Emory study team

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
3/11/2021	Added steps for reporting continuing review data and updating approval and expiration dates at CR, clarification about SJHC and JC site process, revised processing of deviations so the owner/AA handles instead of the listserv monitor.
5/24/2021	Adding links to other SOPs; updating Master CT list information, minor edits
8/30/2021	Updated WIRB to WCG where applicable and added need to request WIRB approval letter and master consent and Archived logs of updates over 1 year old
1/07/2022	Revised SOP to reflect only listserv duties, WIRB study processing now follows SOP "XIRB Study Processing When Emory Relying on An External IRB Other than the NCI CIRB"
7/5/2022	Removed steps to email OCR and OTT, added guidance to follow cost option SOP
7/6/2023	Replaced AA

<b>SOP Title:</b>	NCI CIRB studies processing
<b>SOP Category:</b>	Collaborative Research / Central IRBs
<b>Established:</b>	5/31/16
<b>Last Revision:</b>	9/11/2023

**PURPOSE**

The purpose of this SOP is to outline the steps IRB staff uses to process studies reviewed by National Cancer Institute’s Central IRB (CIRB), and to facilitate maintenance of the Emory investigator roster and institutional information for CIRB.

**SCOPE**

The SOP applies to all studies reviewed by NCI’s CIRB with any Emory-affiliated study sites, including CHOA. The AVAMC may also use NCI CIRB but their process may differ.

**RESPONSIBILITIES**

- IRB Contact (IRB Analyst): responsible for providing access to NCI CIRB study area to study teams, as well document the study submission to CIRB in eIRB.
- Study Team – responsible to submit up to date and accurate information to Emory IRB.

**List of the institutions on the CIRB roster affiliated with the Signatory Institution (Emory)-Code Names:**

1	Emory University/Winship Cancer Institute	Emory University	GA005	CIRB Component
2	Grady Health System		GA003	CIRB Affiliate
3	Saint Joseph's Hospital of Atlanta		GA011	CIRB Affiliate
4	Children's Healthcare of Atlanta – Egleston		GA035	CIRB Affiliate
5	Emory University Hospital Midtown		GA013	CIRB Component

**PROCEDURE**

**Note:** You can find all the checklists on this SOP [in this folder](#).

- If study teams have questions as to how they access NCI CIRB Studies, please review and refer them to the guidance posted on the collaborative research section of our website.
- If a study team member requests to be added to the NCI CIRB roster, please forward the request to the reliance AD or the Associate Director when the reliance AD is out of the office.

**After the Study is Submitted to the Emory IRB**

- Manage the ancillary reviews and complete the steps detailed in the **New Study Checklist for CIRB Studies**.
- The IRB staff logs a private comment in the history tab of the study with the completed checklist.

**Confirm Reliance**

- Click on “Confirm Reliance”.
- Mark Yes to #3 and click OK.

### **Record sIRB Decision**

- Click on “Record sIRB Decision”. A window will open.
  - For #1 (Determination): mark “Approved”
  - For #2 (Dates): Add the dates of approval as follows:
    - Effective Date of Study: Enter the approval date as indicated on the NCI CIRB approval letter. This is the date that will appear on the finalized documents.
    - Last day of study approval period and Last day of local site approval period: In both fields, enter the date shown on the CIRB approval letter (found on the NCI CIRB approval or renewal letter for the **overall** study).
      - Note, if the study team is unable to provide the overall study expiration date, check with the reliance AD.
    - Leave the other date fields empty.
  - Question 3 (Approval Letter from external IRB)- Upload the site-specific approval letter from CIRB.
  - Question 4 (Common Rule regulatory requirements): Click on 2018 requirements if not FDA or DOJ regulated, or select Pre-2018.
  - Question 5 - Follow the [the Pre-review and Ancillary Review SOP](#) to mark the applicable options for Regulatory oversight.
  - Question 6 - Select options as applicable. Note that Emory does not use broad consent, so that option should not be marked.
  - Question 7 - Review the letter to see if the study was reviewed by Full Board and the risk level determination. In general, CIRB studies are considered greater than minimal risk.
  - Question 8 - Select as appropriate (usually biomedical).
  - Question 9 - Select clinical trial (if applicable), Certificate of Confidentiality (because the study is NIH funded), collaborative and multi-site, as applicable.
  - Question 10 – leave blank
  - Question 11 – leave blank as the ICF/Site addendum should be part of the smartform
  - Question 12 - Mark yes to finalize (stamp) the documents.
  - Question 13 - Mark yes and click OK.

Note: If you had to finalize documents and the system requires you to create a letter upload the NCI CIRB approval letter and click “send letter.”

### **Finalizing Documents**

- Click on “Finalize Documents”. A new window will open. Do not stamp the revocation form.
- Select the Site Information and HIPAA Authorization Form Addendum and assent (as applicable). Click OK.
- View the pdf version of the documents under the “Documents” tab. Confirm the approval date is correct on the documents.
- The study state will be “active.” (If the study was submitted as a single site study it will be listed as External IRB.)

### **Processing Continuing Review**

Study teams submit continuing review data as outlined on our website using the “Report Continuing Review Data” activity for studies in the Active or External IRB state. Note that only the PI can use the “Report Continuing Review Data” so the study coordinator might log a comment with the continuing review information. The IRB staff can then complete the Report Continuing Review Data on behalf of the study team.

After ensuring that all information has been reviewed, complete the following steps:

- Ask the study team if they have any study staff changes to make at this time. If yes, have the study team update the study staff in the smart form. Once that is done, continue with next steps.
- Click “Return to Post-Review”.
- Enter the comment “Continuing Review Update.”
- Mark yes to question 3.
- Click OK.
- Click “Edit sIRB Decision”.
- For question 1 Mark “Approved”
- Do not change the initial effective date.
- Change the date shown as the “Last day of study approval period and Last day of local approval period” to the expiration date noted on the CIRB letter.
- For question 3, upload the NCI CIRB approval letter the study team logged as a comment.
- For question 4, click on pre-2018 if not already selected.
- Skip to the last question.
- Mark yes to the last question ***only if the study is an old CIRB study, and there is a consent/HIPAA document in the submission instead of a CIRB consent plus addendum.*** Otherwise mark No.
- Click Ok.
- Finalize documents, if needed. Stamp the consent/HIPAA document with the approval date shown in the CIRB re-approval letter.
- Note: If you had to finalize documents and the system requires you to create a letter upload the NCI CIRB approval letter and click “send letter.”
- Click OK.

**Remember:** You do not need to re-stamp any documents (NCI IRB Consent, Assent or our addendum).

Note: If the study is marked as a single site study, you will see the letter populate twice in the header for the study (top of the study space). If the study is marked as a multi-site study, it will only appear once.

For reportable event CR summaries, follow the SOP entitled “[Reportable New Information \(RNI\) Submission Notification Process for External IRB Studies](#)” for additional steps.

### **CIRB Modifications**

<p><b>NOTE:</b> The study team may opt to submit a Modification/Update to separate the consent from the addendum. This will prevent the requirement of stamping consents in the future.</p>
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The following modifications **require** approval from NCI CIRB, but Emory does not need to review:

- Changes to the CIRB consent and a stamped addendum that do not include changes to the addendum and HIPAA language. If the study team submits a modification with changes to the consent, instruct them to “discard” the modification. The Emory IRB does not process Modifications or re-stamp documents after initial approval.
- Any translated documents not already approved by NCI CIRB. If the study team has questions, direct them to [question 7 of the NCI Institution QA/QI](#)
- Changes to locally produced advertisements/requirements. If the study team has questions, direct them to [question 8 of the NCI Institution QA/QI](#)

The following modifications **require** approval from NCI CIRB **and** local context review by Emory IRB:

**Note:** If the study team is requesting the Emory IRB review documents, they must provide tracked versions of the documents.

- Changes to PI: Request a CIRB approval letter/notice that lists the change in PI.
  - Note: If the study is still enrolling subjects, the site addendum may need to be updated with the new PI’s name.
- Changes to the previously stamped addendum such as changes to HIPAA language. Compare the language in the site addendum to the current version of Emory’s [Site-Specific Consent-HIPAA Addendum](#) posted on our website. If changes are needed, request clarifications. If not, click “Accept Site Updates.”
- Changes to a consent/HIPAA authorization, for studies that still have that type of consent (vs. the separate consent and addendum) (analyst to process): Request a CIRB approval letter that lists the correct version of the document.
- Changes to local study sites
- Updates requiring that will require a new ancillary review (e.g.; Procedures involving radiation, cancer related aims added, new conflict of interest, etc.))

Modifications that **do not require** a Modification in eIRB, but do require re-stamping:

- For studies with a combined consent/HIPAA document: Changes to the overall study that do not include a consent revision. For example, a protocol update will require an update to the consent form just to update the version date to match the revised protocol. If this is the case, the study team must submit a modification or click Update Study. Return the study to post-review to stamp the documents with today’s date. (see below for more information).

### **Processing CIRB Modifications**

Depending on the study status (external vs active), the study team will have the option to submit either a modification or an update to their study.

If the study team submitted a modification

- Under the modification space, click on “View Modification.”
- Review the initial submission to see what documents are being added or modified. Use the “history” and “compare” functions to see the differences in the documents.
- If all of the information appears to be correct, click on Accept Site Updates.

**Pre-Review**

Entered IRB: 2/26/2020 2:41 PM  
Last updated: 2/26/2020 2:43 PM

**Next Steps**

- View Modification
- Printer Version
- Accept Site Updates
- Request Pre-Review Clarification
- Assign Coordinator
- Manage Ancillary Reviews
- Correspond with sIRB

**SITEMOD001-STUDY000**  
**Update #1 for CIRB 123**

**Principal investigator:** Rebecca Simms (pi)  
**Submission type:** Modification / Update  
**Primary contact:** Rebecca Simms (pi)  
**Institution:** Brown University

Workflow diagram: Pre-Submission → Pre-Review → Pending Review. A feedback loop exists from Pre-Review to Clarification Requested, which then feeds back into Pre-Review.

History | Contacts | Documents | Reviews

- Click “Record sIRB Decision”.

**Pending sIRB Review**

Entered IRB: 2/26/2020 2:41 PM  
Last updated: 2/26/2020 2:46 PM

**Next Steps**

- Edit Modification
- Printer Version
- Record sIRB Decision
- Assign Coordinator
- Manage Ancillary Reviews
- Correspond with sIRB
- Add Comment
- Add Private Comment

**SITEMOD001-STUDY000**  
**Update #1 for CIRB 123**

**Principal investigator:** Rebecca Simms (pi)  
**Submission type:** Modification / Update  
**Primary contact:** Rebecca Simms (pi)  
**Institution:** Brown University


Workflow diagram: Pre-Submission → Pending Review. A feedback loop exists from Pending Review to Clarification Requested, which then feeds back into Pre-Submission.


History | Contacts | Documents | Reviews

Filter by

- A new window will open.
- Confirm the approval/expiration dates did not change from the initial or last CR approval by CIRB.
- Click “Approved.”

- Mark that you are ready to submit (see below)

12. \* Do you need to finalize documents or send a letter?   Yes  No [Clear](#)

13. \* Are you ready to record the sIRB's decision?   Yes  No [Clear](#)

OK

Cancel

- Click OK
- Click on “Finalize documents”
- Select the addendum to be re-stamped
- Click OK.

#### If the study team updated the study

If the study team does not have the option of submitting a modification, they will need to use “update study” option. The study team may reach out to you if they do not see the “finalize update” option. Confirm everything looks correct and click “Finalize Update”.

- Click “Return to post review”
- Mark yes to question 3
- Click on “edit sIRB Decision”.
- Click “Approved” for question 1.
- If you don’t need to finalize documents, you don’t have to change approval/expiration dates. If you need to finalize documents, change the effective approval date to today’s date. Make sure that the expiration date matches the current approval period.
- Upload the letter the team logged as a comment under question 3
- Click on pre-2018 under question 4 (if not selected already)
- Skip questions 5 to 11.
- Say yes to question 12 if you need to finalize documents. If no, answer “no” to this question.
- Click OK
- Finalize documents, if needed.
- Note: If you had to finalize documents and the system requires you to create a letter upload the NCI CIRB approval letter and click “send letter.”

#### **Processing Reportable new information submissions**

Follow the SOP entitled “[Reportable New Information \(RNI\) Submission Notification Process for External IRB Studies](#)” for additional steps.

#### **Processing Close-Outs**

PIs are responsible for submitting a Study Closure to NCI CIRB via IRBManager. The PI logs a comment in the submission with a letter from the NCI CIRB indicating the study has been closed. Click “close site”.

**REFERENCE**

- NCI CIRB SOPs: <https://www.ncicirb.org/about-cirb/sops>

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
9/11/2023	Clarified CIRB processing Archiving logs older than one year



<b>SOP Title:</b>	Reportable New Information (RNI) Submission Notification Process for External IRB Studies
<b>SOP Category:</b>	Collaborative Research / Central IRBs
<b>Established:</b>	12/9/15
<b>Last Revision:</b>	07/6/2023

## PURPOSE

This SOP details the process for reviewing RNIs reported to the Emory IRB for studies reviewed by external IRBs. This SOP also includes the process for the review of the CR at the time of the study renewal.

## TIMEFRAME

Once the Emory IRB is notified of an RNI for an external IRB study, other than in summary format at Continuing Review, the Emory IRB aims for 2 business days to review it and forward it to the appropriate Emory officials as detailed below. Once the RNI determination letter from the external IRB is received, the Emory IRB must complete the procedure described below within 5 business days.

For CR summaries, contact team Q if the study team is reporting an egregious event that was not submitted promptly during the last approval period.


## BACKGROUND

- Emory study teams are responsible for submitting RNIs to the external IRB as required by the external IRB’s reporting policies but should follow our reporting requirements if the external IRB’s requirements are less stringent.
  - If these events are determined to represent an unanticipated problem, serious noncompliance, or continuing noncompliance the external IRB will forward the determination letter to the Emory IRB.
- The study team is also responsible for reporting to the Emory IRB for studies reviewed by external IRBs when the following **internal** events occur:

Event Type	Reporting Timeline
Egregious events <ul style="list-style-type: none"> <li>• Wrong side surgery</li> <li>• Wrong drug</li> <li>• Wrong patient</li> <li>• Fabrication of data</li> <li>• Falsification of data</li> <li>• Breach of confidentiality (HIPAA Privacy Breach)</li> <li>• Study Suspension (related to compliance concerns)</li> <li>• Internal related death</li> </ul>	Promptly with an RNI
Unanticipated Problem that <ul style="list-style-type: none"> <li>• Is an Internal event</li> </ul>	In summary format at Continuing Review

<ul style="list-style-type: none"> <li>• Is unexpected</li> <li>• Is related or possibly related to the research</li> <li>• Suggests the research poses a greater risk of harm than was previously known</li> <li>• <b>Does not fall under “Egregious events” above</b></li> </ul>	
<p>Noncompliance</p> <ul style="list-style-type: none"> <li>• Other failure to comply with laws, regulations, or Emory policies and procedures</li> </ul>	<p>In summary format at Continuing Review</p>

### PROCEDURE FOR SUMMARY AT CR

- The study team should submit via  [Report Continuing Review Data](#) once the external IRB has reapproved the study. The report should include a completed [CR workbook](#).
  - If the study team is including an egregious event in the workbook, ensure this was reported to the Emory IRB via an RNI in the last approval period. If the study did not report it to us using an RNI, please contact team Q for the next steps.

### PROCEDURE FOR RNIs

#### Egregious Events

1. Upon receipt of the RNI, the QA Director/Team Lead reviews it to determine if it falls into one of the egregious events listed in the chart above. If the event is not an egregious event, the QA Director/Team Lead will assign themselves as coordinator and administratively discard the event with a logged comment to the team.
  2. If it falls into one of the above categories, the QA Director/Team Lead will email the reliance lead to let them know and will delegate the case to a member of Team Q for Institutional notification.
    - a. Complete the internal notification as noted below.
    - b. The team Q member then creates a file under on the H: drive in the QA Working Files\NC UP Complaints\RE Notifications from External IRBs folder with study number and PI name, using the following format (1234 Jones) and save all documentation related to the RNI.
    - c. Enter the information of the reported event in this [spreadsheet](#) located at OneDrive/IRB-Staff/Documents/H drive/General
  3. The external IRB should send notice of its determination and the determination letter to the Emory IRB. Request the Emory researcher to upload the determination letter in the RNI via logged comment if it is not provided at initial submission.
  4. Once all reporting is complete and any fed letters have been filed in the QA folders, the Q team member should update the spreadsheet and should self-review the RNI submission. The Q team member should not check any determination boxes, since these determinations were not made by our IRB. The Q team member should instead enter the reviewing IRB’s determination in the Notes field and submit the review. The final state is “acknowledged.” There is no need to write a letter.
4. Follow the post determination notification procedure noted below.

5. Once the external IRB determination is in, follow the 'external IRB determination' notification process below for SNC, CNC, UP, suspension as applicable.

### **Institutional Notification (pre-IRB-determination)**

While awaiting a determination from the reviewing IRB, a member of Team Q will draft an email to the appropriate parties and will copy and paste the lay summary into the body of the email. They will attach a pdf copy of the RNI report and any relevant attachments. Include a link to the RNI submission in the body of the email as well.

See [contact grid](#) for who to copy in the notifications.

### **PROCEDURES FOR REPORTS RECEIVED DIRECTLY FROM EXTERNAL IRBs**

1. For external IRB determinations of serious noncompliance, continuing noncompliance or unanticipated problems received directly from external IRBs, the Emory IRB person who was notified will forward the email to the AVP for the HRPP, Reliance AD and Team Q with the information with the RNI number (if applicable).
  - a. Upload a copy of the letter under the RNI submission (as applicable).
  - b. If an RNI does not exist, Team Q will review the information to determine if the submission was needed (in case it was not submitted).
  - c. Follow the procedure under "Notification to Internal IOs" as appropriate. These notifications are only required for determinations of SNC, CNC, or *internal* (at Emory sites) UPs.
2. For external IRB determinations that an event was **not** SNC/CNC/internal UP, proceed to EGREGIOUS EVENT RNI CLOSURE IN EIRB.

### **PROCEDURE AFTER DETERMINATION IS MADE**

#### **IRB DETERMINATION NOTIFICATION TO INTERNAL IOs**

For egregious events or events the external IRB determined to be SNC, CNC, UP, update the External IRB reporting [spreadsheet](#). The Q team member drafts an email to the Emory PI with the IRB # and Study Short Title in the subject line stating the following:

- i. *Dear Dr. \_\_\_\_\_:*  
*We have received notification that the [Reviewing IRB] determined that a reportable new information submission during the course of the above-referenced study constitutes a [type of determination]. Attached, please find the determination letter from [Reviewing IRB]. This determination may be reported to the sponsor and federal oversight agencies, as applicable.*  
*It is imperative that you follow your CAPA Plan as written. If you find that there are any inaccuracies in this letter, please notify your point of contact at [Reviewing IRB].*

*Please let me know if you have any other questions. Thank you for your cooperation.*

2. CC based on the [contact grid](#) Once sent, save a copy of the determination letter and the email in the study folder under QA Working Files.
3. Note: If you receive copies of external reports from agencies or notices of receipt of external reports from agencies, scan and/or save them under QA Working Files in the appropriate study folder. If the report produces any results, save the contents in the same manner, and email it to the IOs using the same process described above.
4. Save letters to federal agencies in the folder in QA working files, but there is no need to send the letters to the IOs.

#### **EGREGIOUS EVENT RNI CLOSURE IN EIRB**

- Once all reporting is complete and any fed letters have been filed in the QA folders, the Q team member should update the spreadsheet and should self-review the RNI submission. The Q team member should not check any determination boxes, since these determinations were not made by our IRB. The Q team member should instead enter the reviewing IRB's determination in the Notes field and submit the review. The final state is "acknowledged." There is no need to write a letter.

#### **LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
02/24/2023	Revised IO notification letter in reference to the other notifications, linked out to contact grid
07/06/2023	Added clarification around study suspension and archived log older than one year

<b>SOP Title:</b>	Vetting NIH Single IRB Plans
<b>SOP Category:</b>	Collaborative Research / Central IRBs
<b>Established:</b>	5/15/2018
<b>Last Revision:</b>	8/21/2020

## PURPOSE

This SOP outlines the process the reliance team uses to review Single IRB plans for federally-funded multi-site research at the grant application stage.

## PROCEDURES

1. Upon receipt of a request to review a single IRB plan, review the information provided by the investigator and ask for additional information if needed. The information that is needed is the research related activities that will take place at each site and the number and location of sites that will participate in the research. Note: Emory is not currently resourced to serve as the Single IRB for studies involving more than 5 sites in the U.S. and will not provide oversight to international sites.
2. The Single IRB plan may state that Emory will serve as the Single IRB, that another IRB will serve as the Single IRB, or that the Single IRB has not yet been determined.
3. Consult with an AD or Director to determine whether Emory can serve as the Single IRB.
4. If Emory IRB is willing to be the IRB of record, notify the investigator they may proceed with the Single IRB Plan naming Emory IRB as the sIRB.
  - a. Provide the Emory investigator with a Letter of Support to include with the sIRB Plan. Use the template letter located in this folder: H:\External IRB Relationships 6.3.2020\07. Templates
5. If Emory IRB is not willing to be the IRB of record, notify the investigator and provide two options:
  - a. The investigator can contact the IRBs of other participating sites to see if they are willing to serve as the reviewing IRB. Suggest to the investigator that the IRB will need to be AAHRPP accredited and have experience serving as the reviewing IRB for multi-site research. Instruct the investigator to confirm whether or not the IRB charges a fee to serve as the sIRB so the anticipated expense can be included with the budget.
  - b. The investigator can request a quote from WIRB or another commercial IRB and include that in the budget submitted with the grant. Refer the investigator to the information on our website including the quote request form.
6. Once a single IRB is identified, the investigator may use the templates on the Emory IRB website to draft the Single IRB Plan.
7. If Emory is not serving as the Single IRB, remind the investigator to use the Single IRB Quote Request Form found on the Emory IRB website to request a quote from WIRB and include in the budget submitted with the grant.
8. Save the email correspondence and any letters of support on the H Drive at H:\External IRB Relationships 6.3.2020\04. Single IRB Plan Requests. Create a new folder and name it as follows:  
*Last Name, First Name – Title.*

## LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
8/31/2019	Removed "reliance specialist"
2/11/2020	Updated to reflect current practice
8/21/2020	Revised process to update current folders, email address and remove Single IRB Intake Form

<b>SOP Title:</b>	XIRB Study Processing When Emory Relying on An External IRB Other than the NCI CIRB
<b>SOP Category:</b>	Collaborative Research / Central IRBs
<b>Established:</b>	1/3/2018
<b>Last Revision:</b>	7/5/2022

## PURPOSE

The purpose of this SOP is to outline the steps IRB staff use to process submissions when Emory is relying on an external IRB (other than the NCI CIRB).

## SCOPE

This SOP applies to any multi-site study where Emory is relying on an external IRB other than the NCI CIRB. It outlines steps for processing initial submissions as well as follow-on submissions.

## PROCEDURES

1. For WCG studies, create a new folder to save a copy of the study checklist for the study here:  
(H:\External IRB Relationships 6.3.2020\03. Current Umbrella IAAs\WIRB\WIRB Study Documents).
2. For other studies, create a new folder for the external IRB checklist and reliance documents:
  - Go to this folder: H:\External IRB Relationships 6.3.2020\01. Current IAAs
  - Right click and copy the folder “USE THIS TO CREATE NEW FOLDERS”
  - Double click on the “Emory Relying” folder
  - Paste the “USE THIS TO CREATE NEW FOLDERS” folder and then rename it with the following naming convention:<initials of reviewing IRB or short name>\_PI Last Name (short title of protocol) STUDY ID

Examples:

- Mayo\_Cohen (LEO) 2973
  - JHM\_Smith (ROP3) 4567\_
3. Rename the study checklist to include the study number.
  4. Review smart form for completeness. If the following are not included, withdraw the submission and log a comment to the study team letting them know what is needed and to resubmit once the following information is available (see template text in AA OneNote page):
    - For WCG and Advarra – Completed Form A
    - For other external IRB studies – Supplement to protocol
    - EPEX number (if funded)
    - Review the SOP titled “Cost Option for Clinical Trial Agreements and ICFs” to determine the correct cost option.
    - Confirmation of in case of injury option from RAS/OSP (Note: Fed funded = option 1)
    - Ancillary review approvals (PRMC, EHSO Radiation Safety, EHSO Biosafety, COI, etc.)
    - Current CITI training for all study team members

5. If the short study title does not begin with “XIRB:” and the name or abbreviation of reviewing IRB, request that it be added. (Examples: XIRB: Advarra, XIRB: UNC, XIRB: WUSTL, XIRB: Utah) Studies going to WCG may just begin with “WIRB” or “WCG.”
6. Use the XIRB study checklist to review external IRB studies. Complete the checklist and attach to a logged comment listing pending items so the study team is aware of what is needed before we can issue institutional signoff. Repost an update weekly.
7. Manage any required ancillary reviews as applicable. Refer to the SOP “Pre-Review options and Ancillary Review Information.” You will need to update the review to “accept” it and upload the approval document provided by the study team.
8. Confirm that all required training is current for all Emory study team members. If unsure what is required, review guidelines posted on our website.
9. If the study team has requested Sensitive Study Status -selecting Yes to Q5 in For Clinical Research/Expanded Access Only:
  - Manage Ancillary Reviews
  - Assign the review to Dr. Gunthel – Do not select a department or a review type.
  - The response is required
  - E-mail Dr. Gunthel with a study link, study number, and an explanation of the review. Please request Dr. Gunthel log a comment so that it shows in the study history.
10. If applicable, ensure that Margaret Huber in the Office of Compliance (mhuber@emory.edu) has completed a REMS (REMS mentioned in protocol) review of the study, or Controlled Substance form (box is marked in smart form). See new study checklist for more information.
11. If changes to the smart form or uploaded documents are needed, click “Request Pre-Review Clarifications” and describe the changes that are needed.
12. If provided, complete the Local Context Review form provided by the reviewing IRB. If the form requests specific information regarding the study activities that will be conducted by Emory, forward the document to the Emory study team for completion of their portion of the form. Review completed form with reliance AD. If a LCR form is not provided in the smart form, use the Emory template found in this folder: H:\External IRB Relationships 6.3.2020\06. Forms and Checklists.
13. Once the local context review process is complete, confirm with the Reliance AD if there is a fully executed reliance agreement in place (there is a master agreement in place with Advarra and WCG IRBs) and click on the Confirm Reliance button on the left side of the study workspace in eIRB.
14. Upload the executed reliance document (N/A for WCG or Advarra), the completed local context form, completed external IRB consent checklist and COI management plan (if applicable).
15. Click the Yes button to confirm reliance on the single IRB of record. Click OK. The study should now be in the Pending sIRB Review state. (Once the site-specific approval letter and ICFs are available from the reviewing IRB, the study team is responsible for providing these documents to the Emory IRB via a logged comment in the smart form.)
16. Review the external IRB approval letter to confirm it is for the correct study and PI and is a full approval. Discuss with the reliance AD if you have questions about the letter.
17. Click on Record sIRB Decision on left of study workspace.
18. Select the correct determination. (This should be “Approved.”)
19. Enter the initial approval date of the study and the initial approval date of the site. Enter the last day of study approval period and the last day of local site approval period.
20. Upload the approval letter from the reviewing IRB.



21. Mark the appropriate options for the remaining questions 4-9.
22. Mark No to Finalize Documents.
23. Mark Yes to record decision and click OK.
24. The study should now be in an Active state.
25. Confirm the dates are correct under the word Active on the top left corner of the main study page. If the dates are not correct, return the study to post-review.
26. Click on Edit sIRB Decision and enter the correct dates. Click OK. The study should appear back in the active state.
27. Log this comment to the study team “Emory has acknowledged the approval letter from the reviewing IRB and your study has been moved to an Active state. Refer to the Collaborative Research page on the Emory IRB website regarding study team responsibilities for submitting continuing reviews, modifications, and reportable events when Emory is relying on an external IRB.”

### **Beyond Initial Approval:**

#### **Modifications:**

1. Study teams are responsible for notifying the Emory IRB of certain changes to ongoing research as noted on the collaborative research section of the Emory IRB website. Depending on the study status (“Active” vs “External IRB”), the study team may report changes by submitting a modification (that we **approve**) or will use the “update study” function (that we **accept**). We prefer study teams to use the modification function if they have it. If they do not have that option, the study team will need to use the update study activity. Be aware that study teams are able to accept site updates themselves. They should not do this, and AAs are still responsible for reviewing updates.

Review the external IRB approval letter and confirm the changes being reported to the Emory IRB match what is noted in the approval letter.

2. For modifications to add or remove Emory study personnel, follow the SOP “Adding/Removing Study Personnel.” AAs can approve these modifications.
3. For modifications indicating increased risk, follow the SOP titled “Modifications: Mods indicating increased risk.”
4. For modifications that require new ancillary reviews such as a new COI, change to radiation procedures, infectious agents, etc., consult an Assistant Director for guidance.
5. **For S-I Studies Only:**
  - If study team submits a modification that includes addition of external sites or identifies new risks, trigger a new S-I ancillary review so that Margaret Huber receives notification.
  - If the study team is requesting to add external sites, log this comment to the study team: “If you plan to add participating external sites, contact the reliance team lead at [irb.reliance@emory.edu](mailto:irb.reliance@emory.edu). In addition, you are required to notify the S-I advisor before external sites are activated by sending her a completed S-I IND Responsibilities Checklist Multi-site Trials for review / S-I IDE Responsibilities Checklist Multi-site Trials for review.”
  - The modification cannot be approved without S-I ancillary signoff.

### **Changes Reported using Update Study activity**

6. When the study team uses the “update study” function, the owner/AA receives an email. Review each update.
7. When updates are finalized, the owner/AA will receive an email “Emory eIRB Notification of Finalize Updates.” The owner/AA needs to look at each one to confirm the study team has not finalized the update themselves.
8. Review the changes reported and finalize the update. The owner/AA can approve modifications for study staff changes.
9. Click “Accept Site Updates”

### **Continuing Reviews**

#### **For S-I studies only:**

- Once a month the Reliance Team Lead will run a report of XIRB studies where the Emory PI holds the IND or IDE that shows studies expiring within 60 days.
- The Reliance Team Lead will log the following comment to the study team and trigger a new S-I ancillary review. Insert the date of expiration and the date of the deadline to complete the S-I review which is 30 days prior to study expiration:  
“This study is due to expire on MM/DD/YYYY. As the Sponsor-Investigator of this study, you are required to complete the IND Responsibilities Checklist Continuing Review Update / IDE Responsibilities Checklist Continuing Review Update for this study at each continuing renewal if subjects remain in follow-up and send to the S-I advisor (Margaret Huber, mhuber@emory.edu) for review. You must complete the S-I review at Emory by MM/DD/YYY”
- Continue processing as below.

#### **Begin here for Studies that are not S-I studies:**

- Study teams are expected to report CR data to the Emory IRB. The report should be made upon receipt of the CR approval letter provided by external IRB. If the PI is not available to report the data, it may come in via logged comment.
- If the data comes via logged comment, confirm that the IRB renewal letter is for the correct study and the CR Workbook is attached.
- If relevant documents are attached, click “Report Continuing Review data” on the left menu. A new window will open.
- In #4, upload the IRB approval letter and CR Workbook and click OK.

**1. Specify enrollment totals at this investigator's sites:**

**2. Specify enrollment totals at this investigator's sites since last approval:**

**3. Check the items that are true for this site since the last IRB approval:** (initial review or last continuing review)

- NO subjects experienced unexpected harm
- Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- NO subjects withdrew from the study
- NO unanticipated problems involving risks to subjects or others
- NO complaints about the study
- NO publications in the literature relevant to risks or potential benefits
- NO interim findings
- NO multi-center trial reports
- NO data safety monitoring reports
- NO regulatory actions that could affect safety and risk assessments
- NO other relevant information regarding this study, especially information about risks
- In the opinion of the PI, the risks and potential benefits are unchanged
- All modifications to the protocol have been submitted to the IRB
- All problems that require prompt reporting to the IRB have been submitted

**4. Supporting documents:** (include an explanation of each item left unchecked above)

Name
There are no items to display

**5. Comments:**

- Click "Return to Post-Review" on left menu.
- Click the box to the right of question #3.
- Click OK.
- Click "Edit sIRB Decision." Do not change initial approval or initial effective dates.
- Enter the expiration date noted on the approval letter in the field for the last day of local site approval period.
- Upload the CR approval letter in #3.
- Click OK.
- Confirm the dates entered are correct on the main study page. If not, click "Return to Post-Review" and complete the process again.

**Active**

Entered IRB: 8/12/2020 1:03 AM  
 Initial approval: 1/4/2020  
 Initial effective: 1/5/2020  
 Effective: 1/7/2021  
 Approval end: 1/7/2022  
 Last updated: 2/22/2021 12:31 PM

- The study team is also be expected to update their study personnel list at this time. Specifically, they need to add any team members that were added during the prior approval period. If you do not see a corresponding update with the report of CR data, please request. Once the personnel are added, training should be confirmed per the SOP entitled "Training Verification."

## Reportable New Information (RNIs)

### For S-I studies Only:

1. Notify Reliance Team Lead upon receipt of RNI.
2. Trigger S-I ancillary review for the RNI and notify Q.
3. If S-I review determines there is an issue that should be escalated to the external IRB, the S-I Reviewer will notify the Reliance Team Lead and Team Q lead within two business days if egregious event and within five business days if not egregious event.
4. The Reliance Team Lead or Team Q Lead if Reliance Team Lead unavailable, will notify the reviewing IRB point of contact within two business days.
5. Upon receipt of response from reviewing IRB point of contact, Reliance Team Lead or Team Q lead if Reliance Team Lead unavailable, will log a private comment in the history of the study with the correspondence.
6. Reliance Team Lead or Team Q lead if Reliance Team Lead unavailable will follow up with the reviewing IRB point of contact weekly until the matter is considered closed at the reviewing IRB.

### For All Studies:

Study teams are required to report local adverse events directly to the external IRB if according to the external IRB's reporting criteria. They are also required to report events to the Emory IRB per the guidance posted on the Emory IRB website.

Save all emails related to RNIs and Unanticipated Problems under the WCG IRB Study Document folder (H:\General\External IRB Relationships 6.3.2020\WIRB\WIRB Study Documents W00000XXX) after notifying the Q team.

Follow the SOP entitled "[Reportable New Information \(RNI\) Submission Notification Process for External IRB Studies](#)" for additional steps.

## LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
5/24/2021	Adding additional information to the checklist process
8/30/2021	Updated process and archived log of changes over 1 year old
9/20/2021	Revised to make applicable to Advarra studies, removed detailed steps that are covered in the checklist
01/07/2022	Revised to reflect new process, include WCG studies, and provide steps for follow on submissions
04/6/2022	Added guidance for S-I studies
4/22/2022	Archived Updates over 1 year old in log of changes
4/28/2022	Minor edits to remove specific logged comment and specific criteria for mods
7/5/2022	Added guidance to follow cost option SOP

<b>SOP Title:</b>	XIRB Study Processing for Studies Transitioning from Emory IRB Approval to External IRB Review
<b>SOP Category:</b>	Collaborative Research / Central IRBs
<b>Established:</b>	8/21/2020
<b>Last Revision:</b>	02/24/2023

**PURPOSE**

This SOP outlines how the IRB Analyst/Reliance RPA will process studies transitioning from Emory IRB to External IRB review when required by federal regulations.

**SCOPE**

This SOP applies to any study currently approved by the Emory IRB that is required to use an sIRB due to the NIH Single IRB Mandate or the Cooperative Research Component of the Revised Common Rule.

**PROCEDURE**

1. Instruct the study team to submit an external IRB study in eIRB and include the following documents:
  - Emory original IRB approval letter
  - all current documents from the previous IRB smart form
  - study-wide approval letter from the sIRB
  - local context review form and reliance document if provided by the sIRB
2. Instruct the study team to log the following comment when they submit the XIRB study.  
 “This is a resubmission of Emory IRB00xxxxxx. This study is now required to transition to the [NAME] IRB that will serve as the single IRB of record for this study. Per the Emory IRB, department review and other ancillary reviews do not need to be repeated.” If the study team did not log this comment, the analyst will need to do it.
3. Follow the SOP titled “XIRB Study Processing When Emory Relying on An External IRB Other than the NCI CIRB .”
4. Email OCR and OSP, copying the PI and study coordinator that the IRB number for the project has changed from the original Emory IRB number to the new external IRB study number.
5. Instruct study team to close out original Emory-approved study.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
3/11/2021	Added notification to OCR and OSP when IRB number for study changes
8/30/2021	Minor edits for clarity and archiving logs of changes over 1 year old
4/28/2022	Simplified to refer to SOP
02/24/2023	Removed reference to reliance request form which we no longer use.

<b>SOP Title:</b>	Closing Out Multi-Site Studies
<b>SOP Category:</b>	Collaborative Research / Central IRBs
<b>Established:</b>	3/30/2018
<b>Last Revision:</b>	3/11/2021

## **PURPOSE**

This SOP details how to close out studies that are multi-site 1) when Emory has ceded review to an external IRB and 2) when Emory is the IRB of record for external sites.

## **RESPONSIBILITIES**

- Analyst – processing the close-out from the IRB side for studies where Emory is the IRB of record.
- Reliance RPA- processing the close-out from the IRB side for studies where Emory is relying on another IRB.
- Emory study team- collecting all necessary information and documents for the close-out and initiating the close-out. Being a liaison between the IRB and the other study teams.

## **PROCEDURE**

### For External IRB Studies:

1. The study team submits a “Report Continuing Review Data” and uploads the closeout letter from the external IRB.
2. Click on “Close Site” from left menu.
3. This activity will discard all pending modifications but pending RNIs will remain. Review the pending modifications that appear in the window before closing the study.
4. Enter a comment and click OK.
5. The study is now closed.

### Where Emory is the IRB of Record:

#### **Site Closure:**

1. To close a site while the rest of the study remains open, the study team submits “Report Continuing Review Information.” The study team provides a study summary detailing why the site is closing and providing the information requested in the activity.
2. Click “Close Site” from left menu.
3. Log a close out comment using the template language document on the H drive and click OK. The site is now in a closed state.
4. Click Prepare Letter from left menu. There is no option for a site closure letter, so use the Closure Template letter saved here on the H drive External IRB Relationships Folder 6.3.2020 Folder> 07. Templates.
5. Upload revision.
6. Name the letter “STUDYXXXXXXXXX\_Site Number\_Site Name\_Closure\_date” and click OK.
7. Click “Send Letter” from left menu.
8. Click OK.

#### **Study Closure:**

1. The Emory study team clicks on Sites tab, selects a site, and reports continuing review information. They will do this for each active site. The study team marks “Yes” to “Report Completed” for each site and clicks “Submit” on the left menu.
2. The Emory study team submits a Continuing Review indicating they want to close the study and completes the fields.
3. Review the CR.
4. Complete the pre-review.
5. Assign to a designated reviewer.
6. The designated reviewer completes their review.
7. The study will be in post-review.
8. All pSites, CRs ad Mods must be closed before the study can be closed. Click on Sites tab and select a site.
9. Click “Close Site” from left menu, enter a comment and click OK.
10. Click Prepare Letter.
11. Select the PI Study Closure Letter and edit as needed.
12. Upload revision
13. Name the letter “STUDYXXXXXXXXX\_Closure\_date” and click OK.
14. Click Send Letter. The CR is now approved, and the study is closed.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
8/31/2019	Replaced “reliance specialist” with “reliance RPA”
9/7/2020	Updated process for SaaS

<b>SOP Title:</b>	Issuing Partial HIPAA Waivers for XIRB Studies
<b>SOP Category:</b>	Collaborative Research / Central IRBs
<b>Established:</b>	2/1/2019
<b>Last Revision:</b>	1/04/2023

## PURPOSE AND SCOPE

This SOP outlines the process for the Emory IRB to issue a partial HIPAA waiver for recruitment purposes to Emory study teams when Emory has ceded IRB review to an external IRB and that IRB does not issue such waivers. This SOP **only** applies when Emory has been designated as the Privacy Board for the Emory study team under the reliance agreement.

**Note:** WCG IRB and Advarra IRB both serve as the Privacy Board as do most academic IRBs.

## PROCEDURE

1. Ensure the study team has completed the HIPAA Applicability and Waivers Requested section of the smart form and uploaded the HIPAA Applicability and Waiver Worksheet.
2. Review the information provided by the study team and request clarification if needed.
3. Send an email to the Emory IRB Asst or Associate Director requesting the partial HIPAA waiver for recruitment purposes. The IRB number should be included in the subject line of the email.
4. The authorized individual should review the waiver request within five (5) business days. (If not, send a reminder email.)
5. The authorized individual will log a comment in the history tab in eIRB indicating if the waiver has been granted.
6. Include the determination regarding the partial HIPAA waiver in the institutional sign off and if applicable, the local context review form that Emory completes for the reviewing IRB.

## LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
4/11/2019	Updates to follow current process
8/31/2019	Replaced "reliance specialist" with "reliance RPA"
8/21/2020	Updated for current process
1/20/2021	Updated to provide more details
4/28/2022	Revised SOP title and added clarification about scope.
7/05/2022	Added Advarra



<b>SOP Title:</b>	Processing New Studies When Emory is the Single IRB of Record (sIRB) for a Multi-Site Study
<b>SOP Category:</b>	Collaborative Research / Central IRBs
<b>Established:</b>	8/21/2020
<b>Last Revision:</b>	02/24/2023

## **PURPOSE**

This SOP outlines the steps to process studies when Emory IRB is serving as the sIRB.

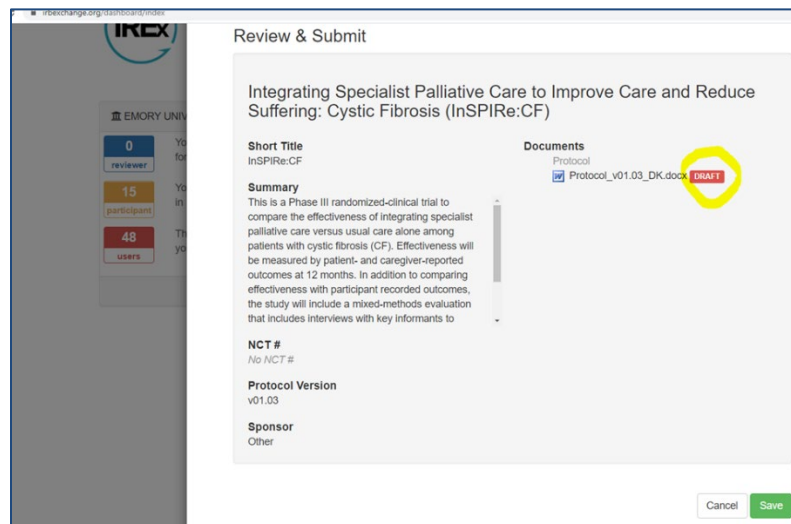
## **SCOPE**

This SOP applies to any new multi-site study for which Emory has agreed to serve as the sIRB for other sites that will enroll participants. (For studies with external collaborators that will not enroll participants but who wish to rely on Emory IRB for review, see the SOP titled “Analyst Process of IRB Authorization Agreements (IAA) or Individual Investigator Agreements (IIA) Reliance Agreements When Emory is the Reviewing IRB for External Collaborators.”)

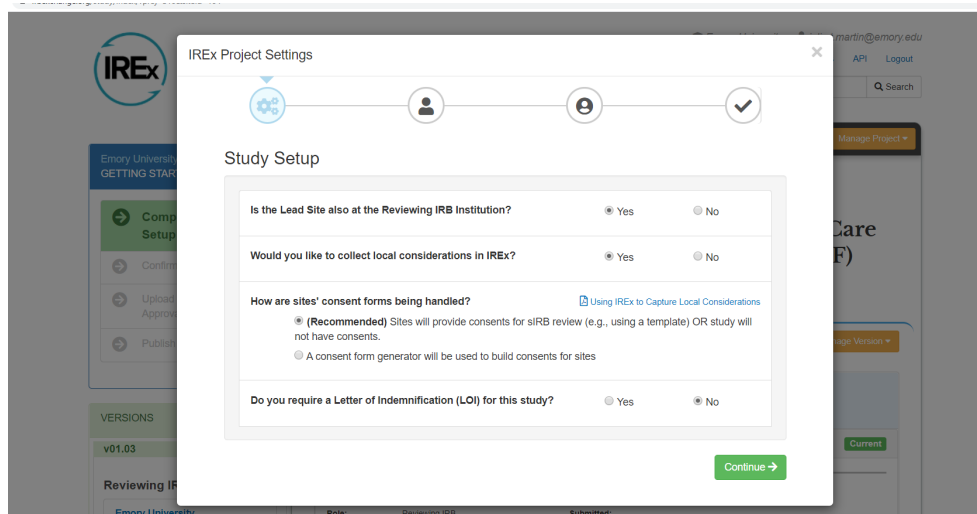
Note: If the study is an S-I study, consult the Assistant Director for the reliance team before proceeding.

## **PROCEDURE**

1. Upon confirmation that Emory will serve as the sIRB for the study, the reliance analyst will instruct the study team to submit a multi-site sIRB study in eIRB.
  - a. Instruct the study team to insert “sIRB - ” prior to the short study title.
  - b. If the study is also an S-I study, instruct the study team to insert “S-I” after the short study title.
2. If more than one relying site will enroll participants, the Emory study team’s project manager/lead coordinator will set up a study in the IRB Reliance Exchange (IREx) by logging into the website at <https://www.irbexchange.org/p/>. Directions provided below to assist if needed.
  - a. Create a Study
    - i. Provide description of the study
    - ii. Enter the protocol date/version
    - iii. Upload the protocol and mark as Draft. It is important to mark as Draft so the protocol can be updated later.
    - iv. The Review & Submit screen as shown below will appear. Confirm the protocol is marked as a draft in red. If all information is accurate, click Save at the bottom.



- v. Complete the Study Setup. Mark Yes for the first two questions, mark that sites will provide the consents for sIRB review, and mark No for LOI. (LOI will be included in the SMART IRB LOA if applicable for each site.)



- b. Identify the study manager. Confirm the study manager with the PI if it is not clear. The study manager will manage the flow of documents between the Emory IRB and sites.

**Study Processing Steps:**

1. Once the study is submitted in eIRB and assigned to a reliance analyst, the reliance analyst will follow the SOP titled “eIRB Processing of New Study Applications – Preliminary Analysis Through Approval.” If the study is an S-I study it will be assigned to an S-I analyst.

**Note:** The initial approval will be for the protocol and master consent form that will be distributed to the external sites as well as the approval for the Emory site.

- a. Ensure the study team uploads all master consent forms, recruitment materials, and any other study-wide documents in the Study-Related Documents section of the smart form.

- Enrolling sites will use the site addendum to add their institutional language to the approved master consent form later in this process.
- b. Ensure the Emory site-specific consent form and recruitment materials are uploaded in the Local Site Documents section of the smart form.
  - c. Finalize only the Emory site-specific consent form and not the master consent form.
  - d. List the master consent form(s) in the list of approved documents in the approval letter.
2. The reliance analyst will upload the approved documents in IREx.
  3. After the study is in an approved state, it will appear in the study team's External IRB tab in eIRB with an "Active" state.

**Adding Participating Sites:**

1. The reliance analyst will submit a ticket to ORA-IT requesting the external site PIs be added to the eIACUC user database. Provide them with the last name, first name, email address, and name of the PI's institution. The person is usually added within two business days.
  2. While awaiting addition of the pSite PIs to eIRB, confirm whether the relying site institutions are signed on to the SMART IRB Master Reliance Agreement by searching participating institutions on the Smart IRB website.
  3. Prepare the reliance instructions using the IREx template located in this folder: H:\External IRB Relationships 6.3.2020\10. Emory as sIRB Materials\IREx Materials. If the relying institution is not part of SMART IRB, use the standard reliance agreement template for that site. Prepare the template reliance documents with the study-specific information.
  4. Complete the study-specific information in the reliance instructions template for IREx.
  5. The reliance analyst will send the following materials to the Emory study team point of contact for distribution to relying sites:
    - i. Reliance instructions form for IREx
    - ii. Emory IRB approval letter
    - iii. Emory IRB approved protocol
    - iv. Emory IRB approved master consent form
    - v. SMART IRB LOA (and/or standard reliance agreement if an institution is not part of SMART IRB), can also just use documentation in IREx system
  - a. In the email to the study team point of contact, instruct the point of contact to send the materials to the site PIs, copying both the relying IRB point of contact for the site(s) and the Emory IRB reliance email address.
  - b. Remind the study team point of contact that they will need to follow up on the collection of documents until they are completed and upload them in the pSite study workspace once completed.
  - c. Let the study team know that you will be creating the sites while waiting on the study teams to complete the documents.
6. Once the reliance analyst receives confirmation that the external PIs have been added in the eIACUC database, the reliance analyst will click "Add Participating Sites" from left menu in the study

workspace and follow the prompts to add the participating sites. The sites automatically appear under the “Sites” tab with the state “Invitation Pending.”

7. Select Submit Invitation Decision and complete the questions. This moves the site into the state “Awaiting Site Materials.”
8. Once the documents are completed for a pSite (reliance agreement, local context review form, site-specific consent form) instruct the Emory study team to select the site(s) under the Sites tab and complete the smart form for each site.
9. Confirm the study team has uploaded clean and tracked versions of the draft site-specific consent form, in the Local Site Documents section along with site-specific recruitment materials, executed reliance agreement, and signed local context review form or pdf copy of local context review from IREx.
10. Once the smart form is complete and the PI clicks “Finish”, they must click “Submit Site Materials” from the left menu.
11. Review the smart form for completeness and send back to study team if edits are needed.
12. Once the smart form is complete, click “Assign Designated Reviewer” from left menu and assign to the Reliance Team Assistant Director, another AD or the Director.
13. Once the Designated Reviewer has submitted the review, the site will appear in the “Post-Review” state.
14. Click “Finalize Documents” and finalize the site’s consent form. Click OK.
15. Prepare the site’s approval letter using the Site Approval template from the drop down.
16. Click on the draft letter.
17. Add post nominals if necessary and edit the letter as needed.
18. Upload the revised letter.
19. Send the letter.
20. The site will now appear in the Active state.
21. Upload the approval documents for each site in IREx.
22. Repeat the process for each site that is to be added to the study.

#### **LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
04/06/2022	Revised to reflect new process (no need for external team member list)
04/22/2022	Archived log of updates over 1 year old
02/24/2023	Minor clarifications such as studies being assigned to reliance team for processing

<b>SOP Title:</b>	Processing Modifications When Emory is the Single IRB of Record (sIRB) for a Multi-Site Study
<b>SOP Category:</b>	Collaborative Research / Central IRBs
<b>Established:</b>	01/20/2021
<b>Last Revision:</b>	01/05/2023

## PURPOSE

This SOP outlines the steps to process modifications when Emory IRB is serving as the sIRB for external sites enrolling participants.

## SCOPE

This SOP applies to multi-site studies for which Emory has agreed to serve as the sIRB.

**Note:** If the study is an S-I study, assign the modification to an S-I specialist for processing.

## Process:

1. For modifications to add or remove Emory study personnel, follow the SOP “Adding/Removing Study Personnel.”
2. For modifications to add or remove external site study personnel, the external study team is responsible for ensuring study team members maintain current CITI and credentials in accordance with their institution’s policies and procedures. Emory IRB only reviews the PI for each external site. If the PI for the site changes, the relying IRB must complete a new local context review form or provide confirmation via email that the new PI has met all local training requirements and can be added as PI. If this is provided via email, the email must be uploaded in the modification.
3. For modifications indicating increased risk, follow the SOP titled “Modifications: Mods indicating increased risk.”
4. For modifications that require new ancillary reviews such as a new COI, change to radiation procedures, infectious agents, etc., a new local context review form must be obtained from each relying IRB and the completed forms must be uploaded in the modification prior to approval. The local context review form is titled “Emory sIRB Relying Site LCR Form” and is located in the folder H:\External IRB Relationships 6.3.2020\06. Forms and Checklists.
5. If the study is an S-I study, trigger ancillary review by Margaret Huber if applicable (see S-I SOP for guidance.)

If the Emory study team requests to add a new pSite, contact the reliance team lead to discuss. If it is an S-I study, trigger ancillary review for Margaret Huber to approve new site.

## LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
8/30/21	Clarity in purpose
04/06/2022	Added language pertaining to S-I studies
01/05/2023	Minor edits for clarity

<b>SOP Title:</b>	Processing CRs When Emory is the Single IRB of Record (sIRB) for a Multi-Site Study
<b>SOP Category:</b>	Collaborative Research / Central IRBs
<b>Established:</b>	01/20/2021
<b>Last Revision:</b>	02/24/2023

## PURPOSE

This SOP outlines the steps to process CRs when Emory IRB is serving as the sIRB for external sites.

## SCOPE

This SOP applies to multi-site studies for which Emory has agreed to serve as the sIRB.

**Note:** If the study is an S-I study, assign the CR to an S-I specialist for processing who will trigger ancillary review by Margaret Huber

## Process:

1. The reliance analyst will follow the SOP titled “Continuing Review Processing-Preliminary Analysis through Approval” to process the Emory site CR.
2. The Emory study coordinator will distribute the “pSite Continuing Review Form” to each pSite to complete and return to the study coordinator.
3. The Emory study coordinator will enter each site’s information from their completed CR form into the spreadsheet titled “Continuing Review Report for sIRB Study.” Once the spreadsheet is complete, the study coordinator will upload the spreadsheet in the supporting documents section of the Emory site’s CR in SaaS. The forms and spreadsheet are in the folder H:\External IRB Relationships 6.3.2020\06. Forms and Checklists.
4. While in the CR workspace, click “Sites”, select the site, then “Report Continuing Review Data” and enter the information provided by the study team in the pSite Continuing Review Form. Upload the completed form in the Supporting Documents section. The sites will now appear as shown below.

Active Participating Sites							
Filter by <span>+</span> Institution <span>▼</span> <input type="text" value="Enter text to search for"/> <span>🔍</span> <span>+</span> Add Filter <span>×</span> Clear All							
Execute Activity	Institution	Report Date	Total Enrollment	Enrollment Since Last Approval	Potential Concerns	Documents	Report Completed?
<span>▶</span>	UNIVERSITY OF CALIFORNIA SAN DIEGO	6/29/2021	5	5	None	pSite Continuing Review Form UCSD.pdf	<input checked="" type="checkbox"/> yes
<span>▶</span>	University of North Carolina at Chapel Hill	6/29/2021	0	0	None	pSite Continuing Review Form-UNC.pdf	<input checked="" type="checkbox"/> yes

2 items ◀ page 1 of 1 ▶ 10 / page

5. Mark yes for “Report Completed” for each site.
6. Once the study is reapproved, follow the steps outlined in the SOP “Continuing Review Processing-Preliminary Analysis through Approval” to finalize documents, prepare letter and send letter.
7. From the CR workspace click “Sites” and then select the site.
8. Click Return to Post-Review and enter comment “Continuing Review Update.”
9. Click Submit Site Designated Review and enter the determination and dates from the main study CR approval. Enter the same approval and effective dates unless the specific site was approved with modifications and the modifications were approved at a different time.

10. Complete the rest of the Site Designated Review form and click OK.
11. Finalize Documents
12. Prepare the letter. There is only one letter template available for sites which is the initial approval. Modify the letter template to mirror the Emory site CR approval letter but with the site information. (Change title of the letter, add post nominals to PI, use the same approval language as the Emory site, etc.)
13. Send the letter.
14. The site should now be in an Active state with the same approval and expiration dates as the Emory site.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
8/30/2021	Added steps for re-approval of pSites
04/06/2022	Added guidance for S-I studies
02/24/2023	Minor edits for clarity

**MEETING FACILITATION**

<b>SOP Title:</b>	Meeting Facilitation Responsibilities
<b>SOP Category:</b>	Meeting Facilitation
<b>Established:</b>	08/02/2013
<b>Last Revision:</b>	7/6/2023

## SECTIONS

- [Two Weeks Before the Meeting](#)
- [One Week \(or more\) Before the Meeting](#)
- [Pre-Meeting Pod Meeting \(Monday on the Week of Meeting Day\)](#)
- [Meeting Day](#)
- [Closing Activities after the Meeting](#)
- [Post- FB Meeting \(as soon as feasible after the meeting, no later than the next day\)](#)

## PURPOSE

This SOP provides an overview of the steps to be taken to effectively prepare for, facilitate, and perform tasks for a convened IRB Full Committee meeting. The responsibilities of facilitating a full board meeting will be shared by several members of the meeting team (Pod). The Pod will consist of a Sr. RPA, one or two RPAs and/or an AA.

**NOTE:** you will see the studies/CRs/MODS/RNIs assigned to your committee under “My Inbox”

## RESPONSIBILITIES

<b>AA</b>	<ul style="list-style-type: none"> <li>• sends invitation emails</li> <li>• keeps track of quorum</li> <li>• works with RPA and using RAS reviewer assigns reviews in eIRB</li> <li>• sends agenda email</li> <li>• sends email reminders to IRB staff</li> <li>• sets up for meeting</li> <li>• drives during meeting (completes omnibus forms as needed)</li> <li>• updates attendance in the attendance log (Attendance log - Update after every meeting)</li> </ul>
<b>RPA</b>	<ul style="list-style-type: none"> <li>• collaborates with AA on reviewer assignments</li> <li>• takes notes during meeting (can be in OneNote or a word document)</li> <li>• polishes minutes before sending to the AD or Director for review</li> </ul>
<b>Sr. RPA</b>	<ul style="list-style-type: none"> <li>• leads the pre-meeting and post-meeting Pod meetings</li> <li>• takes backup notes during meeting</li> <li>• advises pod members as needed</li> <li>• sends email to pay community member</li> </ul>
<b>Directors</b>	<ul style="list-style-type: none"> <li>• takes backup notes during meeting</li> <li>• reviews final version of minutes for QA/QI purposes</li> </ul>



**Tool to use in tandem with this SOP:** H:\General\CMTE\1. Meetings\1-Meeting Facilitation Prep Kit – Meeting Facilitator Checklist

## **PROCEDURE**

### Two Weeks Before the Meeting

- The AA sends an email to all regular and alternate members of the committee panel.
  - The invitation email template may be found under H:\General\CMTE\Meetings\1-Meeting Facilitation Prep Kit\Invitation and Agenda Email Templates\Invitation email text for all CMTEs\Invitation for Full Board NAMEMTG Meeting.
  - Lists of regular and alternate panel members are on the roster. As responses are received, the AA files the emails into a folder in their outlook and tracks attendance.
  - The AA will update the attendance by clicking on “Edit Meeting Attendance”. Alternatively, the members can update their attendance by clicking on “Confirm Attendance” or “Decline Attendance”.
- The AA creates a RAS for the meeting. The template can be found under <H:\General\CMTE\Meetings\1-Meeting Facilitation Prep Kit\RAS and CMTE Attendance>. The AA records who will be in attendance, those who will not attend, but will do secondary reviews and those who will not attend or do reviews.
- The AA ensures that quorum will be met, with a minimum of 6 members in attendance in person or by conference-bridge for the duration of the meeting. This must include at least one physician-scientist and one unaffiliated non-scientist (community member). **Important:** As items are added to the agenda, note whether or not any of the members who constitute quorum are listed in the IRB applications and thus conflicted with that agenda item. If so, it may be necessary to have an additional IRB member attend or call into the meeting during discussion and vote of that agenda item to maintain quorum.
- The AA checks that members’ CITI certifications are up to date. This information can be found in the roster.
- The AA reviews the meeting agenda before the pre-FB meeting to assess what expertise will be required for new studies and other agenda items.
  - When mandatory expertise (oncology, pediatric or cardiology on a new study or modification) is not available, the AA notifies the Directors. With the help of the Director, the AA coordinates with other Pods to move the item to another agenda where that expertise will be present. The AA informs the IRB staff analyst-owner if the agenda item is transferred to another meeting agenda.
  - The AA and Directors may also inquire if a member expert from another panel will attend the meeting or call-in for the discussion of the specific agenda item(s) (in addition to his or her responsibilities to their primary panel that month.) If this is needed, it is recommended to first try members whose primary meeting is farthest from the meeting requiring assistance. The AA consults with the Director for any issues involving the size of the agenda. If it appears that the

agenda will be too light, the AA sends an email to IRB staff asking them to add agenda items. If the agenda is too full, a decision will be made to move items to a different meeting.

- The AA also ensures that agenda items are listed under the correct agenda item type.

### **One Week (or more) Before the Meeting**

- The AA closes the meeting agenda to additional items by going to the meeting space and clicking on “edit meeting details”. Add “[CLOSED]” to the agenda name. Other informational iterations may be used such as “[CLOSED to Peds NS]”.
- The AA puts a message in MS Teams (using @General so everyone is notified) or emails the IRB staff, about the meeting closure and reminds IRB staff to upload an updated pre-review submission by close of business on Friday before the meeting week (that includes an updated NS checklist). ***Analysts are responsible for making sure that any pending information is updated in the pre-review information the morning before the meeting.*** An email template can be found at H:\General\CMTE\1. Meetings\1-Meeting Facilitation Prep Kit\Invitation and Agenda Email Templates\Staff Reminder About Pre-review update.
- If there are still any quorum issues, the AA notifies the Director to resolve these issues. When assessing issues with the quorum, it is important to note whether or not any of the members who constitute quorum are listed in the IRB applications of the items on the agenda and thus conflicted. If so, it may be necessary to have an additional member attend or call into the meeting during discussion and vote of that agenda item to maintain quorum.

#### **The Meeting or a category of review may be closed when:**

- Total number of items on the agenda meets or exceeds 25
- A review category (New, Mods or CRs) reaches the limit for a good mix of study categories on the agenda
- The total number of reviews that can be effectively handled by members scheduled to attend has been reached

- The AA (with the assistance of the RPA if needed) fills in the RAS sheet. Save the RAS/Attendance sheet document under [H: General\CMTE\Meetings\Committee A or B\CMTE \(Panel\) \Review Assignments\](#)(Year).
- For Modifications with new risks added to the agenda, check the **Risk changes via MOD reviewed at FB tracker** linked [here](#) to see if the risk has already been reviewed at FB with a determination that future MODs with this new risk can be expedited. If this new risk is listed in the tracker, check if this MOD falls under any exceptions. If the risk is on the tracker and doesn’t fall under an exception, remove from the agenda and notify the MOD owner analyst via a private comment why the MOD was removed referencing the relevant row on the risk tracker.
- The AA (with the assistance of the RPA if needed) assesses the number of members attending in the PS and NPS categories (only one A-NS and one UA-NS may attend each meeting). If the number exceeds the set limit (more than 5 for PS, more than 4 for NPS) the AA discusses the next steps with the IRB Director.

- The AA populates the member conflicts of interest (COI) for each item on the RAS, noting any member who is listed on the study team or who has a previously established conflict of interest made known to the IRB (such as marriage, supervisory relationship or financial conflicts). The AA assesses the impact of all conflicts of interest on quorum and the recommended order of the agenda, considering the availability of the member to attend the meeting. If there are any questions, the AA contacts a Director.
- The AA and RPA designate a time to meet and assign members to review agenda items on the RAS based on required expertise and review experience and/or ability. The AA and RPA ensure that a prisoner representative is available at the meeting in person or by conference if a prisoner study is on the agenda.

**Assignment Considerations for RPAs/AAs:**

- Try to limit reviews for members who are not VCs/CCs or community members to 4 or 5.
- Ensure that for new studies involving cancer drugs, children or cardiology, there is a specialist with that area of expertise present in person or by phone for the discussion of that item.
- Always have an MD as one of the reviewers on a study (the MD can be a secondary reviewer from another Committee, if necessary). Rarely, where a non-MD is a specialist in the field (e.g. Dr. Galt for radiation, Ms. Garrett for pediatric oncology studies), or where the study is low risk, then it is ok for the reviewer to be someone other than an MD.
- It is preferred that the specialist *presents* a study, but if a specialist is getting too loaded down with presentations, choose lower-risk, less complicated studies for presentation by a non-specialist (keep the specialist as a secondary reviewer). A genetics member should be assigned to studies with genetics if possible.
- Do not give a non-scientist a presentation for high risk, complicated cancer/cardiology/etc studies.
- Community members should generally be assigned to NEW studies for a thorough review of the consent form and for a layperson perspective, representative of the subject.

- The AA uses the completed RAS to assign the study reviews in the eIRB system. The AA logs a comment to the study team on each new study to provide a contact number should the Committee wish to contact the study team during the meeting. This is not required for Modifications or continuing review submissions.
- The following meeting processing steps take place in the meeting agenda space of eIRB. To assign reviewers to study submissions:
  - On the meeting space (*not the agenda item space*), click on “Assign Reviewer”
  - Click on the “Update” Field in each submission to assign reviewers. You can assign primary, secondary, tertiary, scientific (not used) and community reviewer. Choose the member and click OK to finish with the assignment.
  - After all the assignments are made, you could notify all assigned reviewers clicking yes to question 3. If you click no, you have the option to notify the members at a later time by clicking on “Notify Reviewers” in the main meeting space.
- The AA distributes the meeting agenda to members at least one week before the meeting date with copies to the Pod members and Director attending the meeting.

- Create Agenda for distribution:
  - To create the meeting agenda, go to “Prepare Agenda” in the main meeting space.
  - Select the agenda template and click “generate”. Review the draft agenda, and edit document removing empty information.
  - Upload the revised agenda (by clicking on the ellipsis and selecting “upload revisions”, if needed and then click OK.
  - Click on “Update Meeting Attendance” if members have not confirmed attendance via the electronic system.
  - Click on “Send Agenda”. Click on “Select/Deselect all” you can only select the members who have confirmed attendance to the meeting.
- In the main study history, upload the following documents using the “Update Documents” button.
  - Reviewer presentation tools
  - Pertinent guidance or worksheet materials
  - Other information related to the upcoming meeting
    - [Guidance on How IRB Makes Determinations of Serious or Continuing Noncompliance and UPs](#) in case a UP is on the agenda
- The AA notifies the Chairperson and any affected members of an addition or change to the agenda that occurs after the agenda has been distributed to members.
- The AA emails individual reminders to Chairs or members **of other panels** who have been assigned a secondary or tertiary review for the meeting with a link to each study assigned. The email is to be titled “Secondary Reviewer Assignment for IRB Committee (Panel Letter/Number) on (Meeting Date)” and sent high priority.
- If the agenda includes VA agenda items, the Pod may consider adjusting the order of the agenda to accommodate the VA liaison.

**Additions to a Closed Agenda or Closed Category may include:**

- Team Q items and/or other emergencies where a patient is waiting for treatment, or items involving risks to current participants that necessitate immediate attention and the next available meeting is not a Q meeting.
- Requests for continuing review that are FDA-regulated and will expire before the next meeting as long as there is sufficient time for a proper review.

***Note: The meeting pod must be contacted before any addition to a closed agenda.***

**Pre-Meeting Pod Meeting (Monday on the Week of Meeting Day)**

- During the meeting, the Pod reviews any outstanding regulatory questions, current quorum, and member reviews already submitted for changes before the meeting.
- If a deferral is recommended, the Pod emails the assigned analyst-owner to see if a deferrable issue(s) can be resolved before the meeting with sufficient time to return and review the information. If the deferrable issues cannot be resolved before the meeting, the Pod emails the IRB Director and Meeting Chair for approval. During this meeting, the Pod updates the RAS to document the reviewer’s recommendation (vote) on an agenda item (Approval, Pending Approval, Deferral, etc.).

- If a member has not completed his/her review, the AA sends reminder emails to those members during the meeting.
- The Pod checks the “Meeting Notes” folder against the RAS to ensure that all omnibus forms are uploaded and complete at <<H: [General\CMTE\Meetings](#)\Meetings\((Committee A or B or C)\(Panel)\Meeting Notes\((Year)\(Month)>>. If omnibus forms are missing, incomplete or contain unclear information, the Sr. RPA reminds the analyst owner to resolve the issues before the committee meeting. The Sr. RPA sends this email during the Pod meeting and copies the analyst owner’s supervisor.
- During the Pod meeting, the RPA creates a OneNote page for the meeting under the specific Committee section. Each member of the Pod creates a subpage to add their notes during the meeting. Alternatively, the notes can be saved in a word document.
- The Pod captures the pending administrative items for each new study in the RAS.
- The Pod reviews Mods to confirm they need to be reviewed by the committee and to review the current accrual to ascertain whether the committee needs to make a re-consent determination.
- The Pod reviews CRs for logged comments regarding missing DSMB and study progress reports so that the Pod will be prepared to mention these during the discussion of the CR.
- For unanticipated problems (UPs) cases: The case manager (Q team member) contacts the Pod team as soon as it is known that the UP case needs to be added to the agenda because the event represents an immediate safety concern. This occurs in cases where the next available meeting is not CMTE Q.
  - The case manager attends the meeting to assist with the notes for the case and emails them to the meeting Pod before the minute draft deadline.

**Workaround to pull submissions off of full board agenda for changes in advance of the meeting**

- Click “Remove from Agenda”
- Assign the item to Non-Committee Review
- Assign the item to yourself as Designated Reviewer
- Request clarifications as Designated Reviewer
- When changes are submitted, click Assign to Committee Review
- Assign to the Agenda
- Log the private comment “Study required changes after assignment to Committee Review”

**Note:** This should be used if there is enough time to allow member review of the submission before the meeting or if all members have already submitted their changes. Review assignments may require resubmission.

**Meeting Day**

- For new studies, the RPA checks the study history for missing cost option information, if not option #2, and checks the OSP [ICOI Database Daily Spreadsheet](#) for missing injury option information. See

SOP titled “Cost Option for Clinical Trial Agreements and ICFs” for more information regarding cost option.

- The RPA updates the RAS as reviews come in or new information is obtained.
- The RPA finalizes the Pre-Meeting Huddle information. Note in the huddle doc next to any MODs increasing risks that the FB committee needs to determine if this same new risk can go expedited in future and if there are any exceptions.
- The pod completes meeting set-up responsibilities no later than 3:45 pm.

FYI: The ORA Event Coordinator places drinks and snacks for the meeting in the conference room by 3:30 pm. In case of any issues, consult with administrative support.

- The Pod team sets up their laptops for the meeting.
- The assigned Driver (AA) for the meeting prepares to conduct driver responsibilities before, during and after the meeting (See [Drivers for IRB Meetings SOP](#) )
- The RPA conducts the Pre-Meeting Huddle around 3:45 pm or when the Meeting Chair arrives.
- Click on “Convene Meeting” under the meeting space to document the meeting is about to start. If this is not completed at this point, it can be completed after the meeting as long as it is completed on the same day. Do not close the meeting until the minutes have been approved by the IRB members, in case the meeting notes need to be revised.
- The AA greets meeting guests. [Confidentiality Agreements \(templates in H:\General\CMTE\1. Meetings\Confidentiality Agreements, use docusign\)](#) are required for any guest to an IRB meeting. The IRB recommends that guests schedule observations at least the day before the meeting for building security purposes and to be made aware of logistics and changes.
  - The AA ensures that confidentiality agreements are been signed before the meeting convenes. Guests arriving after the meeting has started may not enter and may reschedule their observation.
  - Member candidates attending a meeting as part of the appointment process should have already signed a member confidentiality form. The AA confirms a confidentiality form is on file or has the candidate complete the form at that time. (The person arranging the candidate’s visit should have already emailed the meeting Pod that the candidate is planning to observe the meeting.) The AA sends the candidate a courtesy reminder email or notification of any change of date, time, or place.
- The Pod makes sure doors are closed for privacy and confidentiality when the meeting convenes.
- The RPA announces the pending administrative issues before each agenda item when requested by the meeting Chair and reminds the Committee of those items before their vote should the Chair forget to ask for them.
- The Director, RPA, and Sr. RPA take notes. Everyone should capture the following in their written notes:
  - Controverted issues during Committee discussion on an item and how they were resolved
  - Under “determinations and findings that require documentation” include:

- Comments on the submission whether positive or negative (e.g. the protocol was well-written. The consent form used too many medical terms). Refrain from taking notes of the description of the science of the study such as the description of why the study is being done, research activities, etc., as these are already documented in the submission.
- All pending issues discussed in the meeting and agreed upon by the Committee.
- All deferrable issues discussed in the meeting and agreed upon by the Committee.
- All determinations required by the Committee for the agenda item (e.g. IND or IDE exemption, determination on short-form request, sensitive study request, Subpart determinations, or HIPAA waivers).
- Any instruction or comment to the study team that the Committee indicated should be placed in the letter to the study team.
- For any MODs increasing risks for a specific drug, note the FB decision on whether future MODs with this risk can be expedited and if there are any exceptions.

Facts and statistics available in the submission should not be made part of the minutes unless related to pending, deferred, or unresolved controverted issues discussed during the meeting.

An experienced Back-Up Note Taker, usually the IRB Director or her representative, may take free-form notes for the meeting indicating time meeting started, the agenda order, controverted issues, pertinent discussion, Committee instructions/comments to the study team, member recusals, returns and departures, the Committee determination(s), total vote (for, against, and abstain/names) and the time meeting ended.

- After the meeting discussion, the RPA/Director at the meeting will display and ask the members to verify the information used to fill out the Full Board Information for each new study.
- The AA then documents the outcome of each agenda item by clicking on “Submit Committee Review”. You can save the notes and click “no” on question 10 (Are you ready to submit this review?). This step can also be completed during the post-meeting meeting. The notes must include:
  - Determination made
  - Risk Level
  - Pediatric risk levels if applicable
  - Dates (confirm, as dates are populated by the system)
  - Motion and Votes
    - Include all the recusals and other departures, and returns and permanent departures by individual members to and from the meeting.

#### **Closing Activities after the Meeting**

- The Pod team powers down, disconnects and plugs laptops into the laptop cart, disconnects, and stores other electronic devices in the containers provided, turns off the projector, retracts the large screen, returns the conference room furniture to the standard-setting when applicable, turns off the lights, and disconnects the conference bridge and returns it to its container. Alternatively, the

Pod team may decide to use iPads instead, taking into consideration the additional time to set up the wi-fi connections for them.

- The laptop cart, mice, laptop chargers, and large power strip must be returned to the IT offices on the 4<sup>th</sup> floor by staff closing the meeting. The laptop cart must be plugged into the source provided in the IT office so that the equipment may charge overnight.
- The keys that open the laptop cart and the IT office must be left in the Lock Box on the 4<sup>th</sup> floor outside the IT office. The Lock Box requires an ID issued by IT and a unique passcode to access and return keys.
- The Pod returns sodas and water to the refrigerator in the pantry closet within the meeting room and places the chips on the designated IRB shelf with a note indicating: “IRB items remaining from IRB Meeting for ORA Events Coordinator Only”. The ORA Events Coordinator must retrieve these items the morning after the meeting to ensure a proper count for the IRB account.
- The Pod returns the candy to the locked Member File Cabinets in the IRB area.
- The Pod returns the IRB Keys (pantry closet and IRB member file cabinets) to the Lock-Box in the IRB Director’s office.
- The Pod ensures that the meeting area does not have any documents left behind. Any meeting-related documents are discarded in the “CONFIDENTIAL” bin outside the conference room. The Pod ensures all loaned portable meeting equipment is removed from the meeting room or properly secured.
- The AA plugs the phone in an office to ensure it is fully charged for the next use.

**Post- FB Meeting (as soon as feasible after the meeting, no later than the next day)**

- During the meeting, the AA updates the attendance log (Attendance log - Update after every meeting)
- The Pod meets to review their notes from the meeting and fill out, as a group, the meeting determinations and other information captured during the meeting.
- The information should be added under each study reviewed, by clicking on “submit committee review” (for NS/MOD/CRs) or “submit RNI committee review” (for RNIs).
  - If there were no controverted issues or additional discussion for a study, please enter “None” on those boxes.
  - For RNIs, upload the meeting materials in the supporting documents section so a link will populate in the minutes. These documents are not accessible by the RNI submitter.
- For new studies only: From the Full Board Information document add all the language that corresponds to approved/pending sections. For example, if a PHW was approved, copy, and paste the approval language to this section. You can find more information in the [Non-exempt NS checklist template](#).
- Under question 7, ‘additional information and notes’, note the FB decision on MODs with new risks as to whether they can go expedited in future and any exceptions.
- Under question 8 (supporting documents) add all the worksheets that were approved during the meeting, plus the Full Board IRB Information Sheet that was completed (only for new studies)



- Click on yes under 9 to submit the review. You can revise this information again if needed, even after clicking yes.
- For any MODs with new risks for a specific drug that can be expedited in the future, complete a row on the **Risk changes via MOD reviewed at FB tracker** linked [here](#)
- After the notes are reconciled, the AA sends an email or logs a comment in Teams letting the staff know that they can prepare letters. Note in logged comment which drugs had new IBs that were added to the **Risk changes via MOD reviewed at FB tracker**. Also, the RPA or the person designated to work on the minutes should generate them to prevent changes to the study to affect the minutes. The notes used for the letters should not be changed later (see more in the Minutes Processing SOP). If any errors need modification after the letters are created, please contact Team Q for additional steps.
- The Sr. RPA or designated person, notifies Carol Corkran of the member(s) who should be compensated for attending the meeting. The email contains the following information:
  - Members name
  - Date of meeting
  - Panel's name

Note: Follow the [Minutes Processing SOP](#) for timeframes and procedures to finalize the meeting minutes.

#### LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
7/6/2023	Removed AA and archived logs older than one year

<b>SOP Title:</b>	Drivers for IRB meetings
<b>SOP Category:</b>	Meeting Facilitation
<b>Established:</b>	5/14/2015
<b>Last Revision:</b>	8/31/2019

**PURPOSE**

The purpose of this document is to detail the responsibilities of the IRB meeting drivers in preparation for the full board meeting, and steps to follow during and after the meeting.

**SCOPE**

The SOP applies to the IRB staff serving as meeting drivers.

**PROCEDURE**

- The day of the meeting:
  - Arrives at the meeting room at approximately 3:30 pm to prepare his/her laptop:
  - Opens MS Word to make sure it is ready before the meeting.
  - Logs into eIRB to access the meeting’s agenda
  - Opens tab for each new study on agenda if desired
  - Opens the “[Words to PI](#)” file, located in the Meeting Facilitation Prep-Kit
  - Opens the omnibus forms for the studies
- During the meeting:
  - Responsible for Omnibus Forms for NEW studies only
  - First, display the item being presented. Display the History in case there are important notes (both the main study and Mod or CR being discussed.)
  - Omnibus forms: When the discussion begins for each **new** study, the meeting driver will fill out the section of the omnibus form “Findings by the Board”, including checkboxes and adding and protocol-specific comments. The driver will scroll down the form and document any determinations made by the panel during their discussion, including IND/IDE exemptions, device determinations, HIPAA waiver(s) granted, Subpart determinations, the motion, the vote and vote count, the risk level, and the approval period. The driver will follow the RPA and vice-chair instructions when filling out the forms.
  - When not completing the omnibus form, follow the members’ discussion and open documents and SmartForm sections being discussed, especially if you hear controverted issues.
  - Be prepared to navigate to secondary reviews when reviewers are not present if the VC does not mention them first.
  - After a vote on each new study (**only**): log a determination comment to Study Team in the Study History for each item on the agenda using language in the “Words to PI” file.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
7/14/2017	Updated to reflect new process in OneNote and limited driver responsibilities
6/8/2018	Changes to reflect current process
6/28/2019	Updates to driver functions
7/16/2019	Updates to reflect current process
8/31/2019	Replaced RPA with “meeting driver”

<b>SOP Title:</b>	Minutes Processing Procedures
<b>SOP Category:</b>	Meeting Facilitation
<b>Established:</b>	8/12/2013
<b>Last Revision:</b>	7/2/2021

**NOTES:** Specific guidelines for review of Minutes are found in the “Minutes Keys”: <H:\General\CMTE\1. Meetings\1-Meeting Facilitation Prep Kit\Minutes Related\Minutes Key>

#### **PURPOSE**

The purpose of this document is to delineate the process of minute processing after a Full Board (FB) Meeting. The Minutes should meet the criteria outlined in 45 CFR 46.115(a)(2), 21 CDR 56.115(a)(2), and Emory IRB Policies and Procedures number 34.

#### **SCOPE**

The SOP applies to items reviewed at Full Board (FB) Meetings.

#### **RESPONSIBILITIES**

- Designated Pod Member (DPM)-will draft minutes after FB meeting.
- IRB Associate, Assistant, or IRB Director (Directors)- will review minutes draft for final approval

#### **DEADLINES**

The first draft of minutes: Before the second Friday after the meeting.

Minutes distributed after Director review: When next month’s meeting invitation is sent

#### **PROCEDURE**

##### **Before working on the Minutes**

- After the Post-FB meeting, set Outlook event for the due date of the first draft, and invite the responsible Director
- After the Pod post-meeting meeting, the notes should have been reconciled and reflected for each study review using the “Submit Committee Review” activity.
- GENERATE MEETING MINUTES IMMEDIATELY after the pod has submitted all committee reviews for that meeting. If minutes are instead generated later, the motions on pending/deferred submissions may show as “approved” and the “Recommended changes and reasons section” may no longer contain the pending/deferral issues noted by the committee.
- The RPA should look at the notes and adjust the information in the meetings if needed, for grammar or syntax. Once you have given IRB analysts the “all-clear” to draft letters, do not modify the information that was already sent to the study team in the approval, pending, or deferral letters unless there was missing information.
  - If the Pod missed information that should have been communicated to the study team, let the study analyst know and modify the submission meeting determination by clicking on “submit committee review”.

##### **Preparing the Minutes**

### **Generating Minutes from SaaS eIRB:**

- The majority of minutes content comes from the “Submit Committee Review” activity in each agenda item’s workspace in SaaS eIRB.
- Under the meeting’s space, click on “Prepare Minutes”
- A new window will open. On that window, click on the drop down menu under question 1. Review the minutes and make sure that all the pending notes, discussion and controverted issues were captured.

### **Once Minutes are generated:**

- Front end section:
  - Check the header for the correct committee, date, and start/end times
  - Vote count – remember the max # of MDs and NPS’
    - Include the first and last names of members along with his/her post-nominal degree.
    - There must be a UA/NS in the grid
  - IRB Staff & Observers should be listed first and last name.
  - Quorum – Remember that the Biomed committee includes **11** members, not the number that attended the meeting. The Socio-b committee has **9** members.
    - In this section, please note the comings and goings, COIs, and any MDs and/or NPS’ who are not voting. This doesn’t have to include all of the comings and goings but an overview. More detailed information will be included with affected agenda items.
- If the meeting was conducted via videoconference (Zoom), please indicate in the minutes, under voting member attendance, specifically below the meeting attendees’ chart. Here is some suggested language: “All members participated via Zoom teleconference.”
- Rearrange agenda items into the order they were reviewed at the meeting.
  - There is a combination of keyboard strokes that allow for easier reordering.
    - If you’re using automatic numbering in the agenda list, click in a paragraph and press “Alt+Shift+Up arrow” or “Alt+Shift+Down arrow” to move that paragraph up or down. The numbering will automatically adjust.
    - You can also select two or more adjacent paragraphs and use the same keystrokes to move them as a block; or you can select and drag paragraphs with the mouse.
    - You will also have to copy/past the blue row with section title to preface the rearranged agenda items as needed.
- Ensure that, for new studies, the language listed in the Full Board Information portion of the “Non-Exempt New Study Checklist SaaS” worksheet or other templates is used for all determinations.
- Ensure language complies with the minutes writing guidelines.
- Ensure that all issues are fully detailed in the minutes, instead of referencing separate reviewer comments (e.g. do not say “See Reviewer’s comments” in the minutes)..
- If the meeting was conducted via videoconference (Zoom), please indicate in the minutes, under voting member attendance, specifically below the meeting attendees’ chart. Here is some suggested language: “All members participated via Zoom teleconference.”
- Ensure that items a-c have been populated for each item:
  - a. Motion: Approved, Modifications Required to Secure “Approved,” Deferred, Disapproved. For new studies, this should be followed by this Regulatory Approval language:

- For new studies only, after “Motion”, add the following information for each, depending on the board decision:
- For Pending studies: The convened IRB determined that this study meets the criteria for approval of research per 45 CFR 46.111, with conditions. These conditions are detailed under “Recommended changes and reasons”.
- For Deferred studies: The convened IRB determined has deferred approval of this study as it requires modifications to secure approval per 45 CFR 46.111. The specific reasons why this study was been deferred are detailed under “Recommended changes and reasons”.
- For Approved studies: The convened IRB determined that this study meets the criteria for approval of research per 45 CFR 46.111.
- Add the following under each study submission to document attendance. Delete these instructions in red and non-applicable sections of the following information (for example, if no changes, just leave the section out). This information should be copy/pasted just under the table with study specific information and above where the “Motion” is noted:

**Attendance, Quorum, and Conflicts of Interest**

N/A

The following member(s) stepped out of the room before the discussion and vote on this study: Member Name. Absent this member, the total number of voting members present was Number. After the vote on this protocol, Member Name returned to the meeting and the number of voting members present went to Number.

Before recusal, this member disclosed a conflict of interest with this study.

[If applicable] Committee member left the meeting permanently after the discussion and vote on this item. The number of voting members present went to

The following member(s) joined the meeting during the discussion of this study: Member Name. The number of voting members present went to Number.

- b. Risk Level: Greater than minimal risk, No greater than minimal risk, N/A
- c. Last day of approval period: \*\*Make sure to delete generated time stamp
- d. Recommended changes and reasons section:
  - All pending administrative items should be included here.
  - All items must be in complete sentences, written as clear, concise, and directive as possible.
  - Please do not include “see Dr. X’s review.” Instead, get their pending/deferral items from their review and include them in the “Submit Committee Review” activity..
  - All items should be numbered, if you can group items together based on the subject that would be preferable, i.e. all ICF related issues together, all protocol items together.
- e. Controverted issues and their resolutions section: If there is a controverted issue, the resolution must be included.
- f. Determinations and Findings that require documentation: This section should have all of the “Determination for minutes” template language noted in the Full Board Information Worksheet that is part of the “Non-Exempt New Study Checklist SaaS” worksheet.
  - Short Form Consent
  - Partial HIPAA Waiver
  - IND/IDE Exemptions that the IRB may need to acknowledge
  - Non-significant/Significant Risk Device Determination
  - Sensitive Study Status

- Vulnerable Population Subpart Determinations
- g. Additional information and notes section: If there are no instructions then state “None”.
  - We do not need to write a description of the study. All of the background on the study can be reduced to “XX presented the study” or however it is described in the omnibus form. The only thing we should capture in the minutes are statements of opinion about the quality of the study, scientific and regulatory issues, and controverted issues.
- h. Supporting Documents section:
  - This should be pre-populated from study workspace and may include
    - Full Board Information Determinations
    - Non-Exempt New Study Checklists
    - Vulnerable Population Checklists
  - If there are none, please indicate that in the draft minutes
- i. Votes: Ensure that the votes are accurately reflected as noted in the attendance table on the first page of minutes and that any adjustments in vote count accurately reflect when a member was absent or recused from the vote.
- Save the draft and email the responsible director to let them know that the minutes are ready for review. The director will find the revised minutes in the meeting space or under the history tab.
- If the Director has changes to the minutes, she will save a tracked change document to share with the RPA via email but will only save a clean copy in the system.
- After the director has reviewed and approved the draft minutes, the RPA will send draft minutes to AA for distribution with an attached draft during the next meeting invitation email. In the email, let members know that changes may be requested up to 7 business days from receipt of the email.
- If changes to the Draft Minutes are requested by the committee members, the AA will let the RPA know. The RPA shall make the revisions and upload a revised copy by clicking on “prepare minutes” and then selecting “upload revision” under question 2. The RPA will then send out the revised minutes to committee members for review again. Members should reply within 7 business days and then the minutes are deemed finalized.

### **RNIs**

For RNIs, we will need to add all the information from the “RNI Full Board Document” under each study information section.

### **Modifications**

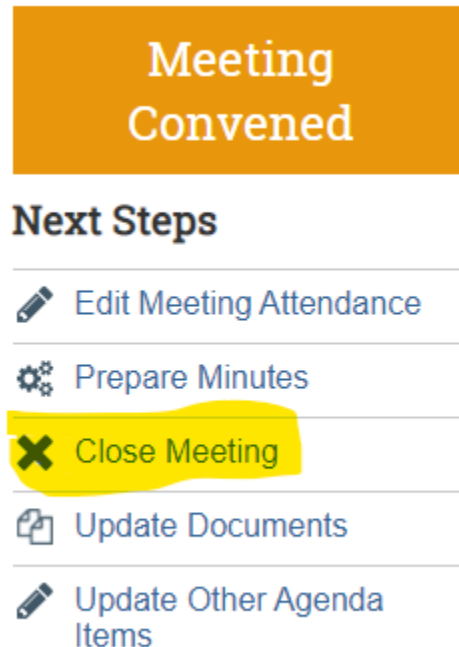
- Ensure that all of the above sections are completed the same way for Modifications when the “Submit Committee Review” activity has been completed.
- Re-Consent? Please make sure whether the committee has indicated that the subjects should be re-consented – this should be noted for the analyst to include in the approval letter.

### **Continuing Review**

Ensure that all of the above sections are completed the same way for Continuing Reviews when “Submit Committee Review” activity has been completed. Please be aware that the system may ask for a rationale for continuing review requirements depending on the common rule version the study is in.

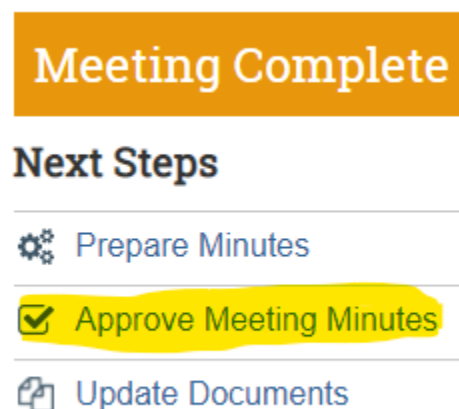
### **Finalizing minutes**

- After any requested edits are made per member feedback, the draft minutes are considered finalized. Save a copy of the final minutes here H:\General\CMTE\1. Meetings\Minutes
- The RPA changes the status of the meeting from “Meeting Convened” to “Meeting Complete” by clicking on “close meeting”.



The screenshot shows a user interface for a meeting. At the top, there is an orange header with the text "Meeting Convened". Below this, the section "Next Steps" is displayed. It contains a list of five actions, each with an icon and a horizontal line below it: "Edit Meeting Attendance" (pencil icon), "Prepare Minutes" (gear icon), "Close Meeting" (X icon, highlighted in yellow), "Update Documents" (document icon), and "Update Other Agenda Items" (pencil icon).

- Click on “Approved Meeting Minutes” to finalize the minutes in the system



The screenshot shows a user interface for a meeting. At the top, there is an orange header with the text "Meeting Complete". Below this, the section "Next Steps" is displayed. It contains a list of three actions, each with an icon and a horizontal line below it: "Prepare Minutes" (gear icon), "Approve Meeting Minutes" (checkmark icon, highlighted in yellow), and "Update Documents" (document icon).

- Update the spreadsheet “[Minutes Tracker Draft and Approved versions MD updates 2013 to Present](#)” found under H:\General\CMTE\1. Meetings\Minutes
- The RPA should enter data related to the current set of minutes in the columns highlighted in yellow:

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
5/13/2015	Added purpose and Scope change of title and other updated to reflect the current process. Combined with the previous SOP entitled "Combining Omnibus Forms for Minutes"
11/1/2017	Revised to update this SOP with the current process
6/28/2019	Changes in the process after Pod meeting structure, not need to approve minutes anymore.
2/11/2020	Updating to reflect the current process after new eIRB system implementation
3/5/2020	Update of minutes process as we are no longer required to save a draft copy outside the system
3/8/2020	Additional clarifications to minutes process
4/14/2020	Adding approval/deferral/pending approval information to the minutes
6/14/2020	Clarifying the suggested location to document that a meeting was conducted via Zoom teleconference.
7/15/2020	Adding Minutes key to SOP, process clarification
8/21/2020	Adding a note about the fact that a question asking for a rationale for a continuing review for minutes for CR applications
6/9/2021	Additional changes to the process
7/2/2021	Added a note to save the final copy of the minutes on the H:drive



<b>SOP Title:</b>	In Office Meeting Preparation
<b>SOP Category:</b>	Meeting Facilitation
<b>Established:</b>	1/30/2017
<b>Last Revision:</b>	7/6/2023

## **PURPOSE**

The purpose of this document is explaining the tasks a pod is responsible for when setting up for a full board meeting

## **SCOPE**

The SOP applies to the pod's preparation for a full board meeting.

## **RESPONSIBILITIES**

- Pod: to perform all activities assigned to them in preparation and closing for their assigned full board meeting

## **PROCEDURE**

### **PRIOR TO MEETING**

- Set up recurrent meetings for laptop pick up, involving see [contact grid](#). This could be done once every two years, as the recurrent calendar invite ends in 2 years.
- In order to set up the recurrent outlook meeting invitation, do the following:
  - Create a new Meeting and put following information:
    - To: see [contact grid](#) (or replacement)
    - Subject: Laptop checkout – IRB
    - Location: 5C
    - Date of meeting and time frame (3:30pm to 6:30pm)
    - Body: name, department, phone number, e-mail

### **DAY OF THE MEETING**

- Setup start time is 3:30pm.
- Sometimes you are able to set up a little earlier, depending on the room availability.
- Name cards: check you Reviewer Assignment Sheet to make sure you have all the card needed for the meeting.
- Keys (located in RR office): required to access computer and pantry closets in 5C. Also, to pull name cards from the members cabinet.
  - Key box Code: 000
  - Key names: Laptop cabinet key, Pantry Key, laptops keys and member cabinet keys
  - The Pod will coordinate to make sure the keys are placed back on Rebecca's office.
  - IT equipment/Laptop cart: set up laptops according to number of members/staff attending
  - Obtain the keys from the key Box on the 4th floor
  - Will Brown is the point of contact if you have any question regarding the IT equipment.

**Note:** Check with your Pod in case you need to set up computers for your Pod members and follow the meeting facilitation SOP for that process. In addition, don't forget to turn on the projector/release the

screen. Sometimes we help set up the driver computer. For now just make sure the computer is connected via the HDMI cord. We have connectors in case the HDMI cable is not working, so we may use those.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
5/12/2017	Deleting binder prep as it is no longer done
7/14/2017	Adding step before leaving meeting
11/1/2017	Changes made to align to current procedures
1/31/2018	Removed Mike Deryck
6/28/2019	Updates SOP to follow new Pod structure
7/6/2023	Replaced AA title in this and removed phone

<b>SOP Title:</b>	IRB Member Onboarding
<b>SOP Category:</b>	Meeting and Member Support
<b>Established:</b>	02/25/2021
<b>Last Revision:</b>	6/9/2021

## PURPOSE

The purpose of this document is to detail activities from the time an individual becomes a member candidate until appointment and first official IRB meeting.

## SCOPE

The SOP applies to IRB staff working with the IRB Member Onboarding process.

## DEFINITIONS

**Member Candidate:** An individual who has submitted a completed application, a signed IRB Confidentiality Agreement and a copy of his/her CV or resume to apply for IRB membership.

**Appointment Date:** Date on the appointment letter returned with the signature of the Emory Institutional Officer (I.O.)

## PROCEDURES

### IRB Director/Assoc/Asst Director:

1. Conduct an informal 3-5 minute phone call. Confirm the individual's interest in membership, prior IRB experience if any, expertise and availability. OR send the following recruitment email to potential candidate if no phone number is available:
  - a. H:\General\CMTE\2. Members and Roster Docs\Recruitment - New Members\Application Materials for Membership\2. Email Templates\Community\_Member\_UA-NS-Recruitment Email Text.docx
2. Once interest and eligibility is confirmed in consultation with the Director, send the relevant Emory IRB Membership email outlining the appointment process (either the one for Emory-affiliated members, or for Community members):
  - a. Template: H:\General\CMTE\2. Members and Roster Docs\Recruitment - New Members\Application Materials for Membership\2. Email Templates  
Attach copies of the following to the email:
    - IRB Member Application Fillable Form (latest version date)
    - IRB Confidentiality Agreement Form
    - Instructions for completion of the CITI Member Module "What Every New IRB Member Needs To Know"\* Or CITI IRB Community Member\_New\_Account\_&\_module\_training\_document
    - IRB New Member Pre-requisites document OR IRB New Member Pre-requisites-community members document
    - New Member Orientation-(latest version)
    - \*\*Community Members only – Supplier\_Individual\_Information Form & Guidance for filling in vendor form for community members

*The above documents are attached to the email template or can be found here:  
H:\General\CMTE\2. Members and Roster Docs\Recruitment - New Members\Application  
Materials for Membership\3. Forms and Documents*

3. Update a copy of the New Member Onboarding Checklist with date materials were returned or trainings completed.
4. Create folder for the member in the H: drive (H:\irb\_shared\General\CMTE\2. Members and Roster Docs\Individual Member Files\01. Appt-Resig and CVs - by member) and store signed appointment letter, CV, and completed application, and copy of New Member Onboarding Checklist. You may wish to copy a shortcut to the checklist onto your Desktop until onboarding is complete.
5. Ask future Pod leader to set up a date and time for the candidate's orientation and training of the IRB/eIRB system at the IRB offices or over Zoom. Email time, place and logistics to the candidate.

**Relevant Pod Leader** (*loop in Director re: all steps, so that Roster can be updated promptly*):

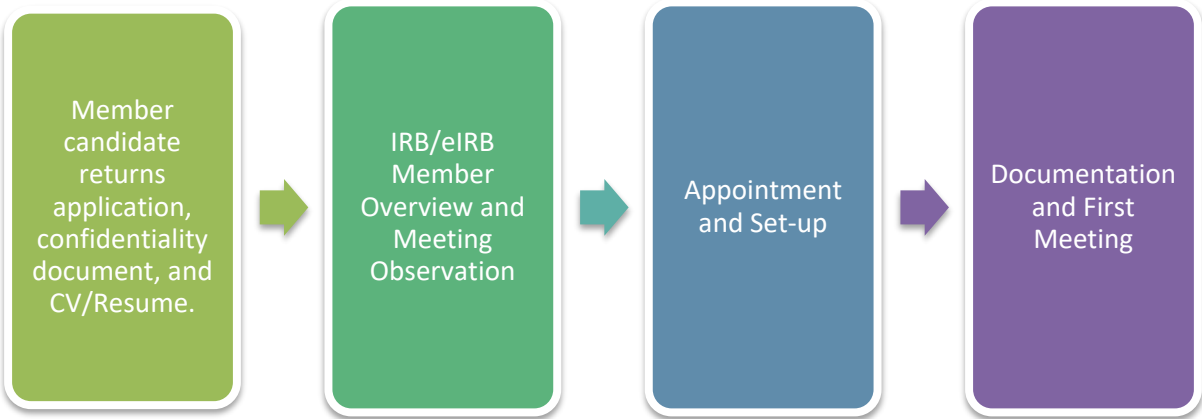
6. Update the New Member Onboarding Checklist with the scheduled training date.
7. Send a reminder email to the candidate before the scheduled training with review of the logistics.
8. Conduct the New Member orientation training using the New Member Power Point.  
H:\General\CMTE\2. Members and Roster Docs\Recruitment - New Members\Application  
Materials for Membership\4. Training Materials  
Key Points to include and/or emphasize:
  - Emory IRB Committee (A/B panels and Team C)
  - Meeting time and place
  - Meeting structure/presentations
  - Quorum
  - Member attendance once monthly and completion of assigned reviews in the eIRB system
  - Review of a NEW study, CR and AM in the system
  - The schedule for Reviewer Assignments Completion
  - Member commitment to serve 2 years with option to renew for a third year
  - Role of Meeting Pod
  - Role of IRB Staff Analyst/Study Owner
  - Decide the panel assignment with the candidate.
  - Set up a meeting observation date.
  - Meet IRB Director if available.
  - Show conference room 5C when walking candidate out to the elevators
9. Update the Director and the New Member Onboarding Checklist with date of training completion and scheduled date for meeting observation.
10. Email candidate on what to expect after the observation. Confirm panel assignment.
11. Update the New Member Onboarding Checklist with observation completion date.
12. Draft appointment letter (template). Request review by the Director.
13. After Director review, email the appt letter to the office of the I.O. with a copy of the candidate's CV/Resume.
14. Update the New Member Onboarding Checklist with the date sent to the I.O.'s office.

15. Update the New Member Onboarding Checklist when the signed letter is returned to the IRB with the official appointment date (date on letter).
16. Email official welcome to the new member with appointment letter attachment and instructions for acknowledgment.  
Copy the following persons on the welcome email:
  - IRB Director
  - IRB Co-Chairs
  - Meeting Chair
  - Team Lead
  - All Pod members
17. Confirm all documents (including fully signed appointment letter) have been stored in the member's folder on H: drive
18. If the new member is unaffiliated, request a sponsored account for her/him through IT Service Now.
19. Submit IT request for the user to receive the appropriate Role in eIRB
20. Update eIRB system to list new member on the appropriate panel. (Anyone in Pod can do this)

**IRB Director:**

21. Update member roster per instructions on Roster's first sheet
22. Add new member to the Outlook member group email listing (new).
  - a. Find list here: H:\General\CMTE\2. Members and Roster Docs\All Member Email List - update as needed.
  - b. Open file – Click on “Add Members” and “Select Members: Offline Global Address List.” Search by last name.
  - c. Highlight the member you are adding, then click the “Members” button at the bottom of window. The members name will be added to field, then click “OK.”
  - d. Save & close mailing list.
  - e. Open new message in your Outlook and copy the updated “IRB All Member Mailing Group – Updated \_\_\_\_\_(date)” to the email.
  - f. Send email the IRB Staff.
23. Confer with appropriate meeting pod on date of first official meeting and how the candidate fared.
24. Update member roster with first meeting date and any missing information to close out former candidate tracking.
25. Announce new member at next IRB staff meeting.

**PROCESS FLOW**



**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
6/9/2021	Removing an old statement

## QA AND EDUCATION

<b>SOP Title:</b>	Acknowledgments & Noncompliance Determinations Made by Senior Team Q Staff
<b>SOP Category:</b>	QA and Education
<b>Established:</b>	10/19/2011
<b>Last Revision:</b>	6/9/2021

### PURPOSE

The purpose of this document is to specify in which circumstances a designated senior Team Q staff may acknowledge reportable new information submission submitted to the Emory IRB.

### SCOPE OF SOP

The SOP applies to the reportable new information submissions submitted for studies reviewed by the Emory IRB.

### RESPONSIBILITIES

- Senior team Q staff: Reviews and triages reportable new information submissions submitted to the Emory IRB. Under this SOP, the staff will also acknowledge certain type of events as explained below. “Senior” is defined as Associate or Assistant Director, or other Q staff designated by the Director as having sufficient experience and expertise to be considered “Senior.”
- Non-senior team Q staff: May administratively process acknowledgments on behalf of senior team Q staff, but would not make the determination themselves.

### PROCEDURE

The designated senior Team Q staff is allowed to acknowledge the events as detailed in this SOP. The designated senior Team Q staff may, at his/her discretion, send any of these events to an IRB vice-chair even if noted in this SOP to get confirmation of appropriate review. The designated senior Team Q staff may acknowledge the following events:

- Study staff not added to IRB submission, as long as staff was proper research (CITI and, if applies, Emory Clinical Research training) and protocol training before starting study activities
- ICF/HIPAA documentation issues where:
  - The form used was expired but it was the correct version approved by the IRB
  - The subject signing the consent forgot to time and date. A note to file is required to clarify this matter.
  - The study team member forgot to time and date the signature. A note to file is required to clarify this matter.
  - Discrepancies in signature/date/time by subject or study team unless there is a pattern of noncompliance.
  - ICF missing fields in the consent form that do not involve options made by the subject or signature, e.g. initials in pages.
- Lapses in approval for FDA trials where research activities did not take place during the lapse. Other

studies do not need the submission of a RE.

- Errors in reporting enrollment numbers at continuing review (whichever is greater):
  - Gap difference in enrolment number is within 10, no matter sample size
  - No greater than 20 % of total enrolled.
- Over-enrollment in a NMTMR study, when subjects have undergone study procedures (not only signing consent), as long as it is the first occurrence for a study, if HIPAA does not apply.
- Any event caused by the subject's (not the study team's) lack of adherence to the protocol that, in the opinion of the principal investigator, does not affect the subject's safety, rights and welfare or willingness to continue with study participation, and is not an unanticipated problem.
- Adverse event (that is not an internal death) that is considered unanticipated by the principal investigator but for which the causal relationship to study participation is unknown, and no more information is or will be available. Such events will be acknowledged with directions to submit a new reportable new information submission if the cause of the event is determined as related at a later date.
- Adverse event reported to the IRB per sponsor requirements, that the principal investigator considers anticipated or unrelated to study participation. For VA studies, this will need to be acknowledged by a VA reviewer.
- Protocol deviation which the principal investigator considers not substantive and not affecting subjects' rights, welfare, safety, or willingness to continue with study participation, and not affecting integrity of the research data, reported per sponsor requirements.
- DSMB letter indicating that study can continue per the protocol without change, submitted per sponsor requirement only.
- Protocol deviation that may minimally affect the integrity of research data, but does not affect subjects' rights, welfare, or safety and which does not represent a pattern of noncompliance. Team Q staff should review prior reports and consult the vice-chairs when in doubt.

Examples of such deviations are:

- Visit occurred out of window.
- Test done for research (not for safety) purposes which was not drawn or was drawn out of window, which does not reflect a pattern of noncompliance.
- Missing data caused by subjects' noncompliance with protocol (specifically, missed data when not completing surveys not used for diagnosis or treatment) or missing data due to programming errors that do not affect subjects' safety.
- Surveys or survey items completed in error, when the surveys or survey items' completion does not negatively affect subjects' rights, welfare or safety. For example, the completion of a survey asking for information that may upset the study participant should be sent to a vice-chair reviewer.

#### LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
1/4/2016	Change in the procedure section
6/28/2016	Change in the procedure section
7/14/2017	Changes to procedure section
6/9/2021	Adding a new criterion for acknowledgment



<b>SOP Title:</b>	IRB Noncompliance
<b>SOP Category:</b>	QA and Education
<b>Established:</b>	3/24/2015
<b>Last Revision:</b>	07/26/2023

## PURPOSE

The purpose of this SOP is to describe the process of reviewing situations in which the IRB, either through the actions of the IRB Committee or its administrative office, may not have followed applicable regulations or its internal policies and procedures; this policy does not apply to instances of non-compliance by investigators or research team members. (NC). The Emory AVP of the HRPP, the Emory IO, and the ORA Office of Research Compliance and Regulatory Affairs (RCRA) are tasked with making sure the Emory IRB complies with the IRB policies and procedures and applicable federal regulations.

## SCOPE

The SOP applies to all actions and determinations taken by the IRB.

## DEFINITIONS

- IRB Noncompliance (NC): a failure of the IRB to follow IRB Policies and Procedures, IRB Internal Standard Operations Procedures or federal regulations during the review and oversight of study submissions.
- Minor IRB NC: IRB NC that does not significantly impact the rights, welfare, safety of participants, or the integrity of the research data.
- More than Minor IRB NC: IRB NC, or identification of a repeated pattern of Minor IRB NC, that could significantly impact the rights, welfare, safety of participants, or errors that cause a disruption for the study team that would take significant steps to resolve (for example, a large number of subjects will need to be reconsented)
- Findings: issues discovered during an IRB internal QA/QI process that may indicate an error during a study submission's review and approval by the IRB. A finding would not rise to the level of minor or more than minor noncompliance if it does not affect the rights, welfare, safety of participants, or the integrity of the research data.

## RESPONSIBILITIES

- AVP for (RCRA) and Director of the Office of Research Integrity and Compliance (ORIC) – after the IRB identified trends reviews information with the INS before routing to the IO.
- AVP of the HRPP - reviews more than minor IRB NC issues to determine if they should be routed to the INS.
- IRB Q Team: Compiles information to be sent to the IRB NC Subcommittee.
- IRB NC Subcommittee (INS): reviews issues coming from the AVP of the HRPP (through a Team Q representative). The IRB INS is composed of the AVP of the HRPP, IRB Co-Chairs, and the AD who supervises the IRB analyst for the affected submission (if applicable). INS's role is to determine the

CAPA is adequate for any IRB Noncompliance that is more than minor. They also determine whether a trend is more than minor IRB NC.

- [AVP of the HRPP and Associate or Assistant Directors \(ADs\)](#) - manage spreadsheet to trend issues found during routine record reviews, or other issues identified by IRB staff, researchers, or other members of the HRPP.
- [IO](#): reviews more than minor IRB noncompliance to assess reporting requirements and adequacy of Corrective and Preventive Action (CAPA) plan.

## PROCEDURE

1. IRB noncompliance issues may be identified during monthly routine internal review or during incident-based reviews by IRB staff, researchers, or other members of the HRPP. An AD or Q team member will log all potential IRB NC in the IRB NC spreadsheet in the pending tab.
2. All potential IRB NC (that hasn't previously been determined to be no more than minor) should be elegantly summarized and sent via email to the AVP for the HRPP. Include links in eIRB if relevant. The AVP for the HRPP will determine if findings constitute IRB NC and will determine which are minor and which are more than minor.
3. If the matter constitutes no more than minor (NMM)IRB NC, there is no CAPA required..
4. If the matter constitutes more than minor IRB NC, the AVP will email the Team Q representatives to route the matter to INS and the IO.
  - A root cause analysis and a CAPA plan must be drawn up for each matter that is potentially more than minor (MM) IRB NC. The Team Q representative should work with the parties involved to document this before sending to INS and the IO.

## Cumulative Report Process for minor IRB NC

1. All minor IRB NC will be logged by an AD in this [spreadsheet](#) located at OneDrive/IRB-Staff/Documents/H drive/General.
2. Team Q will review this form during standing team meetings, but at least monthly, to identify trends.
  - **If a trend is identified**, a Team Q representative will provide a summary of the trend, the trend's impacts, and CAPA to INS via email.
  - **If no trends are identified**, document the absence of trends in the spreadsheet.

## INS Review

The below process will be followed for identified trends during the review of the spreadsheet information.

- A worksheet will be completed with the case/trend information
- To close the case, the AVP for RCRA (or designee) must vote for no more than minor IRB NC, and at least two members of INS must agree.
- The event will be updated in the spreadsheet and the case will be considered closed when the CAPA plan is completed, if applicable.
- After receiving all required responses to close the email communication, the email thread should be saved under H:\General\QA Working Files\NC UP Complaints\IRB NC\Emails sent to

INS with cumulative reports. The email thread should have the date of when this information was sent to the INS

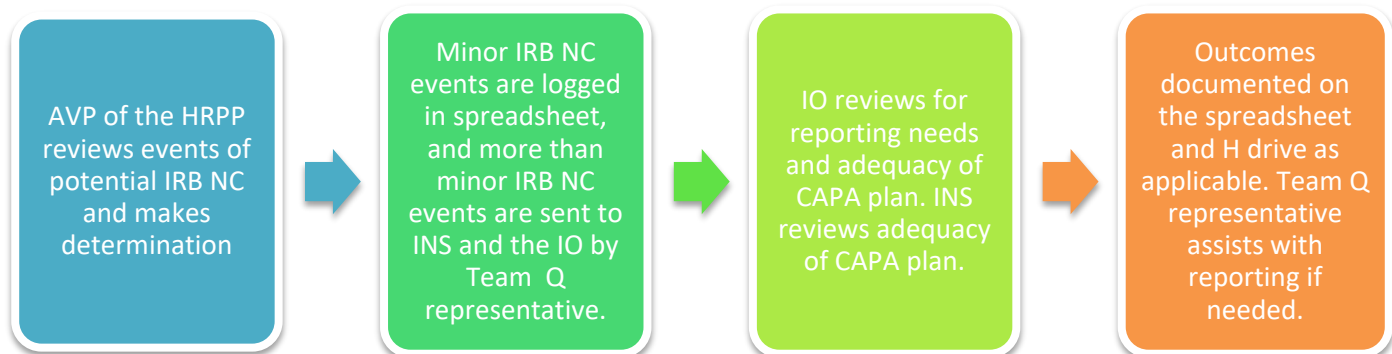
3. If the INS determines that the case constitute more than minor IRB noncompliance, follow the process under "IO Review".

### IO Review

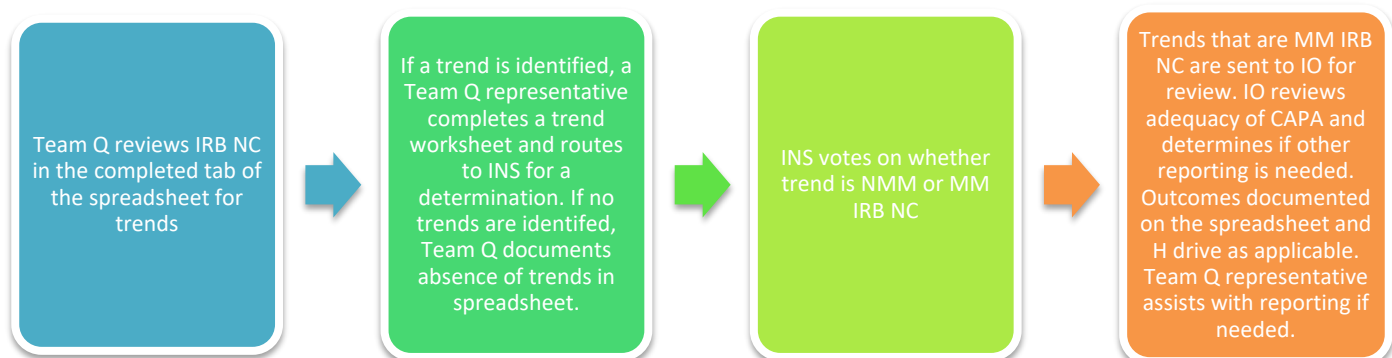
1. If the responses indicate that the cumulative report or case information needs to be sent to the IO, email the information worksheet, email treat, and any other related information to the IO for their review. Copy the AVP of the HRPP, AVP for RCRA and ORIC Director in this communication. Specify in the email that you have sent this information to the INS and that you need them to decide if this represents more than minor IRB noncompliance that should be reported to the federal oversight agencies.
2. The IO will review the information to assess reporting requirements and adequacy of the CAPA plan.
  - a) If the IO determines the case requires reporting, the Team Q representative will work with the AVP of the HRPP and IO in creating a letter to the oversight federal agencies, and AAHRPP, as applicable. Update the [spreadsheet](#).
  - b) If the case does not require reporting,, update the [spreadsheet](#) and save the communication from the IO in this folder: H:\General\QA Working Files\NC UP Complaints\IRB NC\IO review.

### PROCESS FLOW

#### Each individual incident of IRB NC:



#### Ongoing Monthly Trending



**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
07/06/2023	Clarity on spreadsheet and archived changes over a year old

<b>SOP Title:</b>	IRB Team Q CAPA Follow Up
<b>SOP Category:</b>	QA and Education
<b>Established:</b>	2/14/2012
<b>Last Revision:</b>	5/24/2021

## PURPOSE

The purpose of this document is to describe how the IRB Team Q will follow up on the IRB-approved Corrective and Preventive Action (CAPA) plans presented during Committee Q meetings. In addition, this SOP will cover the process of auditing CAPA plans for studies conducted at Emory and reviewed by External IRBs.

## SCOPE

CAPA plans from studies reviewed by an External IRB or during Emory IRB Committee Q meetings for possible serious (SNC) and/or continuing non-compliance (CNC), and unanticipated problems (UP) resulting from study staff oversight or error.

## DEFINITIONS

- Corrective and Preventive Action Plan – a plan developed by an investigator, with or without the assistance and guidance of the HRPP, following a root cause analysis into an instance of noncompliance or other problems in the conduct of human subjects research. The CAPA must include measures designed to correct the immediate problem and prevent its recurrence or the recurrence of a similar type of problem. CAPA plans are reviewed and may be modified by the IRB before being approved. Investigators are responsible for implementing CAPAs in a timely manner.
- Committee Q – Full Board Committee that reviews cases of possible serious non-compliance, unanticipated problems, and conflict of interest issues for ongoing studies. The COI committee prepares management plans for review by the IRB who has authority for final approval.
- Team Q: IRB staff team specializes in Education and QA efforts including non-compliance, unanticipated problems and protocol deviation review, analysis, data-gathering and presentation.
- CoRe team: A designated group of the IRB Chair, Director, and qualified IRB staff to investigate cases of alleged non-compliance and UPs. Their findings are documented as part of the IRB record. All cases of non-compliance, UPs, and suspensions and terminations will be investigated and followed by the CoRe team. Additional investigations by other units or individuals may proceed concurrently or in sequence with those of the CoRe team.

## RESPONSIBILITIES

- Committee Q –reviews, request changes in, approve or disapprove CAPA plans, and follows-up reports at Committee Q meetings.
- Team Q – Team Q designated member will compile CAPA updates. The follow-up report will be presented at the Committee Q meeting every month. Every Team Q case manager will email the designated person CAPA updates. The Team Q designated member will add the information to the follow-up report for the next available Committee Q meeting.
- Study Staff: Responsible to complete CAPA plan in the time allowed by the Committee Q members. This period is normally 30 calendar days from the date of the meeting unless specified otherwise.
- External IRB: Provides information about determinations of SNC, CNC, and UPs for studies conducted at Emory University/Healthcare.

## PROCEDURE

### Steps for Studies Reviewed by CMTE Q

- After Committee Q reviews and approves the CAPA plan for a specific case, the CAPA will be added by answering yes to question 2 (is further action required) under “Submit RNI Committee Review”. The person adding the notes will assign the RNI Action to the appropriate party and will click ok. The RNI Action Plan will be included in the determination letter sent to the principal investigator
- After the meeting and the RNI will enter “Action Required” state.
- Every responsible party will follow up with the study team about the CAPA plan completion and the deadline.
- When the CAPA plan (RNI Action Plan) is completed, the responsible party will submit an Action Response in eIRB. The case manager will review the action response. The case manager will complete the Required Actions Reviewed activity and will mark the action completed as required or not.
- If the action is completed, the case manager will prepare and send an RNI Action Complete letter to move the RNI to “Review Complete” status.
- If the CAPA plan has not been completed in the allowed period, the case manager will notify the study team that non-completion by this deadline is deemed non-compliance and will request an explanation of the delay to be submitted along with a notice of completion. This new NC will be reviewed by CoRe. The CoRe team will be notified about the delay for any additional determination. The Team Q designated member will create a report of incomplete CAPAs for the Full Board after CoRe review if this is considered reportable to FB.

### Extension for CAPA Plan

The study team may request a deadline extension. This extension may be reviewed and granted or denied at the CoRe team discretion.

### Steps for Studies Reviewed by an External IRB

- The reliance team will inform Team Q of an external IRB determination of SNC, CNC or UP.
- Team Q may review the CAPA plan and schedule an audit to check the progress with the implementation of the CAPA
  - The audit can be conducted in person or via email correspondence, depending on the case and/or CAPA plan. For example, if the CAPA plan requires the creation of a document, Team Q can request a copy and examples of when it was used via email.

### REFERENCES

- IRB QA Plan 12.15. 08
- 45CFR 46.
- 21CFR 820.
- IRB policies and procedures

### LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
2/11/2020	Updates to align with new system
3/4/2020	Additional changes for clarification
5/24/2021	Added procedure for studies reviewed by External IRBs

<b>SOP Title:</b>	CMTE Q Meeting Facilitation
<b>SOP Category:</b>	QA and Education
<b>Established:</b>	6/11/2013
<b>Last Revision:</b>	12/11/2020

**PURPOSE**

Outline the necessary steps of facilitating a Committee Q meeting; before, during, and after the meeting.

**SCOPE**

Applies to Team Q and administrative staff who help conduct Committee Q meetings.

**PROCEDURE**

<b>Q RPA</b>	<ul style="list-style-type: none"> <li>• creates a folder in H drive</li> <li>• sends invitation emails</li> <li>• keeps track of quorum using CMTE Q attendance Workbook</li> <li>• <b>preps for the meeting using CMTE Q Recap and Prep workbook</b></li> <li>• works with Sr. RPA and using RAS assigns reviews in eIRB</li> <li>• sends agenda email</li> <li>• sends email reminders to IRB staff</li> <li>• sets up for meeting</li> <li>• drives during the meeting (completes omnibus forms as needed)</li> <li>• updates attendance in attendance tracking sheet and emails Carol Corkran for Payment</li> <li>• <b>sends minutes to members</b></li> </ul>
<b>Q Sr. RPA</b>	<ul style="list-style-type: none"> <li>• collaborates with RPA on reviewer assignments</li> <li>• takes notes during the meeting (can be in OneNote or a word document)</li> <li>• polishes minutes before sending to the AD or Director for review</li> </ul>
	<ul style="list-style-type: none"> <li>• leads the pre-meeting and post-meeting Pod meetings</li> <li>• takes backup notes during the meeting</li> <li>• advises pod members as needed</li> </ul>
<b>Directors</b>	<ul style="list-style-type: none"> <li>• takes backup notes during the meeting</li> <li>• reviews final version of minutes for QA/QI purposes</li> </ul>

Before the Meeting

1. The Q RPA creates a meeting folder in H:\IRB\General\QA Working Files\CMTE Q\YYYY. The folder title should be MM-DD-YYYY.
2. Create a meeting agenda and save it in the meeting folder. Individual items can be added as they are identified. A copy of the worksheets, plus any additional materials should be saved in PDF format under the “Meeting Materials” folder. The “RNI Full Board Document” should be saved under “FB Forms”. The meeting agenda is populated to the meeting space by clicking on prepare agenda, and then uploading the agenda under question 2 by clicking on the ellipsis and selecting “upload revision”.

3. Each meeting folder should include subfolders for PI letters, Fed Letters, Investigator slot spreadsheets, Meeting Notes, Meeting Materials, and FB forms. The Recap Spreadsheet is located under the YYYY folder.
4. The Q RPA uses the CMTE Q Recap and Prep Workbook to ensure documentation from prior meeting is complete, including CAPA and federal notifications.
5. During the first week of the month, the Q RPA sends an email invitation to all members to ensure quorum and get an accurate count of attendance. Each committee may have a maximum of five (5) physician scientists, a maximum of four (4) non-physician scientists and must have one (1) non-scientist and one (1) unaffiliated community member present (the non-scientist and unaffiliated scientist may be the same person). It is preferable to have a VA member present if VA cases are reviewed, but it is not required. Any identified conflicts of interest should be taken into account when ensuring quorum. To assign reviewers:
  - 5.1. Click on “Assign Reviewers” under the meeting space
  - 5.2. Click on “update” to each RNI and add the reviewers
  - 5.3. If there are other agenda items that need to be reviewed, assign a reviewer if applicable
  - 5.4. Say yes to question 3 to notify members of their assignments, if ready. If not ready, say no, and send when ready.
6. The agenda should be finalized and materials sent to all attending members no later than the Friday before the meeting, if possible using the meeting space. The VA Compliance Officer and Director of Research/IRB Director at CHOA should receive an invitation to the meeting, and a copy of the VA/CHOA materials to be reviewed, if applicable. Guest arrivals should be noted on the agenda (for example, Dr. Jones and Ms. Smith will be present at 4:15 pm). *The case manager of each study is responsible for inviting guests, providing directions, and noting arrivals on the agenda.*
7. If any items are added or removed after the agenda and materials are sent, the members should be notified via email and through the system as soon as possible and provided any additional materials that are needed. New materials pertaining to a specific case may to all members. The case manager should notify the meeting facilitator when these changes have occurred.
8. If there will be call-ins to the meeting, the caller should be given the appropriate phone number. The meeting facilitator is responsible for setting up the teleconference equipment or teleconference electronic meeting. If the meeting takes place online, the waiting room must be enabled to allow guests in only at the appropriate time.

#### Day of the Meeting

1. The administrative staff will set up drinks and snacks about 30 minutes before the meeting.
2. The Q RPA will place a sign near the elevator to indicate PIs attending the meeting to wait in room 5A.
3. The Q RPA will make all meeting materials available (as a viewer) to attending committee members on Emory Box.
4. The Q RPA will make available name cards and copy of the agenda for all committee members and staff at the meeting.
5. The Q RPA will ensure that laptops are set up for members and staff.
6. If necessary, Q RPA will set up the speakerphone.

#### After the Meeting



1. IRB staff should work together to clean up after meeting, including putting away IT equipment and locking the storage closet.
2. The laptop cart and other IRB equipment should be taken to the IT area for storage.
3. The day after the meeting, IRB staff will meet to recap the meeting and strategize plans for sending determination letters. Each case manager is responsible for creating his/her own letter and ensuring it is sent to the PI. If specific follow up activities are required (site visit, Modification required, etc.), the case manager is responsible for that follow up. CAPA plans will be reviewed.
4. Letters to federal oversight agencies should be drafted concurrently with the follow-up letters to the PIs. Send draft letters (FDA/OHRP) to the IRB Director for review. Occasionally, the Institutional Official will also be asked to review and comment. Letters should be sent to the feds within 1 month. If the matter is considered of great urgency, the letter should be sent earlier as possible. The IRB co-Chair or vice-chair with medical expertise should sign any letters to the FDA; the IRB Director may sign letters to OHRP. A copy of the email sent to FDA and OHRP should be kept in the "Letter to Feds" folder under the meeting date folder.
5. Minutes should be completed and sent to the Associate or Assistant Director for review at least one week prior to the next meeting. Follow the [Minutes SOP](#) for details about this process.
6. Every Team Q member will be responsible for follow-up with the study PI regarding CAPA completion. The meeting facilitator should remind the Q team to add outstanding CAPA items to the CAPA report worksheet in the meeting materials folder.

#### LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
11/3/2020	Clarified that only attending members should receive meeting information
12/11/2020	Added additional actions to be taken by the Q RPA; corrected steps for virtual meetings
10/14/2021	Replaced Julie with Carol regarding notification for community member payment and archived log of updates over 1 year old

<b>SOP Title:</b>	Communication of Report of Internal Study Subject Death
<b>SOP Category:</b>	Administrative
<b>Established:</b>	7/17/12
<b>Last Revision:</b>	1/21/2022

## **PURPOSE**

The death of a subject who is an Emory Healthcare (EHC) Patient or University Employee or Student while in a study raises major institutional concerns if the death is deemed unanticipated, related to study participation, and potentially increasing the risk for participants or others. This SOP is intended to guide the IRB in communicating with EHC and University Officials.

## **SCOPE**

Deaths considered unanticipated problems in Emory study participants

## **PROCEDURES**

1. Assess whether we have enough information to notify others who need to know. In most cases, we will need more information or clarification; in such case, the IRB Director, Education & QA Lead, or Co-Chair should communicate directly with the PI, without cc'ing others who will want to know about it once we have all the relevant information. The reason for this is to avoid premature questions flooding in.
2. Recommend to the PI to let his clinical chair and any relevant research coordinators and study staff know about the event and any immediate implications for other study subjects.
3. Ask the PI whether they know anything about whether the subject's family is talking about bringing suit against Emory or has other serious concerns about the study's relatedness to the death. This information should be included in the notification to Risk Management and OGC.
4. Once we have enough information to say whether the PI thinks it is related (probably, possibly, etc.) or not, and whether the PI thinks it is anticipated or unanticipated, and whether he thinks the protocol/ICF should be changed and subjects notified, the IRB Director or Education & QA Lead should do the following:
  - a. Sent to CoRe for review.
  - b. If CoRe considers the event to be a possible unanticipated problem, the following people should be alerted via email, (including the date when the full board will review the event):
    - i. Robert Nobles, VP for Research Administration
    - ii. Kimberly Eck, AVP for Research Compliance and Regulatory Affairs and RIO
    - iii. Maria Davila, Director for Research Compliance and Regulatory Affairs and RIO
    - iv. Margaret Huber, IRB and FDA Compliance Manager
    - v. David Stephens, VP for Research
    - vi. Jeffrey Lennox, Associate Dean for Clinical Research
    - vii. If Winship: Ramalingam, Waller, El-Rayes, Rodger, and PI
    - viii. Katie Lewis (OGC)
    - ix. Cheryl Ritchie (Risk Management)
    - x. Anne Adams and Stephanie deRijke (CTAC)

- xi. Laura Deane (ORisk Management)
- xii. William Bornstein (Emory Healthcare Chief Quality Officer)
- xiii. Susan Rogers (IDS) – if it is a drug trial (Non-VA)
- xiv. IRB analyst owner of the study
- xv. Chair of IRB meeting that will be reviewing the possible UP
- xvi. Anyone else it makes sense to alert (check with IRB Director first)

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
2/25/2021	Updates to reporting lines
5/24/2021	Updates to reporting lines
1/21/2022	Updates to reporting lines and archiving log of changes over 1 year old

<b>SOP Title:</b>	Review of Single Use, Expanded Access of Unapproved Drugs or Devices
<b>SOP Category:</b>	QA and Education
<b>Established:</b>	7/27/12
<b>Last Revision:</b>	12/11/2020

## BACKGROUND

The FDA allows the use of an unapproved medical drug or device both for research and under what is known as expanded access or compassionate uses. This allows for the use of drugs or devices for treatment purposes outside a research protocol.

## PURPOSE

The purpose of this document is to describe the review process of a new study for the use of an unapproved (or not approved for a specific indication) drug or device for Compassionate or Emergency use, from submission to approval.

## SCOPE

Compassionate/Emergency use of an unapproved drug or device in an Emory study participant or patient, done by an Emory affiliated physician. If the use is submitted from a doctor without an Emory affiliation, even if treating a patient in an Emory facility, it would be reviewed by WIRB or another external IRB. Expanded access uses at CHOA should be routed to the CHOA IRB.

## DEFINITIONS

- **Sponsor:** A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator
- **Sponsor-Investigator (S-I):** means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor

## RESPONSIBILITIES

- **IRB Team member:** facilitates the submission of compassionate and emergency use request, verifying that the information provided is complete.
- **IRB Co-Chair:** reviews compassionate or emergency use requests before full-board review.
- **Investigator:** makes sure that the information submitted is complete and accurate, according to the information submitted to the FDA and/or the sponsor.
- **Sponsor:** submits an IND/IDE supplement to the FDA before use to obtain permission (for compassionate use only), and an IDE supplement after use as a follow-up report.

## PROCEDURE

**NOTE:** Make sure to use our letter templates for IRB Chair concurrence, IRB acknowledgment of use or IRB approvals for these compassionate uses. The Team Q member should review the submitted information, and assist investigators when possible, directing them to the Emory policies and procedures, FDA guidance or to the Office of Compliance for the submission of the IND/IDE supplement (in case of an Emory Sponsor-Investigator).

**Emergency use of a device:** does not require IRB or FDA approval before its use but the study team needs to contact the FDA to inform them of the use. In addition, the study team should submit an application to the IRB for acknowledgment of this use. This will be reviewed at Full Board for acknowledgment. The application should contain information about all the protection measures used before use and the following:

- A description of the circumstances that required the use.
- IDE protocol with a description of the device and name of IDE holder.
- Copy of uninvolved physician's assessment of use
- Copy of authorization from IDE holder if applicable
- Copy of consent document used for expanded access use (template use OK)

Before using the device, the physician should take as many of the following patient protection measures as possible, and provide the following information in the submission:

- Obtain a written independent assessment of the use of the device by an uninvolved physician
- Obtain documented informed consent from the patient or his/her Authorized Legal Representative
- Obtain documented authorization from the holder of the IDE for the Investigational Medical Device, if an IDE exists.
- Notify the Emory IRB by contacting the IRB Chair or his/her designee, and provide the Emory IRB with a written description of the circumstances necessitating the use of the device, along with copies of the uninvolved physician's assessment, informed consent and the IDE's holder's authorization.
- Notify any other institutional officials who require notice under institutional policies.
- If the patient did not consent before the use of the device, the physician should document this matter as described under the Emory IRB P&P, entitled Waiver or Alteration of Informed Consent for Research.

After the Emergency use submission has been initially reviewed, the Team Q member will contact the study team in case of any required changes, while alerting the IRB Chair via email about the Emergency use. Once ready for review by the full board, the Team Q member will place the study in the next available meeting agenda, notifying the meeting facilitator and meeting Vice-chair. The Team Q member will assign the review of the Emergency Use to the meeting Vice-Chair and the IRB chair.

After the Emergency use is approved by the IRB FB, the IRB approval letter should be created and it should include the following:

- The patient should be followed-up for any unanticipated adverse device effects
- The treating physician should inform the IDE sponsor of the patient status after receiving the device, so they can comply with their IDE reporting obligations
- If an IDE does not exist, the treating physician should provide the FDA with a written summary of the conditions constituent the emergency, patient protection measures taken and patient results
- Evaluate the likelihood of similar use of the device occurring again at Emory, and if such future is likely, begin steps to obtain a new IDE or a modification to an existing IDE to cover the device's future use and to obtain Emory IRB approval.

**Compassionate use of a device:** should be approved by the FDA before the use. The use will also need IRB approval or, alternatively, IRB chair concurrence of use. If the IRB chair determines that the use

would benefit from expedited review, the use would be routed that way, even if IRB chair concurrence was requested.

If the study team is seeking IRB Chair concurrence, the following information is required:

- A description of the circumstances necessitating the use.
- IDE protocol with a description of the device and name of IDE holder.
- Copy of uninvolved physician's assessment of use.
- Copy of authorization from IDE holder.
- Copy of consent document for expanded access use (using our current template)

The Team Q member is required to do the following:

- Create a [folder](#) with the information received from the treatment team. To document the use in the system, the study team will create an RNI submission and will add all the documents required for the concurrence.
- Contact the study team in case of any required changes, while alerting the IRB Chair about the Compassionate use.
- Redact any identified information in the RNI submission and upload revised copies to the submission.
- Send the concurrence to the study team after the IRB chair confirms it in the submitted RNI

The physician should not use the drug or device unless and until FDA approval of the Compassionate Use and IRB concurrence (or Approval, in the case of a Compassionate Use for a group of patients) has been obtained. If the FDA approves the Compassionate Use and the IRB concurs, then the use may occur.

If the study team is submitting to the IRB instead of asking for IRB chair concurrence, or if the IRB chair decides the use should be reviewed via expedited review, the Team Q member will assign the study to the IRB clinical chair or vice-chair and process as normal.

After the approval of the device use, the IRB approval letter should include the following<sup>1</sup>:

- The physician should develop a monitoring schedule for the patient and follow it in an effort to detect any possible problems arising from the use of the device.
- The physician should prepare a follow-up report on the use of the device, including a summary of patient outcome and a description of any problems encountered using the device. This report should be provided to the IRB within 5 days of the use, as well as to the sponsor.
- The Sponsor should provide the FDA with a copy of the follow-up report as an IDE supplement.
- If the compassionate use has not been approved by the FDA, the letter should state that the device cannot be used until FDA approval.

**Emergency use of unapproved drug:** This use does not need to be approved by the IRB although requires authorization by the FDA. Authorization of the emergency use may be given by an [FDA official by telephone](#), provided the physician explains how the expanded access use will meet the requirements and agrees to submit an expanded access application within 15 working days of FDA's initial authorization of the expanded access use. The physician may choose to use [FDA Form 3926](#) for the

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<sup>1</sup> <https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices>

expanded access application. The IRB will require a full submission within 5 working days of the use. This will be acknowledged by the Full Board. The submission should include:

- A copy of all information submitted to the FDA in connection with the Expanded Access use request.
- Informed consent form to be used or information demonstrating qualification for Emergency Use exception from informed consent. See the P&P entitled: Waiver or Alteration of Informed consent for Research, subsection entitled Emergency Medical Care Exception – Exception to the Requirement to Obtain Informed Consent for the Use of a FDA-Regulated Item in Emergency Medical Care Situations.
- Documentation of FDA approval for the Expanded Access Use request

**Compassionate use of unapproved drug:** this use will require FDA and IRB approvals (or IRB chair concurrence as explained later) before use. The physician may use [FDA Form 3926](#) for the FDA submission. A physician submitting an individual patient expanded access IND using Form FDA 3926 may select the appropriate box on that form to request authorization to obtain concurrence by the IRB chairperson or by a designated IRB member before the treatment use begins, in lieu of obtaining IRB review and approval. If the sponsor is submitting a Modification to an existing IND via Form FDA 1571, and because the form does not have a similar box, the information can be included in a separate request with the application.

If seeking IRB concurrence, the request should include the following:

- A copy of all information submitted to the FDA in connection with the Expanded Access use request
- Informed consent form to be used

If the FDA does not grant waiver of IRB approval or if the request was not made to the FDA via FDA Form 3926, the study team should submit an IRB application that would be routed to the Full Board per the regulations.

If the documentation received indicated the FDA has approved a waiver of IRB approval, the Team Q member will create a folder with the information received from the treatment team. To document the use in the system, the study team will create an RNI submission and will add all the documents required for the concurrence. The Team Q member should redact any patient information in the RNI submission and upload revised redacted copies of documents, if applicable.

The Team Q member will contact the study team in case of any required changes while alerting the IRB Chair about the Compassionate use. The IRB chair will confirm his/her concurrence with the use of the drug via e-mail. This concurrence will be sent to the study team. The use can only start after the FDA approves the Compassionate Use and the IRB concurs. The Q team member acknowledged the RNI.

If the study team is submitting to the IRB instead of asking IRB chair concurrence, or if the IRB chair decides the use should be reviewed via Full Board, the study will be routed as usual via a new study submission.

## REFERENCES

- FDA webpage: Expanded Access (Compassionate Use) at [https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm#Investigational\\_Drugs](https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm#Investigational_Drugs)

- FDA Guidance: Expanded Access to Investigational Drugs for Treatment Use — Questions and Answers at <https://www.fda.gov/downloads/drugs/guidances/ucm351261.pdf>
- FDA Expanded Access for Medical Devices Guidance at: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm>
- FDA Presentation: Emergency Use and Compassionate Use of Unapproved Devices at <https://www.fda.gov/downloads/Training/CDRHLearn/UCM180888.pdf>

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
1/31/2018	Revamp of process per FDA changes; adding drugs to SOP
3/4/2020	Change in the process to align with the new system
12/11/2020	Added that PHI should be redacted from documents



<b>SOP Title:</b>	External Webinars presented by Team Q
<b>SOP Category:</b>	QA and Education
<b>Established:</b>	1/23/2018
<b>Last Revision:</b>	2/25/2021

## **PURPOSE**

The purpose of this document is to explain the process Team Q members will follow to schedule an external webinar for our staff, ORA/OC staff or IRB members

## **SCOPE**

The SOP applies to external webinars presented by the Q team

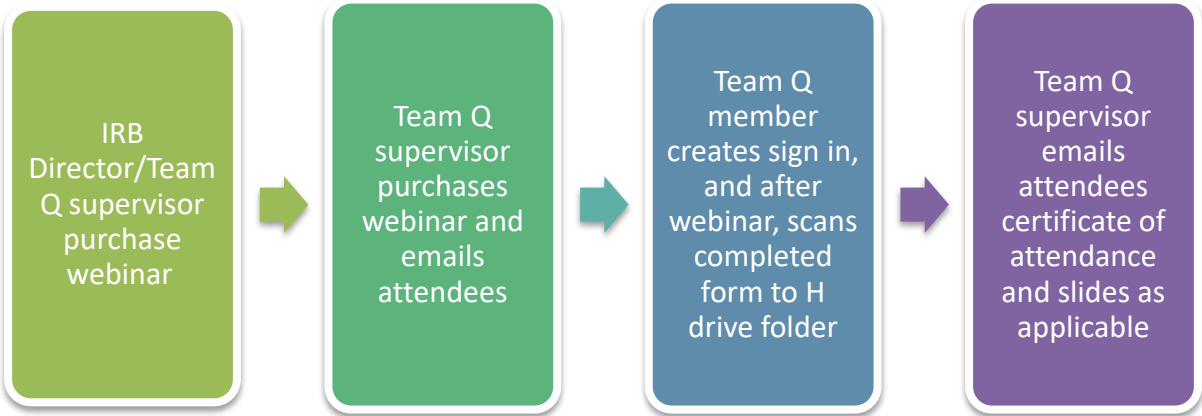
## **RESPONSIBILITIES**

- QA IRB analyst – if applicable, make sure to obtain a sign in information for attendees and scan it to the designated folder in the H drive
- Q IRB Team Supervisor-schedules the webinar and emails potential attendees.
- IRB Director- may schedule a webinar and indicates if a webinar is required for the IRB Staff

## **PROCEDURE**

- The IRB Director or Q IRB Team Supervisor (per Director's suggestion) will purchase an external webinar. The IRB Director will let Team Q members know if staff attendance/viewing is mandatory
- The Q IRB Team Supervisor will schedule the webinar, finding a room suitable for the presentation (if allowed). The room information will be emailed to the attendees. This list may include other IRB staff, IRB members, or staff from other divisions (at the director's request). The email should contain:
  - Link to the webinar information
  - If the webinar offers credits and, if so, how to obtain those
  - Copies of the PowerPoint for the presentation, if available
- The registration information will be saved in a folder under the external webinar folder in the Emory IRB H drive. This can be found at H:\General\Education\External Webinars
- If allowed, the room reserved for the webinar should be reserved from 15 to 30 minutes before the webinar start time to allow for set up. This reservation will be sent only to Team Q members
- On the day of the presentation, the QA IRB analyst will create a sign-in page to capture all attendees. If not in person, the analyst should keep their certificate of attendance when available and forward it to their supervisor when requested.
- After the webinar is finalized:
  - If applicable, the QA IRB analyst will scan the sign-in page and save it under the external webinar folder that corresponds to the webinar. This can be found at H:\General\Education\External Webinars.
  - The Q IRB Team supervisor will send the powerpoint presentation (if not sent earlier), and an attendance certificate/survey if applicable.

**PROCESS FLOW**



**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
2/25/2021	Updates to reflect remote working arrangements

<b>SOP Title:</b>	Process of Review of Consent Process Errors after Notification from OCR
<b>SOP</b>	QA and Education
<b>Established:</b>	1/2/2014
<b>Last Revision:</b>	1/2/2014

## PURPOSE

The purpose of this document is to explain the process the IRB Team Q designee will follow after receiving an email from the Office for Clinical Research (OCR) about the use of an expired consent form.

## SCOPE

The SOP applies to Emory studies that meet the NIH definition of Clinical Trial with or without EHC billable items and services, AND clinical research which doesn't meet the definition of Clinical Trial, but does have EHC billables items and services. For these studies, a copy of the informed consent form (ICF) is placed on the electronic medical record by OCR.

## DEFINITIONS

- Expired ICF: ICF that has an expiration date in the header of the document that precedes the date the subject signed the ICF. An expired ICF is not necessarily equivalent to an unapproved ICF version.
- ICF version: the number or date in the footer of the document. Any changes to the ICF's content, approved by the Emory IRB, are reflected in a new ICF version date.

## RESPONSIBILITIES

- IRB OCR representative – emails the IRB Team Q designee and the study team about the use of an expired ICF in a study approved by the Emory IRB. This person also will upload the ICF, and letter from IRB to the Emory electronic medical record (EeMR) if appropriate.
- IRB Team Q designee- reviews information, and emails OCR and study team as appropriate.

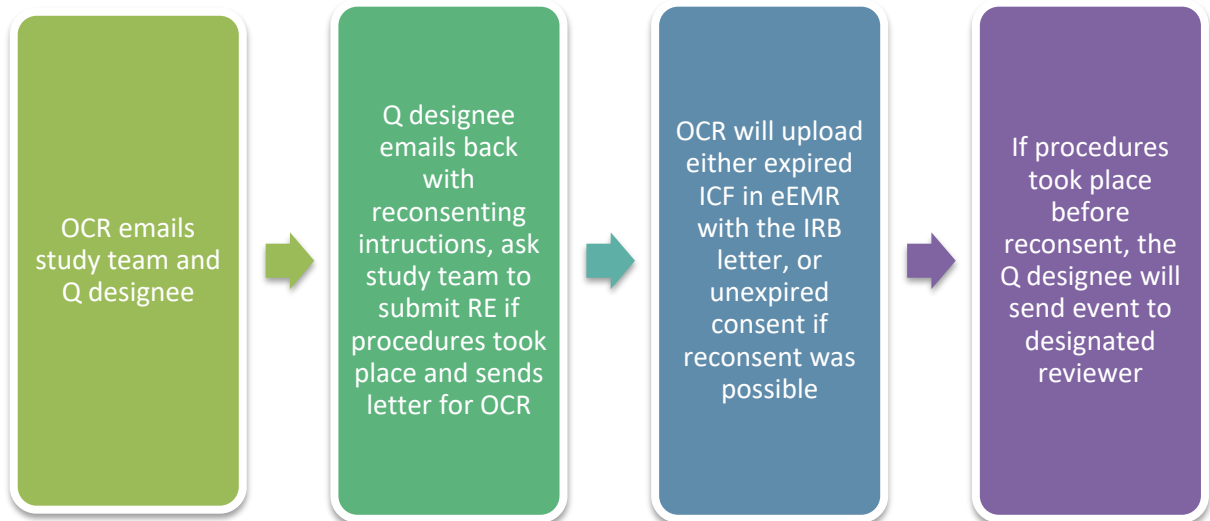
## PROCEDURE

- When OCR receives an expired ICF via fax, email, or hardcopy, the OCR representative will email the study team to let them know that the consent may not be acceptable, copying the team Q designee and the IRB Director.
- The Team Q designee checks the ICF to see if the version of the ICF is that which is currently approved by the IRB.
  - **If the expired ICF is the current version:**
    - Following the OCR email to the study team, the Team Q designee will reply-all stating this, and asking the study team to have the subjects sign an un-expired copy of the ICF.
    - The Team Q designee will also ask the study team to submit a reportable new information submission if any procedure took place before the subject reconsented.
    - In addition, the Team Q designee will email a letter to OCR stating that the expired ICF is the version currently approved by the IRB (See attachment 1).
    - OCR can then, at their discretion, upload the expired ICF into the medical record and the letter from the IRB.
  - **If the expired ICF is *not* the currently approved version:**
    - The Team Q designee will reply-all stating the expired ICF is not the currently approved version, and will ask the study team to reconsent the subject(s) as soon as possible, and to send the signed correct ICF(s) to OCR to upload to the EeMR.

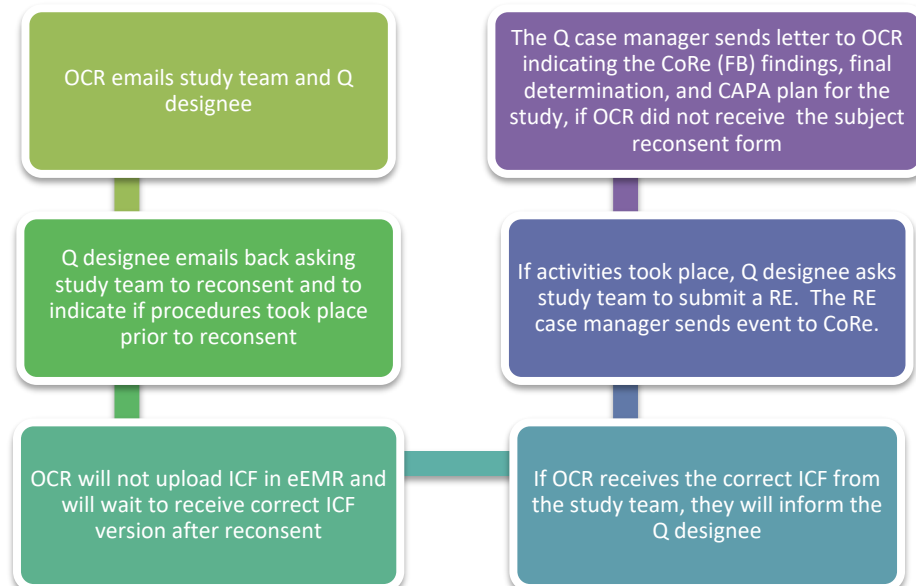
- The Team Q designee will also ask the study team to submit a reportable new information submission if any procedure took place with the affected subject(s) before they were reconsented. The information will be sent to the CoRe team per the IRB’s current process if applicable.
- If OCR receives the correct ICF forms, a letter will not be necessary.

**PROCESS FLOW**

Process flow when the ICF version used is the same one approved by the Emory IRB



Process flow when the ICF version used is not the same one currently approved by the Emory IRB



**Attachment 1**

*\* Use IRB letterhead for this letter. Delete instructions in red.*

DATE

Office for Clinical Research

RE: IRB# \_\_\_\_\_; PI: NAME

To whom this may concern,

On **DATE** we received an email from your office indicating an issue during with a subject's informed consent process documentation (**list the name of the subject; it should be one subject per letter for privacy requirements when uploading to the EeMR**). Specifically, **DETAILS OF EMAIL**. During our review, we found the following:

The informed consent form (ICF) used to consent this subject has the same content as the currently IRB approved version of the ICF. We have instructed the study team to re-consent the subject for documentation purposes, and to submit a reportable new information submission if any research activities took place before the subject was re-consented.

You may use this letter for documentation purposes. Please let us know if you have any questions.

Sincerely,

NAME

TITLE

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	Informed Consent Monitoring SOP
<b>SOP Category:</b>	QA and Education
<b>Established:</b>	2/24/2010
<b>Last Revision:</b>	2/24/2010

## **PURPOSE**

Representatives of the IRB (generally, members or staff) may conduct real-time informed consent observations as part of Emory’s human research protection program. This is a valuable measure for providing constructive feedback to investigators and ensuring the highest quality experience for prospective research subjects.

## **AUTHORITY & SCOPE**

Federal regulations authorize an IRB to observe or have a third party observe the consent process and the research. The IRB staff will conduct informed consent monitoring in studies under the Emory IRB oversight.

## **PROCEDURES**

- The IRB staff will give study teams advance notice of a proposed informed consent monitoring visit.
- The Emory IRB Informed Consent Monitoring Checklist should be used to capture relevant information for each session.
- The following procedure should be followed for consent observation:
  - In a private room or waiting area, the person obtaining informed consent should tell the prospective subject that a representative of the IRB is on site to observe the informed consent discussion. The IRB representative should then introduce him/herself to the prospective subject and ask for permission to observe the consent session. If the subject declines, the IRB representative will not observe that consent discussion.
  - The person obtaining informed consent will then conduct the informed consent discussion as usual, while the IRB representative observes silently, without taking notes or interjecting into the discussion.
  - The subject should be free to ask the IRB representative questions. If this happens, the IRB representative should answer them in a helpful manner.
  - At the conclusion of the discussion, the IRB representative will thank the subject and person obtaining informed consent and will leave the room. At that time, s/he should complete the checklist.
  - If the study team requests it, the IRB representative may give immediate feedback on the discussion and mention any deficiencies in the process.
  - The IRB representative will send the PI a letter in follow up describing the deficiencies from the observation, if any, within three business days. Recommendations for improvements should be included in this letter. Study teams are encouraged to discuss the findings with the IRB representative or IRB Director.
  - If deficiencies in the consent process are noted, the IRB staff member may refer those findings to the IRB Compliance Review team, require additional education on the consent process, or provide on-site informed consent training for the study staff.

**REFERENCES**

- 45 CFR 46.109(e)
- 21 CFR 56.109(f)

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	Internal QA/QI review of documents after IRB Review
<b>SOP</b>	QA and Education
<b>Established:</b>	6/1/2012
<b>Last Revision:</b>	6/9/2021

## **PURPOSE**

The purpose of this document is to describe the process of auditing studies reviewed by the Emory IRB members and staff.

## **SCOPE**

The SOP will apply to human subject research studies reviewed by the Emory IRB.

## **OBJECTIVES**

- To ensure that the review categories are correct in more than 95% of the items reviewed
- To verify that the IRB staff is meeting the turnaround time targets in at least 90% of cases.
- To make sure the documents issues by the IRB are correct (including dates, information such as device risk determination, ICF/HIPAA, etc.)
- To verify that the Emory policies and procedures, and federal regulations are followed during study review, including studies under Department of Education, Department of Justice, Department of Defense, Department of Energy and the Environmental Protection Agency.

## **RESPONSIBILITIES**

- IRB QA Team member – reviews determinations made by IRB staff and IRB members, and minutes that applied to the item, if applicable.
- IRB staff- The analyst will correct the documents, after confirmed findings from an audit which are corroborated by the IRB Associate or Assistant Director or IRB Director. Analyst also handles proper archiving of corrected documents.
- IRB Full-Board- reviews comments and approves corrected documents/minutes, if applicable.
- Designated reviewer- approves corrections of otherwise approved information, if applicable
- Full Board designated reviewer: an experienced person from our staff team who will review studies that were reviewed at Full board after the minutes are approved.

## **PROCEDURE**

Monthly, team Q will review a sample of expedited or exempt new studies, Modifications and continuing reviews submitted to the IRB office during the past month. The review will include at least one item per study analyst. The Team Q member will populate a dedicated excel document for this purpose. The findings will be reviewed by the Associate or Assistant Director and/or IRB director. Once the findings are verified, the IRB Associate or Assistant Director or Director will decide on the following steps. If necessary, the study team will be contacted for other follow up measures.

During the review, team Q will review the following documents:

- IRB Approval letters
- Electronic study history
- Informed consent and HIPAA forms.
- For CRs: submission of summary of events and other attached information



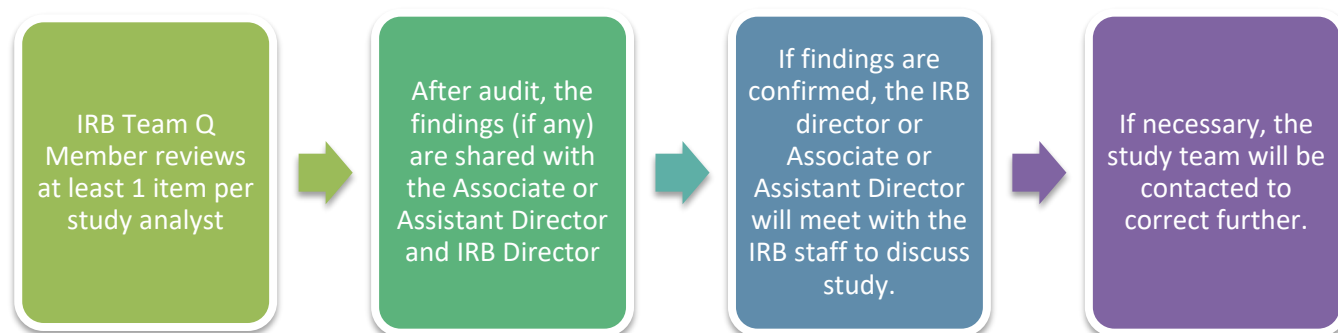
- Review of the correct use of review categories, subparts (for vulnerable populations), consent waivers, and applicable regulations.

The Team Q member will verify that the approval letters contain all the required information (e.g. device risk determination), and that the informed consent and HIPAA form have all the required elements.

For Full Board studies, a designated person will review a set of full board minutes, and will ensure the following:

- IRB determinations after study approval, or pending/deferred, are adequately addressed in the letter to the study PI and resolved, if applicable
- IRB-approved consent/assent forms are stamped correctly
- Other issues as applicable.

### PROCESS FLOW



### REFERENCES

- IRB policies and procedures
- 45 CFR 46.101
- 45 CFR 46.102
- 10 CFR 745
- 34 CFR 98.3
- 28 CFR part 46
- 28 CFR part 512
- 40 CFR 26 Subparts C and D

### LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
5/13/2015	This SOP replaced Audit of Expedited, Exempt and Non-Human Subject Research Determinations and Internal QA/QI review of documents after IRB Full Board. Major overhauled to document the current review process
11/1/2017	Changes to the subject matter reviewed, as ADs are reviewing FB studies at the moment of auditing the FB minutes
6/9/2021	Added additional details for the review of full board studies

<b>SOP Title:</b>	Letters after FB with PIs, OHRP and FDA after SNC, CNC and UP determinations
<b>SOP Category:</b>	QA and Education
<b>Established:</b>	5/15/2013
<b>Last Revision:</b>	9/6/2013

- Letters to the PI and federal oversight agencies will be drafted by the case manager.
- Any letter to inform PIs about SNC, CNC or UP determinations should be reviewed by another member of Team Q for accuracy and readability before sending.
- Any letter to notify the FDA or OHRP about a SNC, CNC or UP determinations should be reviewed by the AVPP of the HRPP or their delegate before sending.
- For notifications to the FDA, the letter should be signed by the IRB chair (who is a MD or clinician). In the case of an absence of the IRB chair, a MD vice-chair may sign on the IRB chair’s behalf. For notifications to OHRP, the AVPP of the HRPP or their delegate should review the content of the online submission. In case the AVPP of the HRPP or their delegate is absent, the a co-chair or the Institutional Official could review the submission details.
- Once the letter has been signed, the letter should be scanned as a PDF document and saved in H:\irb\_shared\General\QA Working Files\CMTE Q\YEAR\DATEofMTG\Letters to Feds
- All letters should be saved in their respective location for archiving purposes.
- The electronic copy of the letter to the PI should be emailed to the PI and Institutional officials, per our guidance document entitled: *Everything you need to know when writing letters to PIs, FDA and OHRP after a FB determination of SNC, CNC or UP*. A copy of this email should be kept under H:\irb\_shared\General\QA Working Files\CMTE Q\YEAR\DATEofMTG\Letters to PIs.
- For letters to FDA/OHRP, use guidance document entitled: *Everything you need to know when writing letters to PIs, FDA and OHRP after a FB determination of SNC, CNC or UP*. See Contact Grid for IOs who should be copied and Fed (FDA, OHRP) contacts. When sending the email to the federal agencies:
  - Email the FDA by themselves
  - Forward that sent email to the PI, copying the IOs
  - Save a copy of the email to the PI (that also contained the information of the email to the federal agencies) under H:\irb\_shared\General\QA Working Files\CMTE Q\YEAR\DATEofMTG\Letters to Feds
- If you receive an acknowledgment of receipt from OHRP or FDA, file it in the appropriate folder.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
10/14/2022	Updated some of the process steps

<b>SOP Title:</b>	Reportable new information submission Review Process
<b>SOP</b>	QA and Education
<b>Established:</b>	7/29/2013
<b>Last</b>	02/24/2023

## **PURPOSE**

The purpose of this document is to describe the review process of reportable new information (RNIs) submitted to the Emory IRB office.

## **SCOPE OF SOP**

This SOP scope is all RNIs submitted to the Emory IRB.

## **SOP SECTIONS**

[Screening of RNIs](#)

[Events sent to the CoRe team](#)

[Events sent to Committee Q](#)

[Cases involving a UP decision that affects multiple studies](#)

## **DEFINITIONS**

- **IRB Team Q:** Specialized IRB staff who reviews reportable events, work on fact-finding with study team, and submit events to a designated reviewer, Compliance Review (CoRe) team and/or Committee Q as applicable
- **Designated Reviewer:** A member who has been designated by the Chair to perform expedited reviews on a term basis, or as needed case by case, preferably in writing.
- **CoRe Team:** A designated group of the IRB Chair, Director, and qualified IRB staff that reviews reported events (including alleged non-compliance, potential UPs, potentially serious or continuing non-compliance), suspensions, and terminations. The CoRe team triages cases to determine whether they need a review at a convened meeting of the Emory IRB. The CoRe may engage the assistance of ad hoc consultants.
- **Committee Q:** A Full board meeting that primarily reviews potential serious and/or continuing noncompliance and unanticipated problem cases.
- **Non-reportable event:** An event that is not reportable to the IRB per the IRB Policies and Procedures.

## **REPORTS TO AAHRPP**

Within 48 hours but as soon as possible after the organization (or individual researcher) becomes aware, the IRB must report to AAHRPP:

- Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.
- Any litigation, arbitration, or settlements initiated related to human research protections.

- Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.

Work with the Team Q Lead or the IRB Director to assist with reporting.

## **PROCEDURE**

### Screening of RNIs

The Senior Q team member will screen the submission.

- If the case reported is potentially noncompliance, a reportable protocol deviation, or an unanticipated problem, it will be assigned to a Team Q member (see next section on CoRe Review).
- If the case is considered a minor protocol deviation, the Senior Q team member may send the RNI to a designated reviewer. In some cases, the RNI may be acknowledged by a designated member [per SOP](#).
- Other cases sent for Acknowledgment: If there is precedent for a case, via CoRe and/or FB, that indicates that the RNI is potentially noncompliance, but neither serious nor continuing, the Senior Q member may send the RNI for expedited review. The following specific precedents are already in place for sending to expedited review:
  - Noncompliance involving the data collection from more charts than what was approved by the Emory IRB.
  - Over-enrollment of subjects, in cases where the study is expected to enroll a large number of subjects as, for example, in a multi-site trial. If the study is considered of higher risk (for example a Phase I study) or the study has over-enroll with more than 25% of the approved number, the RNI should be sent instead to the CoRe Team.
- To send to a designated reviewer
  - Complete the pre-review and select "Additional review required" along with other applicable information.
  - The review can then be assigned to the designated reviewer for processing
  - If you are not sure if the case needs to go to CoRe, ask the designated reviewer to weigh in and determine if it should be acknowledged versus sent to CoRe. If they want to route the RNI to CoRe, ask them to email you instead without completing the review.
  - Once the review is submitted, this completes the acknowledgment process. A letter is not required in these cases; however, it is a best practice to log a comment to the team informing them of our process for managing acknowledgments.

Events sent to the CoRe team – [see contact grid for who should be included in CoRe email](#).

- Create a folder on the H drive in the QA Working Files\Non-Compliance or UP folder with study title and PI name, using the following format (RNI IRB/STUDY##PILASTNAME plus initials of case manager).
  - When the case is under review, it should be located under the Pending folder.
  - If closed, the case should be moved to the closed folder. It should be located at H:\General\QA

Working Files\NC UP Complaints\NonCompliance\Closed\ RNI IRB/STUDY##PILASTNAME  
removing the case manager initials.

- The Team Q member should contact the PI and study team for the input and clarification of data, corrective and preventive action plan, or any other information if needed. Use current [SOP Ed & QA Team Mission](#) and Process.
- The information obtained is added to the worksheet. The form can be located at: H:\General\QA Working Files\Forms, templates and Guidance\ Forms for RNI review
- The team Q member emails the worksheet information to the CoRe team. The information from the form should contain information from the title of the study to the CAPA plan. Other appropriate documents may be attached as well.
- The CoRe team as of June 14, 2021, , is composed of Carlton Dampier, Cliff Gunthel, Shara Karlebach, Julie Martin, Rebecca Rousselle, Aryeh Stein, and Larry Tune.
- The CoRe team should “Reply All” via email with the recommendations. If anyone on the CoRe team thinks the case could represent serious or continuing noncompliance (SNC/CNC) or an unanticipated problem (UP), refer the case to the next Com. Q meeting. If three CoRe members think the case is not SNC, CNC, or UP, including at least one clinician, or at least one Vice-chair or Co-Chair, the case can be closed and you can prepare the letter. Also, if any member of the CoRe has a conflict, they should recuse him/herself from the review of the RNI.
- The cases will be divided into Clinical CoRe cases and Procedural CoRe cases.
  - Clinical CoRe cases may be those involving clinical care or participant safety such as a missing clinical test or dosing issues..
  - The Procedural CoRe cases may be those that are nonclinical in nature such as HIPAA issues, protocol deviations, noncompliance and unanticipated problems not involving a clinical matter.
  - Team Q may decide at their discretion to whom to send a case, but members will be selected according to their area of expertise. In cases that involve both clinical and nonclinical issues, route it to clinical CoRe. Only 5 CoRe members will be selected for each case, always including a Co-Chair and the three staff members.
- If the CoRe team determines that the RNI represents no noncompliance, not serious or continuing noncompliance or not an unanticipated problem, the RNI will be closed. The RNI worksheet should be completed and non- applicable sections should be deleted.
  - The RNI should be closed in eIRB by submitting the RNI pre-review with the appropriate determination. Once the pre-review is submitted, the case manager should still send a letter to the study team in the system.
  - Some pre-review determinations will automatically move the RNI to “acknowledged” status, but a letter should still be written for cases closed by CoRe. You may have to navigate to find the RNI if it moves from your inbox as a result of the pre-review determination.
- If CoRe has determined that a safety report submitted in an RNI is not a UP, additional studies reporting the same safety event can be sent in an abbreviated form to the CoRe, with information about the study, to confirm that applies to this new study. The email should be saved in the folder on the shared drive in lieu of a worksheet. The RNI letter should also be saved in the same folder.
- If the case is closed after a CoRe determination, the folder should contain the following:

- Letter to the PI: study number, PI last name, Letter to PI, date of issue (example 123 Smith Ltr to PI 11-5-12)
- CoRe correspondence
- Completed RNI worksheet

#### Events sent to Committee Q

- If the CoRe assesses the RNI as potentially SNC or CNC, the RNI should be forwarded to committee Q for review.
- If the CoRe assessed the information as a potential UP, the RNI should be sent to the next available full board meeting or CMTE Q if the RNI does not represent an immediate safety issue for subjects.
- The following actions should be completed:
  - Submit RNI Pre-Review
    - Select additional review required to assign to the Q meeting
  - The case manager is also required to inform and forward the invite CHOA or VA colleagues as per the contact grid of any cases going to CMTE Q involving CHOA or VA facilities via email. VA cases are required to be reviewed within 30 days.
  - Save the materials in the appropriate CMTE Q folder (do not include CoRe emails).
  - Contact the PI to schedule the SNC/CNC/UP review for a Committee Q meeting. The PI must be invited to attend by zoom, in person, or phone. Attendance is only required for compliance reviews. If the PI or a PI representative cannot attend, the study team may submit a response in writing. Schedule the case for an agenda based on the PI's availability. If the PI cannot come to the meeting, consult with CoRe about moving the case to the next available meeting. In the case of UPs, the case should be reviewed at the next available meeting if it represents imminent harm to subjects, despite PI availability.
- If the board determines that an RNI constitutes an unanticipated problem or serious or continuing noncompliance, some or all of the following actions could be required:
  - Suspension of the research
  - Termination of the research.
  - Notification of current participants when such information might relate to participants' willingness to continue to take part in the research.
  - Modification of the protocol.
  - Modification of the information disclosed during the consent process.
  - Providing additional information to past participants.
  - Requiring current participants to re-consent to participation.
  - Modification of the continuing review schedule.
  - Monitoring of the research.
  - Monitoring of the consent process.
  - Referral to other organizational entities.

#### After the meeting

- Team Q will meet to review findings from the meeting and submit committee reviews by adding the worksheet to the RNI Committee Review information under question 5. During this time, the CAPA plan will be added as well [per the IRB Team Q CAPA Follow Up SOP, if applicable](#). Question 6 should be marked as yes if you are ready to finalize.
- The PI should receive a determination letter within 2 business days. Follow available templates and make sure institutional officials are copied per the contact grid if the issue was determined to represent an UP, SNC or CNC by the convened IRB. For external UPs, follow the contact grid for who should be copied.
- If applicable (after a UP, SNC or CNC determination), a letter to OHRP and FDA should be drafted and sent to the AVP for the HRPP for review (refer to SOP). Specifically:
  - For studies funded with federal funds: report to OHRP
  - For studies using an FDA regulated product: report to FDA
  - If both of the above apply, report to both. You may be able use a PDF of the OHRP online submission to the FDA.
- Once the FDA/OHRP letters/online submission have been reviewed by the AVP for the HRPP, they can be reported to the applicable Fed agencies. Once that reporting is complete, email the PDF of the online submission or forward the FDA email to the study PI and university officials as per the contact grid.
- The letters to OHRP and FDA should be logged in a comment under the RNI history and saved in the RNI folder. These letters should also be saved under the CMTE meeting folder entitled “Letter to Feds.”
- The RNI is closed in eIRB by sending the letter to the study PI. Once the case is considered closed, the RNI folder should be archived in the closed folder.
- Save a copy of the sent email correspondence under “Letter to Feds” folder
- If the case is closed after a FB determination, the folder should contain the following:
  - Letter to the PI: study number, PI last name, Letter to PI, date of issue (example 123 Smith Ltr to PI 11-5-12)
  - CoRe correspondence: CoRe determination on DATE
  - Copy of worksheet
  - Copy of Letter to Feds: study number, PI last name, Letter to FDA or OHRP, date of issue (example 123 Smith Ltr to FDA 11-5-12)
- If the case has a CAPA pending item (RNI Action), the case should be moved from the “pending” folder to the “working on CAPA” folder. When the CAPA issue (RNI Action plan) is completed, the case can be moved to the “closed” folder.

For AVAMC Research:

- If the convened IRB or the IRB reviewer/CoRe determines that the problem or event was serious, unanticipated, and related to the research, a simultaneous determination is required regarding the need for any action (e.g., suspension of activities; notification of participants) necessary to prevent an immediate hazard to participants in accordance with VA regulations.
  - All determinations of the IRB reviewer (regardless of outcome) must be reported to the IRB at its next convened meeting.

- The VA medical center director must report the problem or event to the appropriate VA Office of Research Oversight research officer within five business days after receiving such notification.
- If it was determined that the problem or event is serious, unanticipated, and related to the research, the convened IRB must determine and document whether a protocol or consent document modification is warranted.
- If the convened IRB determines that a protocol or consent document modification is warranted, the IRB must also determine and document:
  - Whether previously enrolled participants must be notified of the modification.
  - When such notification must take place and how such notification must be documented.

#### Cases involving an UP decision that affects multiple studies

- During the meeting, the board may make a UP determination. If the determination affects studies using the same drug or device, the board should make a note on the meeting minutes stating one or more of the following options:
  - IRB case manager informs other study teams that are using that drug or device. Study teams should review the information for the UP, and assess if an RNI and a MOD if applicable, is needed to add the new risk to their study documents.
    - The study team may disagree, and if so, they should document why this UP does not affect their study.
    - The RNI and MOD submission can be reviewed via the expedited process as a risk/benefit ratio analysis was done during the convened IRB meeting.
- After the meeting, the case manager will send an email to the IRB staff, letting them know that this UP may affect several studies, and that the RNI and MOD can be reviewed expedited, if applies. The email should contain the list of the studies.
- In addition, the case manager will log comments to each study, asking the study team to submit an RNI and a MOD as applicable. If the original RNI had letters from the sponsor explaining the issue, they should be added to the comment. Here is an example for this comment:

*Dear study team,*

*The IRB received the attached letter in a reportable new information submission involving a different IRB study using the same investigational agent than your study. The reportable new information was reviewed at an IRB convened meeting on DATE, and determined that the event of NAME OF EVENT, represents an unanticipated problem.*

*The Board determined that this UP determination may affect your study. As such, you are may be required to submit a reportable new information. Please review the attached document, and submit a reportable new information with your assessment of this risk. If you do not agree with the submission of the reportable new information please let us know why this event does not apply to your study population. If you agree with the UP determination, you may also be required to submit an amendment to add the risk to the informed consent form. If this risk is already in your consent form, you may disregard.*

*Your reportable new information and amendment will be reviewed via expedited process, as approved by the full board meeting on DATE. You have 10 business days to submit the RNI and*



*AM or provide your assessment of why this event does not apply to your study. If your study is reviewed by an external IRB, please report to them directly.*

*Let us know if you have any questions,*

- The case manager is responsible to check that the RNIs and MODs have been submitted if required. The MODs will be processed by the study owner. If the study team does not take action in the allowed time, the case manager needs to escalate emailing the study team and the Senior Q member with the following information:

Dear Dr. X,

On DATE, you were notified of an unanticipated problem determination that may affect your study. You were required to get back to us and indicate if this determination negatively impacts your study. Please, respond to this email with your assessment by close of business on DATE (*Friday of this week*). Failure to respond by this dateline represents noncompliance.

If you have any questions, please let us know,

NAME

- When the RNI is submitted, the information can be sent to a designated reviewer (DR) for expedited process. The DR should be a member of CMTE Q members who is a medical doctor. The message to the DR should include this information:
  - Determination was made during CMTE X on DATE
  - Assess if the UP determination also affects this study
  - Attach copy of the meeting materials and determination letter
  - Here is an example of the information for DRs:

*Dear Dr. X,*

*This same event was reviewed by CMTE X on DATE for another study (IRB 123456). The event, NAME OF EVENT, was considered an UP. This same event is being reported for several studies. We need your help assessing if this event also applies for this study. If so, we will acknowledge this event as an UP for this study as well. Please submit an RNI to document the event. If you feel this event may affect this study differently and needs to be assessed again, let me know and I will send to the CoRe team.*

*Looking forward to hearing from you,*

NAME of TEAM MEMBER

*PS: See attached documents from the Q meeting for your reference*

- After the DR reviews the RNI, the RNI may be acknowledged or sent to CoRe for new review (if the DR does not think the UP determination affects this study). If the latter, the RNI will follow the CoRe review process as outlined before.

- If the RNI was confirmed as an Unanticipated Problem by the DR, the case manager will close the RNI with a letter to the study team.

**REFERENCES**

- IRB policies and procedures
- Emory SOP: Acknowledgments & Noncompliance Determinations Made by Senior Team Q Staff
- Emory SOP: Letters after FB with PIs, OHRP and FDA after SNC, CNC and UP determinations

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
2/25/2021	Adding required reporting to AAHRPP. Clarified reporting lines.
5/24/2021	Adding a step for cases routed to a DR, changing CoRe composition starting on June 14, 2021.
7/2/2021	Clarified a component of CORE email voting
10/14/21	Revised CHOA contacts and archived updates over 1 year old
1/21/2022	Revised CHOA contacts and revised SaaS steps to move something from CoRe to Committee Q review
4/28/2022	Replaced Meredith Capasse with Anna Lum
02/24/2023	Revised for clarity throughout

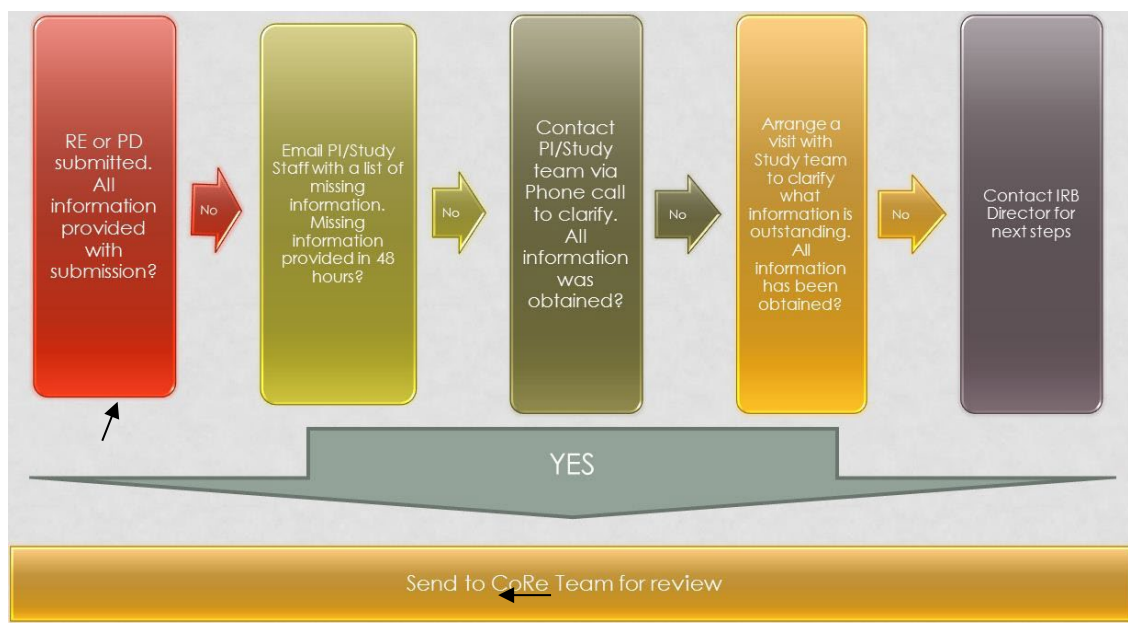
<b>SOP Title:</b>	Education and Quality Assurance Team Mission and Process
<b>SOP Category:</b>	QA and Education
<b>Established:</b>	9/30/2011
<b>Last Revision:</b>	9/30/2011

**MISSION**

To support the Emory Research Community via Education/Outreach and effective quality assurance practice on behalf of the Emory IRB.

**PROCESS**

When a case is assigned to a member of the Education and QA team, the process will continue as follows:



If all attempts to obtain information for a case are unsuccessful, the E/QA team member will consult with IRB Director for next steps.

- a) Communication strategies when obtaining information via email.
  - (a) Always remember to remind the study team that you are a liaison between the IRB and the study staff and that you are gathering information needed by the IRB (or IRB members) so they can make a determination.
  - (b) Have a friendly tone in your email, including words such as “collaborative” or “working together”, to reflect the cooperative mission of the E/QA team.
  - (c) Help the study team with their corrective action plan, suggesting plans that worked for other teams.

- (d) Do not jump to conclusions when asking questions. Remember to obtain complete information before sending the case to the CoRe team (if it is not something that could increase the risk for participants or others).
  - (e) If the information is not effectively obtained via email, call the PI/Study team and offer guidance and the opportunity for an in-person meeting.
- b) Communication strategies when obtaining information via phone conversations.
- (a) Remember the tone of your voice and inflection when discussing problems with the study team. Remember to smile when talking.
  - (b) Remember to include words that reflect the cooperative mission of the E/QA team as explained above.
  - (c) Reassure the study team regarding their case. Explain the steps and, if needed, give them the definitions for Non-Compliance, Protocol Deviations and Unanticipated Problems.
  - (d) If the conversation turns confrontational, avoid making any remarks or use of words that could sound challenging. Always remember to keep a friendly tone and explain why the questions are asked (you are a liaison for the IRB).
  - (e) After the phone conversation has ended, promptly email the PI/Study team with a summary of the conversation, always offering additional help.
  - (f) If the information is not effectively obtained, offer to have an in-person meeting.
- c) Communication strategies when obtaining information in person
- (a) In meetings with PI/Study staff, remember that your body language is very important. Always shake the hand of your interviewee and look him/her in the eyes.
  - (b) Do not cross your arms and always have a neutral expression on your face when asking questions.
  - (c) If the answer is surprising, avoid making gestures that could make your interviewee feel uneasy or uncomfortable.
  - (d) Make notes without being exclusively focused on note-taking. It is important to look at the interviewee eyes.
  - (e) Finalize the meeting by thanking the interviewee for his/her time and giving him/her information to contact you if additional questions arise.
  - (f) After the meeting, promptly email the study team with a summary of your conversations and next steps.

Remember that when dealing with difficult PIs or staff teams, you can always direct the call/email to the IRB Director for assistance.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	IRB Record Review of Studies approved by the Emory IRB
<b>SOP</b>	QA and Education
<b>Established:</b>	8/30/2011
<b>Last Revision:</b>	8/5/2016

## PURPOSE

The purpose of this document is to describe how the IRB Team Q conducts record reviews of studies approved at the Emory University IRB. The Emory IRB is committed to helping the research community maintain a high standard of compliance through education and guidance. Record Reviews will play an integral role in achieving this goal as it will allow the identification of problems offering opportunities for education.

## SCOPE OF SOP

Record Reviews conducted in human subjects' research overseen by the Emory University IRB and studies conducted at Emory under external IRBs.

## DEFINITIONS

- Not-For-Cause Compliance reviews – Periodic compliance reviews are conducted using a systematic method to review IRB-approved research or IRB records and activities on a regular basis. The IRB will perform 10 routine record reviews per year.
- Directed Reviews – Assigned to Team Q from the IRB, ORA offices, or Emory affiliates to address a concern or previously identified potential for noncompliance.
- For-Cause Compliance Reviews: Designed to assess the Investigator's compliance with federal regulations, state laws, and Emory IRB P&Ps. These reviews of IRB-approved research studies are in response to credible evidence of identified concerns or alleged noncompliance.

## RESPONSIBILITIES

- Principal Investigator – After the IRB has notified the PI of the record review, the PI and study staff are responsible for providing all the required documentation as described in the notice. The PI is also responsible for responding to the record review findings within 5 calendar days of receiving the record review summary.
- IRB reviewers – The reviewers are responsible for giving a report of findings within 5 calendar days of the completion of the record review. The written report to the PI will include the IRB reviewers' findings and a suggested corrective and preventive action (CAPA) plan, along with a reasonable deadline for completion (e.g. a month)The PI may adopt the CAPA as provided, or modify it to match his or her needs. The IRB reviewers will schedule reminders for follow up to ensure compliance
- Reporting: After the report has been reviewed by the PI and the CAPA plan has been accepted, the IRB reviewer will send the report to the compliance review (CoRe) team. If the CoRe team makes a determination of possible serious or continuing non-compliance or an unanticipated problem increasing the risk for participants or others, the report will be reviewed at the full board meeting.

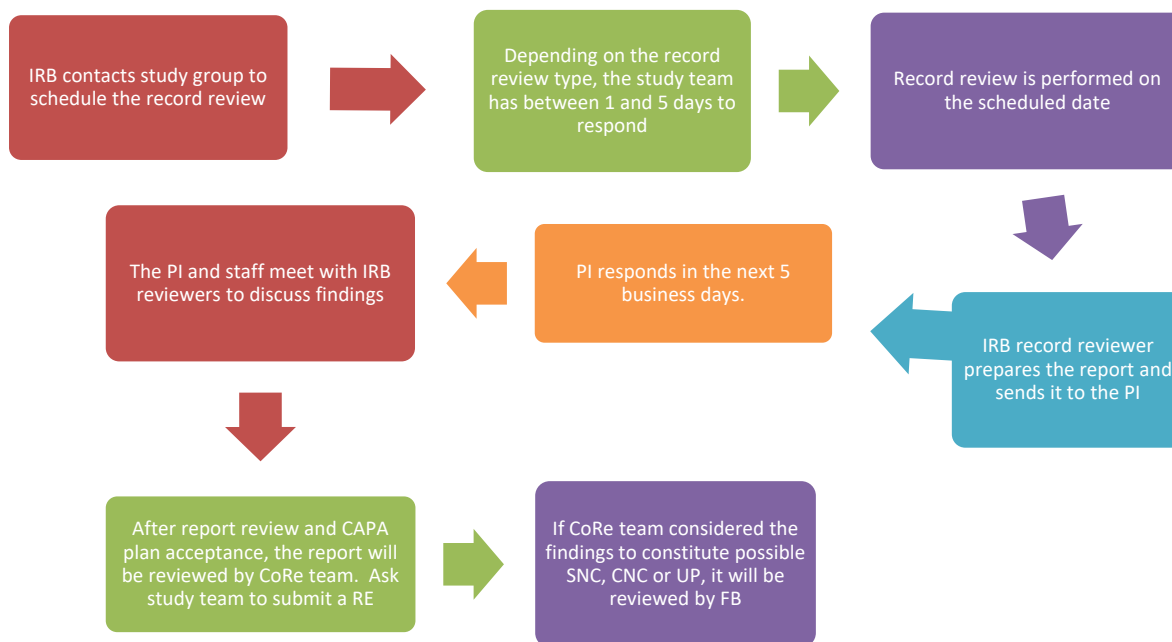
## PROCEDURE

The process will start by communicating with the research staff and coordinator about the record review visit. The notice for the record review may vary according to review type. For Not-For-Cause compliance reviews, the study team will have two-week (10 business days) notice from the date of the

initial communication to the date of the record review. For-cause compliance reviews will be conducted within 2 business days of the IRB's initial contact with the study team. The study team should respond within 24 hours to schedule the record review. Directed record reviews will be conducted according to study team needs or as mandated by the IRB.

1. The IRB will contact the study team to schedule the meeting. The study team has from 1 to 5 business days to respond to this request, depending on the record review type.
2. The IRB will conduct the record review on the scheduled date. The minimum documents needed for review are the study regulatory binder (for clinical research), protocol (all versions), informed consent and HIPAA consent forms (all versions), correspondence with the IRB, IRB submission records and individual study subject information. The IRB reviewers may give real-time feedback and answer questions about the information that is being reviewed. The IRB reviewer may also ask questions to the PI and study staff in case of doubts when performing the record review. The IRB reviewer may not communicate expected actions of the IRB.
3. The IRB reviewer will send the record review report within 5 business days of the record review's completion. The PI will review the findings and CAPA, and determine if the findings are accurate and if he or she accepts CAPA as is, or if he or she would like to modify it.
4. The PI has 5 business days to respond to the reviewer findings.
5. The IRB and PI, and the study team if desired, will meet the following week to discuss the findings and next course of action including CAPA implementation and education opportunities.
6. The IRB reviewers will send the report and accepted CAPA plan to CoRe team for review, and later to the full board meeting if needed.
7. If findings required CoRe review, the study team should submit a RNI in 10 business days. If the study team do not comply with the request, the Team Q member will create the RNI for them and ask a super user for submission, documenting the communication with the study team about this requirement.

**PROCESS FLOW**



**APPLICABLE REFERENCES**

- IRB QA Plan 12.15. 08
- 45CFR 46.
- IRB policies and procedures

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
8/5/2016	Adding RNI requirements if findings need CoRe review.

<b>SOP Title:</b>	Review of Safety Reports submitted by sponsors holding an IDE
<b>SOP Category:</b>	QA and Education
<b>Established:</b>	6/8/2012
<b>Last Revision:</b>	6/8/2012

## PURPOSE

The purpose of this document is to describe the process of reviewing progress reports received under 21 CFR 812.150 (b) (5).

## SCOPE OF SOP

The SOP will apply to Emory human subject research working under an IDE.

## DEFINITIONS

- **Investigational Device:** means a device, including a transitional device that is the object of an investigation. An investigational device is permitted by the FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.
- **Investigational Device Exemption (IDE):** An IDE allows an Investigational Device to be used in a clinical study in order to collect the safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification submission to the Food and Drug Administration.
- **Sponsor:** A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator

## RESPONSIBILITIES

- **IRB QA Associate or Assistant Director** – reviews the progress report submitted by the sponsor or sponsor-investigator.
- **Sponsor or Sponsor-Investigator:** at regular intervals, and at least yearly, a sponsor shall submit progress reports to all reviewing IRB's per 21 CFR 812.150 (b) (5).
- **IRB administrative assistant:** scans the progress reports, so they can be added to the study electronic record by the QA Associate or Assistant Director.

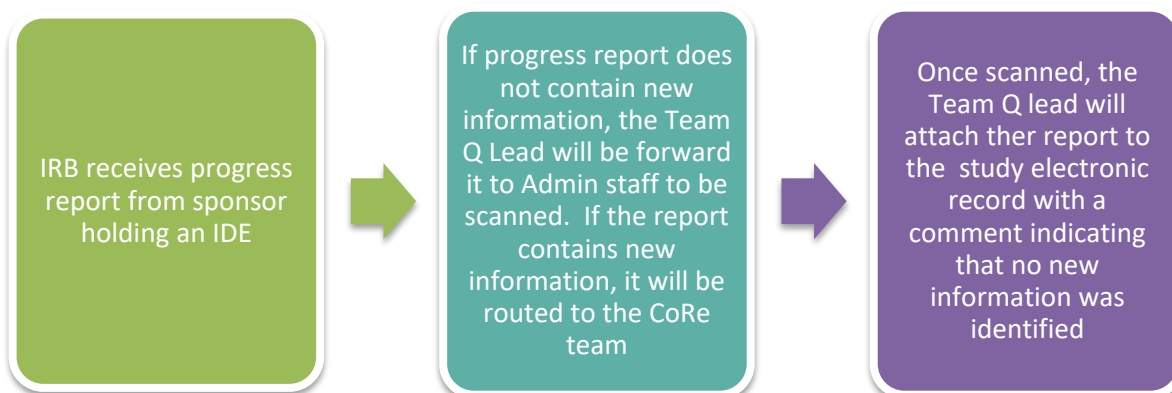
## PROCEDURE

Once the IRB receives a progress report (different from the annual report that should be submitted at continuing review), the Team Q Lead will review the report to verify that it does not contain any new information that should be reported promptly to the board. If the progress report does not contain new information, the QA Associate or Assistant Director will forward it to the IRB administrative assistant who will scan it. The scanned progress reports will be saved under H:\General\Scanned Documents\IDE progress reports from Sponsors. Once scanned, the IRB administrative assistant will return the hard copies to the Team Q lead. The Team Q Lead will attach the scanned records to the study electronic history with a comment indicating that the report did not include any new information and requesting comments from the study staff about the report review. If the report includes new information that should be reviewed by the full board, the Team Q Lead will send the report to the CoRe per our SOP entitled Team Q NC-UP process SOP.



The report may be destroyed after scanning and archiving under the study history.

**PROCESS FLOW**



**REFERENCES**

- 21 CFR § 312
- 21 CFR § 812
- IRB policies and procedures

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	Routing External UPs (FDA Regulated)
<b>SOP</b>	QA and Education
<b>Established:</b>	7/17/2012
<b>Last Revision:</b>	7/17/2012

## PURPOSE

The purpose of this document is to describe how the IRB Team Q will route external unanticipated problems from studies considered FDA regulated.

## SCOPE OF SOP

FDA regulated trials conducted in human subjects' research overseen by the Emory University IRB.

## DEFINITIONS

- **Investigational Device:** means a device, including a transitional device that is the object of an investigation. An investigational device is permitted by the FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.
- **Investigational Drug or Investigational New Drug:** An Investigational Drug or Investigational New Drug means a new drug or biological drug that is used in a clinical investigations or a biological product that is used in vitro for diagnostic purposes.
- **Investigational Device Exemption (IDE):** An IDE allows an Investigational Device to be used in a clinical study in order to collect the safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification submission to the Food and Drug Administration.
- **Investigational New Drug (IND) Application:** An application that must be submitted to the FDA before a drug can be studied in humans. This application includes results of previous experiments; how, where, and by whom the new studies will be conducted; the chemical structure of the compound; how it is thought to work in the body; any toxic effects found in animal studies; and how the compound is manufactured.
- **Sponsor:** A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator
- **Sponsor-Investigator (S-I):** means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor
- **Unanticipated Problem:** any unexpected problem related to the Research, including any unexpected adverse experience, whether serious or not, that affects the rights, safety or welfare of subject or others or that significantly impacts the integrity of the research data. OHRP considers unanticipated problems, in general, to include any incident, experience, or outcome that meets all of the following criteria:
  - Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

- Related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
- **Unanticipated Adverse Device Effect (UADE):** any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects

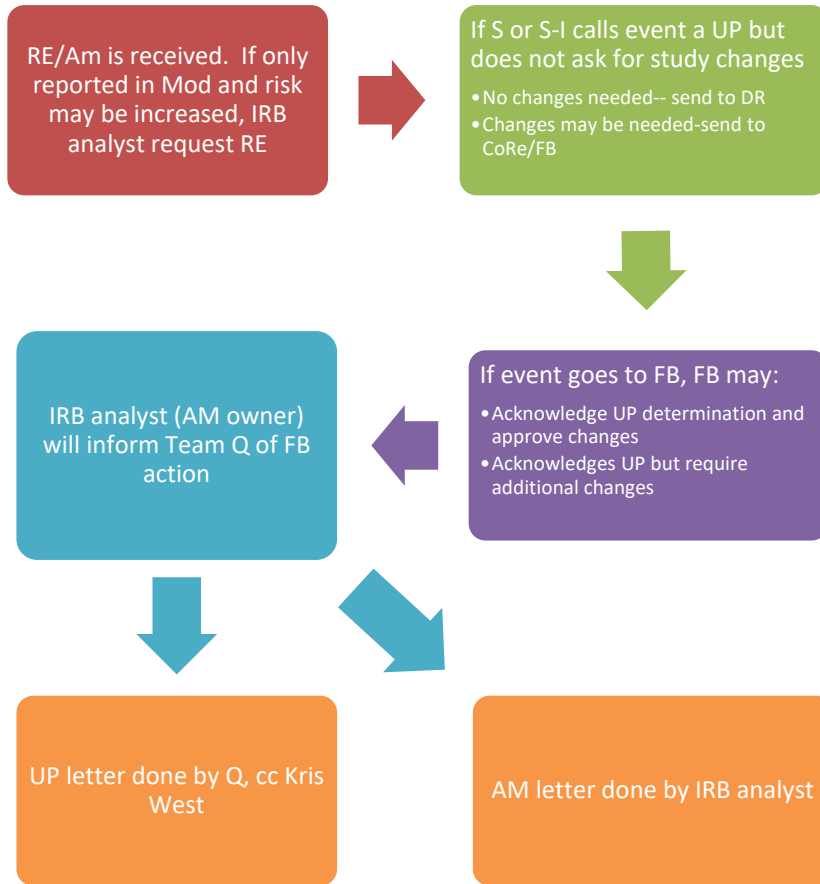
## RESPONSIBILITIES

- **IRB Team Q member:** reviews initial reported events and sends them to CoRe or FB if appropriate.
- **IRB analyst:** Makes sure study team reports events through a reportable new information submission (RE) form.

## PROCEDURE

- If an external event is called an unanticipated problem by the sponsor (or S-I), then the event will be reported via RNI (and Mod if necessary).
  - If event does not merit changes via Mod (e.g. study is closed for enrollment without active subjects), Associate or Assistant Director will send event to DR.
  - If the sponsor has not requested changes in the study but the event may merit changes, (e.g. study is still enrolling or have active subjects) the event will be reviewed by CoRe. CoRe may acknowledge the event/no changes in study or may recommend FB to review the CoRe suggested changes to study.
  - If sponsor or S-I reports events as unexpected and related but does not call it a UP, the event will go through CoRe/FB as normal.
- If the event is reported only as an Modification, the IRB analyst will request the submission of a RNI as well.
- The IRB analyst will contact Team Q lead to notify about the Mod. Team Q only needs to know about Mod involving increased risk (e.g. changes to the ICF involving new adverse event).
- Team Q lead will assign the RNI to a Team Q member who will be in close communication with the IRB analyst.
- When the RE/Am goes to FB, the FB should make one of these two determinations:
  - The IRB acknowledges the UP determination, and determines that changes as submitted are appropriate.
  - The IRB acknowledges the S or S-I determination, but thinks additional changes are necessary.
- After the FB meeting, the IRB analyst will notify Team Q of the UP determination.
- The Team Q member will send FB determination letter to the PI, copying Kris West.

## PROCESS FLOW



**REFERENCES**

- IRB QA Plan 12.15. 08
- 45 CFR 46.103
- IRB policies and procedures
- 21 CFR 812.3

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

## **S-I SUBMISSION MANAGEMENT**

Definition for the SOPs on this Section

- **Investigational New Drug (IND) Application**: a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans which must be secured prior to administration of any new drug, biological product that is not the subject of an approved New Drug Application, or Biologics/Product License Application. An IND may be required for a clinical investigation using a marketed drug for a use other than the indications in the approved labeling. [21 CFR § 312.3].
- **Investigational Device Exemption (IDE)**: An IDE allows an Investigational Device to be used in a clinical study in order to collect the safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification submission to the FDA. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE (either abbreviated or issued by the FDA) before the study is initiated. [21 CFR § 812.3].
- **Sponsor**: A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. [21 CFR § 312.3, 812.3].
- **Sponsor-Investigator**: an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor. [21 CFR § 312.3, 812.3].
- **Annual or Progress Report Submission**: A report submitted to the FDA by the IND or significant risk IDE holder within 60 days of the anniversary date that the IND went into effect or at regular intervals and at least yearly for an IDE for a significant risk device. The report contains the study progress information, general investigational plan for the following year, and other applicable information. [21 CFR § 312.33, 812.150].

Scope for SOPs in this Section

FDA regulated studies, involving an Emory faculty member holding an IDE for a significant risk device or an IND.

References for SOPs in this Section

- 21 CFR § 312
- 21 CFR § 812
- IRB policies and procedures
- Emory Sponsor IND Responsibility Checklist
- Emory Sponsor IDE Responsibility Checklist

- Emory Sponsor Responsibility Checklist Continuing Review Update
- Emory Sponsor Responsibility Checklist Multi-site Trials

<b>SOP Title:</b>	New study screen process for S-I studies
<b>SOP</b>	S-I Submission Management
<b>Established:</b>	7/26/2012
<b>Last Revision:</b>	1/20/2021

#### **PURPOSE**

The purpose of this document is to describe the review process of new study submissions by the IRB analyst and Office of Compliance designated person (ODP), when the study involves an Emory Sponsor or an Emory Sponsor-Investigator (S-I) holding an IDE for a significant risk device or IND.

#### **RESPONSIBILITIES**

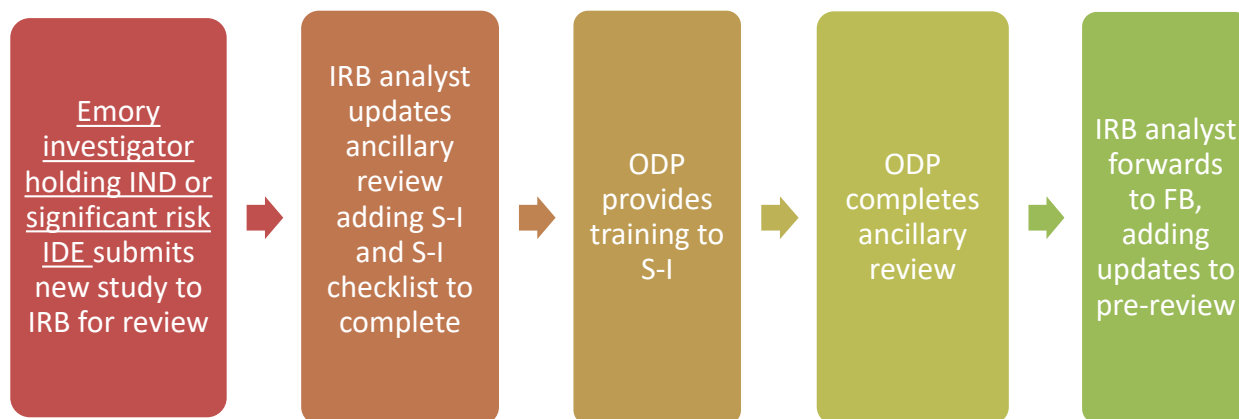
- IRB analyst – verifies that the information in eIRB, including the protocol and DSMP, is complete, requests the S-I or Sponsor to contact the ODP and informs ODP accordingly.
- ODP designated person: responsible for providing Sponsor/Sponsor-Investigator training and reviewing IND and IDE information on the Emory S-I Responsibility Checklist, ensuring that it reflects the information submitted under the IND or IDE application to the FDA.
- Emory investigator holding IND or significant risk IDE: makes sure that the information submitted in eIRB and on the Emory IND or IDE Responsibility Checklist is complete and accurate, according to the study protocol submitted to the FDA.

#### **PROCEDURE**

- The IRB analyst will update the ancillary review option adding “S-I advisory”.
- The IRB analyst will notify the Sponsor/S-I to contact the ODP for training. The analyst will ask Sponsor/S-I to provide additional information about the study IND/IDE (e.g. IND/IDE submission date, if IND/IDE is required, FDA correspondence, etc.) and to fill out the Emory S-I IND or IDE Responsibility Checklist.
- A study cannot be placed on a FB agenda until we receive an FDA “study may proceed” letter or the date of IND/IDE submission is more than 30 days
  - If the team pushes back, the analyst will contact the Associate Director for additional steps
- If the study team received an IND or IDE letter stating that it is *pending some contingencies* before proceeding, the IRB analyst will ask the team for the information received from the FDA (via email, for example) and the changes to the protocol and consent forms sent to the FDA to address said contingencies. The study cannot be placed in a FB agenda until we receive documentation that 30 or more days have passed since the IND or IDE submission to the FDA. The FDA correspondence should be uploaded under the drug section, question 4 (protocol/ICF changes should be uploaded in their respective section in eIRB).
- When the study is ready for Full Board (FB), the IRB analyst will add the study to the next available meeting agenda
- The ODP will upload the Emory IND or IDE Responsibility Checklist when submitting the S-I Advisory sign-off by clicking on “Submit Ancillary Review” and uploading the checklist under question 4. The review will be updated under the “review” tab.

- For studies with non-Emory sites, the Emory sponsor will complete the appropriate multi-site Responsibility Checklist. This is only needed if the site is listed by name in the protocol. If the site is not activated yet, the study team should change the protocol and submit the multisite responsibility form at a later time via a modification.
- If the non-Emory sites include an international site, the Emory sponsor should provide:
  - Analysis from Emory’s General counsel review.
  - Approval letters from the international site IRB/EC review.
  - Include the use of a CRO with expertise in the rules and laws of the international site in the protocol’s site monitoring plan section

**PROCESS FLOW**



**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	CR screen process for S-I studies
<b>SOP</b>	S-I Submission Management
<b>Established:</b>	7/26/2012
<b>Last Revision:</b>	1/20/2021

## **PURPOSE**

The purpose of this document is to describe the review process of continuing review (CR) submissions by the IRB analyst and Office of Compliance designated person (ODP) when the study involves an Emory Sponsor or an Emory Sponsor-Investigator (S-I) holding an IDE for a significant risk device or IND.

## **RESPONSIBILITIES**

- IRB analyst – verifies that the information in eIRB, is complete, requests the S-I or Sponsor to contact the ODP, and informs ODP accordingly.
- ODP designated person: responsible for reviewing IND and IDE information on the Emory S-I Responsibility Checklist, ensuring that it reflects the information submitted under the IND or IDE application to the FDA.
- Emory investigator holding IND or significant risk IDE: makes sure that the information submitted in eIRB and on the Emory IND or IDE Responsibility Checklist is complete and accurate, according to the study protocol submitted to the FDA.

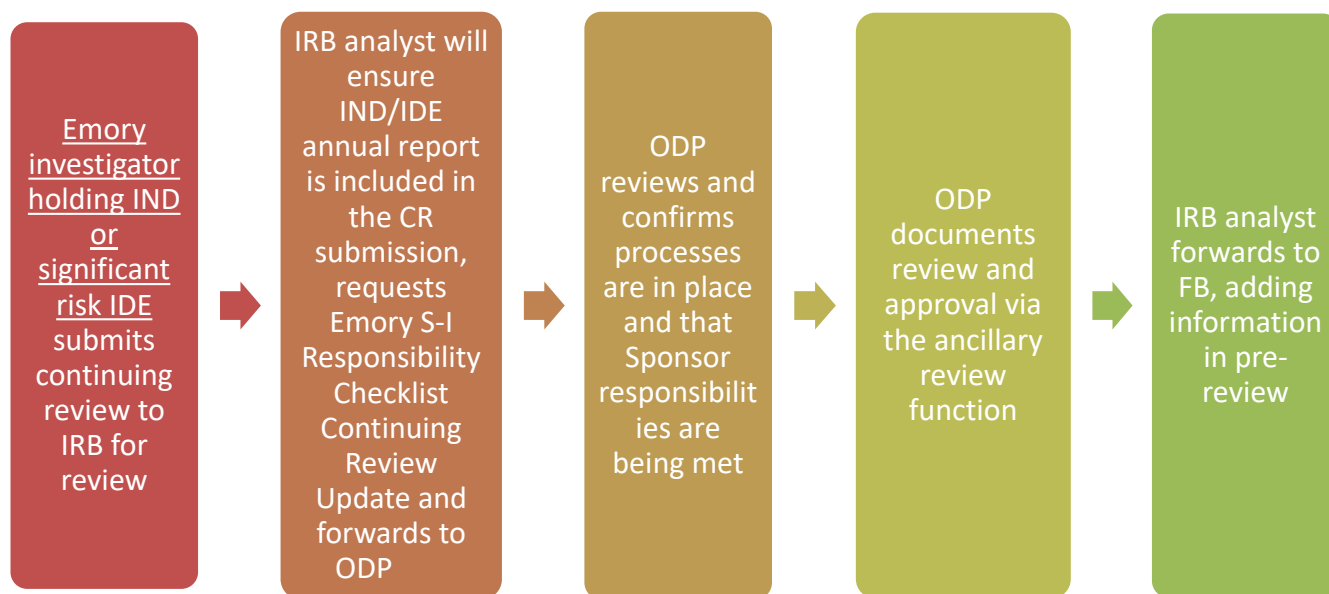
## **PROCEDURE FOR CONTINUING REVIEWS**

- The IRB analyst will request that the Emory Sponsor/S-I complete the Emory Sponsor Responsibility Checklist Continuing Review Update and forward it to the ODP.
- The ODP will review the Emory Sponsor Responsibility Checklist Continuing Review Update to confirm that processes are in place so that processes are in place to meet Sponsor/S-I responsibilities.
  - If processes are not in place, the ODP will work with the Sponsor/S-I and make the IRB analyst aware of any significant concerns, including the DSMB report.
- Once the Emory Sponsor Responsibility Checklist Continuing Review Update is complete and the ODP has confirmed that the processes are in place to meet Sponsor responsibilities, the ODP will notify the IRB analyst via email and will attach the completed Responsibility Checklist under question 4 under the “manage ancillary review” activity.
- If the study is in data analysis only, the Sponsor-Investigator Responsibilities Checklist is not required.
- The IRB analyst will ensure that the IND or IDE annual or progress report submission to FDA is included in the continuing review application.
  - If the annual report submission is not included in the application, the IRB analyst will determine from the ODP the anniversary date that the IND or IDE went into effect.
  - If the date will occur in the future, the IRB analyst will create an Outlook reminder to follow up with the study team to submit the annual report at the next continuing review.
  - If the anniversary date has already passed, the IRB analyst will request a copy of the annual report submission.
  - If the annual report submission is not provided, the IRB analyst will notify the ODP and the Team Q lead.



- The continuing review can still be assigned to a Full Board committee meeting without the IND or IDE annual report; however, this might be deemed a pending issue by the committee.
- When the continuing review is ready for Full Board review, the IRB analyst will add it to a meeting agenda and include the following information in the pre-review: 1) S-I has/has not completed the Emory Sponsor-Investigator Responsibility Checklist Continuing Review update if the form is required; 2) ODP has/has not confirmed that processes are in place to meet Sponsor responsibilities, and 3) the status of the IND/IDE annual report submission.

**PROCESS FLOW FOR CONTINUING REVIEW**



**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	Modification (MOD) submission screen process for S-I studies
<b>SOP</b>	S-I Submission Management
<b>Established:</b>	7/26/2012
<b>Last Revision:</b>	1/20/2021

## PURPOSE

The purpose of this document is to describe the review process of modification (MOD) submissions by the IRB analyst and Office of Compliance designated person (ODP) when the study involves an Emory Sponsor or an Emory Sponsor-Investigator (S-I) holding an IDE for a significant risk device or IND.

## RESPONSIBILITIES

- IRB analyst – verifies that changes in the submission requests the S-I to fill out a responsibility form if applicable, and informs ODP accordingly.
- ODP designated person: responsible for providing Sponsor/Sponsor-Investigator training, as applicable, and reviewing IND and IDE information on the Emory S-I Responsibility Checklist, ensuring that it reflects the information submitted under the IND or IDE application to the FDA.
- Emory investigator holding IND or significant risk IDE: makes sure that the information submitted in eIRB and on the Emory IND or IDE Responsibility Checklist is complete and accurate, according to the study protocol submitted to the FDA.

## PROCEDURE FOR MODIFICATIONS TO ADD NON-EMORY STUDY SITES, CHANGE SPONSOR OR INVESTIGATOR, AND/OR MODIFY THE PROTOCOL

**Note for any change to the protocol/IB/IC:** if there are any delays in the submission of these documents (check cover letter or dates on the documents), please check with Team Q as the study team may require the submission of a reportable event.

## CHANGE SPONSOR

- The IRB analyst will request that the Emory Sponsor/S-I holding an IND or significant risk IDE complete the Emory Sponsor-Investigator Responsibility Checklist (if changing Sponsor) and forward it to the ODP.
- The ODP will review to confirm that processes are in place so that Sponsor responsibilities are met and appropriate regulatory actions have been taken.
- If processes are not in place, the ODP will work with the S-I and make the IRB analyst aware of any significant concerns.
- Once the Emory Sponsor-Investigator Responsibility Checklist is complete and it is evident that S-I responsibilities are being met, the ODP will notify the IRB analyst via email and will edit the modification in eIRB to include the completed form(s) under question 4, under the “manage ancillary review” activity.
- The ODP will also log a comment in the modification study history regarding the completed form(s) before IRB review.
- The IRB analyst will also confirm that the Sponsor submitted an IND amendment or IDE supplement to the FDA to change sponsor.
- The study analyst will verify that the FDA amendment/supplement was submitted and that the protocol and ICF have been changed accordingly.

### **CHANGE OF PRINCIPAL INVESTIGATOR**

If the study changes the study PI, without changing the Emory Sponsor, the Emory Sponsor is required to not only change the eIRB record but also to submit an IND amendment or IDE supplement to the FDA. The study analyst will verify that the FDA amendment/supplement was submitted and that the protocol and ICF have been changed accordingly.

### **CHANGES THAT MODIFY THE PROTOCOL**

If the Emory Sponsor/S-I holding an IND or significant risk IDE is making modifications to the protocol required to be submitted to FDA as defined by [21 CFR 312.30](#) / [812.35](#), the Emory Sponsor/S-I holding an IND or significant risk IDE will need to either (1) include documentation that they have submitted the change to the FDA or (2) add a date for when they will submit to the FDA. If the FDA submission date is a future date, the study team is also responsible for logging a comment in the study, confirming that they have notified the FDA of the change; this will not be a pending issue for the review and approval of an amendment.

### **Studies where the Emory Sponsor/S-I holds an IND**

Substantial modifications to the protocol must be approved by the FDA and IRB. Substantial modifications include any change in a Phase 1 protocol that significantly affects the safety of subjects or any change in Phase 2 or 3 protocol that significantly affects the safety of subjects, the scope of the investigation, or the scientific quality of the study. Examples of changes requiring an amendment under this paragraph include:

- Any increase in drug dosage or duration of exposure of individual subjects to the drug beyond that in the current protocol, or any significant increase in the number of subjects under study.
- Any significant change in the design of a protocol (such as the addition or dropping of a control group).
- (The addition of a new test or procedure that is intended to improve monitoring for, or reduce the risk of, a side effect or adverse event; or the dropping of a test intended to monitor safety.

### **Studies where the Emory Sponsor/S-I holds a significant risk IDE**

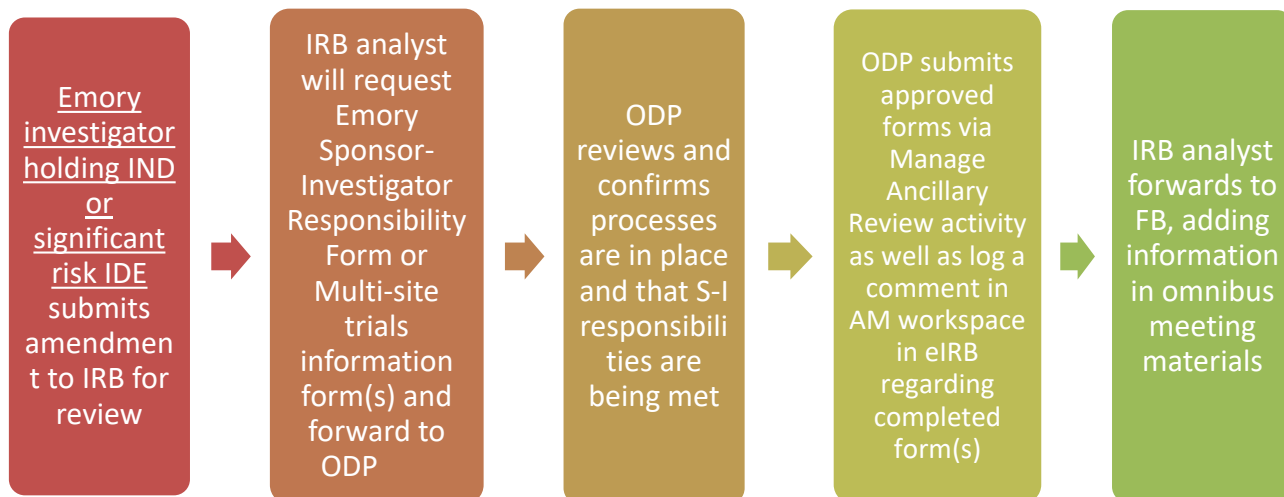
A sponsor must obtain (FDA and IRB) approval before implementing a change to an investigational plan unless the change does not affect:

- The validity of the data or information resulting from the completion of the approved protocol, or the relationship of likely patient risk to benefit relied upon to approve the protocol;
- The scientific soundness of the investigational plan; or
- The rights, safety, or welfare of the human subjects involved in the investigation.

### **CHANGES ADDING SITES TO THE PROTOCOL**

If the study team adds a site (not previously listed) to the IDE or IND protocol, the study team should submit a new modification letting the IRB know about this addition. The SI analyst will add the ODP as an ancillary reviewer to the modification. The study can be sent to FB without the ODP approval as long as states in pending approval status after the meeting. If appropriate, the study cannot be sent to a designated reviewer without the ODP approval.

**PROCESS FLOW (AMs)**



**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	Closeout submission screen process for S-I studies
<b>SOP</b>	S-I Submission Management
<b>Established:</b>	7/26/2012
<b>Last Revision:</b>	1/20/2021

#### **PURPOSE**

The purpose of this document is to describe the review process of closeout submissions by the IRB analyst and Office of Compliance designated person (ODP), when the study involves an Emory Sponsor or an Emory Sponsor-Investigator (S-I) holding an IDE for a significant risk device or IND.

#### **RESPONSIBILITIES**

- IRB analyst – verifies that the information in eIRB is complete, ensures proper submission of annual/final reports for IDEs.
- ODP designated person: reviews if required.
- Emory investigator holding IND or significant risk IDE: submits information to IRB as required.

#### **PROCEDURE**

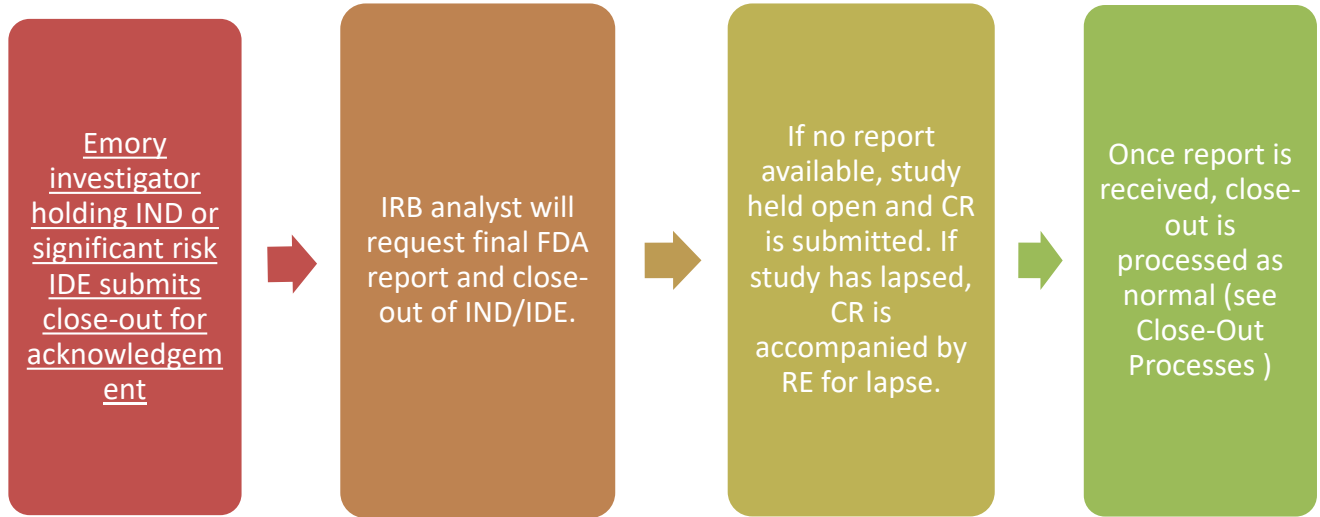
##### **Studies where the Emory Sponsor/S-I holds a significant risk IDE**

- Once a close-out request is submitted, the IRB analyst will ensure that the Emory Sponsor/S-I holding a *significant risk IDE* provides: 1) a copy of the final IDE report (which is due to the FDA within 6 months after the completion or termination of the investigation) and 2) confirmation that they have submitted the report to the FDA.
- If a final IDE report is not available, then the study team must keep the study open until they confirm that the Final Report has been submitted to the FDA.
- *If the study approval lapses*, even if a close-out is submitted before expiration, the study will be considered to have lapsed, and an RE will also be required for completion of the close-out.
- Once all supporting documentation is submitted (final FDA report, RNI if necessary), then the study can be closed-out using normal close-out procedures (see [Close-out Processes](#))

##### **Studies where the Emory Sponsor/S-I holds an IND**

Once a close-out is submitted, the IRB analyst will ensure that the Emory Sponsor/S-I holding an IND provided a timely annual report to the FDA (if one is required).

#### **PROCESS FLOW (Close-outs)**



**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	S-I, Single IRB Study Screening Process
<b>SOP</b>	S-I Submission Management
<b>Established:</b>	1/20/2021
<b>Last Revision:</b>	8/30/2021

## **PURPOSE**

To describe the additional steps to review an S-I study when Emory is serving as the sIRB for external sites.

## **SCOPE**

S-I studies where Emory is serving as the sIRB for external sites.

## **RESPONSIBILITIES**

- IRB reliance analyst – responsible for completing the reliance process and processing the addition of external sites in the smart form.
- IRB S-I specialist-responsible for the initial screen of the study, and subsequent follow-on submissions
- IRB Directors- assigns the new study submission to the S-I specialist
- Office of Compliance Designated Person (ODP): responsible for providing Sponsor/Sponsor-Investigator training and reviewing IND and IDE information on the Emory Sponsor Responsibility Checklist, ensuring that the protocol and IRB submission reflect the information submitted under the IND or IDE application to the FDA and that regulatory requirements have been met.

## **PROCEDURE**

### **Initial Study Review**

- The IRB Director will assign the study to an S-I specialist letting them know this is a potential sIRB study.
- The S-I specialist will contact the reliance team to confirm that the use of a single IRB is required, and that Emory agreed to serve in this role.
  - If Emory is not willing to serve as the sIRB for the study, the reliance team will provide guidance on how to proceed.
  - If use of a single IRB is not required, Emory may choose to review for the Emory site.
  - If use of a single IRB is required, Emory may rely on an external IRB.
- The S-I specialist will follow the SOP entitled “Sponsor/Sponsor-Investigator at Emory Holding an IND/IDE: Review of Studies Involving Emory University”.
- The S-I specialist will ensure the smart form includes a master consent form(s) which mirrors the Emory site-specific consent form(s) with place holders for relying site-specific information to be inserted. External study team members should not be included in the smart form.

- When the study is approved, the S-I specialist will include this statement in the approval letter “The Emory IRB has approved the study-wide protocol and master consent form(s) and has agreed to serve as the IRB of record for this multi-site study. External sites have not yet been approved and may not begin conducting research activities until official site-specific approval has been received.”
- After the study has been approved, the S-I analyst will reassign the study to a reliance team member.

### **Adding Participating Sites (pSites)**

- The reliance specialist will follow the SOP titled “Study Processing When Emory is the Single IRB of Record (sIRB) for a Multi-Site Study.”
- Once the pSites have been added and the smart forms are complete, the reliance specialist will trigger an ancillary review of the pSites in the main study workspace (will be added to the existing ancillary review for the overall study) by the Office of Compliance (Margaret Huber).
- Once Margaret Huber has reviewed the pSites and provided her review, the reliance specialist will assign the pSites to the Reliance Team Lead for review.
- The Reliance Team Lead will approve the pSites or request clarifications.
- The reliance specialist will process the approvals for the sites.
- The reliance specialist will reassign the S-I study to the S-I specialist.

### **Modifications and Continuing review**

- The S-I specialist will follow the SOP entitled “CR screen process for S-I studies”.

### **Study Closeout**

- The reliance specialist will follow the SOP entitled “Closing Out Multi-Site Studies” to close pSites.
- The reliance analyst will reassign the closeout submission to the S-I specialist to close the parent study in SaaS.
- The SI specialist will follow the SOP entitled “Sponsor/Sponsor-Investigator at Emory Holding an IND/IDE: Review of Studies Involving Emory University”.

### **LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
8/30/2021	Updated process



## **STUDY MANAGEMENT**

<b>SOP Title:</b>	Not Research/ Not-Human-Subjects/Not-Human-Subjects-Research/Not-Engaged
<b>SOP Category:</b>	Study Management
<b>Established:</b>	6/28/2013
<b>Last Revision:</b>	04/22/2022

### **PURPOSE**

Outline the necessary steps for processing a determination of not research (NR), not-human-subjects (NHS), not-human-subjects research (NHSR), or not-engaged. Determinations are made in response to:

- Requests for a determination via MS Form [NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM](#)
- Requests for a determination via email (typically after using the form on the website but have been instructed to contact the IRB)
- eIRB submissions which upon initial review are determined NR/NHSR/NE

### **SCOPE**

This applies to all IRB staff, particularly those who manage listserv and analysts who conduct initial review of new eIRB submissions.

### **RESPONSIBILITIES**

- Listserv Monitors: Assist investigators to confirm whether IRB review is required or not based on the responses entered into the MS Form, NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM
- IRB Analysts: Conduct initial review of eIRB submissions and determine if the project is NR/NHS/NHSR. Receive NHSR requests via email when determination form refers requestor to IRB, and determine whether the project is NR/NHS/NHSR/NE, or if it requires a formal submission in eIRB. Compose NR/NHS/NHSR/NE letters if required and:
  - Send to PI via logged comment, then withdraw the study (if received via eIRB submission).
  - Send to PI via email (if received via listserv).

### **PROCEDURES**

#### **REVIEW OF NR/NHSR/NE DETERMINATIONS**

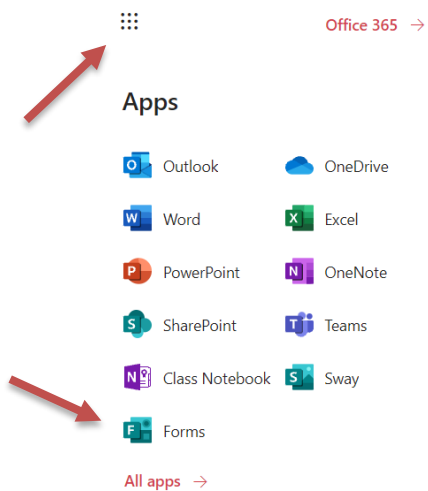
*NR/NHSR/NE determinations are typically made in response to either MS Forms NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM requests, email requests after the determination form refers requestor to IRB, or upon initial review of eIRB submission. These scenarios are separated into respective sections below:*

Email Requests for NR/NHSR/NE Determinations – No prior MS Forms submission

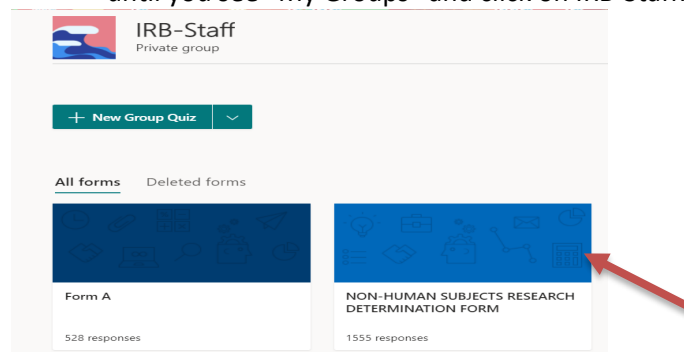
If not clearly HSR, request that the person use the MS Forms NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM tool first and come back if the tool determines IRB consultation is needed. If requestor has been told a formal letter is required, skip to [“Email Requests for Formal NR/NHSR/NE Determinations – MS Forms not accepted by third party,”](#) section below.

Email Requests for NR/NHSR/NE Determinations – Requestor has already used MS Forms

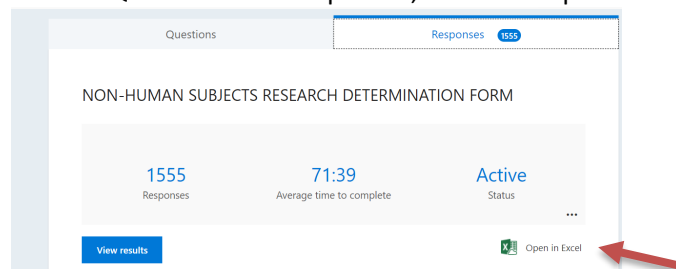
1. If the investigator has not provided any attachments that may include their NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM request responses, you will first need to locate the investigator’s NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM responses.
  - a. Ensure that you are logged into Emory Office 365
  - b. Click on the “waffle” in the upper left-hand corner of the display and navigate to the Office 365 App Forms



- c. When you first navigate to Forms, you may not see any Forms to choose from. Scroll down until you see “My Groups” and click on IRB-Staff. The view may look like this:



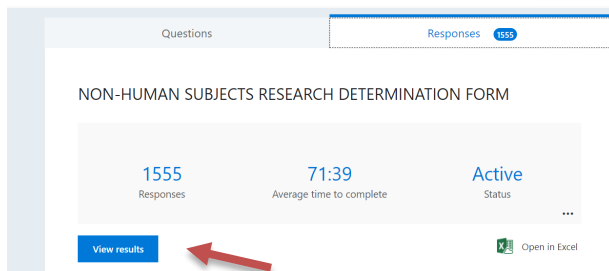
- d. Click on NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM – there will be two tabs, Questions and Responses, click on Responses. Click on the “Open in Excel” icon.



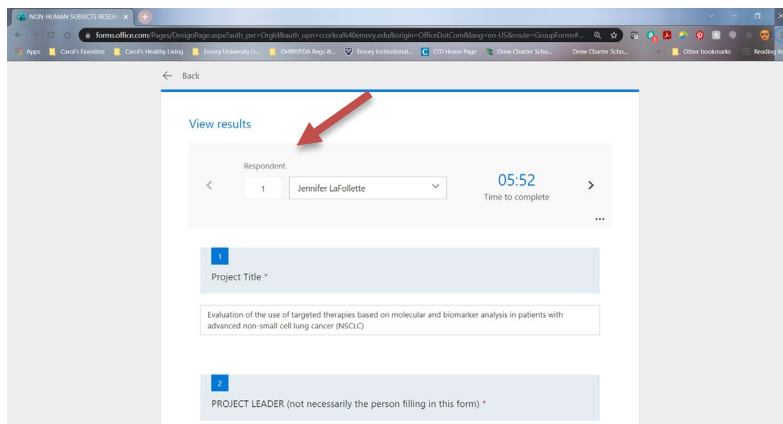
**e. Search the Responses Excel spreadsheet for the investigator’s name or email address**

ID	Start time	Completion time	Email	Name	Project Title	PROJECT LEADER	FUNDING
1510	9/20/21 21:25:35	9/20/21 21:27:55	BRABIN@emory.edu	Benjamin Rabin	Evaluation of Climate Change and Health Curriculum for Undergraduate Medical Students at Er	Rebecca Philipsborn	No
1511	9/21/21 9:28:46	9/21/21 9:42:53	TKSMIT5@emory.edu	Tracy Smith	Structural Competency in Government Organizations through the Lens of New Mexico	Tracy Smith	No
1512	9/21/21 10:27:00	9/21/21 10:29:57	smadkin@emory.edu	Shari Madkins	The Pandemic Pivot: How Black Churches Adapted to Address Poverty During COVID-19	Elizabeth Bounds	No
1513	9/21/21 11:46:34	9/21/21 11:47:09	KKLEINE@emory.edu	Kjersti Kleine	The Comprehension & Assessment of Consent: A Review of the Assessments of Understanding	Dr. Srilatha Edupuganti	No
1514	9/21/21 13:51:39	9/21/21 13:55:20	AGRACZ@emory.edu	Adam Gracz	Intestinal organoid biobank	Adam Gracz	Yes
1515	9/22/21 11:38:00	9/22/21 11:45:49	ccorkra@emory.edu	Carol Corkran	Training RPAs on NHSR determinations	Carol Corkran	No
1516	9/22/21 16:20:05	9/22/21 16:35:44	MSELBY@emory.edu	Maurice Selby	Real Talks: Bias and Anti-racism in Healthcare	Maurice Selby	No
1517	9/23/21 18:37:50	9/23/21 18:42:15	n584172@eushc.org	Gilbert Harding Jr	Supporting Front-Line Nurse Managers Within the Work Environment	Gilbert Harding, Jr.	No
1518	9/23/21 12:59:55	9/23/21 19:02:32	JHANNA8@emory.edu	Jasmah Hanna	COVID Vaccine Hesitancy Among Metro Atlanta Healthcare Workers, May-June 2021	Sheetal Kandiah, MD, PhD	No

**f. If you want to review their actual responses in the Form layout, you can click on the blue “View results” button**



**g. If you have already found the Respondent ID number from the spreadsheet you can enter it here:**



- h. Review the investigator's responses to determine which item on the form recommended that they submit their project proposal to the IRB for review and confirmation that their project does not constitute human subjects research at Emory. You will also need to read the project proposal.
- i. Either ask the study team to correct the MS Form if they made an error and it should have resulted in a "no IRB required" determination or confirm that they need to submit in eIRB.

Email Requests for Formal NR/NHSR/NE Determinations – MS Forms not accepted by third party

1. Take a preliminary review of the information submitted about the project; determine whether additional information is required
  - a. The NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM requires most basic information to be included (emails directly to the listserv may be lacking)
  - b. Typically it is necessary to have a copy of the protocol summary along with information about objectives, procedures, funding and data source
2. If the project involves the VA in any way (study site, affiliation of researchers, data source, etc.), send the determination request to the Emory/VA liaison. Copy the person who made the request when you forward the email to the liaison to let the person know that the request has been received and it is being rerouted.
3. After receiving all the necessary information, consider whether the project qualifies as human subjects research
  - a. Is it a "systematic investigation designed to contribute to generalizable knowledge?" Does it involve human subjects with whom an investigator has interaction or intervention, or about whom an investigator receives identifiable private information? (See 45 CFR 46.101)
    - 1) Remember that the FDA has a different interpretation of human subjects; even if using only de-identified samples, clinical investigations that support applications for research or marketing permits for products regulated by the FDA require IRB review.
  - b. There are several resources to aid your determination; refer to the guidance folder and consult with colleagues for assistance.
    4. Reply by email to the investigator with an official determination
      - a. The email should state that the IRB has reviewed the provided information and determined that the project does not require IRB review because it (a) does not meet the definition of "research" or (b) does not involve "human subjects" or (c) Emory is not "engaged" in the human subjects research. (Refer to the letter template for guidance on the language to include in the email: "[H:\General\Admin IRB Documents\Checklists, Forms, and Templates\Letter templates and suggested language\NHS NR Letter Template.doc](#)" and "[\Not Engaged Template Letter](#)")
      - b. The more specific the better, remember that we may need to refer back to this determination in the event that a concern arises later. Cite specific regulations if possible, and explain any possible points of confusion. For example, "...not research because this is a quality improvement/case report/educational initiative designed to..."
      - c. At the end, explain that the email is sufficient documentation of the IRB's determination but if a more formal letter of determination is necessary in the future please let us know.
5. Document the determination on the H: Drive

- a. Create a new folder under [H:\General\NR-NHS Letters\](#)[Last Name, First]
- b. Add to the new folder:
  - a. Submitted documents (e.g. protocol, survey, etc.);
  - b. PDF of all email correspondence;
  - c. The formal letter of determination, if drafted.
- c. *Remember: this documentation is the only proof that the IRB will have in the future. If, for example, an academic journal requests our reasoning for not requiring IRB oversight, we need to have this documentation. It's also necessary for internal record reviews, and possibly external audits.*

eIRB Submissions Determined NR/NHSR or “Not Engaged”

1. Review the eIRB submission and determine whether the project constitutes human subjects research, and if so, is the Emory team “engaged” in the research
  - a. Is it a “systematic investigation designed to contribute to generalizable knowledge?” Does it involve human subjects with whom an investigator has interaction or intervention, or about whom an investigator receives identifiable private information? If a multisite study *does* involve HSR, is Emory actually *doing* any of it (i.e. are we “engaged”)? (See 45 CFR 46.101)
    - 1) Remember that the FDA has a different interpretation of human subjects; even if using only de-identified samples, clinical investigations that support applications for research or marketing permits for products regulated by the FDA require IRB review.
    - 2) Also remember that if Emory is the prime awardee of a federal grant where the grant proposal was submitted as human subjects research, we are still considered “engaged” in the research, even if we’re farming out the human subjects research activities.
  - b. There are several resources to aid your determination; refer to the guidance folder and consult with colleagues for assistance.
2. If determined NR/NHSR or “Not Engaged,” submit the pre-review, documenting any regulatory oversight that applies. A pre-review checklist is not required.
3. Assign yourself as a designated reviewer and conduct the review, noting that the project is not research with human subjects.
4. Finalize only the protocol so that it is referenced in the letter that’s generated.
5. Click “Prepare Letter” to generate the appropriate letter. Draft the letter and upload it.
  - o Be sure to include in the letter a brief rationale for your determination, making it clear whether the work is “not research,” “not human subjects,” or that Emory is “not engaged,” and why.
6. Click “ok.”
7. Click “Send Letter” to send the letter to the team. The study should **not** have an expiration date since it was not “approved.”

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
04/22/2022	Large overhaul of SOP: Addition of instructions for how to handle when the NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM responses indicate that the investigator should consult the IRB via emailing the IRB listserv. Also included “Not Engaged” determinations.

## MODIFICATIONS

<b>SOP Title:</b>	Adding/Removing Study Personnel
<b>SOP Category:</b>	Modifications
<b>Established:</b>	4/11/2014
<b>Last Revision:</b>	7/5/2022

### PURPOSE

This SOP describes the process for IRB personnel to review Modifications that include only staff changes on their assigned day. An “assigned day” begins at 4:00 pm the day before the assigned day and ends at 3:59 pm on the assigned day. For example, if the assigned day is Wednesday, the IRB personnel will process modifications submitted from Tuesday at 4:00 pm to Wednesday at 3:59 pm. The person assigned to Monday process modifications submitted from Friday at 4:00 pm to Monday at 3:59 pm.

### SCOPE

The SOP applies to all approved, non-expired studies.

Note: If the personnel change is for a study with AVAHCS (the Atlanta VA) as a Research Location, only the VA liaison can perform the review as there are additional considerations (Daniel Roysden, [droysde@emory.edu](mailto:droysde@emory.edu)).

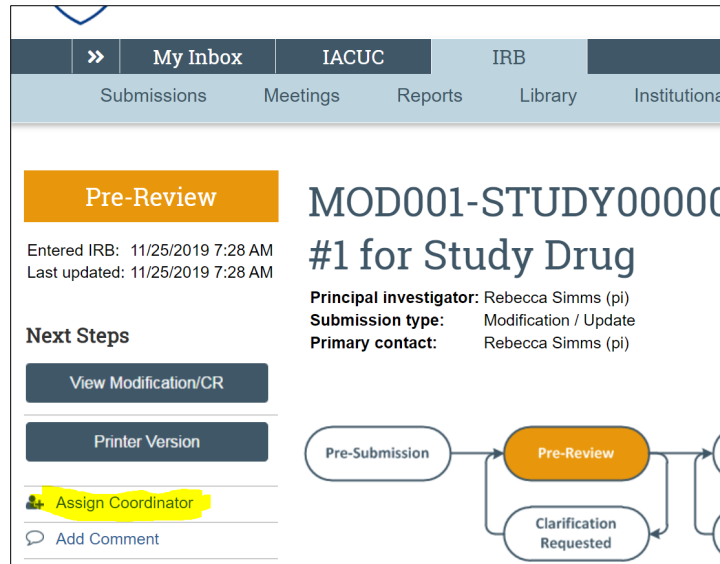
### PROCEDURE

1. Log into eIRB.
2. Click the “My Inbox” tab if not already there.
3. Click on the “Personnel Changes” tab.
4. Review the “Date Modified” column to determine the modifications that were submitted on your assigned day.
  - o Click the words “Date Modified” once or twice to sort that column by date order, newest to oldest.

The screenshot shows the eIRB system interface. At the top right, it says "Hello, Jackson Parker". Below that is a navigation bar with tabs: "My Inbox" (highlighted), "IACUC", and "IRB". Under "My Roles", it lists "IRB Coordinator" and "Registered User" with buttons for "Create New Study" and "Report New Information". The main content area is titled "Personnel Changes" and includes a search bar and a table. The table has columns: ID, Name, Date Created, Date Modified, State, Coordinator, and PI. One row is visible with ID "MOD001-STUDY00000025", Name "Modification / Update #1 for Study Drug", Date Created "11/25/2019 7:27 AM", Date Modified "11/25/2019 7:28 AM", State "Pre-Review", Coordinator "Maria Davila", and PI "Rebe Simf (pi)".

5. To open a modification, click the link under the “Name” column.

- Right click and select “Open in new tab” if desired.
- 6. Review the “History” tab. If the main study analyst is clearly already processing the Modification, close the tab (or click “Back” if you did not open a new tab). Move onto the next Modification.
- 7. If the study title has AVAMC or AVAHCS in it, also close the tab/click “Back” and move on to the next Modification.
- 8. Click “Assign Coordinator” on the left menu.



- 9. A new window will pop out. Click on your name and click OK.

**Select an IRB coordinator for this submission:**

<input type="radio"/>	Maria-Gracia	Beltran	Emory University
<input type="radio"/>	Jessica	Blackburn	Emory University
<input type="radio"/>	Sara	Choe	Emory University
<input type="radio"/>	Carol	Corkran	Emory University
<input type="radio"/>	Brandy	Covington	Emory University
<input checked="" type="radio"/>	Maria	Davila	Emory University
<input type="radio"/>	Regina	Drake	Emory University
<input type="radio"/>	Clarissa	Dupree	Institutional Review Board
<input type="radio"/>	Anisha	Easley	Emory University
<input type="radio"/>	Hannah	Helmstetter	Emory University
<input type="radio"/>	Ashton	Hughes	Emory University
<input type="radio"/>	Shara	Karlebach	Emory University
<input type="radio"/>	Amaree	Lawrence	Emory University
<input type="radio"/>	Julie	Martin	Emory University
<input type="radio"/>	Orlando	Max (irbc)	Emory University
<input type="radio"/>	Jackson	Parker	Emory University
<input type="radio"/>	Parul	Reddy	Emory University
<input type="radio"/>	Sam	Roberts	Emory University
<input type="radio"/>	Rebecca	Rousselle	Emory University
<input type="radio"/>	Daniel	Roysden	Emory University
<input type="radio"/>	Emilie	Scheffer	Emory University
<input type="radio"/>	Reonna	Taylor	Emory University
<input type="radio"/>	Heather	Yates	Emory University

[Clear](#)

**i** The submission appears in My Inbox for the assigned coordinator.

10. Click on “View Modification/CR” on the left menu.

**Pre-Review**

Entered IRB: 11/25/2019 7:28 AM  
Last updated: 11/25/2019 7:57 AM

**Next Steps**

---

[Submit Pre-Review](#)

---

[Request Pre-Review Clarification](#)

---

[Assign Coordinator](#)

---

[Manage Ancillary Reviews](#)

---

[Add Comment](#)

---

[Add Private Comment](#)

---

[View CITI Training](#)



11. Review the information in the summary to confirm it is consistent with the changes made in the smart form. The summary should list the people that the study team is adding or removing. View the changes made in the smart form by clicking “Compare” on the top left and review the changes that are indicated by a pencil icon.

Compare current state of version:  
0.4 Changes submitted to IRB  
with  
0.3 Submit to IRB  
6/7/2022 11:06:41 AM ▼  
Changes found on 1 step:

**Modification / Continuing Review**

Modification Summary

Modification Details

▼ IRB00172124

Local Study Team Members

You Are Here: Preoperative Education in Hand... > Modification

Reading: MOD002-STUDY00003074

**Modification / Continuing Review / S**

\* What is the purpose of this submission?

Continuing Review

**Modification / Update**

Modification and Continuing Review

**i** To change the PI, choose 'Other parts of the study/site' scope

**Modification scope:**  
Study team member information

**Active Modification For This Study**

12. For all study staff being added to the smart form, confirm the person is affiliated with Emory by entering the person’s name in the [Emory Online Directory](#).
  - If the person’s name does not appear in the Directory, send an email to the reliance AD at [Julie.t.martin@emory.edu](mailto:Julie.t.martin@emory.edu). Include the modification number and the person’s name that is not showing in the Directory. The reliance AD will either log a comment in the history tab of the study confirming the person is affiliated with Emory or will re-assign the modification to the owner of the study.
13. If the modification includes any of the following, click “Assign Coordinator” and assign it back to the owner of the study with an explanation (see screenshots below):
  - This Modification includes more than just study staff changes because “Other Parts of the Study” is selected in the second question of the Modification smartform.
  - One of the study staff being added has the “Financial Interest” question marked “Yes”
    - Or, the modification is *changing* the Financial Interest question to “Yes” for someone who was *already* on the study team.
  - The modification adds an External study team member (someone not affiliated with Emory or Children’s Healthcare of Atlanta (CHOA)).

- To confirm someone is affiliated with CHOA, check their email address to confirm it reflects CHOA.
  - The modification includes a change in the PI (this requires an “Other parts of the study” Modification).

You Are Here: VRC 313 > Modification / Update #1 for S...  
 Reading: MOD123-IRB00108969  
**Modification / Continuing Review / Study Closure**  
 \* What is the purpose of this submission?  
 Continuing Review  
 **Modification / Update**  
 Modification and Continuing Review  
*i* To change the PI, choose 'Other parts of the study/site' scope  
**Modification scope:**  
 Study team member information  
 Other parts of the study

**Local Study Team Members**

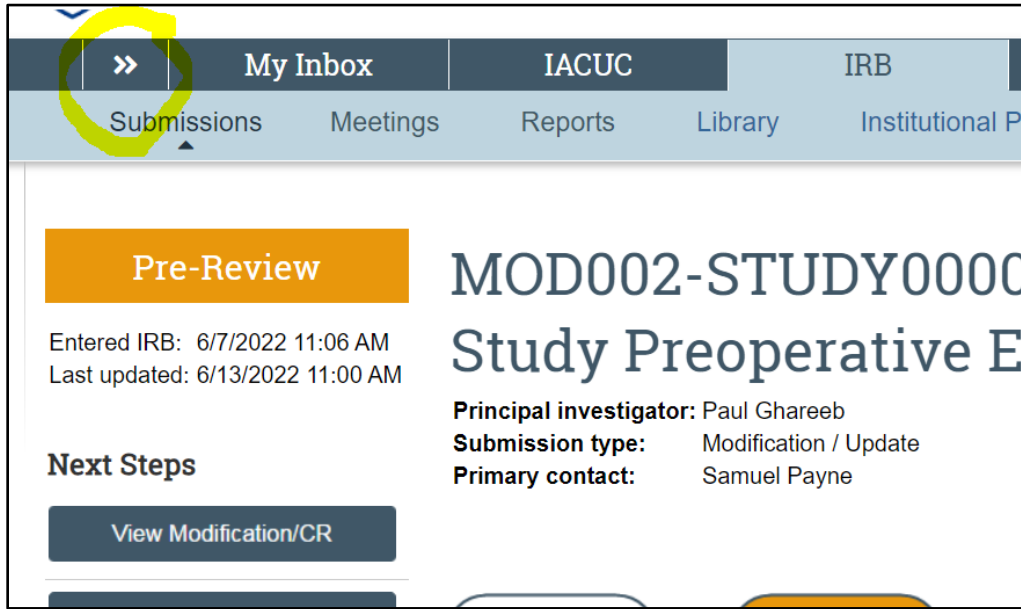
- Identify each additional person involved in the design, conduct, or reporting of the research. In addition to Emory personnel, this may include non-Emory persons with sponsored eIRB accounts, for persons who need access to the eIRB study record. If a name does not appear for selection, the person may not have an eIRB account. For more information about obtaining an eIRB account, click here.

	Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
View	Jessica Blackburn	Study Coordinator	no	yes	jessica.baker@emory.edu	
View	Jorge Davila	Study Coordinator	no	yes	jorge.davila@emoryhealthcare.org	
View	Shara Karlebach	Co-Investigator	yes	yes	swill17@emory.edu	
View	Julia Xia	Co-Investigator	no	yes	jxia26@emory.edu	
View	Anna Yaffee	Study Coordinator	no	yes	ayaffee@emory.edu	

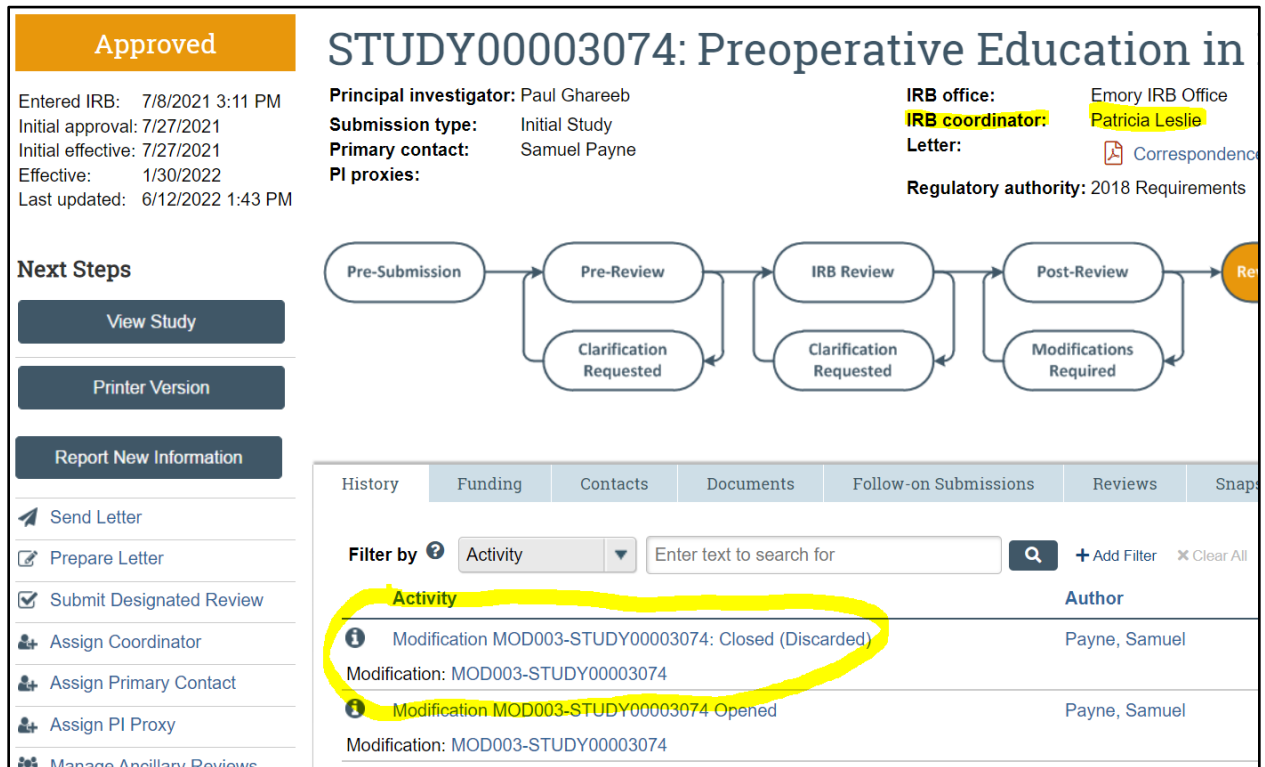
- External team member information (for non-Emory personnel, under Emory PI's direction, who will not be logging into eIRB).

Name	Description
There are no items to display	

To assign the modification back to the owner, click the “ >> ” area on the top left corner.



Then click on the title of the study. This will take you to the main study page. Look to see who is assigned as the IRB Coordinator (see top right of screenshot below).



To return to the modification you were working on, click on the modification under the history tab (see bottom of screenshot above).

- Click “View CITI training” on the left menu (see below) and verify that the personnel being added have proper CITI training. Review the [“Training verification” SOP](#) for more information.

Entered IRB: 11/25/2019 7:28 AM  
Last updated: 11/25/2019 7:57 AM

**#1 for Study Drug**

Principal investigator: Rebecca Simms (pi)  
Submission type: Modification / Update  
Primary contact: Rebecca Simms (pi)

IRB office: IRB coordinat  
Regulatory au

**Next Steps**

- View Modification/CR
- Printer Version
- Submit Pre-Review
- Request Pre-Review Clarification
- Assign Coordinator
- Manage Ancillary Reviews
- Add Comment
- Add Private Comment
- View CITI Training**

Pre-Submission → Pre-Review → IRB Review

Clarification Requested (under Pre-Review)

Clarification Requested (under IRB Review)

History | Contacts | Documents | IRB Assignment Details

Filter by Activity

Activity	Author
IRB Coordinator Assigned	Parker, Jackson

- If any are missing required CITI modules, click “Request Changes” to send the Modification back to study team
- In the text box for requested changes, state which study team members need updated CITI training. Instruct the study team to submit back once complete. Example text:
  - “Thank you for this submission. Per the “View CITI Training” activity at left, (person’s name(s)) needs to complete (training module). Please have the PI or PI Proxy click ‘Submit Response’ to send this Modification back to the IRB once complete. If the person does have valid certification but it is not showing up, please attach the CITI certificate when you click “Submit Response.”

- After confirming valid training for all study staff being added, click “Submit pre-review” in the left menu (see activity right under “Printer Version”).

Entered IRB: 11/25/2019 7:28 AM  
Last updated: 11/25/2019 7:57 AM

**#1 for Study Drug**

Principal investigator: Rebecca Simms (pi)  
Submission type: Modification / Update  
Primary contact: Rebecca Simms (pi)

IRB office: IRB coordinat  
Regulatory au

**Next Steps**

- View Modification/CR
- Printer Version
- Submit Pre-Review
- Request Pre-Review Clarification
- Assign Coordinator
- Manage Ancillary Reviews
- Add Comment
- Add Private Comment
- View CITI Training**

Pre-Submission → Pre-Review → IRB Review

Clarification Requested (under Pre-Review)

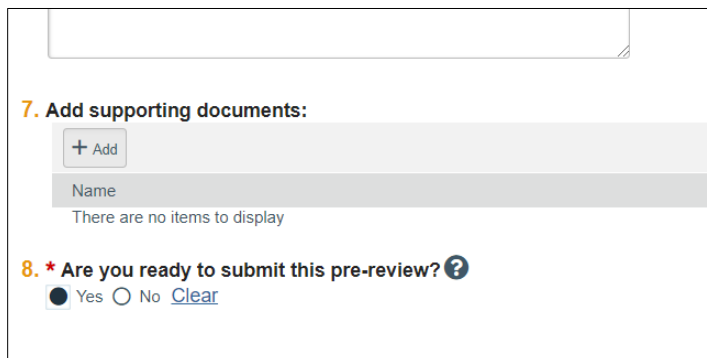
Clarification Requested (under IRB Review)

History | Contacts | Documents | IRB Assignment Details

Filter by Activity

Activity	Author
IRB Coordinator Assigned	Parker, Jackson

16. A new window will open. Scroll to question 8.0 and click “Yes”. *Do not touch any other questions.*



7. Add supporting documents:

+ Add

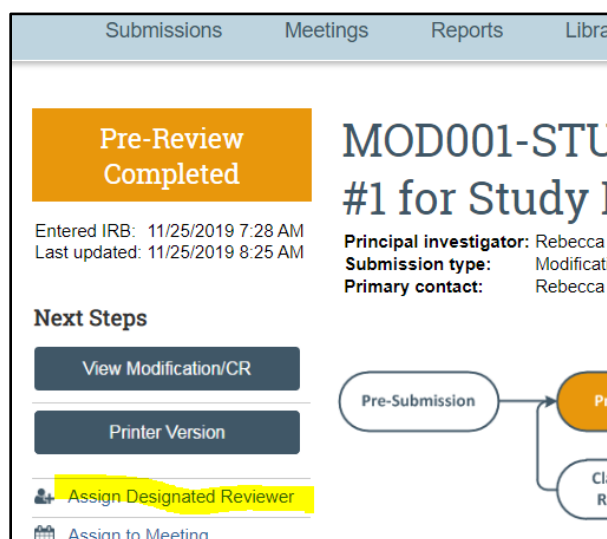
Name

There are no items to display

8. \* Are you ready to submit this pre-review? ?

Yes  No [Clear](#)

17. Click “Assign Designated Reviewer” in the left menu (see below).



Submissions Meetings Reports Libral

Pre-Review Completed

MOD001-STU #1 for Study I

Entered IRB: 11/25/2019 7:28 AM  
Last updated: 11/25/2019 8:25 AM

Principal investigator: Rebecca S  
Submission type: Modificati  
Primary contact: Rebecca S

Next Steps

View Modification/CR

Printer Version

Assign Designated Reviewer

Assign to Meeting

Pre-Submission

Pre

Cl

Re

18. Select yourself as the designated reviewer from the list (click the upside-down little arrow on the box in the first question), then click “OK” at bottom-right of the popup window.

**Assign Designated Reviewer**

Select a designated reviewer if you believe the submission should follow the non-committee path.

**1. \* Designated reviewer:** (select from designated members of all IRB committees)

Maria Davila

**2. Notes for reviewer:**

**3. Supporting documents:**

+ Add

Name	Description
There are no items to display	

Clicking OK sends a notification to the reviewer.

19. Click "Submit Designated Review."

**Non-Committee Review**

Entered IRB: 11/25/2019 7:28 AM  
Last updated: 11/25/2019 8:28 AM

**Next Steps**

Review Modification/CR

Printer Version

**Submit Designated Review**

Assign Designated Reviewer

MOD00  
#1 for S  
Principal investi  
Submission type  
Primary contact

Pre-Submission

20. Go to question 1 and click "Approved."

**Submit Designated Review**

**1. \* Determination:**

Name	Related Worksheet
<input checked="" type="radio"/> Approved	HRP-314 - Worksheet - Criteria for Approval
<input type="radio"/> Modifications Required to Secure "Approved"	HRP-314 - Worksheet - Criteria for Approval
<input type="radio"/> Not Human Research	HRP-310 - Worksheet - Human Research Determination
<input type="radio"/> Modifications Required to Secure "Not Human Research"	HRP-310 - Worksheet - Human Research Determination
<input type="radio"/> Human Research, Not Engaged	HRP-311 - Worksheet - Engagement Determination
<input type="radio"/> Modifications Required to Secure "Human Research, Not Engaged"	HRP-311 - Worksheet - Engagement Determination

[Clear](#)

21. Scroll to question 3 and select "expedited."

**3. \* Review level:**

Name	Related Worksheet
<input type="radio"/> Exempt	HRP-312 - Worksheet - Exemption Determination
<input checked="" type="radio"/> Expedited	HRP-313 - Worksheet - Expedited Review

[Clear](#)

22. Once you click "expedited" a new question will open. Select "minor modification."

**4. \* Indicate the categories:** (see HRP-313 for full regulatory criteria, check all that apply)

- (1)(a) Drug studies
- (1)(b) Device studies
- (2)(a) Blood samples from healthy, non-pregnant adults
- (2)(b) Blood samples from others
- (3) Noninvasive biological specimens
- (4) Noninvasive procedures
- (5) Data, documents, records, or specimens
- (6) Voice, video, digital, or image recordings
- (7)(a) Behavioral research
- (7)(b) Social science methods
- (8)(a) Long-term follow-up
- (8)(b) No subjects enrolled
- (8)(c) Data analysis
- (9) Convened IRB determined minimal risk
- (mm) Minor modification
- Other

- **If you are asked to provide reasoning why a study needs to come back for continuing review, write "This is just a study staff change."**

23. Scroll to question 9 and check the box. Then click "Yes" for question 10.

9. \* I do NOT have a conflicting interest: ?

10. \* Are you ready to submit this review? ?  
 Yes  No [Clear](#)

24. Click “Prepare Letter” on left menu.

**Post-Review** MOD #1 for  
Entered IRB: 11/25/2019 7:28 AM  
Last updated: 11/25/2019 8:31 AM  
Principal inv  
Submission  
Primary con

**Next Steps**

- View Modification/CR
- Printer Version
- Finalize Documents
- Prepare Letter**
- Submit Discontinued Review

Pre-Submiss

25. In the new window shown below, select the “Acknowledgment of Personnel Update” template and click the “Generate” button.
26. Open the letter by clicking the link under “Draft Letter” in the same window.
27. The letter will open in Microsoft Word. Click “Enable Editing” on the top of the screen. Sign it with your name and title, and save it on your computer and make note of what folder it is saved in. No other edits to the letter are necessary.
28. Back in the window below, click the three dots (...) to the right of the letter link. Select that you want to upload a revised document.
29. Navigate to the right folder on your computer, select the revised version, then click OK on the window below.

**Prepare Letter**

Generate, upload, and/or revise a letter to the investigator here.

**Generate a draft letter from a template:**

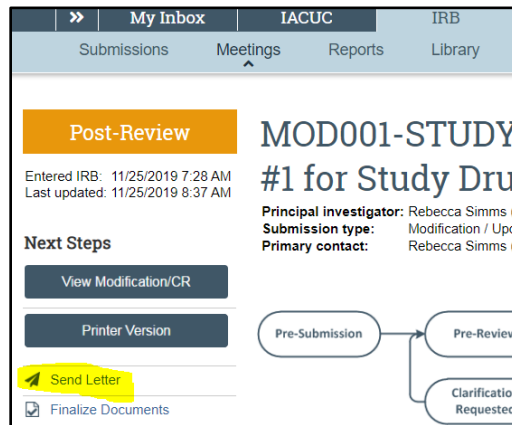
Acknowledgement of Personnel Update

**Draft letter:**

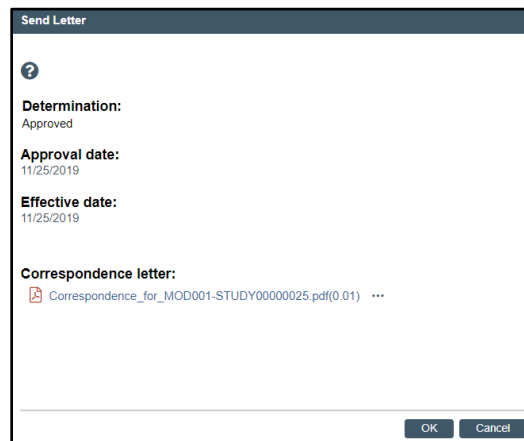
Correspondence\_for\_MOD001-STUDY00000025.doc(0.01) ...

30. Click “Send Letter.”

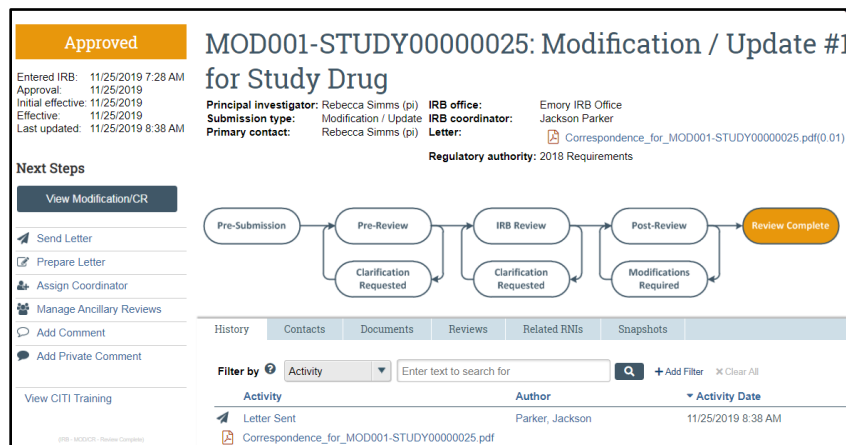




31. A new window will open. Click on the link to the letter to make sure it is the correct version you uploaded. Click OK to send the letter.



32. The submission will be complete after this step.



33. If the study is a VA study, add the effective date of the study staff addition/change/ removal (the date the VA Staff Changes Request form was approved by the VA WOC coordinator) to the

body of the approval letter. Note that no VA staff additions/changes/removals may be processed without the approved VA Staff Changes Request form. The VA study records are updated before the Emory IRB study records and reflect the VA approval of the staff update(s).

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
5/13/2015	Added purpose and scope and update of the information
6/22/2016	Added guidance for incomplete requests
5/17/2018	Added information to respond to ineligible requests, replaced SOM contact name for volunteer verification and added VA information
2/11/2020	Overhaul of this SOP due to change of electronic system
2/26/2020	Added more detail about how to look for changes in the submission, and added graphics to identify MODS that should not be approved by the student workers
3/4/2020	Adding instructions in case the system ask for a justification of why a CR needs to take place again
5/18/2020	CHOA personal can be added under External personnel
11/3/2020	Adding information for VA studies
7/5/2022	Many minor edits for clarity and added step to confirm study staff being added are in Directory

<b>SOP Title:</b>	Modifications- Processing from Preliminary Analysis through Approval
<b>SOP Category:</b>	Study Management
<b>Established:</b>	8/9/2013
<b>Last Revision:</b>	07/6/2023

## PURPOSE

The purpose of this SOP is to outline the step-by-step procedures for processing a Modification from submission to approval.

## SCOPE

This SOP applies to Modifications that need both expedited and full board reviews. If the modification is for staff change only, ignore as the dedicated staff members these modifications will take ownership of them.. This SOP only applies to the modification process. Please see CR SOP for details on handling renewal submissions.

## DEFINITION

- **Modification:** Any change to a current study that would require review from the IRB before implementation.
- **Ancillary Committee:** Refers to outside committees including Biosafety, Radiation Safety (RSC), PRMC etc., that would need to review a Modification based on any additional procedures being added that would trigger their departments review.

## RESPONSIBILITIES

- **IRB Analyst:** Take the Modification through the entire process from submission to approval

## PROCEDURES

### Analysis of Modification Application

**Note: Find all the checklists on this SOP in this folder** H:\General\Admin IRB Documents\Checklists-Staff, Forms, and Templates\1. Staff Screening Checklists and Tip Sheets.

- Have the MOD screening guide accessible while analyzing the Mod application H:\General\Admin IRB Documents\Checklists, Forms, and Templates. For more information about pre-review and ancillary review information, [review our SOP](#).
- Lapsed studies: add to the modification approval letter that no research activities can take place unless the study is re-approved after the approval of a continuing review application.
- If the Mod includes a 483 report after an FDA inspection to the study or sponsor, ask the study to remove this report and to submit via RE.
- If this Mod adds a drug under REMS or a drug considered a controlled substance;

- Studies using controlled substances drugs should fill out the [Investigator Checklist for the Use of Schedule I Controlled Substances](#) and email to Margaret Huber at [mhuber@emory.edu](mailto:mhuber@emory.edu). Make sure you communicate with Margaret about next steps.
- REMS process has been followed, per our SOP entitled: “[REMS study review](#)”. Please review REMS SOP and talk to a TL or IRB Director about following steps
- If adding a new funding source, please reference [Guidance to connect Grants and IRB Approved Protocols](#). If new DoD funding, see [study checklist](#). The amendment screening guide includes additional considerations around new funding sources.

**Verify that the proposed modifications have been made in the revised eIRB smartform and Mod application.** For guidance on viewing changes please see the [Huron Staff Quick Reference](#) Document. **If changes are needed, click the “Request Pre-Review Clarification” and inform the study team of the requested changes.**

- The state of the Mod will change to “Clarification Requested (Pre-Review)”
- Follow up with the study team if a response is not received in a timely fashion. If a submission is in requested changes for more than 30 days with no answer from the study team, the analyst should withdraw it. The analyst needs to document their efforts in contacting the study team and email them before withdrawing the study.
- The study team will need to hit the “submit response” button to return the Mod back to the IRB to be processed. Sometimes the study team will make changes without submitting the study back. Be sure to occasionally review the “In Process” tab for logged comments to catch these Mods.

**If no further changes are needed, determine the appropriate routing of the review (i.e expedited or full board). Please also complete the Pre-Review Note: Do not modify selections under “Regulatory oversight” and “Special determinations and waivers” sections unless the Modification impacts the applicable area.** Reference the following SOPs to determine the appropriate route and reviewer of the Mod:

- [Determinations and Reviews by IRB Staff](#): for minor administrative changes that can be approved by the analyst assigned to review the Mod
- [Categories of research reviewable by IRB staff as IRB designated members](#): for selected Mod that could be reviewed by Associate or Assistant Directors or other Sr. RPAs.
- [Modifications Indicating Increased Risk](#): for a Mod that may require Full Board review

**For guidance on assigning for designated review, please see the [Huron Staff Quick Reference](#)**

Some considerations when assigning reviewers:

- For expedited studies: Assign expedited reviews to the reviewer whose specialty is most closely related to the study. For full board reviews assign to the committee who has a representative who has the needed specialty.
- For exempt studies: In situations where IRB staff can complete initial review for an exempt study, analysts can self-review Modification submissions. Modifications for studies that underwent limited IRB review initially (reviewed by a staff designated reviewer) must also be sent to a staff designated reviewer for a determination that the study’s exempt status has not changed.

- Under the Comments section, include a brief description of the proposed Mod when assigning the Mod for review. The description should allow a reviewer to quickly ascertain the contents of the Mod.
- Press “OK”
- The current state of the Mod should change from “Pre-Review” to “Non-Committee Review.”
- At this point you wait for the expedited reviewer to complete their review

**After the review is submitted the state will change to “Post-Review”. Go to the “Reviews” tab to find the reviewer's determination.**

- **If changes are requested**, select “Prepare Letter” and choose the template for “Modifications Required to Secure Approval”
  - Once your letter has been created, click “send a letter” and wait for changes to be submitted back from the team.
  - Screen the changes. If the changes seem complete, do not click on “review required modifications”. Instead, click on “assign designated reviewer”. When sending the submission to the reviewer, make sure that your comment explains this is a contingency review. After the designated reviewer has submitted their review, ensure that the approval/expiration dates, especially after a pending review, are correct. You can submit a review yourself to correct the issue, adding a comment of why you are resubmitting. If unsure, ask one of the TLs.
- **If you are ready to finalize approval**, first review the expiration date in the designated review space. Ensure that the expiration date is the overall study expiration date.
  - **If the expiration date is incorrect, click on “submit designated review” and correct it.**
- After this check, click “Finalize Documents” on the study workspace. Select only the new or revised documents to change to PDF and watermark. Click OK. The Documents tab on the study workspace will include links to the final versions of the documents.
- If no changes are requested, select “Prepare Letter” and choose the appropriate approval template from the drop-down selections.

#### Tips for drafting letters:

##### Prepare Letter

Generate, upload, and/or revise a letter to the investigator here.

**Generate a draft letter from a template:**

- Choose an appropriate letter template and generate it from the dropdown menu. Download the generated letter by selecting “Download Copy” and make the following edits:
- Remember to include the PI’s post-nominal (degree – MD, PhD, MPH, etc.)
- Delete the template letter language that does not apply to the current MOD and remove rows that state “No Items to Display.”
- Edit the “ENTER NAME OF LETTER SIGNATORY” and “title’ fields to add your name and title. Save a copy of the letter on your desktop and “upload revision”



- Click “Send Letter”
- MOD/CR (see CR SOP for details on processing the CR portion of the submission). Reference the [Huron Staff Quick Reference](#) for details about handling this type of submission.
  - a. Ensure that all documents were finalized appropriately by opening them from the “Documents” tab.

### **Full Committee Modifications:**

- **To start, log a private comment indicating why the modification requires Committee review.**
- See the [Huron Staff Quick Reference](#) for details on assigning for Committee review.
- Click on “Edit pre-review”, and add the following under question 6 (Notes):
  - Add if the study is currently enrolling subjects (especially if the study team did not answer that question in the modification submission)
  - If adding study personnel, if the CITI is not up to date (this will be a pending item otherwise)
  - If this is a Sponsor-Investigator study:
    - If this Mod is adding new sites (Y/N)
    - If yes, the responsibility form should be included in the submission with an S-I consult approval (*This is required before the Mod can be approved*)
  - If this is a Risk Evaluation and Mitigation Strategy (REMS) (Y/N)
  - If yes, has a REMS consult approval submitted? (*This is required before the Mod can be approved*)

### **Steps to Check the Full Board Committee’s Decisions Reviewer’s Review**

Once the meeting pod has reconciled the meeting notes and omnibus forms and releases the agenda for letter writing via email, review the applicable forms to obtain committee decision.

- Follow steps outlined above and in the [Huron Staff Quick Reference](#) for further processing for either “modifications required” or approval.
- If modification is deferred, once the team submits changes check that deferred issues have been addressed, schedule the Deferred modification to be reviewed by the same committee that conducted the initial review of the modification application (i.e. if CMTE B1 reviewed the modification in the January meeting and deferred it, send to the next available meeting for CMTE B1).
- After the meeting, if the Deferred issues are approved, follow the steps for processing approval.
- If a modification is pending approval, once the team submits the changes:
  - Email the study link to the designated reviewer. Ask them to review the changes but to not make any changes in the submission. They may log a private comment or email you back. If the

member does not log a comment, make sure you log a private comment with their email response.

- Click on “Review Required Modifications” The “approval date” would be the date of the meeting. The “effective date” is the date the vicechair confirmed the changes were adequate and the study can receive final approval.

**Modifications Submitted**

Entered IRB: 3/12/2020 1:19 PM  
Last updated: 4/9/2020 11:10 AM

**Next Steps**

View Modification/CR

Printer Version

Review Required Modifications

Assign Designated Reviewer

Assign to Committee Review

Edit Pre-Review

## MOD002-IRB00103595: Modification Neuroendocrine PTSD

**Principal investigator:** Jennifer Stevens  
**Submission type:** Modification / Update  
**Primary contact:**

History   Contacts   Documents   IRB Assignment Details   Reviews

### Review Required Modifications

Verifying the changes either updates the submission to its final determination (such as approved) or returns it

**1. Dates:**

\* **Approval date:** ?

3/20/2020

**Effective date:** ?

3/20/2020

**Last day of approval period:** ?

7/9/2020

**2. Notes:**

**3. Supporting documents:**

+ Add

Name

There are no items to display

**4. \* Were the modifications completed as required?** ?

Yes  No [Clear](#)

- You can now proceed with generating a new approval letter and sending it.
- Follow up with the study team if a response is not received in a timely fashion. If a submission is in requested changes for more than 60 days with no answer from the study team, the analyst should withdraw it. The analyst needs to document their efforts in contacting the study team and email them before withdrawing the study.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
7/6/2023	Update to remove reference to analyst assistant and archiving log over a year old



<b>SOP Title:</b>	Modifications: Mods Indicating Increased Risk
<b>SOP Category:</b>	Study Management
<b>Established:</b>	7/18/2012
<b>Last Revision:</b>	8/30/2021

## PURPOSE

To explain the process of reviewing Modifications (Mod) that indicate an increase in risk, and to describe when a reportable new information (RNI) submission may be necessary.

## SCOPE

The SOP applies to studies approved by the Emory IRB.

## RESPONSIBILITIES

- IRB Analyst - will review the submission and assess if the Mod may need a RNI submission.
- IRB Team Q member – will assist analyst in determining if an Mod needs a concurrent RNI submission.

## PROCEDURE

1. Determine if an RNI should be submitted along with the Modification:
  - a. If this Mod information comes from an analysis of aggregated data by the sponsor (action letter, post-marketing data analysis, etc.) and if it appears to be unrelated to a specific adverse event, then no reportable new information submission is required.
    - i. For example: the Mod states that, after reviewing data from all sites, they have discovered an increased frequency of event X, and they have decided to modify the protocol, ICF or IB. Such sponsor-prompted Mods do NOT require a concurrent RE. This is because the sponsor has done a review of these aggregated data and the IRB would have no additional information with which to do a better review, or call something an UP. The IRB's task now is to review the proposed changes to protocol, IB and *especially the ICF*. This process can be completed by the Full Board, without the need of a reportable new information submission.
  - b. If the Mod information includes a safety memo about an event involving an individual subject or subjects, a reportable new information submission may be required.
    - i. For example, the Mod may state that X number of subjects experienced event X, detailing each clinical case in the report, and that is why the sponsor thinks the matter is unexpected, serious and will make changes to the protocol, ICF or IB. The study analyst should alert Team Q about the Mod. Team Q will verify if a RNI is required or not. If Team Q received a RNI that requires the submission of an Mod (if not already submitted), Team Q will log a comment into the study history to alert the study analyst.
2. Determine the mode of review for this Mod: When receiving a new risk via a Mod, check [this document](#) to verify if the information in the Mod was previously reviewed at FB and can go expedited in subsequent studies. If not, the new risk information should go to FB EXCEPT when it falls under 3(b) below.

**\*Note:** *If there are changes to the Investigator's Brochure (IB) without ICF changes, then ask study team when changes to ICF are expected. If the study team said the changes to ICF are forthcoming, send to FB with a note explaining the study team has not provided ICF changes. Note in the omnibus form under "pending" section in Mod.*

**3. Handling of Modification with respect to Reportable new information submission (when required)**

- a. If a reportable new information submission **HAS** been submitted and it **HAS NOT** already been reviewed by CoRe or Full committee (i.e., a determination of UP or not an UP has not been made), then analyst should contact the case manager for the reportable new information submission for more information. Case manager should also log a comment in Mod and communicate with study owner about RNI disposition.
- b. If the CoRe determines that the reportable new information submission is not a potential UP, and determines that there is no change to the overall risk/benefit ratio of the research study, then the Modification may go to expedited review.
- c. If the CoRe determines that the reportable new information submission is a potential UP that represents an immediate safety concern, then it must be reviewed at the next full board meeting. The IRB analyst should add the Modification to the same meeting’s agenda where the reportable new information submission will be reviewed, if possible. In general, Modifications and REs with new safety information should be reviewed in the next available meeting. Please, discuss this with the Q Team and meeting facilitators.
- d. If the CoRe determines that the reportable new information submission is a potential UP that does **not** represent an immediate safety concern, then it will be reviewed at the next Committee Q meeting . The Modification can also be reviewed at the Committee Q meeting if the only changes relate to the reportable new information submission and/or other changes do not need to be reviewed sooner (discuss with your Associate or Assistant Director or Director if not sure).
  - i. Let the Team Q case manager and Q meeting facilitator know that the Modification will be reviewed at Committee Q so materials can be prepared. After the Team Q Meeting, the case manager will log a comment in the Modification history detailing if the Modification was approved as it is or if it has pending issues.
  - ii. If the Modification was approved, the analyst should assign the review to him/herself for completion. This does not mean the analyst is making a determination; the Modification was approved at the Committee Q. The analyst is simply completing the review to move the Modification to the draft letter state.
  - iii. If the Modification has pending issues, the Modification should be assigned to the Q chair (Dr. Stein) for review and final approval.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
8/30/2021	Removed reference to old location for tracking new risks and archived log of updates older than 1 year

## NEW STUDIES

<b>SOP Title:</b>	Pre-Review options and Ancillary Review Information
<b>SOP Category:</b>	Study Management
<b>Established:</b>	2/24/2020
<b>Last Revision:</b>	09/11/2023

### PURPOSE

To detail all the options to check during the pre-review of a new study submission. Also, this SOP will cover the current ancillary review information.

### SCOPE

The SOP applies to all studies reviewed by the Emory IRB.

### RESPONSIBILITIES

- IRB analyst – reviews study documents to verify the selection of the correct options during pre-review and ancillary reviewer selection
- IRB directors- assist analyst if needed

### PROCEDURE

#### Pre-review options

Review the protocol, consent form, and funding section to identify the correct options to select. If the study is sponsored by a sub-award, review who is the primary awardee to make selections in this section. For example, if the study is funded by a sub-award, if the sub-award is funded with DoD funds, the study at Emory should be considered DOD funded. See below for more information about each option in the pre-review section:

1. Common rule regulatory requirements (for CR submissions only)
  - Pre-2018 requirements: select for FDA-regulated, DOJ sponsored or studies that are not migrating to the revised common rule
  - 2018 requirements: select if you are transitioning the study to the revised common rule with this submission.
2. Regulatory oversight: (check all that apply)
  - DOD (Department of Defense) – select as appropriate per funding
  - DOE (Department of Energy) – select as appropriate per funding
  - DOJ (Department of Justice) – select as appropriate per funding
  - ED (Department of Education) – select as appropriate per funding
  - EPA (Environmental Protection Agency) – select as appropriate per funding
  - FDA (Food and Drug Administration)- If the research is using a drug, device, biologic, dietary supplement or medical food, medical mobile app, or any other regulated investigational product even if previously FDA approved or if funded by the FDA (rare). If the use of the device is routine but not part of the research question, you may not need to select this box.

- GDPR (General Data Protection Regulation)- select if this study has international sites under the [GDPR mandate](#). [See here a list](#) of countries affected GDPR. If your study is affected, email [Carol McMahon](#) at OC to confirm steps moving forward (copy Rebecca and your team lead)
  - HHS (Department of Health and Human Services)- select as appropriate per funding. Generally, studies funded by NIH and other groups that may include a “National” in their title (not always, like CFAR). Use google if it is not clear.
  - ICH GCP (International Center for Harmonization of Good Clinical Practice)- Look for the term on the study protocol. If it says ICH-GCP, as adopted by FDA no additional action is required other than checking this box. If they say ICH-GCP E6, loop IRB Director if not done already per NS worksheet.
  - NSF (National Science Foundation) - select as appropriate per funding
  - OCR (Office of Civil Rights)- if HIPAA applies or is requesting HIPAA waivers or any kind
  - VA (Department of Veterans Affairs)- For VA studies only
  - Other federal agencies- if not contemplated above, contact IRB Director
  - Tribal law- if involving the study of a tribe. Also, loop in IRB director if study involves the study of a tribe.
3. Special determinations and waivers-attach the following checklist to your pre-review per population or situation selected:
- Broad consent: Institutionally, Emory is **not** allowing broad consent for any study. If a study requests the use of broad consent, please let them know this is not allowed. If the study team pushes back, contact a director.
  - Children: Subpart D checklist
  - Children who are wards of the state- Subpart D checklist
  - Cognitively impaired adults- HRP-417 - CHECKLIST - Cognitively Impaired Adults
  - Neonates of uncertain viability- Subpart B checklist
  - Nonsignificant risk device- Device checklist
  - Non-viable neonates-Subpart B checklist
  - Pregnant women- Subpart B checklist
  - Prisoners- Subpart C checklist
  - Students / Employees- no checklist required
  - Waiver of consent documentation- [HIPAA attestation and waiver document](#)
  - Waiver of consent for emergency research-HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research (found in eIRB library)
  - Waiver of HIPAA authorization- [HIPAA attestation and waiver document](#)
  - Waiver/alteration of the consent process- [HIPAA attestation and waiver document](#)
4. Type of research: (check all that apply)
- Biomedical/clinical- studies focused on medical test or procedures, or that involve medical chart review
  - Social/behavioral/educational- studies focused on humanities areas, public health, and psychology
  - Other- if does not fit any of the above
5. Additional study features: (check all that apply)

- Clinical Trial- If it meets the NIH definition of a clinical trial (a research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes). Review the study team answer under question 1, section “For Clinical Research/Expanded Access Only) on the last page of the submission. If you do not agree with the answer, [email Jennifer Prozonic](#) for guidance.
- Certificate of Confidentiality (CoC)- if the study is using a CoC. This applies to all human subjects’ research studies funded by the NIH or others if they were granted one. [See here](#) for more information.
- Collaborative- research conducted by more than one site when the procedures are divided by institutions.
- Deception- is a study involves deception, even if the deception involves incomplete disclosure
- Multi-Site Study- a study conducting the same procedures (following the same protocol) at different sites.

### **Ancillary Review Information**

Every study should have a department reviewer at a minimum. Review the study protocol and study team members to determine what ancillary reviewers apply to the study. When picking a department reviewer, use the Emory Directory to find the PI’s affiliation.

- School of Medicine: If you find that the PI is not a faculty member (SOM studies), he or she cannot fulfill the PI role.
- School of Nursing: A nurse can be the PI if the study is under the School of Nursing (and minimal risk).
- Rollins Public Health School: students can be PIs with a faculty advisor. To select a faculty reviewer:
  - In question 1, do not select an Organization; instead, select the faculty advisor in the “Person” field. Then select “Faculty Advisor Review” from the “Review Type” dropdown. Select “Yes” for “Is a response required?”. Feel free to send these instructions to the student so they can select their advisor.
  - Faculty advisor cannot be listed as a co-investigator as the system will not allow them to approve the study.
- Undergraduate and other Graduate students at Laney Graduate School: the students cannot serve as PI. They need to select their faculty advisor as the PI on the study, and the student should be listed as a Co-investigator. They need to go through department review using the PI department affiliation.

You can search using part of the ancillary review name with a % sign before. When selecting the department, find the department under question number 1 (do not need to select a person, only the main organization), select the type of review under question 2 and select if the review is required or not.

All ancillary reviews are required before the study can be approved.

See below for the ancillary reviewers to pick per study (does not include department reviewers):

- Conflict of Interest- if a study team member has disclosed a financial interest or said yes to question 3 under “Waiver Requests and Ancillary Considerations” (last page of the IRB submission).
- Controlled Substance Consult- if the study said yes to question 7 under the “Ancillary Review Information” section (last page of the IRB submission) or by identifying the use of a controlled substance in the protocol or consent.

- PRMC (Human Cancer Studies)- if study team said yes to question 1 under the “Ancillary Review Information” section (last page of the IRB submission)
- EHSO Biosafety- if the study team said yes to either of the options under question 2 under the “Ancillary Review Information” section (last page of the IRB submission)
- EHSO Radiation Safety-if study team said yes to question 3 or 4 under the “Ancillary Review Information” section (last page of the IRB submission)
  - **Studies conducted at CHOA only:** If the study will be conducted at CHOA only, the CHOA radiation safety committee will need to review the study use. In this case, do not do add the CHOA ancillary review but ask the study team to fill out [this form](#) and send it via email to Jeff Tays at [jeff@imagingphysics.com](mailto:jeff@imagingphysics.com). When the approval is granted, the approval should be logged in the study submission as a comment (by the study team or IRB staff).
  - Proton therapy: select EHSO radiation and they will route to the proton therapy subcommittee
- CHOA Device review: for studies conducted at CHOA using a home-grown device (no from industry). For example, devices designed and manufactured at GA tech.
- REMS Consult- if the study said yes to question 8 under the “Ancillary Review Information” section (last page of the IRB submission), or by searching the term “REMS” on the study protocol or consent
- S-I Advisory (for Sponsor-Investigators)- if the Emory Sponsor Investigator is listed as the IND or IDE holder in the drug or device section of the smart form and/or the protocol.
- Veterans Affairs Medical Center, Atlanta- for all studies conducted at the Atlanta VA or under VA
- Security Review: If the study requires a security review, ensure the team gets a security review (see the NS checklist and our site guidance regarding security reviews)

**Notes:**

- Contact the IRB Director if the smart form questions 5 (human embryonic stem cells) or 6 (human fetal tissue) under the “Ancillary Reviewers” section are marked YES , if the study involves Exception from Informed Consent (EFIC), or the study in any way involves a tribe.
- Review the “Sensitive Study Status” SOP if smart form question 5 under the “For Clinical Research/Expanded Access Only” section is marked YES.
- Contact a Q Team member if the smart form question 3 (expanded access) is marked YES.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
02/24/2023	Added reminder about security review
7/6/2023	CHOA clarity and archived changes over a year old
9/11/2023	Removed Office of Quality

<b>SOP Title:</b>	eIRB Processing of New Study Applications- Preliminary Analysis through Approval
<b>SOP</b>	Study Management
<b>Established:</b>	03/12/2015
<b>Last Revision:</b>	9/11/2023

### **IRB Staff Initial Analysis/Screening**

**Note: Find all the checklists on this SOP in this folder:** H:\General\Admin IRB Documents\Checklists-Staff, Forms, and Templates\1. Staff Screening Checklists and Tip Sheets.

1. Once assigned as the IRB coordinator, it will appear in the “Pre-Review” state under your inbox. For more information about pre-review and ancillary review information, [review our SOP](#).
2. Open the appropriate checklist (non-exempt, exempt, retrospective)
3. While in the main study workspace, click the “View Study” button. Screen the study per whichever checklist you chose.
  - a. This form is not purely a checklist; you are expected to write notes to yourself for posterity and notes that can be easily transformed into suggested revisions for the study team.
  - b. Manage applicable ancillary reviews including department review.
4. Once done screening, click the “Submit Pre-Review” button in the main study workspace. Look at the [Huron Staff Quick Reference](#) (page 17) for additional information on how to complete this process.
  - a. For any study that requires HIPAA authorization and/or waivers, you MUST check the box for OCR (Office of Civil Rights) in question 1.
  - b. Check applicable boxes in question 2 and fill out any applicable determination/waiver/population worksheets.
  - c. Check one or more boxes in question 3 to best characterize the study.
  - d. Check any boxes that apply in question 4.
  - e. Enter the missing materials in question 5.
  - f. Enter any other notes, including requested changes to the submission, in question 6.
  - g. Upload the new study checklist in question 6.
  - h. Check “No” in question 7 unless the study is ready to be reviewed as submitted, with no revisions.
  - i. Click OK.

### **If study need revisions after your initial review**

1. Click “Request Pre-Review Clarifications” button to send back to study team for revisions. Look at the [Huron Staff Quick Reference](#) (page 15) for additional information on how to complete this process.
  - a. You are required to remind study teams of their changes to the submission, at least at a weekly basis. If they are not responding to your comments or emails, contact a Director to withdraw the study

- b. Follow up with the study team if a response is not received in a timely fashion. If a submission is in requested changes for more than 30 days with no answer from the study team, the analyst should withdraw it. The analyst needs to document their efforts in contacting the study team and email them before withdrawing the study.
2. Once re-submitted, screen the submission for the changes you requested. If the study team made the revisions to your satisfaction, click “Submit Pre-Review” again.
3. Make any necessary changes to the responses in questions 1-7 and change the response to question 8 to “Yes.” This will change the state to “Pre-Review Completed.”

### **Ancillary Reviewers**

1. Click the “Manage Ancillary Reviews” button and click the “Add” button to add any appropriate reviewing bodies. Select the group (not person) under question 1, select the group again under question 2 and click on yes if a response is required.
2. [Review this page](#) (under Submit a study in eIRB) on our website or the checklist for more information about ancillary reviews.

### **Finish Pre-Review**

1. If going the full board route, complete your Pre-Review and include notes that would be helpful to have during the meeting, such as why the study might require FB review (if not readily apparent), special determinations, subparts, potential IRB member conflicts, etc. Fill out the last page of the non-exempt checklist for this purpose.
2. Assign the study to a Designated Reviewer or full board meeting agenda.
3. Note that the pre-review can be edited after it is initially submitted in all states before a letter is prepared in post-review.

### **Designated Reviewer route:**

1. Before sending to a reviewer ensure that:
  - a. All ancillary reviews are completed, including department review.
  - b. All CITI/Intro to Research training is complete for all study team members
  - c. If external staff is being added, that the IAA is completed (if not, the staff member can be removed and later added via a modification)
2. Select a reviewer in question 1 according to our [current SOP](#) on who can review what.
3. In question 2, enter notes to the reviewer such as—but not limited to—exempt/expedited categories, subparts, recruitment methods, verbal/online vs. signed consent, HIPAA waivers, funding source, and whether the study has the appropriate permissions/ethics approvals in place.
4. In question 3, upload any pertinent checklists:
  - a. [Emory Subpart B Checklist](#)
  - b. [Emory Subpart C Checklist](#)
  - c. [Emory Subpart D Checklist](#)
  - d. [Emory Checklist- Cognitively Impaired Subjects](#)



- e. Make sure other appropriate checklists (HIPAA, IND exemption, Device Checklist, REMS, Controlled substance, Dietary supplements, Mobile medical Apps, etc.) are in the record as filled by the study team. These checklists are located on our website under [“Study Submission Guidance”](#)
5. Click OK. This will change the state to “Non-Committee Review.”
6. Once the reviewer submits their review, the state will change to “Post-Review.”
7. If DR requests revisions:
  - a. First, consider whether the revisions would modify any of the findings of the pre-review (federal agency involvement, waivers, etc.) Make the pre-review edits necessary to reflect the changed status of the study by clicking “Edit Pre-Review.”
  - b. Click “Prepare Letter” in the main study workspace.
  - c. Choose the appropriate template and click “Generate.”
  - d. Under “Draft letter,” click the link to download the letter template and make revisions.
  - e. You will need to save a local copy of the letter, make the revisions within that letter, and upload the revised copy to the study using the “Upload Revisions” option in the activity details.
  - f. Once revisions are complete, click “Send Letter.”
  - g. Follow up with the study team if a response is not received in a timely fashion. If a submission is in requested changes for more than 30 days with no answer from the study team, the analyst should withdraw it. The analyst needs to document their efforts in contacting the study team and email them before withdrawing the study.
  - h. After the PI/proxy submits the changes, the study will appear in the “Modifications Submitted” state.

**Modifications Submitted**

Entered IRB: 2/19/2020 12:54 PM  
Last updated: 4/11/2020 11:11 AM

**Next Steps**

View Study

Printer Version

- Q Review Required Modifications
- Assign Designated Reviewer
- Assign to Committee Review
- Edit Pre-Review
- Assign Coordinator
- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews
- Manage Guest List
- Add Related Grant
- Add Comment
- Add Private Comment
- Copy Submission

## STUDY0000020: Ethnography- Mental Health in Latinx Families

Principal investigator: Xochiquetzal Marsilli-Vargas  
Submission type: Initial Study  
Primary contact: Xochiquetzal Marsilli-Vargas  
PI proxies:

IRB office: Emory IRB Office  
IRB coordinator: Ashton Hughes  
Letter: [Chnages to Mental Health\\_MOD129-IRB0011801](#) (1)  
Regulatory authority: 2018 Requirements

**History**   Funding   Contacts   Documents   IRB Assignment Details   **Reviews**   Snapshots

Filter by Activity   Enter text to search for   + Add Filter   × Clear All

Activity	Author	Activity Date
Response Submitted	Marsilli-Vargas, Xochiquetzal	4/11/2020 11:11 AM
Response Time Exceeded	Administrator, System	4/11/2020 9:01 AM
Guest List Updated	Rueda, Schella	4/7/2020 12:49 PM
Comment Added	Hughes, Ashton	4/6/2020 2:17 PM

I am just checking in on your progress with the requested revisions. Please let me know if you have any questions about your initial review.

Stay Healthy,  
Ashton Hughes

- i. Click the “Compare” button in the left-hand top corner of the main study workspace to examine the changes to the submission made by the study team. Look at the [Huron Staff Quick Reference](#) (page 16) for additional information on how to complete this process.

- j. In the *Basic Study Information* section, question 8, click the “History” link under “Document History.”
- k. On that pop-up page, check the boxes for the documents you want to compare, and then click the “Compare” button; this will produce a “track changes” copy of the new protocol. Screen the document for the revisions you requested as well as any other revisions the study team may have made. Once done, click “Exit.”
- l. If the changes requested by the reviewer were not adequately addressed, click the “Review Required Modifications” button.
  - i. A new window will open (see left)
  - ii. Confirm whether the study requires continuing review and make sure that it is reflected in question 1 on the pop-up page.
  - iii. Enter the approval date (and expiration date if applicable) in question 3.
  - iv. Enter any relevant notes in question 4 and upload any documentation in question 5.
  - v. Click no on Question 6. This returns the study to the team for further action. Repeat this process until all changes are adequately addressed
- m. If the changes look complete, click on “Assign to Designated Reviewer” so they can review the contingency review.
- n. After the designated reviewer has submitted their review, ensure that the approval/expiration dates, especially after a pending review, are correct. You can submit a review yourself to correct the issue, adding a comment of why you are resubmitting. If unsure, ask one of the TLs.
  - i. **If you are ready to finalize approval**, first review the expiration date in the designated review space. Ensure that the expiration date is the overall study expiration date.
    1. **If the expiration date is incorrect, click on “submit designated review” and correct it.**
8. Check once more that all Ancillary Reviews are complete. If not, final approval must be held until complete.
9. After this check, click “Finalize Documents” on the study workspace. Select the documents that need to appear in the approval letter and click OK. The Documents tab on the study workspace will include links to the final versions of the documents.

**Full Committee Review route:**

1. Look at the [Huron Staff Quick Reference](#) (page 23) for additional information on how to complete this process. Click the “Assign to Meeting” activity and assign the study to the next available, appropriate meeting; this will change the state to “Committee Review.”
2. Click on “Edit Preview” to include an updated NS checklist and update the board before the meeting. This should happen the Friday before the meeting.
3. Keep in mind the membership of the committee.
4. Try not to assign studies where PI/Co-Is are members of that committee but try to assign studies to committees where the specialty of the study is represented in the membership.
5. Reviewers will be assigned to the study by the meeting pod.
6. After the study is reviewed:
  - a. Study was approved as is: prepare letter as detailed in the next section.

- b. Pending or Deferred:
  - i. Click on prepare letter and select the appropriate pending letter. All pending/deferred items should populate in the letter. Reconcile the letter with the notes in the “reviews” tab to confirm all the information is in the letter. Send the letter to the team.
  - ii. When the study team submit the changes
    - 1. If pending:
      - a. Confirm that all ancillary reviews are complete (except Office of Quality, which is not required to be completed in our system).
        - i. If any Ancillary Committees have required changes to the protocol, those changes should be reviewed at the next available full board meeting instead of being reviewed by the Chair. Notify your Team Lead and note rationale in Pre-Review.
        - ii. If the Ancillary Committees require revisions to the consent form based on their established template language, those changes do **not** need to return to full board.
        - iii. COI management plans must be fully approved by IRB’s CoRe, and required changes made to consent form and smartform, before final approval by Chair. These changes do **not** require full board review.
      - b. Review the study team’s changes.
        - i. If Cost Option was completely unknown at initial review, and comes back as Option 3 (i.e. participants will have to pay for research-driven items or procedures), alert your Team Lead as the IRB may not approve.
        - ii. If other changes were made beyond what was required by the full board (e.g. a new protocol version from Sponsor), assess whether the changes would require expedited or full board review, if they had come in as a stand-alone modification.
      - c. to ensure completeness, email the Chair of the FB meeting with a link to the study. Ask the Chair to not click on “Review Required Modifications”. Instead, they can email you back letting you know the changes were adequate or they can log a private comment. If the Committee requested, the link should also be sent to another reviewer along with the Chair.
      - d. If the Chair is completely unavailable for more than five business days: Contingency reviews may be referred to a Co-Chair who was in attendance. If none available, it may be referred to the primary or secondary reviewer of that item as long as they were in attendance. (e.g. Dr. Stein), and if none, it may be referred to primary reviewer.

- e. Click on “Review Required Modifications”. The “approval date” would be the date of the meeting. The “effective date” is the date the vicechair confirmed the changes were adequate and the study can receive final approval.

**Review Required Modifications**

Verifying the changes either updates the submission to its final determination (such as app)

1. Dates:

\* Approval date: ?  
3/17/2021

Effective date: ?  
3/17/2021

Last day of approval period: ?  
3/16/2022

2. Notes:

3. Supporting documents:

+ Add

Name
There are no items to display

4. \* Were the modifications completed as required? ?  
 Yes  No [Clear](#)

f. After the above is completed, send the approval letter (follow the next section).

g. Follow up with the study team if a response is not received in a timely fashion. If a submission is in requested changes for more than 60 days with no answer from the study team, the analyst should withdraw it. The analyst needs to document their efforts in contacting the study team and email them before withdrawing the study.

2. If deferred:
- After reviewing the changes to ensure completeness, click on “submit pre-review”. Document any changes to your review, if pertinent. Assign to the same committee who review the study.
  - Follow up with the study team if a response is not received in a timely fashion. If a submission is in requested changes for more than 60 days with no answer from the study team, the analyst should withdraw it. The analyst needs to document their efforts in contacting the study team and email them before withdrawing the study.

### Preparing approval letter

- Look at the [Huron Staff Quick Reference](#) (page 25) for additional information on how to complete this process. After all the changes has been confirmed go to the main study workspace, click “Finalize Documents.” Make sure you do not skip this part, as this is step will allow the approved documents to populate in the letter.
- On the pop-up page, select the documents you wish to finalize, and click “OK.”
- Click “Prepare Letter.”
- Under “Draft letter,” click the link to download the letter template and make revisions.
- You will need to save a local copy of the letter, make the revisions within that letter, and upload the revised copy to the study using the “Upload Revisions” option in the activity details.
- Once revisions are complete, click

7. Click "Send Letter."
8. Study will now appear in "Approved" state.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
5/4/2021	Fix errors in designated review and changes in the contingency review process.
04/06/2022	Julie made some updates – see SOP archive for changes
4/22/2022	Updated location of checklist and archived updates over 1 year old
9/11/2023	Contingency review clarifications

<b>SOP Title:</b>	Naming Conventions for eIRB Studies
<b>SOP Category:</b>	Study Management
<b>Established:</b>	10/30/2017
<b>Last Revision:</b>	10/23/2020

## **PURPOSE**

The purpose of this document is to describe the naming conventions used to signify special study designations in the short title of the study.

## **DEFINTIIONS / NOMENCLATURES**

- Emory Sponsor Investigator study – [SI]
- External IRB shell – [XIRB]
- NCI Central IRB – [CIRB]
- Department of Defense – [DoD]
- Veteran Affairs – [VA]
- Western IRB – [WIRB]
- REMS- [REMS]
- Emory as Single IRB [sIRB]

## **PROCEDURE**

When reviewing a study that meets one or more of the special study considerations listed above, edit the study short title to add in the appropriate bracketed designation before the official study short title. If more than one designation applies, list multiple designations in alphabetic order.

When adding the nomenclature to the study title, log a comment to the study team explaining that the IRB added that information for future study tracking.

## **LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
2/21/2018	Added REMS as a nomenclature to use
6/21/2019	Removing non-used options
2/11/2020	Added/removed options
10/23/2020	Added/removed options

<b>SOP Title:</b>	RDRC Studies
<b>SOP Category:</b>	Study Management
<b>Established:</b>	12/09/2015
<b>Last Revision:</b>	12/09/2015

## **PURPOSE**

The purpose of this document is to describe the procedures for the coordination between the Institutional Review Board (IRB) and the Emory Radioactive Drug Research Committee (RDRC) on protocols involving the use of radioactive drugs for research projects designed to obtain basic information regarding metabolism (e.g., kinetics, distribution, and localization) or human physiology, pathophysiology, or biochemistry.

## **BACKGROUND**

The Radioactive Drug Research Committee (RDRC) program under [21 CFR 361.1](#) permits certain basic research using radioactive drugs in humans without an IND. The RDRC is the body charged with classifying all radioactive drugs as either new drugs requiring an Investigational New Drug Application (IND) for investigational use (21 CFR 312), or as generally recognized as safe and effective when administered under the conditions specified in the RDRC regulations. Key requirements include that 1) number of subjects should not exceed 30, 2) only adults with legal capacity be enrolled, 3) all females of childbearing potential either confirm they are not pregnant on the basis of a pregnancy test or state in writing they are not pregnant, and 4) the investigator shall immediately report to the RDRC all adverse effects associated with the use of the radioactive drug.

## **RESPONSIBILITIES**

- **RDRC**- Review and approve the use of research-related administration of radioactive material to subjects. RDRC is also tasked with reviewing all adverse effects associated with the use of the radioactive drug in research and immediately reporting to the FDA all adverse reactions probably attributed to the use of the radioactive drug in research.
- **IRB** – Ensure human research protocols involving the research-related administration of radioactive material to subjects have prior RDRC approval and that the study protocol include the required reporting to RDRC. In addition, alert RDRC and study team of need for IND if study team requests increase in enrollment to over 30 subjects obtaining the radioactive agent.

## **PROCEDURE**

1. When a study is submitted that involves a radioactive tracer not approved by the FDA for the indication described in the study, the IRB analyst will review whether the study has an IND or RDRC approval for the use of the tracer.
  - a. If the study does have an IND, than the study falls outside the scope of this SOP.
2. For studies that meet the qualification for RDRC IND exemption, the IRB analyst will ensure that:
  - a. RDRC approval has been granted before the IRB grants final approval.
  - b. The authorized investigators in the RDRC approval letter are listed as study staff, including the “Authorized User”
  - c. The radioactive tracer is listed in the drug section of the eIRB Smartform

- d. The protocol and DSMP include that the investigator shall immediately report to the RDRC all “adverse effects” associated with the use of the radioactive drug in the research study.
  - e. The protocol and consent note that only adults (18 and older) with legal capacity will be enrolled.
  - f. The protocol and consent note that all females of childbearing potential confirm they are not pregnant.
3. Once all of the above requirements have been verified, the IRB analyst should assign the study to an IRB Committee meeting – these studies do not qualify for expedited review under F(1) due to the possibility of allergic reaction.
4. After the initial IRB approval, IRB analyst should note whether future modifications that substantially change the protocol may require additional review by the RDRC or, alternatively, an IND application. Analyst should consult with RDRC if needed.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES



<b>SOP Title:</b>	Translation of Informed Consent Documents
<b>SOP Category:</b>	Study Management
<b>Established:</b>	11/17/2016
<b>Last Revision:</b>	2/1/2019

## PURPOSE

To instruct analysts about acceptable methods of translation of written informed consent documents into languages other than English.

## SCOPE

Applies to all non-exempt studies that plan to target non-English speakers for enrollment, regardless of whether the study involves international sites. This does not apply to studies requesting to use a “short form” to enroll occasional non-English speakers. The Emory IRB will only review the research activities that Emory agents are engaged in. If consent documents fall outside of the scope of Emory IRB review, there is no need for us to review translations. However, if Emory is the primary awardee of a grant, translated documents will likely be required for IRB review, regardless of whether Emory is otherwise involved in the human subjects’ research activities.

## INTRODUCTION

In order to ensure the quality of translation of consent documents into foreign languages, the Emory IRB requires some level of documentation that the translation is accurate.

### Recommendations for study teams:

- In most cases, it’s best for the team to first seek approval of an English version of the informed consent document before beginning translation to prevent having to revise both the English and translated documents based on IRB change requests. The translations would then be submitted via Modification. The English version of the informed consent document should be stamped after initial approval.
- A local Ethics Committee or IRB may require changes to translated informed consent documents that are submitted for their approval. For this reason, it may be advantageous for study teams to wait to submit their translated documents to the Emory IRB until after the local approval is in place.
- **Note: Emory may collaborate on studies led by an international site where the informed consent document was first created in a foreign language. In that case, the translation policy still applies, but the translation would be into English.**

There are two acceptable methods for documenting the quality of the translation

### Methods of Documenting Translation Quality:

- Certified Translator: The team can hire a certified translator to translate the English version of the form into the foreign language. As proof of translation by a certified translator, the study team may submit:
  - Current, valid certification of translator’s credentials along with an invoice or memo stating the specific document that was translated.

- Other: Consult with your Associate or Assistant Director or the Director any other form of documentation that mentions the specific document that was translated and attests to the translation quality

In addition to the documentation for translation services, the IRB must receive the translated forms.

- Translation by a non-certified translator: This is a two-step process. To start, anyone, including members of the study team, may translate the English version of the informed consent document into the foreign language. For the back-translation, the study team must find someone else to perform a translation into English from the already-translated foreign language document. The IRB reviewer will compare both English documents to confirm that the back-translation retains the same message as the original English version. All versions, appropriately labeled, should be submitted to the IRB.

## PROCEDURE

1. An analyst receives a new study or an Modification that indicates intent to enroll participants that do not speak English (should be evidenced by selecting “Non-English Speakers” as a Study Population type), along with translated versions of consent documents.
2. The analyst reviews the new study or Modification to see if documentation of one of the appropriate translation methods has already been provided.
3. If documentation hasn’t been provided, the analyst should log a comment to notify the study team that they should begin the process of documenting translation through one of the above-listed methods and that translated copies will not be approved until that is complete, though the rest of the study may be approved. The analyst should continue triage of the new study or Modification.
4. The analyst assigns new study or Modification to a designated reviewer or to a full board agenda. The analyst makes a note in the study history as to the current status of translated documents.
  - a. **If adequate documentation has not been provided:** The study or Modification can be approved without documentation of translation, but the study team will not be able to enroll any subjects using the translated consent form until they provide documentation of one of the above-listed methods of translation.  
The IRB analyst should not stamp the foreign language consent forms until a reviewer is able to review the documentation of translation.  
The IRB analyst should notify the team in the approval letter that the foreign language consent forms are not approved for use, and furthermore, that the team cannot enroll any subjects using translated consent documents. Also, the analyst should notify the team that an Modification will be required to submit documentation of translation.
5. Once the new study or Modification has been approved, the analyst lists all of the consent documents in the approval letter. The analyst should stamp all approved versions of the informed consent documents, including the English version even if it’s not going to be presented to subjects.

**Note: Sometimes the formatting and language of translated versions of documents look strange after eIRB applies the stamp. Most often, teams are able to open the documents and see the correct formatting and language with the stamped approval date.**

**Modifications revising approved, translated ICFs**

1. Modifications that are only making administrative changes (such as contact information) can be approved without further translation quality documentation as long as the change can be verified in the revised document.
2. Minor Modifications that can be sent to a staff designated reviewer can receive pending approval with only a tracked changes version of the English consent form. The Modification would be ready for contingency review with a translation of the revised English form and documentation of the translation quality through one of the two approved methods.
3. Modifications that may change the risk/benefit ratio of the study and would require designated review by a vice chair or full board review may require two Modifications to update the study and the translated ICF. One Modification would include the protocol or other study changes and incorporation of those changes into the English version of the consent document. After approval of those changes, the study team would follow up with translation of the revised English ICF and documentation of translation quality through one of the approved methods.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
2/1/2019	It was clarified that the English version of the consent form should be stamped when approved.

<b>SOP Title:</b>	Research Projects led by Non-Emory students
<b>SOP Category:</b>	Study Management
<b>Established:</b>	8/28/2013
<b>Last Revision:</b>	9/16/2016

**PURPOSE**

To determine when a student is engaged in research when the student is from a different school and is also a staff person at Emory and/or Emory is not engaged in research but a student is requesting access to Emory protected health information (PHI).

**PROCEDURE:**

1. Determine if Emory is engaged in research:
  - a. Refer to OHRP Guidance entitled, "[Guidance on Engagement of Institutions in Human Subjects Research](#)."
  - b. Consider questions such as: is the research project is related to the student’s job at Emory? Will the results be used in the context of their job? Are the procedures a part of their job?
  - c. Are they acting in any other way as an agent of Emory for the purposes of the research project? (OHRP considers an *agent* to be an individual who (1) acts on behalf of the institution; (2) exercises institutional authority or responsibility; or (3) performs institutionally designated activities)
  - d. Are there other Emory collaborators acting as agents of Emory?
  
2. Other issues to consider:
  - a. Is the student obtaining IRB review from his or her academic institution?
  - b. If not engaged in research, is the student requesting access to Emory PHI? If so, alert Anne Adams.
  - c. If the student’s name will be listed on the publication, will Emory be listed as their affiliated institution?
  - d. If Emory is engaged, can the student be listed as PI, or must it be a faculty member?
    - I. If an IAA is in place where the student’s academic institution relies on Emory IRB review, refer to our normal P&Ps for student research to determine if the student can be PI, if the student is also affiliated with Emory.
    - II. If the student’s academic institution will review the study, then an Emory person should be PI for the Emory IRB submission
  - e. If Emory is not engaged, then the student researcher does not need to submit to the Emory IRB, but should obtain permission to conduct research at Emory from the appropriate departmental authority

**REFERENCE**

Guidance on Engagement of Institutions in Human Subjects Research  
<http://www.hhs.gov/ohrp/policy/engage08.html>

**LOG OF SIGNIFICANT CHANGES:**

DATE	SUMMARY OF SIGNIFICANT CHANGES
9/16/2016	Added clarification to align with current process

<b>SOP Title:</b>	Training Verification
<b>SOP Category:</b>	Study Management
<b>Established:</b>	10/18/2010
<b>Last Revision:</b>	7/02/2022

## **PURPOSE**

The purpose of this document is to guide IRB personnel in how to verify that required research training is complete. This SOP will cover verification of CITI certification, Clinical Research Training for investigators (now the CITI Good Clinical Practice [GCP] course, Clinical Research Coordinator training in CITI, and the Introduction to Clinical Research 2-day course. It also links to or defines the required Modules for the different roles and different types of studies.

## **SCOPE**

This SOP applies to new studies, Continuing Reviews and Modifications to add personnel to ongoing studies.

## **DEFINITIONS**

- CITI – the Collaborative Institutional Training Initiative the vendor for most of the training we require
- Intro to Clinical Research course : An in-person course at Emory that is required for certain new study nurses and coordinators who are less experienced in their roles. More experienced personnel are allowed to take an online course instead.

## **RESPONSIBILITIES**

- IRB analyst: responsible for checking that the research team staff has received the required training for new submissions, Continuing Reviews, and Modifications (adding new staff)
- Office for Clinical Research: responsible for answering study team and IRB questions about clinical trial training requirements

## **PROCEDURE**

**(For CHOA study team members, see note, below.)**

1. Note whether the study meets the definition of a “clinical trial” and/or whether the study is FDA-regulated. To do this:
  - a. New studies: review lay summary and protocol; see new study checklist for more information
  - b. Continuing Reviews and Modifications: click the “Reviews” tab and look at “Latest Pre-Review” to see if “Clinical Trial” and/or “FDA” appear
2. Click “View CITI Training”
  - a. You will find this button on each workspace in the bottom left.

**Pre-Review**

Entered IRB: 6/8/2022 9:11 AM  
Last updated: 6/23/2022 10:25 AM

**Next Steps**

View Modification/CR

Printer Version

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[Submit Pre-Review](#)

---

[Request Pre-Review Clarification](#)

---

[Assign Coordinator](#)

---

[Manage Ancillary Reviews](#)

---

[Add Comment](#)

---

[Add Private Comment](#)

---

View CITI Training

3. A new window will open. (See example below with names blocked out.)

Study Team Members						
Search: <input type="text"/>						
Study Team Member	Department	E-mail	Role on Study	Training Data		
				Curriculum	Date Completed	Expiration Date
				CITI-BASIC/REFRESHER COURSE HUMAN SUBJECTS PROTECTION - GROUP: GROUP 5 GOOD CLINICAL PRACTICE AND ICH (GCP) - STAGE: BASIC COURSE	4/24/2020	4/24/2023
				CITI-BASIC/REFRESHER COURSE HUMAN SUBJECTS PROTECTION - GROUP: GROUP 1 BIOMEDICAL FOCUS - STAGE: BASIC COURSE	4/23/2020	4/23/2023
				CITI-BASIC/REFRESHER COURSE HUMAN SUBJECTS PROTECTION - GROUP: GROUP 1 BIOMEDICAL FOCUS - STAGE: BASIC COURSE	4/23/2020	4/23/2023
				CITI-BASIC/REFRESHER COURSE HUMAN SUBJECTS PROTECTION - GROUP: GROUP 5 GOOD CLINICAL PRACTICE AND ICH (GCP) - STAGE: BASIC COURSE	4/24/2020	4/24/2023
				CITI-BASIC/REFRESHER COURSE HUMAN SUBJECTS PROTECTION - GROUP: GROUP 2 SOCIAL/BEHAVIORAL FOCUS - STAGE: BASIC COURSE	8/22/2021	8/21/2024
				CITI-BASIC/REFRESHER COURSE HUMAN SUBJECTS PROTECTION - GROUP: GROUP 2 SOCIAL/BEHAVIORAL FOCUS - STAGE: BASIC COURSE	8/22/2021	8/21/2024
				Curriculum	Date Completed	Expiration Date
				CITI-BASIC/REFRESHER COURSE HUMAN SUBJECTS PROTECTION - GROUP: GROUP 2 SOCIAL/BEHAVIORAL FOCUS - STAGE: BASIC COURSE	2/20/2020	2/19/2023
				CITI-BASIC/REFRESHER COURSE HUMAN SUBJECTS PROTECTION - GROUP: GROUP 5 GOOD CLINICAL PRACTICE AND ICH (GCP) - STAGE: REFRESHER COURSE	2/20/2020	2/19/2023
				CITI-CLINICAL RESEARCH COORDINATOR (CRC) - GROUP: CLINICAL RESEARCH COORDINATOR - STAGE: BASIC COURSE	8/4/2021	8/3/2024
				CITI-BASIC/REFRESHER COURSE HUMAN SUBJECTS PROTECTION - GROUP: GROUP 1 BIOMEDICAL FOCUS - STAGE: REFRESHER COURSE	8/3/2021	8/2/2024
				CITI-BASIC/REFRESHER COURSE HUMAN SUBJECTS PROTECTION - GROUP: GROUP 5 GOOD CLINICAL PRACTICE AND ICH (GCP) - STAGE: REFRESHER COURSE	2/20/2020	2/19/2023
				CITI-BASIC/REFRESHER COURSE HUMAN SUBJECTS PROTECTION - GROUP: GROUP 2 SOCIAL/BEHAVIORAL FOCUS - STAGE: BASIC COURSE	2/20/2020	2/19/2023
				CITI-BASIC/REFRESHER COURSE HUMAN SUBJECTS PROTECTION - GROUP: GROUP 1 BIOMEDICAL FOCUS - STAGE: REFRESHER COURSE	8/3/2021	8/2/2024
				CITI-CLINICAL RESEARCH COORDINATOR (CRC) - GROUP: CLINICAL RESEARCH COORDINATOR - STAGE: BASIC COURSE	8/4/2021	8/3/2024

- Verify that all required modules appear for the study team members you are verifying (New Studies and CRs: all study team members; Modifications: only people being added).
- See the information on the website to determine which course is appropriate for the study you are reviewing. The CITI training expires on the date of study expiration. For studies with approval

lapses, the study should not be approved unless all staff members are CITI certified on the date of the study approval.

6. If any proof of completion is missing, please ask the study team to provide or to contact [OCR's Education Team](#) for assistance.
  - a. If the **PI** has not completed the course, the study may not be given final approval until they have completed it.
  - b. If a **Co-I, Sub-I, or Coordinator** has not completed the appropriate course, then the study may receive full approval if that person is removed temporarily from the list of study personnel. That person may later be added back on, via Modification, once they have completed the course.

**Steps to follow if any required trainings are not up to date:**

- If study team members do not have up-to-date CITI or Key Concepts: Study team can opt to remove the offending study team members temporarily (if a new study), instead of waiting on them. The member can later be added back via a modification. If the submission is a continuing review, the team will need to submit a modification to remove the offending study team members. The staff removal modification needs to be approved before approving the continuing review. The modification can be reviewed by any IRB staff by following the Adding/Removing Study Personnel SOP.
  - Reference our [Continuing Review: Processing study staff noncompliance with CITI and Clinical Research Training \(formerly Key Concepts/Intro to CR\)](#) SOP for handling noncompliance.
- Do not send to expedited reviewer until all CITIs are up to date OR the offending member has been removed from the study.
- You can send to full board. The lack of training is a pending issue, if the study team decides not to temporarily remove the offending member. Removing the offending member **DOES NOT** apply to the PI or Co-I whose specialty is required to conduct the study. Their CITIs have to be current before the study can move forward.

**Procedure for Member Search in CITI (for those who have Admin access only)**

- For Emory/CHOA: Login to [www.citiprogram.org](http://www.citiprogram.org) using your own personal login
  - For VA CITI: Check with VA liaison or staff designated person for access to this information.
- Click "Admin" button at top of screen
- Click "Members" tab on screen and then click option to search for a member. Enter last name (and first if desired) to search for the member.
- Once you click on the member's name, scroll to bottom to click "Course Completion History" (must do this in all cases; most recent modules completed do not always show on the first screen)

**REFERENCES**

- Emory Required Training for Investigators, Clinical Research Nurses, and Coordinators [Chart](#).
- CITI Program modules: [www.citiprogram.org](http://www.citiprogram.org)
- [Mandatory Training Requirements for Clinical Research Residents and Fellows](#).
- [Mandatory Training Requirements for Clinical Research Coordinators and Nurses](#)
- [Mandatory Training Requirements for Investigators Conducting Clinical Research](#).

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
12/11/2020	Added that CHOA staff members should comply with OCR training requirements
3/11/2021	Added information from website about CITI expiration
8/30/2021	Updated CHOA and archived log of updates older than 1 year
7/05/2022	Updates for clarity



<b>SOP Title:</b>	Electronic documentation of informed consent via “electronic signature” or “digital signature”)
<b>SOP Category:</b>	Study Management
<b>Established:</b>	12/20/2016
<b>Last Revision:</b>	3/11/2021

## PURPOSE

The purpose of this document is to explain the use and IRB requirements for the currently available options Emory researchers have to use electronic informed consent documentation (eICD) after consenting a subject into a study using (or not) an electronic informed consent method.

This SOP is **not** applicable for cases where the IRB can waive written signature/documentation of consent (e.g. online survey studies) or for studies done at the VA or CHOA, as they do not need to obtain signature after online consent

**Note:** HIPAA authorization may be obtained via electronic signature as well, when in compliance with the below SOP and federal guidance. LITS will not review requests of eICF if the study does not involve IIHI, PHI, or sensitive information but the IRB will need to verify that the app or software. For FDA studies, the IRB needs to ensure that capturing the subjects’ signature after consent complies with the requirements in Part 11.

## SCOPE

The SOP applies to all studies submitted to the Emory IRB and when the Emory IRB provides local context information to external IRBs.

## RESPONSIBILITIES

- IRB analyst – responsible for letting the study team know about the currently available options for the use of eICD, making sure the use aligns with previously approved parameters given to us by LITS
- LITS representative - reviews proposals to implement eICD outside the currently approved options
- QA/QI Associate or Assistant Director- facilitates the discussion with LITS representatives and investigators

## FEDERAL GUIDANCE (OHRP and FDA)

- <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm436811.pdf>

## PROCEDURE

- Review our guidance document ([When is a LITS security review needed?](#)) to verify if the current software needs LITS review.
  - Electronic documentation of consent is not permitted the AVAMC (though they do allow online consent with a waiver of the signature when regulatory criteria are met). Please verify with the IRB Directors if this is still the case when reviewing your study as exceptions may have been allowed due to public health needs.

- Electronic documentation of consent is allowed at CHOA only if using REDCap. For other platforms, the study team will need to put a request for security review by the CHOA IT group.
- The protocol and/or smartform should include a plan for providing copies of the signed consent to participants. (HHS and FDA regulations require that the person signing the informed consent be given a copy of the written informed consent form (45 CFR 46.117(a) and 21 CFR 50.27(a)) unless the requirement for documentation of informed consent has been waived under 45 CFR 46.117(c) and 21 CFR 56.109(c)).
  - Although FDA regulations do not require that the subject’s copy include a signature, FDA recommends that a copy of the signed informed consent form that includes the date when the eIC was signed be provided to the subject.)
  - The copy provided to the subject can be paper or electronic (i.e. be provided on an electronic storage device, not via email unless encrypted). If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained and information should be accessible until study completion (if a paper version is provided, it should contain the necessary content from any hyperlinks).
- The protocol and/or smartform must include a plan for verifying the identity of the subjects that will be electronically signing the Informed Consent, for FDA-regulated investigations.
  - FDA regulations do not specify any particular method for verifying the identity of an individual and accept many different methods. For example, verifying someone’s identity can be done by using information from some form of official identification, such as a birth certificate, government-issued passport, or a driver’s license. Also, the use of security questions to confirm an individual’s identity can be considered.

Redcap

- Besides adding the intention of using Redcap in the study protocol, the study team should submit to the IRB copies of all forms (electronic and paper forms) and informational materials, including any videos and Web-based presentations, which the subject will receive and view during the eIC process.
- The study team should submit an MS Word version of the informed consent language that will be signed electronically by subjects
- Once IRB-approved, the study team should not send the consent form to subjects via email, unless encrypted. If not using the encrypted email they should explain in the submission that the form will be sent via a link to an email previously provided by the study subject or LAR.
- The signature area could be drafted the same as the ICF/HIPAA template or could allow for documentation of the signature of the person obtaining consent at a later time. Here is an example:




\_\_\_\_\_  
Name of Person Conducting IC discussion

\_\_\_\_\_  
Date when IC discussion took place

\_\_\_\_\_  
Signature of Person Conducting IC discussion

\_\_\_\_\_  
Date when IC was signed by person obtaining consent

- The Redcap system must capture the signature of the subject in a way that it can be electronically audited. The ideal format is as follows:

1)	<b>Name of Patient</b> <i>* must provide value</i>	<input type="text"/>
2)	<b>Name of Legally Authorized Representative with authority for research decisions</b> <i>* must provide value</i>	<input type="text"/>
3)	<b>Relationship to Patient</b> <i>* must provide value</i>	<input type="text"/> <input type="text"/>
4)	<i>* must provide value</i>	
5)	<b>Current Date and Time</b> <i>* must provide value</i>	<input type="text"/>   <b>Now</b> <sup>M-D-Y H:M:S</sup> Please press the NOW button

- The study team should later submit, via Modification, a final electronic form to the IRB to show that the eICF version contains the same information as the mock-up approved by the Emory IRB, including document approval and version date. This can be accomplished by sending a link to the consent form for our review. The study team cannot enroll anyone with the electronic method until this Modification is approved.
- The study analyst should include in the approval letter the following:
  - The IRB approved the use of electronic informed consent via Redcap is contingent upon the submission of a Modification showing the final version of the electronic informed consent as it will be seen by subjects
  - Do not use the eICF until this Modification is approved by the IRB
  - Per Emory’s sensitive information policy/HIPAA (as applicable), do not send the copies of the informed consent to subjects via email. You may send a link to the system containing the eICF for the subject’s review. The Modification can be sent for expedited review.

**See below an example of an acceptable electronic ICF in Redcap:**

INFORMED CONSENT FORM



IRB approval date: 07-Dec-2016  
ICF version date: 03-Nov-2016

INSTRUCTIONS

Please review the enclosed information carefully. There are two sections below.

1. The first section is a summary of the study.
2. The second section is the detailed informed consent form for the study.
3. Please complete ALL the fields at the bottom of the form.
4. You will need to re-size this form if you are using a smart phone so that you can see everything.
5. You will need to click on the green + sign at the very bottom of the form. This is where you will sign using your finger on your phone or tablet. If you are using a computer, you will use your mouse to sign.
6. Once you have completed all the required fields and added your signature, please click on the "submit" button to finish.
7. If you have any trouble completing this form, please call the person who explained the consent to you.

Thank you!  
Your Research Team

SUMMARY

A stroke is caused when blood vessels in the brain become blocked. These blocked arteries are caused by blood clots. The only medication approved to treat this is called tissue plasminogen activator or TPA. This medicine tries to break up the clot. It also must be given within 4.5 hours from the time when the stroke happened. Unfortunately, when the blood clot is in the large blood vessels in the brain this medicine doesn't always work.

When these types of blockages occur, a procedure called a "thrombectomy" may be performed. This procedure is when a specially trained doctor uses a catheter to remove the clot and restore blood flow to the brain. Currently, this procedure is only done when the stroke onset was within 8 hours.

The purpose of this study is to determine if regular medical care plus "thrombectomy" is beneficial after the normal time window. To be eligible, stroke onset must be within the last 6-24 hours. The brain images on CT scans will also be used to make sure there is possible brain tissue to save.

Other important information:

- This is completely voluntary
- Patients are randomly assigned to 1 of 2 groups. This is like a flip of coin.

- Group 1 is medical management alone or

- Group 2 is medical management plus thrombectomy

- If assigned to Group 2, you will get an angiogram and then the trevo device will be used to try to remove the blood clot
- The risks are outlined in the full consent below
- The study team will follow your care throughout your hospital stay
- At 30 days and 90 days you will have a follow-up visit

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

Emory University and Grady Health System  
Consent to be a Research Subject and HIPAA Authorization

Consent/HIPAA document is located here. Subject needs to scroll down to read.

You Are Being Asked to Be in a Research Study

What Is a Research Study?  
The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

---

Enter your email address here if you would like to immediately receive a copy of this document.

---

Name of Patient   
\* must provide value

---

Name of Legally Authorized Representative with authority for research decisions   
\* must provide value

---

Relationship to Patient  Self  
 Spouse  
 Adult Child  
 Parent  
 Adult Sibling  
 Grandparent  
 Adult Grandchild  
 Adult Niece or Nephew (if related in the 1st degree)

\* must provide value [Add signature](#)

### DocuSign

- Because DocuSign only adds signature lines to current documents, the study team can obtain approval of their documents with initial approval of the consent. The study team should add to their protocol there are using DocuSign for eIC. If the study is using DocuSign for an FDA regulated study, the team should say in the protocol that the DocuSign they are using is part 11 compliant. [Send this link with information](#) about the process to obtain the account to the team when asking about this. This information includes instructions of how to transmit to the FDA directly but the relevant part about obtaining a Part 11 compliant account if found here:

### Getting Your Emory DocuSign Account

- In order to submit e-documents to the FDA’s electronic submissions gateway (ESG), your Emory NetID will need to be added to the FDA-compliant Emory DocuSign account.

- Go to [emory.service-now.com](http://emory.service-now.com)
- Click on the “Request Something” link on the Service Now homepage
- Use the search field to type “FDA Document Transmission”
- Fill out the available form to request your NetID be added to the FDA-compliant DocuSign account
- You will be contacted by a member of the LITS WebGroup once your request has been processed
- Note: if something unexpected occurs that prevents you from accessing the Service Now request form, you can send an email to [webgroup@emory.edu](mailto:webgroup@emory.edu) to have your request processed. Be sure to include your NetID, your Emory department/school, and the business reason for your request in your email.

#### Logging in to DocuSign

- Go to [docusign.emory.edu](http://docusign.emory.edu)
- Log in through the Emory Login page
- If you are working remotely, you may be required to authenticate using Duo.
- If you do not yet have Duo installed, follow the setup prompts to do so.  
If you have an account in both the general purpose and FDA CFR Part 11 account, you will need to switch accounts. To do so, click on your initials or profile in the upper right-hand corner. Select "Switch Account" or verify you are in the FDA account. Under your name and email, you should see an account name of "Emory CFR 21 Part 11 Compliant".

#### Unapproved LITS software

- If the study team is not using an approved eConsent method, they should submit a ticket for a LITS security review of the app/software they want to use for eConsent.
- After asking the team to submit a LITS ticket, add the information [to this spreadsheet](#).
- The study team should go to this link: [https://emory.service-now.com/sp?id=kb\\_article&sys\\_id=e5c2cd88f5cdf1c055c77bd8604896c2](https://emory.service-now.com/sp?id=kb_article&sys_id=e5c2cd88f5cdf1c055c77bd8604896c2) to place a ticket for this review.
- The form has the information to provide under “more information”
- The study team should be advised that this process may take time, and to work with LITS and let the IRB know if their eICF platform was approved.
- If the study is funded, let OSP know (at [osp@emory.edu](mailto:osp@emory.edu)) that the study will be reviewed by LITS for a security review as this may affect contract negotiations or require additional actions such as a Business Associate Agreement.
- For more information about the LITS security review report, and how to address its findings, see the SOP entitled: “Mobile Devices and Mobile Medical Apps Used In Research”, under “LITS report Review”.

#### **LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
1/20/2017	Updated process when not using Redcap
4/20/2017	Updated broken links
5/17/2018	Remove the need for the study team to send email to Derek or Maria
7/25/2018	Added that we should let OSP know if the study is under a security review when the study is funded
4/11/2019	Adding example of eICF and clarifying when this request needs to be sent to LITS
4/14/2020	Clarified that email can be used if it is encrypted. Other minor clarifications.

5/18/2020	Clarified that, for FDA regulated studies, a part 11 compliant platform is required for eConsent. Clarified other parts of the SOP and added a link to an excel sheet we need to update each time a new LITS request is asked from the study team.
3/11/2021	Added additional information for studies conducted at CHOA



<b>SOP Title:</b>	Mobile Devices and Mobile Medical Apps Used in Research
<b>SOP Category:</b>	Study Management
<b>Established:</b>	12/20/2016
<b>Last Revision:</b>	5/24/2020

## PURPOSE

The purpose of this SOP is to inform analysts, in a step-by-step fashion, how to identify and process studies that are using mobile devices and apps, including the use of mobile medical devices and apps.

## SCOPE

The SOP is intended to cover two types of research studies:

- Studies that use mobile devices for communication/data collection with subjects (e.g. smartphones, tablets) regardless of what specific applications are used on those devices. The main issue is data security/privacy.
- Studies that are testing or using applications (“apps”) on mobile platforms that meet the definition of “medical device” per FDA. The main issue is whether FDA regulations apply, and if so, which ones. Data security is also a possible issue.

## DEFINITIONS

- **FDA Enforcement Discretion:** The FDA does not intend to enforce the requirement of the FD&C Act.
- **Medical Device:** An instrument being used for the diagnosis of a disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man.
- **Mobile App (Application):** A software application that can (but not inherently is) run on a mobile platform. It can also include web-based software applications executed on a server.
- **Mobile Medical App:** Any mobile app that meets the definition of a device, in section 201(h) of the Federal Food, Drug, and Cosmetic Act; and is intended to:
  - Be used as an accessory to a regulated medical device; or
  - To transform a mobile platform into a regulated medical device.
- **Mobile Platform:** Commercial, “off-the-shelf”, computing platforms which are handheld in nature [e.g. smartphones, tablets, portable computer devices].
- **Regulated Medical Device:** Any device that meets the definition of a medical device as defined in section 201(h) of the FD&C Act, and that has been cleared or approved by the FDA review of a premarket submission or is otherwise classified by the FDA.

**NOTE:** The 21st Century Cures Act (12/13/2016) amended the definition of “device” in the Food, Drug and Cosmetic Act to exclude certain software functions, including some described in [this](#) guidance document. FDA is assessing how to revise this guidance to represent their current thinking on this topic. For additional information, refer to <https://www.fda.gov/MedicalDevices/DigitalHealth/default.htm>.

## PROCEDURE

The study team should clarify if the app/software used is collecting/storing individually identifiable health information (IIHI), private health information (PHI), or sensitive information in the protocol, protocol addendum (if a multisite study) and consent. If they are not, then LITS review is not needed,



and the study may proceed with the IRB review. Review our [information chart](#), to make sure the app/software needs to go to LITS for review.

If the study is funded, let OSP know (at [osp@emory.edu](mailto:osp@emory.edu)) that the study will be reviewed by LITS for a security review as this may affect contract negotiations or require additional actions such a Business Associate Agreement.

If the study is not conducted at Emory, see the following:

- For studies taking place at CHOA, ask the team to submit a request to CHOA (via CHOA intranet-Careforce) using <https://choa.careforceconnection.org/docs/DOC-37465>. To access information on how to submit for security review, refer all questions to [BISRA@choa.org](mailto:BISRA@choa.org).
- For studies taking place at Grady: email the device and data use the information to the Grady privacy officer, D'Andrea Morning, at [djmorning@GMH.EDU](mailto:djmorning@GMH.EDU) for her review and approval. Upload the email in the study history for our records.

#### If LITS REVIEW IS NEEDED

If the mobile device/app is collecting/storing IIHI, PHI or sensitive information (from now on, “needs LITS review”), direct the team to put an IT ticket through this link: [https://emory.servicenow.com/sp?id=kb\\_article&sys\\_id=e5c2cd88f5cdf1c055c77bd8604896c2](https://emory.servicenow.com/sp?id=kb_article&sys_id=e5c2cd88f5cdf1c055c77bd8604896c2) The form has the information to provide under “more information”

#### MOBILE MEDICAL APPS USED IN RESEARCH STUDIES

1. Determine whether the mobile platform+app is a medical device per FDA definition (*aka intended for use in the diagnosis of a disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; see References and Definitions above*)
  - a. If not, the mobile device/app does not need to be included in the device section of the Smartform. Skip to section 2 to review ownership of the mobile device.
2. Check to see that the device is listed in the protocol and consent form:
  - a. If the protocol is sponsor generated, a separate addendum in the Research Design of the Smartform may be acceptable to document information about the device data collection (for example, if collecting information that requires LITS review).
  - b. Check to see that the device is listed in the Device Section of the Smartform.
  - c. Review whether the device is likely to be considered a non-significant risk device, significant risk device, or does it fall under the category of devices for which the FDA will practice enforcement discretion.
  - d. For studies with enforcement discretion, where the mobile app is considered a device but the FDA will not require an IDE submission despite not being previously approved (see [FDA guidance](#)) On page 12 [of this guidance](#), you can find some examples where the FDA intends to exercise enforcement discretion because the medical app poses a low risk to patients.
    - The study team should select the following options when filling out the device section of the Smartform:
      - Under question 1 (“Select each device...”), they should add the name of the device (if not found on the list) and attach a manual for a device. If there is not device manual, PI should provide clarification for why there is not a

- device manual. “This is not an FDA approved use of the device” should be selected under Q2.0
  - Under question 2 (“Device exemptions...”), they should select “Claim of abbreviated IDE...).
  - Under question 3, they should attach their completed [Mobile Medical apps worksheet](#)
- 3. Once screening procedures are complete, send to FB or expedited reviewer, as applicable.
  - Mobile medical apps under enforcement discretion will need a device risk determination. The risk determination can be made by the expedited reviewer.
  - For studies with mobile **medical** devices, except if they fall under FDA enforcement discretion, the study will have to go for a FB device determination unless:
    - i. the device is already FDA approved per indication OR
    - ii. The device is IDE exempt
- 4. PROCEED TO “COMMON PROCEDURES” SECTION BELOW.

#### MOBILE PLATFORMS IN A RESEARCH STUDY (NOT MOBILE MEDICAL APP)

1. Before ensuring the mobile platform needs LITS review, determine the ownership/possession of the mobile device/app (whether a medical device or not). This should be described in the protocol.
2. Confirm with the study team whether the mobile device will be given to the subject or if the subject will be using their own mobile device.
  - a. If the subjects will be using their own mobile device, have study teams confirm the following: (the following should be addressed in the protocol and in the consent)
    - Will an app need to be downloaded onto their own mobile device?
    - Will the information on the app be encrypted?
    - Will the study team be able to monitor the activity of the mobile device? If so, how will this be done?
    - What are the security measures being taken to ensure the confidentiality of their information?
    - How will the app be removed from their device?
      - The removal of an app from a subject’s device should be included and detailed in the “exit” procedures associated with a subject’s completion of the study.
      - i. If the subjects will be provided the mobile device, have study teams confirm the following: (the following should be addressed in the protocol and in the consent):
        - Cost questions
          - Is the subject responsible for paying for the device (the device itself)?
          - Who will be paying for the fees (e.g.: data, phone and texting fees)?
          - If the device is being “overused” (beyond what was assumed to be needed for the purposes of the study) who pays for the additional fees
        - Misuse and accidents
          - What will the study team do if the mobile device is lost or stolen? Are subjects liable for damages?

- Is there a security measure put in place to deactivate or wipe the mobile device remotely? If so, what is it? Under what circumstances will this occur?
- What will be done if the mobile device is misused (e.g. visiting illicit sites, using the device for personal reasons such as texting or calling friends).
- If the mobile device is used for personal unauthorized reasons, who will be responsible for the ensuing fees? What are the consequences?
- Access:
  - Will the study team be able to monitor the activity of the mobile device? If so, how will this be done?

2. PROCEED TO “COMMON PROCEDURES” SECTION BELOW.

COMMON PROCEDURES FOR ALL OF THE ABOVE

5. Determine security of data and PHI:

- Will the study team be gathering identifiable data (i.e. location) from the device? If so, why and how will it be used?
- The study team must provide details of how information gather via the mobile device will be stored and how it will be protected
- The study team should establish a system or schedule of contacting subjects via the device (if this is part of the study), so as to avoid calling in the presence of third parties or in situations where it is dangerous to answer (e.g. while driving).

EXAMPLE OF FEEDBACK FROM FDA RE: DOSE-CALCULATION APP

Rebecca Rousselle,

Thank you for your inquiry into the mobile medical apps email inbox. You inquired about drug dose calculators: “The type of app I'm curious about would perform a standard calculation, which previously was available in commonly-used spreadsheets or textbook guidelines, but is now put into an app. The calculation may be complex, but only involves numbers plugged in by the physician (the app doesn't do any data collection/imaging itself). The result would be used to determine the dose of some kind of drug. If the app had a significant error, the patient could be adversely affected, depending on the kind of drug for which the app is designed to calculate.”

Based on the limited information you provided, FDA believes that simple drug dose calculators falls under enforcement discretion. The FDA intends to exercise enforcement discretion (meaning that FDA does not intend to enforce requirements under the FD&C Act) for apps that are simple drug dose calculators that can be performed without the software tool.

Section V B5 of the mobile medical apps guidance states the following:

Mobile apps that perform simple calculations routinely used in clinical practice

These are apps that are intended to provide a convenient way for clinicians to perform various simple medical calculations taught in medical schools<sup>2</sup> and are routinely used in clinical practice. These apps are generally tailored for clinical use, but retain functionality that is similar to simple general purpose tools such as paper charts, spread sheets, timers or generic mathematical calculators. Examples of such general purpose tools include medical calculators for:

- o Body Mass Index (BMI)
- o Total Body Water / Urea Volume of Distribution
- o Mean arterial pressure
- o Glasgow Coma Scale score
- o APGAR score
- o NIH Stroke Scale
- o Delivery date estimator

Based on the limited information on the websites of the six sample calculators that you provided, all the apps would be placed under enforcement discretion for falling within functionalities outlined in FDA's MMA guidance referenced in Section VB5 above.

You also posed the question: "if the risk of the drug to be dosed would affect the FDA's position on this type of app."

If a drug dosing calculator provides automatic dosing or is intended for drugs that have a narrow therapeutic window, the drug dosing calculator may require regulatory oversight.

This response is not a classification decision and does not constitute FDA clearance or approval for commercial distribution.

[1]<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>

### **LITS report review**

After the LITS review occurred, the LITS security rep will send a report to the study team and the IRB. The LITS report will be emailed to our listserv. The listserver will upload the report to the study submission as a comment to study staff.

The report will contain information about the findings. See the following chart to ask for additional information from the team:

### **Risk level definitions, mitigation timelines, and risk acceptance criteria**

Risk Level	Description	Mitigation Timeline	Risk Acceptance Criteria
<i>Critical</i>	The Security Review has determined that the current level of risk associated with the finding is <b>critical (severe)</b> in its current state.	The risk must be fully remediated or mitigated to an acceptable level within 30 days if system is live. If the system is not yet live, the risk must be fully remediated or mitigated to an acceptable level before the system goes live or is connected to a production Emory network.	Critical risks can only be accepted by VP/Dean level leadership with the consent of Emory’s Chief Information Security Officer.
<i>High</i>	The Security Review has determined that the current level of risk associated with the finding is <b>high (substantial)</b> in its current state.	The risk must be fully remediated or mitigated to an acceptable level within 60 days if the system is live. If the system is not yet live, the risk must be fully remediated or mitigated to an acceptable level before the system goes live or is connected to a production Emory network.	High risks can be accepted by Director/Chair level leadership. VP/Dean level leadership must be informed that the risk is being accepted by the study team department Director/Chair.
<i>Medium</i>	The Security Review has determined that the current level of risk associated with the finding is <b>medium (moderate)</b> in its current state.	The risk must be fully remediated or mitigated to an acceptable level within 90 days.	Medium risks may be accepted by study team department Director/Chair level leadership.
<i>Low</i>	The Security Review has determined that the current level of risk associated with the finding is <b>low (tolerable)</b> in its current state.	Risk remediation is recommended, but not required at present.	Low risks do not need to be explicitly accepted.

If a finding was deemed more than low, we should expect a letter from the study team department Director/Chair (or VP/Dean as applicable) to allow the use of a device/software.

**References**

- Emory IRB P&Ps: Chapter 65- INVESTIGATIONAL MEDICAL DEVICES
- FDA Guidance on Mobile Medical Applications at <https://www.fda.gov/media/80958/download>

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
4/20/2017	Updated broken links
1/31/2018	Added information about Grady Privacy officer
2/7/2018	Clarifying that mobile medical apps under enforcement discretion do not have to go to FB for risk determination.
5/17/2018	Removed need to email Derek or Maria; added information from CHOA IT person and the link to our information chart
7/25/2018	Added that we should let OSP/OTT (add email OTT) know if the study is under a security review when the study is funded. Added information about LITS security review report.
4/14/2020	Updated contact for CHOA for security reviews
5/18/2020	Overall update to align with the use in the new system.
5/24/2021	Updating link for CHOA security review

<b>SOP Title:</b>	Certificate of Confidentiality Process in non-federal studies
<b>SOP Category:</b>	Study Management
<b>Established:</b>	6/26/2012
<b>Last Revision:</b>	5/5/2021

### DEFINITIONS

Certificate of Confidentiality: The CoC protects the identifiable research records from forced disclosure, such as subpoena. The CoC only covers information in the research study records, and research results placed BY THE STUDY into the medical record. If there is documentation elsewhere of the subject’s stigmatizing condition (e.g. HIV diagnosis at a non-Emory clinic, or mention of illicit drug use already in their EHC or other medical record from self-report at a past physical exam), the CoC will NOT protect that.

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### PURPOSE

In response to the 21<sup>st</sup> Century Cures Act, federal agencies have started granting Certificates of Confidentiality (CoC’s) to more research projects.

**NIH:** The NIH now automatically grants Certificates of Confidentiality (CoCs) for all NIH- funded human research studies, effective, October 17, 2017. They will still grant CoC’s to non-NIH-funded studies upon request if certain criteria are met related to the sensitivity of information.

Per NIH, sensitive information includes (but is not limited to) information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual’s financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual’s psychological well-being or mental health; and genetic information or tissue samples.

**For NIH- funded studies that automatically receive a CoC:** please ensure that the template CoC language is in the ICF and check the box for “Certificate of Confidentiality” in the pre-review form.

**CDC:** The CDC will automatically grant a CoC, without requiring a separate application, if the IRB determines that the information is sensitive. The study team must inform their CDC funding contact of the IRB’s determination.

**FDA:** The Cures Act revisions made issuance of a CoC mandatory for federally funded researchers “engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs. For *non-federally funded research*, FDA has been issuing

discretionary CoCs pursuant to the amended statutory requirements, on a case-by-case basis upon application to FDA since enactment of the Cures Act. To ensure that discretionary CoCs are issued to those entities who can comply with the requirements of the statutory provision, it is recommended that only sponsors or sponsor-investigators, submit requests for discretionary CoCs. This will help eliminate duplicative request to FDA for the same human subject research.

**Non-NIH, Non-CDC funded studies:** CoC's may be requested proactively by the study team, or they may be a requirement of the IRB during initial review.

**The remainder of this SOP applies only to non-NIH-funded studies obtaining sensitive information from subjects.**

#### **SCOPE**

The SOP applies to all non-NIH-funded human subject research where the research activities are likely to solicit information considered to be sensitive per the NIH definition above. See our IRB website here for information about CoCs: <http://irb.emory.edu/forms/coc.html> and the NIH's information here: [https://era.nih.gov/files/Cert\\_Confidentiality\\_Ext\\_userguide.pdf](https://era.nih.gov/files/Cert_Confidentiality_Ext_userguide.pdf)

#### **RESPONSIBILITIES**

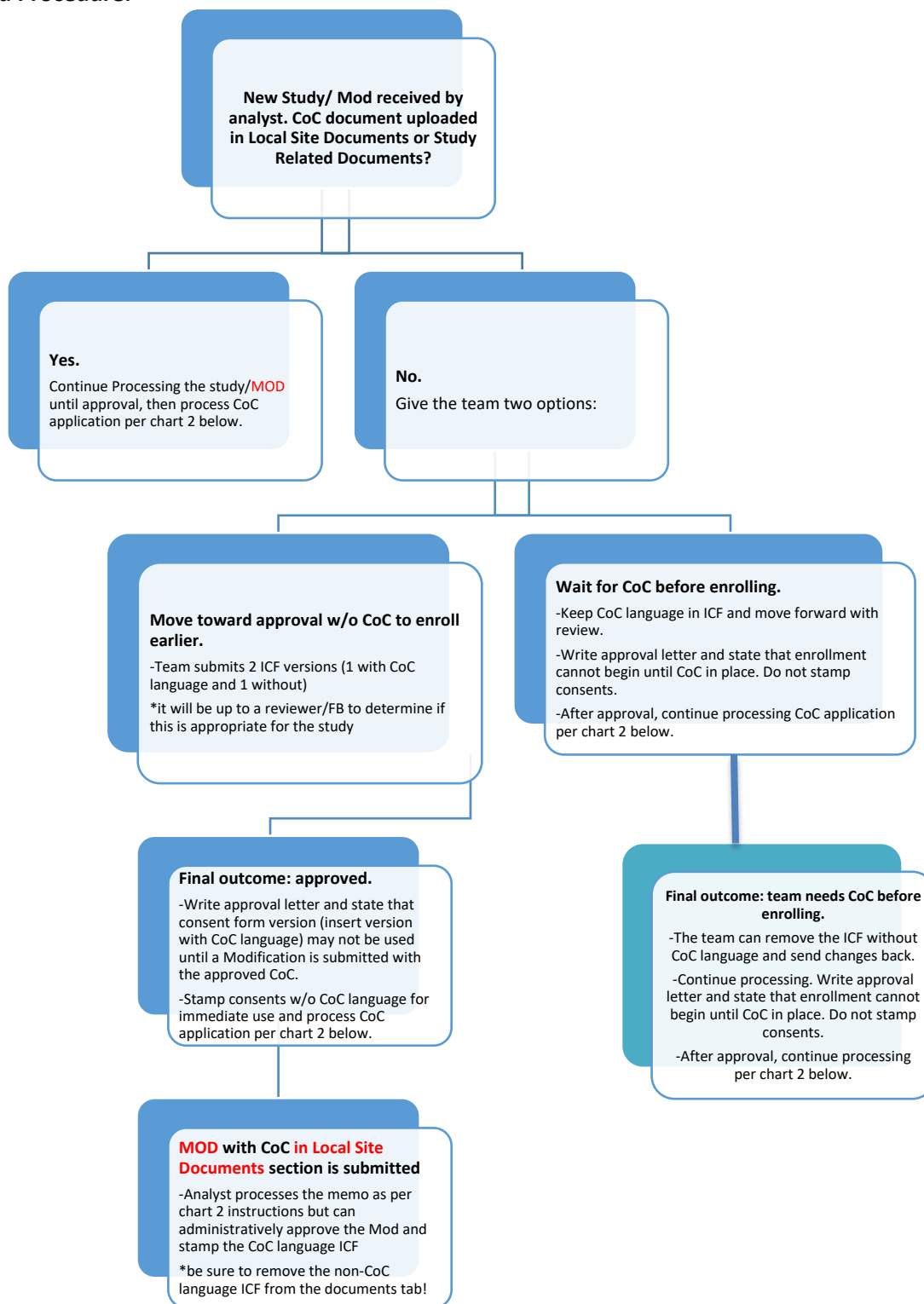
- IRB Study Analyst – Owner of the study to which the CoC applies or will apply; can also acknowledge own Modifications that simply upload approved CoCs; delays stamping of consent forms until CoC is in place, if applicable
- Institutional Official (I.O.) – Completes the Assurance Statement and e-signs electronic CoC applications before they are sent to NIH.
- IRB Reviewer (contingency or expedited) – May require CoC for new studies, or ongoing studies when more sensitive information starts being collected or identifiers are introduced; Determines if subjects can be enrolled prior to CoC being in place

#### **PROCEDURE**

**Processing studies that will have a CoC (new studies or Modifications)**



**Charted Procedure:**



**Written Procedure:**

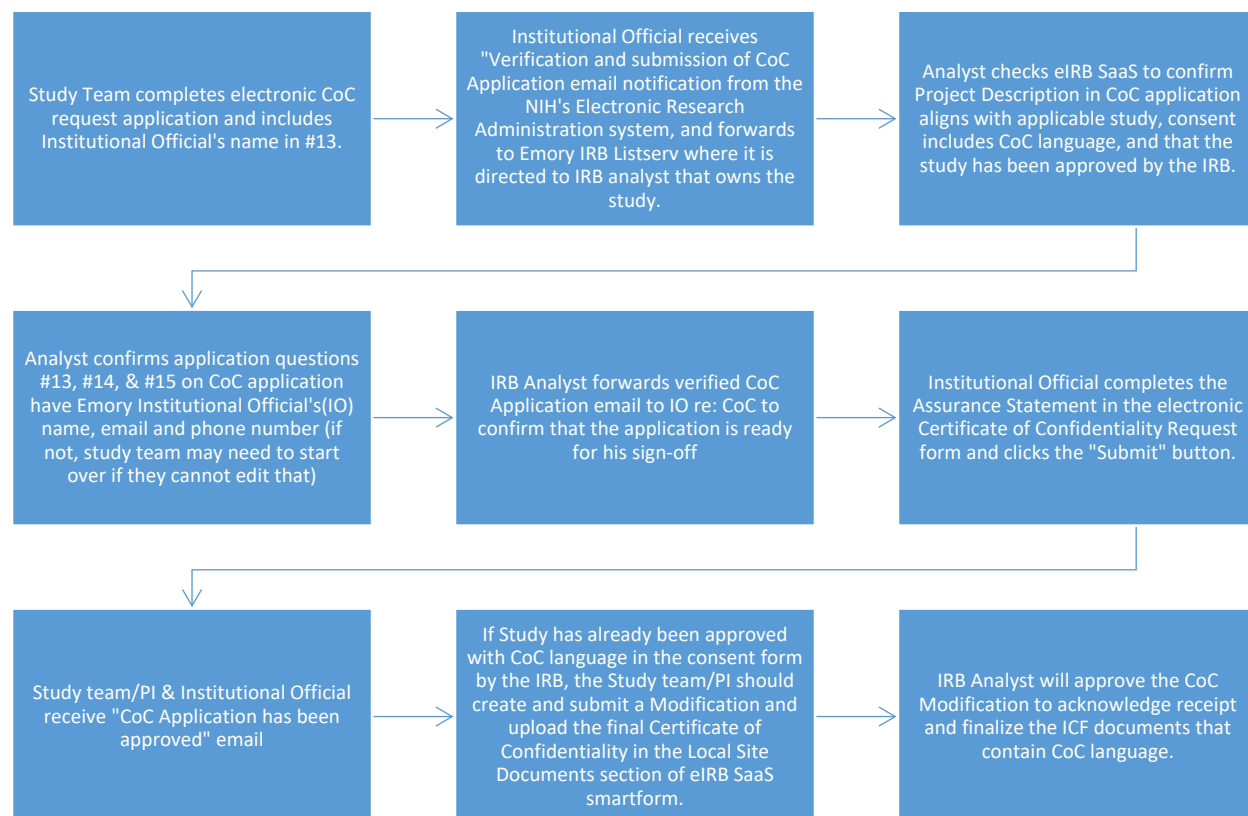
1. If any study documents reflect that there is a CoC in effect for the study, or that one will be applied for, OR the IRB *requires* a CoC to minimize risk to subjects:

- a. Ensure that the consent form language is consistent with the presence of a CoC. (Must have the required language describing the CoC, and also NOT have language about records being subject to subpoena [since CoC prevents disclosure based on subpoena]); require changes if necessary
    - i. If no, request that the study team make the required changes.
  - b. Determine if the study has already obtained a CoC.
    - i. If study team **will** be applying for CoC, there are three choices depending on whether study team needs IRB approval to obtain funding or to start preliminary activities:
      - (i) Leave IRB approval pending until CoC is in place: acceptable if the study team does not need to do any human subjects research activity or obtain a grant award until then (CoC approval from NIH can take some time). No enrollment until CoC is in place: study team submits only the CoC-version of the consent form; or
      - (ii) Issue IRB approval without stamping consent forms until a Modification is submitted with the approved CoC; or
      - (iii) Study team can request enrollment of subjects prior to the approval of the CoC:
        - 1. Study team submits two versions of the ICF(s) – with and without CoC language (NIH advises against using language like “we plan to obtain a CoC”).
        - 2. For full board studies, put a note in the Full Board Information form asking IRB to determine if study team can start enrolling prior to CoC being approved, despite potential exposure of sensitive data to subpoena.
        - 3. For expedited studies, include note to reviewer asking them to make the determination listed above (and email to follow up if they neglect to do so)
        - 4. If IRB does not decide to allow enrollment pre-CoC, the no-CoC version must be removed as a contingency for approval.
2. Post-approval:
- a. If Option (i) or (iii) above: Proceed as with any study.
  - b. If Option (ii) above, CoC version(s) of ICFs must NOT BE STAMPED until the CoC is approved by the NIH.
    - i. In approval letter (whether full board or expedited) state that the consent form version [insert version with CoC language] may not be used until a Modification is submitted with the approved CoC.
    - ii. Once Modification is submitted to upload the approved CoC in “Local Site Documents” section of smartform, **IRB Study Analyst** may “approve” (really just acknowledge) the Modification.
    - iii. If study used Option (iii) above, Modification must remove non-CoC versions of consent form, so they will no longer appear as “Finalized.”

## Handling CoC applications

Note: if this is a new multi-site study for which a CoC already exists (due to other sites already enrolling with a CoC in place), please skip to the CoC Assurance section.

**Chart 2**



- 1) Study team completes the electronic Certificate of Confidentiality (CoC) Request form.
- 2) Institutional Official receives "Verification and submission of CoC Application" email notification from the NIH's Electronic Research Administration system and forwards to Emory IRB Listserv where it is directed to IRB analyst that owns the study.
  - a) IRB Analyst checks eIRB SaaS to confirm Project Description entered by team aligns with applicable study, consent includes CoC language and that the study has been approved by the IRB.
  - b) Analyst confirms application questions #13, #14, & #15 on CoC application have Emory Institutional Official's (IO's) name, email and phone number. If not, study team may need to start over if they cannot edit the application and resend.
  - c) IRB Analyst forwards verified CoC Application email to IO re: CoC to confirm that the application is ready for his sign-off.
  - d) Institutional Official completes the Assurance Statement in the electronic Certificate of Confidentiality Request form and clicks the "Submit" button.
- 3) Study team/PI & Institutional Official receive "CoC Application has been approved" email

If Study has already been approved with CoC language in the consent form by the IRB, the Study team/PI should create and submit a Modification and upload the final Certificate of Confidentiality in the Local Site Documents section of eIRB SaaS smartform.

- 4) IRB Analyst will approve the CoC Modification to acknowledge receipt and finalize the ICF documents that contain CoC language.

There is guidance for researchers available on the web. Please direct researchers there if they have questions, <http://www.irb.emory.edu/forms/coc.html>.

#### **Handling CoC Site Assurances:**

Assurance documents are signed when Emory will invoke a CoC already in place in a multisite study, where Emory is not the main study site. The process for CoC assurances is basically the same as the above procedure. The only difference is that since the CoC is already in place, the team will submit a statement of assurance (on their departmental letterhead) rather than an application. There is template language available in the CoC Kiosk if the study team needs it. In the assurance process, the “packet” will include the cover memo, assurance document, approved informed consent form, and approval letter. The folder name to be saved on the H drive should be titled “CoC Assurance XXXXX PI name.”

#### **Background:**

- <https://grants.nih.gov/policy/humansubjects/coc/what-is.htm>
- <https://grants.nih.gov/policy/humansubjects/coc/who-can.htm>
- <https://grants.nih.gov/policy/humansubjects/coc.htm>
- <https://www.fda.gov/media/132966/download>

#### **LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
5/13/2015	Clarification of process
12/23/2015	Revamping of SOP following current NIH requirements.
3/1/2016	Language addition to reflect use of IRB subcommittee use, use of department letterhead and signature of PI for requests, as well as other language clarifications without content changes.
11/22/2016	Updated name of template Memo to IO
5/5/2017	Addition of section: handling Coc assurances; other minor clarifications
11/1/2017	Added charts, clarified SOP for new NIH CoC policy from 10/1/2017, other minor clarifications.
1/18/2019	Updated Dr. Wynes with Dr. Sherer
7/15/2020	Updates to the process
5/5/2021	Updated to follow new Online Certificate of Confidentiality System User Guide dated 06/25/2020.

<b>SOP Title:</b>	Data sharing certifications including genomic data sharing
<b>SOP Category:</b>	Study Management
<b>Established:</b>	10/31/2018
<b>Last Revision:</b>	10/31/2018

## PURPOSE

The purpose of this document is to explain the steps to follow if reviewing a study under a data sharing requirement, including genomic data sharing.

## DEFINITIONS

- Genomic data sharing repository (e.g. dbGap): public repository for individual-level phenotype, exposure, genotype, and sequence data, and the associations between them. dbGaP assigns stable, unique identifiers to studies and subsets of information from those studies, including documents, individual phenotypic variables, tables of trait data, sets of genotype data, computed phenotype-genotype associations and groups of study subjects who have given similar consents for use of their data.
- Institutional Certifications: Institutions are responsible for assuring, through an Institutional Certification, that plans for the submission of large-scale human genomic data to the NIH meet the expectations of the [Genomic Data Sharing Policy](#) (examples of research within the scope of the GDS Policy can be found in the [Supplemental Information](#) to the Policy). An Institutional Certification must accompany the submission of all large-scale human data to the NIH Database of Genotypes and Phenotypes (dbGaP). The Institutional Certification (for sharing human data), should also be provided to the funding NIH Institute or Center prior to award, along with any other Just in Time information (for extramural researchers) or at the time of scientific review (for intramural researchers).
- [Provisional Institutional Certification](#): to be used in a situation such as for a prospective study where the IRB has not completed its review of the protocol and therefore the institution cannot attest to all of the elements of the formal Institutional Certification

## RESPONSIBILITIES

- [IRB analyst](#) – reviews checklist submitted by study team and verified if consent has required information to allow data sharing
- [IRB Director](#)- reviews information

We have a guidance for investigators in our website at

[http://www.irb.emory.edu/forms/Data\\_Sharing.html](http://www.irb.emory.edu/forms/Data_Sharing.html)

Study teams should fill these forms as appropriate:

[Institutional Certification Request form for Emory submitting data](#)

[Institutional Certification Request form for Emory not submitting data](#)

## PROCEDURE

- If this is a urgent, very tight-turnaround request, strongly recommend to OSP analyst that OSP instead sign the "[Provisional Institutional Certification](#)" – state that IRB believes this is an appropriate use of the Provisional version. This form can be found under the NIH Institutional Certifications [page](#).
- Request comes into IRB from OSP and/or Study team
- Refer study team to IRB form to fill out and await it

- The IRB analyst reviews as follows:
  - Does the Consent Describe Sharing? Y/N
    - If sharing is described if it is optional? Y/N or N/A
  - Genetic or Genomic Research Described? Y/N
  - If Genetic or Genomic Research Described is it optional? Y/N or N/A
  - Data Use Specifications:
    - Appropriate for DbGaP submission (if applies): Y/N
    - Unrestricted or restricted areas: Y/N
    - Controlled access: Y/N
  - If study in question was approved by the IRB before January 23, 2015, ICF will only need to make reference to sharing data or samples, but not as explicit as above
  - If the study wants to access a database or repository approved after January 23, 2015, a waiver of consent will not be valid for this purpose.
- After this process was completed, forward the information the study team sent and what was reviewed to the IRB Director or designee.
- The IRB Director or designee will determine if this information is consistent with the approved study and protocol, and forward letter to IRB chair for signature
  - If the IRB Director or designee finds that the study did not allow for this use, she will communicate with study team
- After the Chair signs the letter, the IRB Director will forward to IRB analyst to communicate with study team and to log a comment in eIRB with the letter.

**REFERENCES**

- NIH webpage: [Institutional Certifications.](#)
- dbGAP submission process: [chart](#)
- NIH Guidance: [Expectations for Non-NIH-funded Submission Requests](#)
- NIH Institutes and Centers Genomic [Program Administrators](#)
- Provisional Institutional Certification [form](#)

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	COI: Handling Studies with Study Team Conflict of Interest
<b>SOP Category:</b>	Study Management
<b>Established:</b>	4/27/2015
<b>Last Revision:</b>	10/23/2020

## **PURPOSE**

The purpose of this document is to detail the steps necessary for the IRB to review studies with an investigator conflict of interest.

## **SCOPE**

The SOP applies to all human subject research where the COI Office / Investigator has identified that the investigator has a conflict of interest.

## **RESPONSIBILITIES**

- COI Office- charged with reviewing and identifying potential conflicts of interest and creating COI management plans as needed.
- IRB Study Analyst- processing studies in which investigator(s) have disclosed COI following this SOP; verifying adoption of the management plan in studies; escalating when study teams do not comply with management plan within the required timeframe
- COI Specialist: COI staff person responsible for coordinating certain communication between the COI Office, the IRB CoRe Team, and the IRB.
- IRB Director or delegate: Responsible for notifying investigators via email of their IRB-approved management plans and deadlines thereof; also for following up if investigators do not comply by the deadline, by requiring the submission of reportable new information (RNI) submission and further action if needed.
- IRB CoRe– IRB subcommittee responsible for reviewing and approving (with additions as needed) COI management plans that affect human subjects research, if Emory is the IRB of record (or Emory IRB is responsible for COI management plan review per the terms of a reliance agreement)
- IRB Full Committee- responsible for re-reviewing management plan when the investigator objects to any additional requirements recommended by IRB CoRe

## **PROCEDURE**

*NOTE: The changes to P&Ps that allow for the CoRe review described below went into effect at the P&P subcommittee meeting on March 17, 2015*

### **COI and External IRB Studies**

- If a study team member has or discloses a COI for a study going to be reviewed by and External IRB:
  - If this is a NEW industry sponsored study, it should be reviewed by our IRB unless single IRB review is required by funding agency or OHRP.
  - If this is a NEW study mandated to be reviewed by a single IRB or otherwise needs to go to an external IRB:
    - Trigger COI Ancillary Review in XIRB submission
    - Await the release of the Emory COI office's management plan before issuing institutional sign-off
    - Provide the COI management plan to the reviewing IRB for their review (the plan document includes suggested informed consent language)

- Ensure that financial disclosure language, if required, is present in the Emory informed consent form before moving study to “Active” state
- If this is an ONGOING study reviewed by an external IRB, that previously had no COI:
  - IRB Director will receive notification that there is a COI, along with the management plan
  - IRB Director will email the study team (conflicted party and PI), copying the Emory IRB Reliance Team, asking them to submit the management plan to the reviewing IRB within 10 business days
  - IRB Director and Reliance Team should set a calendar reminder for 10 business days, to confirm the study team has complied
  - If study team has not complied, IRB Director emails a reminder, and copies COI office.
  - If after another 10 business days the study team has still not complied, IRB Director will inform: the Reviewing IRB (providing the management plan) and the Department Chair

### **IRB Study Analyst**

- 1) New study or MOD submission indicate that the PI or a study team member have a COI (for disclosures that come initially from COI office, please see (3) below)
  - a. Ask the study team if they have disclosed to the COI office (unless this has been done, based on the content of the comment), and if so, what the status of COI review is. If this takes place outside of eIRB, document the exchange in the History.
  - b. Contact COI Program Specialist, copying IRB Director, informing them of the COI disclosure and the IRB study number, and what is known of COI review status.
  - c. Add the COI office as an ancillary review, if the disclosure is new or pending.
  - d. Await feedback as you continue processing the submission as follows:
    - i. For Full Board study/AM, the item can be assigned to an agenda, **as long as COI remains a pending issue** until there is confirmation of COI Committee review or finding of no conflict; and until a management plan (if applicable) is accepted by the investigator and the plan is approved (with additions if needed) by IRB CoRe. **Include this requirement in the Agenda Item Notes and add a logged comment in the History.**
    - ii. For expedited items, do not send to the reviewer until COI review is complete, and if applicable, a management plan is accepted by the investigator, and the plan is approved (**with additions if needed**) by IRB CoRe.
      1. Upon receipt of an IRB CoRe-approved management plan from the COI Specialist (as an email and/or logged comment), the IRB Study Analyst should review the management plan against the eIRB record to ensure that the study team has made the required changes if any (e.g. revising the protocol, Smartform (e.g. recruitment or consent sections, and including updating the COI section, if necessary), consent form(s), etc). Log comment in History stating that you have verified this.
      2. After confirming that the revisions have been completed, the IRB Study Analyst should send the item for the appropriate further review (may be full board initial review, contingency review if COI was a pending issue, or expedited initial review). Indicate in your pre-review notes (if sending for initial full board review) that COI management plan has been reviewed and implemented by the IRB CoRe.
- 2) Continuing Review



- a. If question 5 of the CR application has been checked, verify if this is being disclosed for the first time.
    - i. If already disclosed, there is no need to take further action regarding COI (unless you do not see evidence that there was a COI review or a management plan, in which case contact the COI specialist and IRB Director).
  - b. If the disclosure is new, ask the study team if they have submitted it to the COI office (unless this has been done).
    - i. If far in advance of expiration, send back to the study team to get their response; otherwise can obtain a response via call/email/logged comment as needed, but document the exchange in study History.
  - c. Contact COI Specialist, copying IRB Director, informing them of disclosure and study number, and what is known of COI review status. Log a comment in the History stating that you have done this.
  - d. Add the COI as an ancillary review for the CR.
  - e. Process the CR as usual; this is not a pending issue (though a Modification may need to be submitted once a management plan is approved, per section (3) below).
  - f. Alternatively, if the conflict was incorrectly identified, you may need to ask the study team to correct and send back.
- 3) COI Management Plans for Ongoing Studies In Absence of eIRB Disclosure  
Sometimes a COI will develop in an ongoing study, and the study team does not initially submit a Modification with that information in eIRB. Therefore you may hear about it first from the COI Office or Program Specialist, as follows:
- a. COI Specialist will send an email and log a private comment to the analyst and IRB Director, informing them that the study team has been given 10 business days to submit a Modification to implement the COI management plan.
  - b. IRB Study Analyst should set a calendar reminder for 10 business days to double-check that the study team complies with updating the study to implement the COI management plan and check the COI box.
  - c. If no Modification is submitted within the timeframe, log a comment to the study team reminding them. Also, email the IRB Director and Team Q for escalation, and log a comment in the History stating that you have done this.
    - i. If there is a pending Continuing Review, make that PENDING until the study team has complied with the management plan
  - d. Handoff responsibility for monitoring management plan completion to the Team Q and IRB Director. Director will escalate to COI Office and Department Chair if needed.

**COI Program Specialist or COI staff member**

- 1) Notification of Investigator or Study COI is sent to you by IRB Analyst, due to disclosure in eIRB by COI staff member:
  - a. The COI staff member will reply to the analyst to acknowledge receipt of the disclosure, and will provide an estimated turnaround for next steps (if not able to complete remaining steps immediately)
    - i. If the COI Committee has already determined a management plan, the COI staff member will log a comment in eIRB to notify the IRB analyst of the current approval status
    - ii. If the COI management plan has not been determined by the COI Committee, the COI staff member will log a comment with that information.

- iii. If the COI Committee determined there was no conflict or plan needed, the COI staff member will complete the ancillary review accordingly.
  - b. The COI specialist will follow steps below once COI Committee review is complete (Step 2 when COI is present; Step 3 when COI Office review finds no COI exists)
- 2) COI Exists, Management Plan is finalized by COI Committee and Dept/VP Review Period has Elapsed
- a. The COI specialist saves the Management Plan on IRB shared drive (:\\General\\COI\\COI Mgmt Plans, under the appropriate folder).
  - b. *If study already is present in eIRB:*
    - i. Email the management plan and study link to non-clinical IRB CoRe with the following information using the “CoRE COI determination needed” email template (H:\\General\\COI\\COI Omnibus Forms and Determination Letter Templates):
      - 1. If an investigator’s COI involves multiple studies, you may include the multiple management plans in one email – see template – summarizing them separately if there are differences in the plans. The result is still multiple omnibus forms however.
    - ii. Set reminder to follow up with CoRE to ensure votes received in timely manner.
    - iii. After a determination is made by IRB CoRe (with at least 3 agreements, including a Vice Chair), update the COI Omnibus form and save on H:Drive (H:\\General\\COI\\COI Mgmt Plans) after creating a folder. Also save PDF of all CoRe email responses/votes.
      - a. If multiple studies were involved in the above CoRe email, you may use one folder to hold all documents for those studies. Include the eIRB numbers and PI names in the name of the folder.
    - iv. Create Determination Letter – one per management plan (even if CoRe reviewed multiple plans at once);
      - 1. If the Management Plan is accepted as is:
        - a. Use the Accepted As Is COI Mgmt Plan Determination Letter, found at “H:\\General\\COI\\COI Omnibus Forms and Determination Letter Templates” to craft a final determination letter. Save in case folder on shared drive.
      - 2. If there are changes to the Management Plan (e.g. adding additional requirement):
        - a. Use the Not Accepted COI Mgmt Plan Determination Letter, found at “H:\\General\\COI\\COI Omnibus Forms and Determination Letter Templates” to craft a final determination letter. Save in case folder on shared drive.
      - 3. Forward to IRB Director for final approval of language and authorization for digital signature, then create PDF of signed letter and save on H: drive folder.
    - v. Update COI Office records and tracking spreadsheet accordingly
    - vi. Email approved management plan and the signed PDF’d letter to IRB Director, copying IRB analyst.
      - 1. Include links to each study involved and who is analyst (on each, if more than one study); otherwise not clear
      - 2. If study already approved and ongoing, include in the email a deadline of 10 business days to implement, and reminder to the IRB Analyst to check in 10 business days. “Analyst(s): Please set Outlook reminder to verify that changes are made within 10 business days; if not, escalate to Team Q and Director.”
      - 3. If study is not yet finally approved, indicate to IRB Analyst that the COI management plan implementation must be a pending issue.
    - vii. Upload approved management plan and letter into eIRB submission’s History as *Private IRB Comment* (not visible to study team); also paste in text of above email.

- viii. Log *Comment to Study Team* (visible to study team) stating simply that a Conflict of Interest Management Plan has been approved by the IRB and the IRB Director will be emailing shortly with the formal letter and further instructions.
  - c. *If study not yet present in eIRB*
    - i. Record case on COI tracking spreadsheet and await inquiry from IRB staff once study is submitted.
- 3) COI Office finds No COI Exists
- a. No required action

**Escalation Procedure when Study Team Does Not Comply with Mgt Plan Within Timeframe**

1. If changes to the consent documents are needed, the modification should be submitting within 10 business days of the notification to the study team. If the modification is not submitted during this time, refer the issue to Director for follow up
2. The IRB Director will communicate with the study team, letting them know they are now required to submit an RNI due to the delay.

**IRB Director:**

- As a member of CoRe, submit opinions re: COI management plans on a timely basis (14 calendar day total turnaround for CoRe determination)
- When COI Specialist sends IRB CoRe determination letters, email those directly, within 2 business days, to conflicted party and PI stating that the IRB has accepted the management plan (as-is or with required changes) and that either (a) the requirements of the plan have already been met in the IRB submission and no further action is needed, or (b) the required changes must be submitted in eIRB (1) before the IRB can issue final approval, or (2) via Modification within 10 calendar days, and if the Modification is not submitted within that timeframe a Reportable New Information submission may be required.
  - Copy IRBA and COI Program Specialist
  - Update COI tracking spreadsheet when email sent

**TARGET TURNAROUND TIMES**

**Time 0 (Zero)** = When COI Office receives notification from the conflicted party that they have accepted the COI management plan, or when the timeframe for objection has elapsed

**Targets**

When the plan is approved by CoRe “as is”:

- 14 calendar days (two weeks) from Time 0 to when IRB CoRe determination letter uploaded in eIRB and emailed to IRB analyst and Director
- Two business days for Director to send the plan to conflicted party and PI
- Ten calendar days for the study team to make necessary changes in eIRB via a MOD, before referred to Team Q

When CoRe requires changes:

- 14 days from Time 0 to when IRB determination letter is uploaded into eIRB and emailed to IRB analyst and Director

- 2 business days for Director to send required changes to the conflicted party via email
- 5 business days to allow the conflicted party to object (must be stated in an email to PI)
- 10 additional calendar days for a final CoRe determination letter to be prepared by COI Program Specialist, sent to IRB analyst and Director, and Director to send to conflicted party and PI

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
5/7/2015	Replaced the SOP titled "Conflict of Interest Management Plan Process" with all new procedures
8/17/2015	Added to IRB COI Liaison Analyst's responsibility to keep IRB analyst informed of plan status.
5/18/2016	Updating the number and composition of CoRE needed for acceptance. Also updated responsibilities between IRB and COI.
12/20/2016	Major overhaul of entire SOP. Removal of IRB COI Liaison role.
6/14/2020	Revisions to SOP to improve understanding and readability.
10/23/2020	Updated/enhanced SOP section for studies reviewed by External IRB. Removed name of VPRA (Sherer).

<b>SOP Title:</b>	Institutional Conflict of Interest
<b>SOP Category:</b>	Study Management
<b>Established:</b>	3/21/2016
<b>Last Revision:</b>	3/21/2016

## BACKGROUND

This SOP outlines the Emory IRB's responsibilities pursuant to the Emory Institutional Financial Interests Involving Human Subjects Research (Policy 7.24, <http://policies.emory.edu/7.24>)

## DEFINITIONS

- Institutional Financial Conflict of Interest involving Human Subject Research exists when the University Institutional Conflict of Interest Review Committee determines that a Significant Institutional Financial Interest held by Emory University or an Institutional Leader can significantly and directly affect or reasonably appear to affect the institutional processes for the design, conduct, reporting, review, or oversight of human subject research
- Licensed Intellectual Property in Human Subject Research: When Emory licenses its intellectual property (IP), the University may receive equity in a company as a result of a licensing agreement for Emory IP; receive royalties or other fees as compensation for the use of that IP; and/or may receive equity or other financial interest as part of a co-investment in a licensee or related company.
- Gifts: In compliance with the Emory Gift Acceptance Policies & Procedures, Emory Policy 3.7, any gifts to Emory must be unconditional, in furtherance of Emory's charitable mission, and non-reciprocal. Per the procedures identified in Emory Policy 3.7, any gifts of equity in individual companies will be sold as soon as it can be practically and legally accomplished. These procedures will be used for any gifts of equity in companies that utilize Emory Intellectual Property to produce a drug, device, diagnostic, etc. that is involved in Human Subject Research at Emory
- Significant Financial Interests of Institutional Leaders: Pursuant to this policy, Institutional Leaders shall recuse themselves from any business decision, allocation of University resources or personnel, approval process, or oversight review process involving a company with which they have a Significant Institutional Financial Interest that is related to Human Subject Research at Emory. If recusal is not possible in order to carry out their University obligations, they must divest the Institutional Financial Interest. Any exception must be reviewed by the Provost and the Vice President for Research Administration, who may request an advisory opinion from the University Institutional Conflict of Interest Review Committee. For example, a Department Chair should not review or approve an IRB protocol for Human Subject Research when she has a Significant Institutional Financial Interest in the sponsor or provider of test material in the protocol. Emory may receive gifts from corporate donors that may also sponsor research involving human subjects. When a gift meets the Institutional Financial Interest threshold, the gift must be reviewed pursuant to the procedure in Policy 7.24, Section III, E.

## ROLES AND RESPONSIBILITIES

- Investigator: To the best of their knowledge, Investigators shall identify the use of Emory Intellectual Property in Human Subject Research on the IRB application. Those protocols shall be forwarded to the Vice President for Research Administration or his designee for assessment and review.

- Office of Technology Transfer: shall compile a list that includes: (i) all entities in which the University holds an equity interest as part of a licensing arrangement; and (ii) a list of technologies sorted by licensee where Emory has received more than \$100,000 in royalties annually. These lists shall be updated every six months or as requested by the COI Review Office. Using this list of entities, the COI Review Office will search the IRB databases to determine whether an identified entity is the financial supporter for the study. The COI Review Office shall refer any identified IRB protocols and licensing information to the Vice President for Research Administration. The Vice President for Research Administration, or designee, shall follow the procedures for assessment and review.
- The Office of the Vice President for Health Affairs Development (for Gifts to Emory): shall provide to the IRB Department a list of corporate donors that give more than \$500,000 in cash per annum to a Department or Center. On a reasonable basis, the IRB will review the list of donors against a list of active protocols. If a listed Donor is the sponsor or financial supporter of Human Subject Research, the IRB will refer the research and gift proposal for review by the Vice President for Research Administration, or his designee. The Vice President for Research Administration, or designee, shall follow the procedures for assessment and review.
- University Conflict of Interest Review Committee: When an Investigator submits an explanation of Compelling Circumstances the VPRA may send the protocol to an ad hoc independent organization, including an external IRB independent of Emory, or may form an ad hoc committee that includes one member from outside Emory. These experts will formulate a recommendation as to whether an Institutional Financial Conflict of Interest exists and how it could be managed. In reviewing the research, the Significant Institutional Financial Interest, and the explanation of Compelling Circumstances, the Committee will use the Criteria for Evaluating an Institutional Financial Conflict of Interest in Policy 7.24, Section III, E.3.b.1. The Committee may determine that the Significant Institutional Financial Interest is too great and the research should not occur at Emory, unless divestiture is possible prior to the commencement of the study.
- Vice President of Research Administration (VPRA): Receives notification when Institutional Conflict of Interest is revealed in the context of a human subjects research protocol. The VPRA shall make an initial assessment of whether a Significant Institutional Financial Interest related to the research exists, then require either disclosure in publications/consent/presentations, or ask investigator for compelling circumstances why the research should proceed at Emory.
- IRB Director: Ensures that IRB-COI Liaison follows up as required when alerted of ICOI disclosure
- IRB-COI Liaison: Communicates with COI Office re: any institutional COI issues disclosed to either IRB or to COI Office
- IRB Analyst: Alerts IRB-COI Liaison and IRB Director if any studies come to Analyst where Institutional COI is checked.

## **PROCEDURE**

### **Procedures For When Human Subjects Research Involves Emory Licensed Intellectual Property, or is Funded by Entities Who Provided Large Gifts to Emory**

1. The IRB is alerted to the presence of Institutional COI by either
  - a. the investigator (in the eIRB application)
    - i. IRB Analyst must alert the IRB-COI Liaison and the IRB Director

- ii. The above individuals will inquire with the Emory COI office and the VPRA to see what stage Emory’s review of the potential ICOI is in
  - iii. If/when the VPRA has determined that there is a significant financial institutional COI, and he or the ad hoc Committee has agreed that the research may still be conducted at Emory (i.e. the conflict can be adequately managed), he will share the management plan with the IRB, which may include things like disclosure in the informed consent form, and/or referring the study to an external IRB for review
    - 1. If external IRB will review and study not yet approved at Emory, communicate to study that outside IRB submission is required, and refer to Team Theta for any additional assistance needed.
    - 2. If study will remain at Emory IRB (rare), transfer ownership of study to IRB-COI Liaison.
- b. Or the VPRA
- i. Will then skip to step (a) (ii) above
2. The IRB of record (either Emory IRB or external IRB such as WIRB) must review the Institutional Conflict of Interest management plan and determine if any additional elements are needed.

NOTE: The IRB shall review the management plan as part of its initial review of a new protocol. If an ICOI arises after initial IRB approval has been granted, the IRB will review the management plan following notice by the UCOIRC

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	Cost Option for Clinical Trial Agreements and ICFs
<b>SOP Category:</b>	Study Management
<b>Established:</b>	9/20/12
<b>Last Revision</b>	6/13/2022

#### **PURPOSE**

The purpose of this SOP is to outline the procedure the IRB analyst uses to determine the correct cost option language to include in informed consent forms.

#### **SCOPE**

The SOP applies to research studies that have informed consent forms.

#### **PROCEDURE**

1. Review the response to question #2 in the “Clinical Research/Expanded Access only” section of the smart form to determine if the study has billable items or services.
2. If the study has billable items or services, the appropriate cost language in the consent form is option #2. The Office of Clinical Research (OCR ) will not provide documentation of this selection and the IRB will assume this is the default selection.
3. For studies with no billable items or services, the correct cost option is option #1.
4. If a study team has inserted option #3, they must provide documentation of the cost option from OCR. This justification should be routed to a TL or Director prior to assigning for review to determine if there is an ethical concern regarding participants paying for research-related procedures.

If the OCR pre-award staff identifies a cost option other than #2 for a clinical study, they will send notification of the correct option to the IRB listserv. The notification will include the IRB study ID. The IRB Listserv attendant will forward this email to the designated person who will look up the study and upload the document as an attachment with a comment like: “CTA Cost Option is #\_\_\_ per attached.”

**NOTE:** If the consent form has been approved with the incorrect language, a modification will be required.

In this scenario, the IRB Analyst posts a comment in the History and/or Agenda Item Notes about the Cost Option being verified and correct in the ICF (or not yet verified, etc.)

#### **FOR PEDS/CHOA STUDIES**

1. OCR does not provide cost options to IRB for studies done by Pediatrics.
  - a. In some cases OCR may send a *preliminary* cost option to the Peds RAS, who then needs to finalize the option based on further review.
2. Peds RAS may get input from CHOA, if there are CHOA procedures. This process is conducted between these offices and we do not need to get input from CHOA directly.
3. Peds RAS will email our listserv with the Cost option again.



- a. If confirmation of the cost option is not received, please email Kim Caroline ([kcaroli@emory.edu](mailto:kcaroli@emory.edu))

**Note:** the Monday report to the IRB listserv is about the In Case of Injury option, not the Cost Option.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
2/6/2017	Addition of CHOA process
5/21/2021	Modified PED/CHOA studies procedure
3/28/2022	Updated the Cost option process
6/13/2022	Minor formatting updates, rewording for clarity

<b>SOP Title:</b>	Sensitive Study Status
<b>SOP Category:</b>	Study Management
<b>Established:</b>	9/23/2015
<b>Last Revision:</b>	08/11/2023

## **PURPOSE**

The purpose of this document is to outline the procedure to process sensitive study requests/determinations.

## **SCOPE**

The SOP applies to clinical research studies in which the study team seeks to keep the subject's consent/HIPAA and other sensitive information from being uploaded into EeMR due to the stigmatizing nature of the information.

## **BACKGROUND**

In order to ensure that EHC physicians are aware of a patient's participation in a clinical trial, and how that participation might affect their symptoms or treatment options, the Emory Office of Quality requires that study information be placed in any EHC medical record that a study participant may have.

If a subject has an EeMR Record, or gets one created when they come seeking medical treatment at EHC, then those documents are automatically transferred into the subject's EHC EeMR.

For studies with stigmatizing information that would not already be part of their EHC medical record, the study team can request Sensitive Study Status from the IRB, and complete the "Clinical Research Key Points for Sensitive Study" document to keep certain study-related information out of the EeMR. In either case, the consent form must accurately reflect what study information will be placed in the EHC EeMR.

## **PROCEDURE**

- New Studies/Modifications
  1. Study team should request "Sensitive Study Status" by selecting yes to Q5.0 under the For Clinical Research/Expanded Access Only of the Smartform.
  2. IRB Analyst should review the consent form to make sure that the appropriate template language regarding the exclusion of the consent form and study information from the medical record is included.
  3. IRB Analyst should send the study for appropriate review (FB or expedited). (if declined by expedited reviewer and study team disagrees with outcome, request should be referred to FB).
  4. IRB Analyst should include the reviewer's determination of sensitive study status in the approval letter, if granted (if declined, and study team agrees with outcome, then consent should be reverted to non-sensitive template language)
  5. For studies with sensitive study status, the IRB Analyst should forward the approval letter to [OCR@emory.edu](mailto:OCR@emory.edu).

- Misc.
  - a. For approved studies that are found to contain Sensitive Study Status language in the consent, but have not been granted sensitive study status (i.e. IRB review overlooked this discrepancy):
    1. Consult with the IRB Director and/or OCR to check to see if the consents are actually being uploaded to ERMS
    2. If consents are being uploaded, have study team submit a modification and RE to correct the discrepancy.
    3. If they are not being uploaded, then have study team submit an amendment to use simple language re: no study information will be placed in any EHC medical record you might have, instead of the sensitive study template language.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
2/11/2020	Update to align with new system
8/11/2023	Removed reference to CRKP form in study smart form

<b>SOP Title:</b>	Imaging Studies
<b>SOP Category:</b>	Study Management
<b>Established:</b>	3/10/2014
<b>Last Revision:</b>	6/8/2018

#### **PURPOSE**

The purpose of this SOP is to detail to IRB Analysts what are the required elements for processing imaging studies.

#### **SCOPE**

This SOP applies to any study that utilizes any of the below referenced imaging modalities as a research intervention.

#### **DEFINITIONS:**

- Emory University Radiation Safety Committee (RSC): The RSC reviews Research that involves the use of radioactive isotopes, x-rays or other radioactive materials. Requirements for when RSC review of a Research protocol is necessary can be found at the following website: <http://www.ehso.emory.edu/documents/guideline-for-rsc-review-of-human-research-studies.pdf>
- Radioactive tracer: A radioactive molecule that can be sent through the body's circulatory or urinary system, with its progress followed by a radiation-sensitive machine.
- Radioactive contrast: a solution or colloid containing radioactive material used for visualizing soft tissue structures. Such contrast media indicate their positions or distribution in the body by their gamma ray emissions.

#### **PROCEDURES:**

*Below are two categories of modals related to imaging studies. For additional assistance please see guidance on referring to Radiation Safety.*

#### **fMRI/MRI scans**

- Determine if the study could be expeditable vs Full Board.
  - In general, determine if fMRI or MRI being used does not utilize any radioactive tracers (some MRI's use these). ***If they do, please make sure the study team registers with RSC and the study is assigned to a full board meeting.***
  - fMRI/MRI studies may be expedited if no contrast is being used and the overall study is minimal risk and all other procedures fit into the expedited categories. The designated reviewer must be a medical doctor.
- If the study is using a radioactive tracer or contrast, make sure that the risks section of the consent, contains the following information:
  - A warning that the subject should not participate if they have any type of metallic object implanted in their body. The MRI may cause these objects to move or heat up.
  - The loudness of the machine (*subjects are usually given earplugs*)

- The machine requires the subject to be in an enclosed space for a prolonged duration of time. If the subject is claustrophobic they may wish to opt out of the study. (*language may be altered for open MRI*)
- The incidental findings language from our Modular Consent Language document (posted on IRB website) **must be included verbatim** in every study that utilizes an fMRI or MRI for research purposes only, in either the risk section or its own section called “Incidental Findings”

**Please note**

- A clinical trial with research scans added that are not done as standard of care may need to add incidental findings language to the consent form.
- Often times these studies are done through the Psychology department. The Psychology department is not part of the covered entity and may not need a HIPAA Authorization form. However, if the study staff includes investigators (doctors) that are part of a covered entity, and the study involves billing and treatment, then HIPAA may apply.
- Many of the fMRI and MRI studies will come from Dr. Gregory Berns laboratory called the Facility for Education and Research in Neuroscience (FERN). Although the following fMRI/MRI directions were specifically designed for studies submitted by the Berns lab they are applicable to all studies using fMRI’s and MRI’s as a research intervention.

**Other Scans**

For studies utilizing scans such as MUGA, Bone Scan, PET, PET/CT, Myocardial Perfusion, VQ Scan, Thyroid, or exposure to radiation of any kind, please make sure the study team lists “radiation” in the “Biomedical Research” section, to trigger Radiation Safety Committee review, and the study is assigned to a full board meeting.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
11/6/2014	Expanded the scope from just fMRI and MRI to cover all studies where imaging is done for research
2/18/2015	Adding information about other imaging that may require referral to RSC and review by FB
4/27/15	Adding note about the potential for HIPAA requirement based on study staff.
12/10/2015	Administrative changes made for clarity and note about clinical trials with research scans.
6/8/2018	Minor clarifications

<b>SOP Title:</b>	How to Handle GWAS Data Use Certification Requests
<b>SOP Category:</b>	Study Management
<b>Established:</b>	12/08/ 2009
<b>Last Revision:</b>	9/16/2016

## SUMMARY

Genome-Wide Association Studies (GWAS) and “large-scale genomic analyses” are increasingly common. Investigators at Emory may wish to participate in GWAS via NIH-supported repositories by submitting genetic samples/data and/or requesting the use of it. As part of the process for submitting genetic samples/data, the investigators need to have a Data Use Certification signed by an appropriate Emory official. Per the latest NIH genomic data sharing policy effective January 25, 2015, additional steps are needed for NIH-funded studies including large scale genomic analyses. The IRB has a role in certifying/approving data sharing plans at the time of grant submission for these types of studies, as well as when the data is ready to be submitted to a public repository.

If requests come to the IRB either from OSP or the investigators to certify/sign-off on data sharing plans or data sharing activities, the IRB must have the following:

1. The letter or form that we are being asked to sign, pre-filled with information about the study and the data sharing restrictions as proposed by the investigator
2. The grant application including the data sharing plan portion
3. Indication of whether the samples from which the data was gathered were collected prior to, or after, January 25, 2015 (or both)
4. Copies of all informed consent forms used to collect the samples from which the data was gathered.

The Emory IRB office handles these requests and arranges for signature by the IRB Director after verification that all criteria are met. In her absence, a Co-Chair, Vice Chair, or an Associate or Assistant Director may sign after verifying in the protocol record that all criteria are met.

IRB Staff: if you have questions about GWAS or genomic data sharing issues, please check with IRB Director.

## REFERENCES

- Learn more in the NIH GWAS Points to consider at:  
[http://gds.nih.gov/pdf/PTC\\_for\\_IRBs\\_and\\_Institutions.pdf](http://gds.nih.gov/pdf/PTC_for_IRBs_and_Institutions.pdf)
- You may also obtain more information at <http://gds.nih.gov/>

## LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
9/16/2016	Updated with information about 1/25/15 policy change

<b>SOP Title:</b>	Humanitarian Device Exemption (HDE) Studies
<b>SOP Category:</b>	Study Management
<b>Established:</b>	8/8/2013
<b>Last Revision:</b>	11/3/2020

## PURPOSE

The purpose of this document is to describe the IRB process for reviewing studies under a Humanitarian Device Exemption.

## SCOPE OF SOP

The SOP will apply to Emory human subject research working under a HDE.

## DEFINITIONS

- **Investigational Medical Device:** means a device, including a transitional device that is the object of an investigation. An investigational device is permitted by the FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.
- **Humanitarian Use Device (HUD):** medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year – *21 CFR 814.3(n)*. To obtain approval for an HUD, a humanitarian device exemption (HDE) application is submitted to the FDA.
- **Humanitarian Device Exemptions (HDE):** allows use of an HUD; the HDE application is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market.
- **Sponsor:** A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator

## RESPONSIBILITIES

- **IRB analyst-** initially screens application before sending it to IRB Full Board or the IRB Chair.
- **IRB Chair or Co-Chair –** reviews the progress reports submitted by the sponsor or sponsor-investigator. The Chair or Co-Chair must be a clinician

## PROCEDURE

### Initial Review Submission

*Note: The Emory IRB cannot be the IRB of record for community physicians who want to use a HUD for non-research purposes. We can only serve as the IRB of record for Emory physicians using HUDs at Grady or Emory. If*

the HUD is being used at St. Joseph's Hospital, CHOA, etc., their IRB (or a commercial IRB) should review the HUD submission.

#### Non-research HUD

Screen the study using the [HUD NS checklist](#). When adding this to the FB agenda, make sure to attach the FB section to your pre-review notes. The study team should provide the following documents with the submission (forward [this checklist](#) to the treating physician for their information):

- A copy of the HDE approval order
- A description of the device
- The product labeling
- An ICF is not required if used under the FDA HDE-approved use, but the study team should submit an information sheet for the patient. The information sheet should describe a general definition of the FDA's HDE program, a brief description of the device and related procedures, risk/benefit ratio, and physician contact information if the patient experiences a device-related adverse event.
  - If the HDE holder has developed a patient information packet, this packet always should be distributed to patients prior to receiving their HUDs. Labeling for the HUD may also be made available to the patient to provide further information regarding the device's HUD status and possible risks/benefits packet for the patient. See [here](#) for the Emory IRB template.
- A summary of how the physician proposes to use the device, including a description of any screening procedures, the HUD procedure, and any patient monitoring with follow-up visits, tests, or procedures. Refer [here](#) for a protocol outline.
- The IRB reviewer also may request that the physician submit documentation that he/she is qualified through training and expertise to use the HUD.  
The staff should confirm the approval status of the HUD. The information can be found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm>. Letter template information can be found at H:\General\QA Working Files\Forms, templates and Guidance\Letter templates & guidelines.
- Ancillary reviews required: Department Review, Biosafety/Radiation Safety, and Clinical Research Key Points Summary.
- Requires Full Board initial review- most criteria in the worksheet don't apply since the project isn't research
- Treating staff are not required to have CITI certification.

#### Research HUD

Even though HUD's are "approved" devices, the sponsor may still want to gather data from the uses of the device in order to support a premarket approval. If this is the case, then the PI should provide a research protocol and research informed consent and HIPAA Authorization. The use in the study may require an IDE. This information should be reviewed and approved by the IRB, and all regular IRB P&Ps should apply. You should refer to the "[eIRB Processing of New Study Applications- Preliminary Analysis through Approval](#)" for next steps.

**Note:** Off-label use of an HUD for *research* purposes requires an IDE. And unless it is an emergency, before an HUD is used off-label *treatment*, the FDA recommends that the HDE holder obtain FDA approval of the use following the compassionate use policy for unapproved devices. IRB approval is also required per our policies and procedures.



## **Continuing Review Submission**

### Non- research HUD

- When a continuing review application is submitted to the Emory IRB, the IRB analyst will screen the information.
- As a part of Continuing Review, the IRB reviewer may request the HDE holder to provide safety information on the HUD provided to the FDA in periodic reports required under 21 CFR Section 814.126(b)(1).
- It is mandatory for the PI to provide a detailed list of each use of the HUD within the previous approval period. Summaries should include a brief description of the patient's condition (with no identifiers), how the device was used, whether or not an information sheet was provided to the patient, and the patient's outcome.
  - The analyst will route the continuing review, as permitted by the FDA regulations, to the clinician IRB Co-Chair for expedited review. The chair will make the decision if the HDE should be reviewed at Full Board instead of expedited review for any reason.
  - The IRB analyst and reviewer should compare the uses made of the device to the approved scope of the HDE/indication.
  - If there is a case where the PI appears to have used the device off-label, without informing the IRB in advance or within 5 days of the use, the analyst in charge of the continuing review should alert the Q team of possible non-compliance (NC).

### Reportable new information submission for NC/UPs and Emergency/Compassionate Use

- Research or non-research HUD
  - The study team should follow Emory IRB's usual reporting P&P for reporting protocol deviations, noncompliance, and unanticipated problems.
  - If the protocol deviation involves an emergency use or compassionate use in a single patient:
    - If the device user is or can be added to the HUD submission, study team should submit an RNI to report this matter. Team Q will send the event to FB using the appropriate emergency use omnibus form.
    - If the device user is not and cannot be on the HUD submission (per the PI choice), the device user must submit a new eIRB application of their own. Please make Team Q aware so they may follow up and take ownership of that submission.
    - A study team can add the new device user to an approved study to avoid a new submission.

*Note: The Emory IRB will not review HUD compassionate/emergency use request for community doctors. If the original HUD PI wants to add this community physician to the submission, this may be allowed. Please contact the IRB Director for more information about this process.*

### Close-Outs

- If the treating physician has use the device in new patients since the last CR approval (to the close-out), he/she should include a detailed list of each use of the HUD within this period. Summaries should include a brief description of the patient's condition (with no identifiers), how the device was used, and the patient's outcome. The close out should be reviewed by a medical vice-chair.
- If the close-out is submitted and the treating physician has not used the device in new patients since the last CR, the close-out can be processed by an analyst.

**REFERENCES**

- 21 CFR Part 812 (investigational devices)
- 21 CFR Part 814 (premarket approval of medical devices)
- 21 CFR Part 860 (device classification procedures);
- 21 CFR Parts 862 –892 (device type classifications)
- IRB policies and procedures

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
1/5/2015	Replaced “should” with “must” to state Chair/Co-Chair <i>must</i> be a clinician; added HUD definition
5/14/2015	Added New Study and Reportable new information submission sections.
6/29/2015	Added close out section and information for template letter.
9/16/2016	Added links to current tools and clarified Emory IRB position on reviewing HUDs for community physicians.
6/14/2020	General updates to clarify process, formatting corrections. Added a link to the HUD checklist.
11/3/2020	Added additional required steps in the review process

<b>SOP Title:</b>	ResearchMatch.org as a recruitment tool
<b>SOP</b>	Study Management
<b>Established:</b>	7/28/2014
<b>Last Revision:</b>	5/14/2015

**PURPOSE**

The purpose of this document is detail the steps necessary to add ResearchMatch.org as a recruitment tool.

**SCOPE**

The SOP applies to all studies that want to add ResearchMatch.org (RM) as a recruitment tool.

**PROCEDURE**

- Emory researcher includes RM template language ([ResearchMatch IRB Protocol Template Language](#)) in the research protocol or, more likely, as an addendum (separate document) to the protocol, uploaded in the “Research Design” section next to the protocol. Alternatively, it can be uploaded as a stand-alone document, along with #2 below, to the “Recruitment and Payment” section of the IRB application form in the question where flyers are uploaded.
- Study team adds the use of RM as a recruitment document in the “Recruitment and Payment” section of the eIRB and adds the RM template language as a stand-alone document (usually the same text as the main recruitment flyer, but with all research contact information removed).
- Emory IRB reviews and approves the submission in eIRB
- Study team follows the [ResearchMatch Registration Instructions](#) to register in RM. A copy of IRB’s approval of the overall study, as well as the text for the recruitment ad, is required. When RM use is being added via Modification, registration with RM should be done after the Modification is approved by the IRB.
- Emory IRB ResearchMatch Liaison receives email from RM.org, alerting them that there is a study pending approval. Emory IRB RM Liaison logs into RM system (IRBEmoryRM/ IRB2010RM), confirms study has IRB approval to use RM as recruitment tool with correct ad content, and sets study expiration date in RM.org.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
10/22/2015	Addition of links for template language and instructions. Modification of Process flow

<b>SOP Title:</b>	Checking Biosafety Approval Status
<b>SOP Category:</b>	Study Management
<b>Established:</b>	5/2/2012
<b>Last Revision:</b>	5/11/2016

**PURPOSE**

The purpose of this document is to describe the procedures to check the status of Biosafety Approval.

**SCOPE**

The SOP applies to all studies that may require Biosafety approval (ex. all recombinant DNA use in humans directly (i.e vaccine) or indirectly (autologous cells sent off for treatment with lentiviral vector and then infused back to patient)).

**RESPONSIBILITIES**

- Biosafety Analyst – review and update the Emory Bio\_Chem Protocol Box. In addition, Biosafety analysts may log a comment in eIRB regarding the status of the Biosafety review.
- IRB Analyst – ensure that all studies needing Biosafety review have obtained the necessary approval.
- IRB Superuser – may be required to provide Biosafety approval in eIRB
- Study team – select Biosafety review as a necessary review in the eIRB Smartform and apply for the necessary approval.

**PROCEDURE**

Once the study team has selected Biosafety as a necessary ancillary review, the IRB analyst should wait for confirmation of the completion of the Biosafety review by either:

- 1) Waiting for a Biosafety analyst to log an approval comment into the study OR
- 2) Review the Biosafety [Emory Box](#) File (Bio\_Chem Protocols)
  - a. Note, only select IRB individuals may have access to this Emory Box file. If you do not have access, you can ask either an Associate or Assistant Director/ Biosafety analyst to provide you access.

If you find that one of your studies has been approved by Biosafety, you can ask a superuser to do the approval in eIRB; likewise if you find out it’s not actually required for a study, a superuser can remove the requirement in eIRB.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
5/11/16	Updating SOP to reflect Biosafety Committee use of Emory Box

<b>SOP Title:</b>	Processing Studies that will use Deception or Incomplete Disclosure
<b>SOP Category:</b>	Study Management
<b>Established:</b>	5/17/2018
<b>Last Revision:</b>	5/17/2018

## **PURPOSE**

The purpose of this document is to outline special considerations when processing studies that will utilize deception or incomplete disclosure. The IRB will determine when certain restrictions apply, and consider the extent to which the deception in a given study interferes with the subject's ability to give informed consent. The IRB will need to distinguish whether "deception" or only "incomplete disclosure" (without deception) is involved, whether there is sufficient justification for use of such measures, and whether there is an appropriate consent and debriefing process in place.

## **SCOPE**

The SOP applies to any study that will utilize deception or incomplete disclosure.

## **RESPONSIBILITIES**

- IRB analyst – Review studies to determine whether deception or incomplete disclosure is included in the research plan.
- IRB Associate or Assistant Director and/or Director- Serve a resource for analysts in cases where appropriate process of review is unclear.

## **DEFINITIONS**

**Deception**-occurs when an investigator gives false information to subjects or intentionally misleads them about some key aspect of the research. Examples include:

- The subject is given a "cover story" which falsely describes the purpose of the study, but provides a feasible account of the researcher's objective.
- Participants complete a quiz and are falsely told that they did poorly, regardless of their performance.
- Participants who don't know they are in a research study are observed to see how they behave when they find valuables (e.g., wallet, laptop) unattended in a public location.
- The study includes a researcher's "confederate," an individual who poses as a participant, but whose behavior in the study is actually part of the researcher's experimental design.

**Incomplete disclosure** -occurs when an investigator withholds information about the specific purpose, nature, or other aspect of the research. Withholding information may or may not be considered deception. Examples include:

- Participants are asked to take a quiz for research, but they are not told the research question involves how background noise affects their ability to concentrate.
- Participants are told they are completing a survey to evaluate customer service when the true purpose of the study is to correlate psychological responses with patient care satisfaction.

**Incomplete disclosure that is also deception.** An example:

- The study involves audiotaping or videotaping of subjects without their knowledge or prior consent.

## **PROCEDURE**

Considerations when triaging studies:

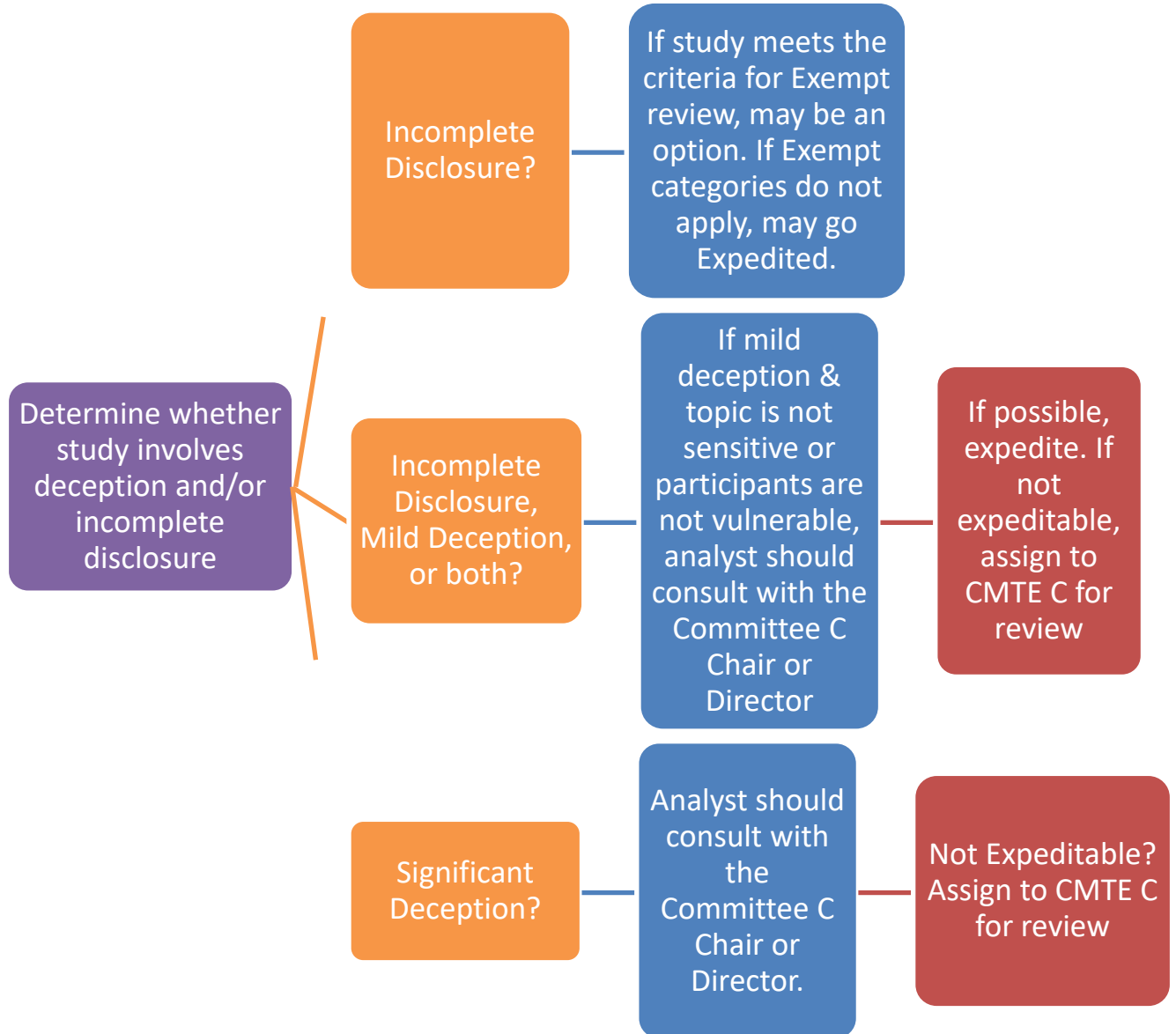
In keeping with federal regulations and ethical codes established by the Belmont Report and the American Psychological Association, the IRB will consider the following criteria when reviewing research involving the use of deception or incomplete disclosure:

- The study must not involve any more than minimal risk to the subjects.
- The use of deceptive techniques must be justified by the study's prospective value AND there should be no reasonable alternative method that would be equally effective (i.e., the researcher must demonstrate that the deception is necessary to conduct the study).
- Prospective subjects must not be deceived about any physical or psychological risks, discomforts, or unpleasant emotional experiences of the study.
- If the study design allows, subjects should be told during the original consent process that some information is being withheld or is incomplete, and that they will receive more information after the research is over. This is sometimes known as "authorized deception" because it provides participants with an opportunity to decide whether or not to participate, knowing that they aren't receiving complete information. However, researchers often believe that even vague references to hidden purposes will affect subjects' behavior and make the study impracticable. Investigators should either add such language to their consent forms when it is possible or note in their protocols why it is not feasible to do so.
- In addition, the research must meet the criteria for a waiver of one or more elements of informed consent.
- Whenever appropriate, researchers should debrief participants. The debriefing should occur as early in the study as the design permits, preferably at the conclusion of a subject's participation, but no later than the conclusion of the research.

**Please note:** Research involving incomplete disclosure but no deception may be reviewed as Exempt. Research employing deception **may not** be reviewed as Exempt under the Pre-2018 Common Rule. Under the Post-2018 Common Rule, such research may be reviewed as Exempt if it otherwise meets the Exemption criteria and the deception is authorized (see [\[§ 46.104 \(d\)\(3\)\(iii\)\]](#)).

Research that involves incomplete disclosure, or that involves mild deception where the topic is not sensitive and the participants are not vulnerable, may be reviewed as Expedited with the discretion of the designated reviewer. Research that involves deception where the topic may be sensitive and/or the participants may be vulnerable should be referred to full board for review, in parallel with consultation with the Committee C Chair in case she determines that the study may receive expedited review. The IRB Analyst should also consult with the Associate or Assistant Director or IRB Director to determine whether Full Board review is appropriate.

## PROCESS FLOW



\*Adapted from University of North Dakota IRB’s ‘Guidance on the Use of Deception or Incomplete Disclosure in Research’

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	Looking Up 'In Case of Injury' Option for Industry-funded Studies via ORA Reporting Export
<b>SOP Category:</b>	Study Management
<b>Established:</b>	3/29/2016
<b>Last Revision:</b>	5/24/2021

## BACKGROUND

The IRB must ensure that the “In Case of Injury” language in the informed consent form(s) is accurate, and for industry-funded studies, the correct language depends on how the contract is negotiated with the Sponsor. The Office of Technology Transfer handles industry contract negotiations, and they allow Sponsors to choose from one of three template options for coverage of research-related injuries (known as Options 1, 2, and 3 – see Emory ICF template for the language). The OTT staff register the negotiated Option in a database, to which IRB staff have access via an Excel report that we can export at any time. This Contracts database export report allows the IRB analyst to learn who among the OTT contracts staff are working on a particular contract, to see what In Case of Injury option was selected (if any), and to check on the status of a research contract when the option isn’t yet registered.

NOTE: the database does not include federal grants; for those, the IRB assumes the In Case of Injury option is “1” (likewise for unfunded or internally-funded studies).

### IF ANALYST DOES NOT HAVE ACCESS TO THE BELOW REPORT:

1. New Staff Training coordinator or IRB Associate or Assistant Director or Director must write to [ora-it@emory.edu](mailto:ora-it@emory.edu) and request access to “Contract

## PROCEDURE

1. Click on [https://oraws2.emory.edu/shared\\_web/secured\\_apps/](https://oraws2.emory.edu/shared_web/secured_apps/)
2. You will be asked to enter your Emory credentials, unless you were previously logged in with Shibboleth:



Network ID

Password

[Forgot Password?](#)

**Login** is Emory's auth applications. If you have contact the University Center at (404) 778-H <http://help.emory.edu>

3. Once logged in, navigate to “IT Resources” tab:



**ORA Web Services - Main Menu** **Logout**

---

ORA | OSP/OGCA | OTT | ORC | IRB | IACUC | COI | EHSO | RAS | **IT Resources** | Request Additional Access | IT Admin |

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**Please Note:** ORA Web Services has been optimized for major browsers that implement non-proprietary HTML standards, this includes most mobile browsers. While parts of the ORA Web Services may function properly on Internet Explorer (IE) and Windows Mobile devices, complete functionality on IE and Windows Mobile devices is not guaranteed nor supported.

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[Click to Modify Display Group Users] Search:

Web Service Name	Description
Five Year Trend Reports	Five year trend analysis of monthly and cumulative reports from the sponsored research database for award information
ORA Kudos	OGCA, OSP and RAS Employee Recognition Program (Kudos Korner)
ORA Standard Reports	Standard monthly and cumulative reports from the sponsored research database for both proposal and award information

4. Click on “ORA Reporting Export” tab:

Web Service Name	Description
<b>ORA Reporting Export</b>	ORA Data Base Exports of OSP Contract Tracking and Award Tracking Databases

5. Click on “OSP Contract Tracking Data Peoplesoft/COMPASS merged data”:

ORA Reporting Bulk Exports

NOTE: These Downloads contain All Data found in the respective Database as retrieved using the applicable View. All Dates are in the format YYYY-MM-DD to facilitate sorting. All Downloads listed are Tab Separated Value spreadsheets with .xls extensions. Excel will try to automatically open them but will prompt you for the separator which should be "Tab" only

Report Data	Description
OSP Contract Tracking Data	OSP Contract Tracking Raw Data, No Calculations, DB Field Names only
<b>OSP Contract Tracking Data - Peoplesoft/COMPASS Merged Data</b>	Merged OSP Contract Tracking and Peoplesoft/COMPASS Raw Data, No Calculations NOTE: Columns with "EU PS" at the beginning of the column name contain Peoplesoft/COMPASS data
OSP Contracts Date First Revision Sent	OSP Contracts Date First Revision Sent - Over 3 business days between Date Received by Contract Group and Date First Revision Sent, sorted by number of days, oldest first.
OSP Contracts Date Fully Executed Notice Sent	OSP Contracts Date Fully Executed Notice Sent - Over 3 business days in between Date Fully Executed and Date Award Notice Sent to DMG
OSP Contracts Date Last Follow Up	OSP Contracts Date Last Follow Up - Over 5 business days since Date Last Follow up
OSP Contracts Date	OSP Contracts Date Negotiations Completed -

6. File will download automatically to the location all your downloads go to, most likely the Download folder.

7. To find Injury Option number:

- Go to “View” tab of MS Excel Ribbon and select “Freeze Panes” and then “Freeze Top Row
- Find the row for the study you are looking for (via EPEX number, study title, etc – EPEX number is easiest)
- Scan over to the columns titled “Subcontract Option 1”, “Subcontract Option

- 2”, and “Subcontract Option 3.”
- If option has been determined, one of those cells will say “Yes” and the other two will say “No.” If all say “No” (the default), then go back to the Status column to see if it says something other than “Completed” – if so, that is why the Option is not yet available. You may be able to see what is going on with the contract more specifically via the Notes column.
8. Communicate the Option Number to the study team for purpose of writing or revising consent form(s).
  9. If you are unable to find the information, you should check the [Master Clinical Trial](#) document. If you still haven’t found an option, you will be required to review our listserv to make sure the information was not already sent via email. If you cannot find it the same day, you are required to put a tickler to receive the email in your inbox. The email will look something like this:

**From:** IRB Departmental List <[IRB-L@LISTSERV.CC.EMORY.EDU](mailto:IRB-L@LISTSERV.CC.EMORY.EDU)> **On Behalf Of**  
[ORAIT\\_NO\\_REPLY@EMORY.EDU](mailto:ORAIT_NO_REPLY@EMORY.EDU)  
**Sent:** Saturday, October 27, 2018 5:00 Mod  
**To:** [IRB-L@LISTSERV.CC.EMORY.EDU](mailto:IRB-L@LISTSERV.CC.EMORY.EDU)  
**Subject:** Corp IRB Options - 4 Record(s) Found

2018-10-27 05:00:05--Started Processing--

2018-10-27 05:00:05--Successfully Found and inserted 4 records into Corp\_IRB\_Options.xls file

Proposal_ID	Title	Investigator	Subcontract Option 1	Subcontract Option 2	Subcontract Option 2 Dollars	Subcontract Option 3	Date Option Update
0000049150	CA204-192:Phase 2 Study of Lenalidomide/Dexam... in Pts. w/R	Kaufman,Jonathan Lyle	YES	NO	-	NO	Oct 26 2018 02:39:45:000PM
0000049164	ADX-503-101:Phase 1/2 Study of ADX-503 w/ Pembrolizumab Pt	Ramalingam,Suresh Sakkarai	NO	YES	-	NO	Oct 26 2018 11:44:10:000AM

0000048727	C1701Phase 2 study of once-daily oral IW 1701 in pts. w/Stab	El Rassi,Fuad	NO	YES	-	NO	Oct 26 2018 11:22:42:000 AM
0000049102	DFCI-17-101:Phase II PACE study for Endocrine ER+HER2 Breast	Meisel,Jane L	YES	NO	-	NO	Oct 26 2018 12:47:36:000P M

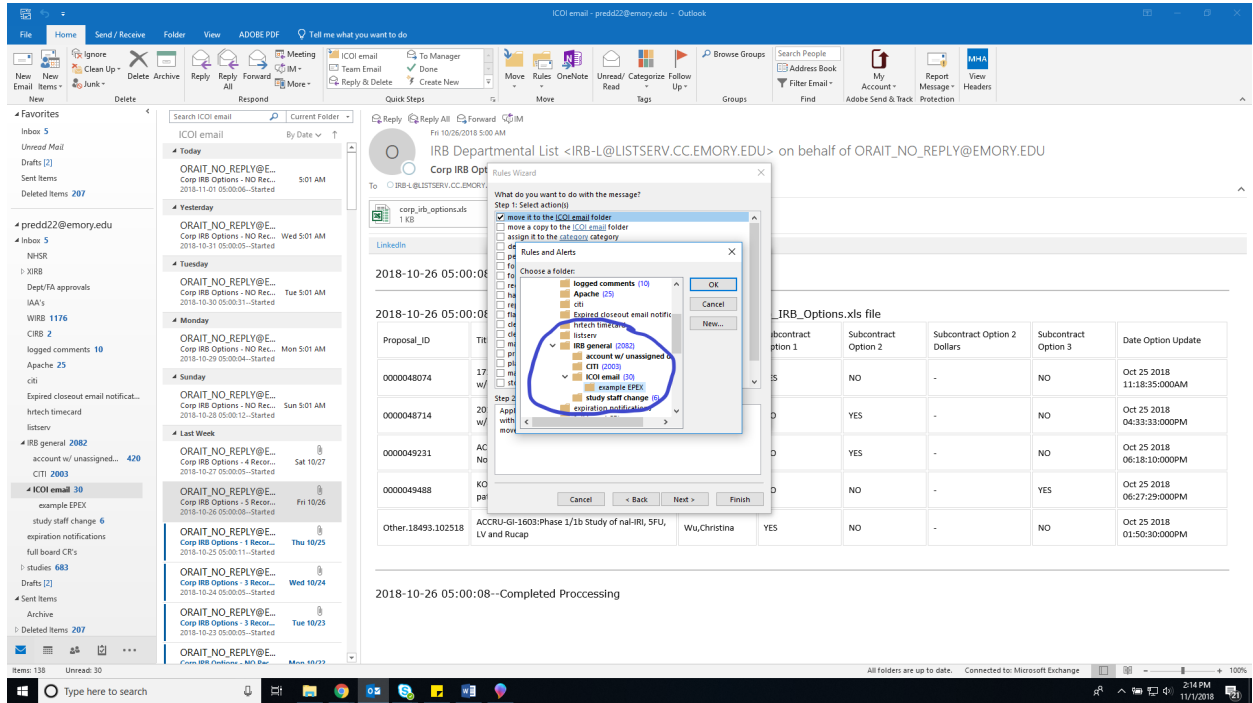
10. To create a rule for a specific EPEX number, to make sure you get this information real time

- Create new folder under listserv folder
- Click on listserv folder, then click “rules” then click “Create new rule”
- Click “Advanced Options”

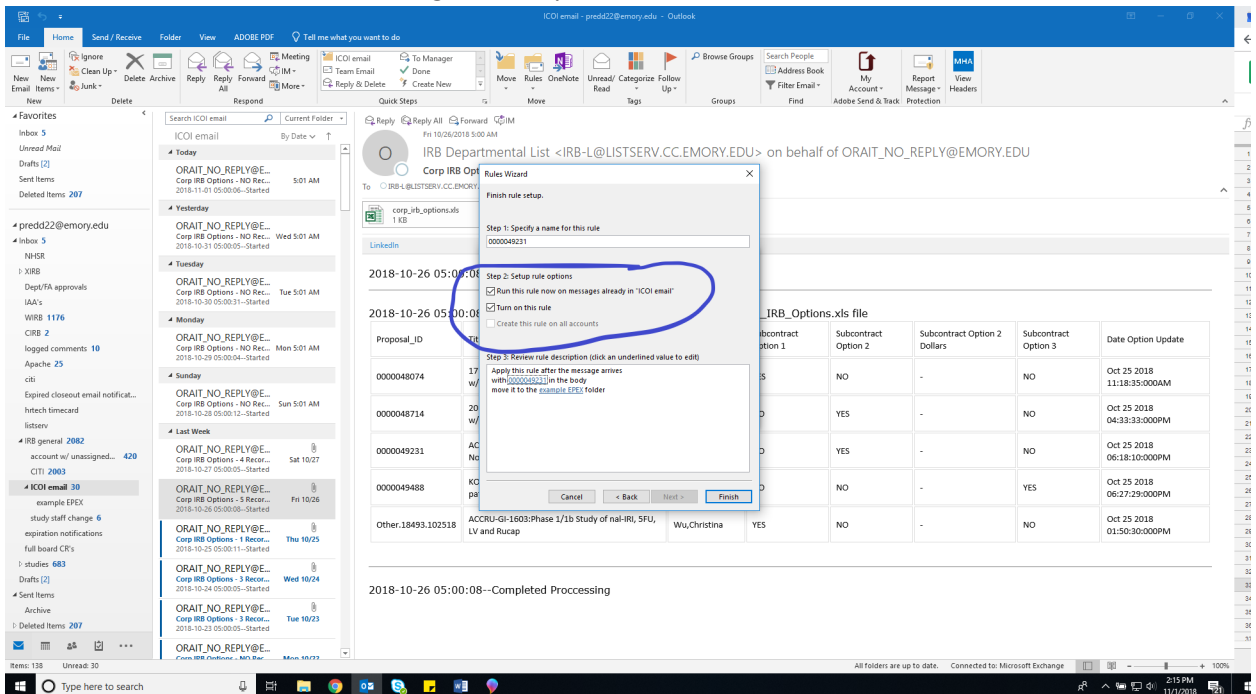
The screenshot shows an Outlook interface. In the background, an email from 'IRB Departmental List <IRB-L@LISTSERV.CC.EMORY.EDU>' is open. Below the email header is a table with columns 'Proposal\_ID', 'Title', and 'Status'. The table contains several rows of data, including EPEX numbers like 0000048074, 0000048714, 0000049231, 0000049488, and 0000049518. A 'Rules Wizard' dialog box is overlaid on the email, showing 'Step 1: Select condition(s)'. The condition 'with specific words in the body' is selected. Below the conditions is 'Step 2: Edit the rule description (click an underlined value)', which contains the text 'Apply this rule after the message arrives with specific words in the body'. The dialog box has 'Next >' and 'Finish' buttons.

- Select “with specific words in the body”

- Click on “specific words” in box below the large list of selections
- Enter the EPEX number, click Add, then click OK
- Click Next
- Select “move it to the \_\_\_\_\_ folder”



- Click Next
- Select “run this rule now on messages already in “listserv folder”



**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
11/1/2018	Change graphic in step 5. Added information about expectation if the ICOI is not in the report when run
1/18/2019	Added step of checking Master Clinical Trial Agreement page.
4/11/2019	Adding instructions of how to set up a rule in outlook for specific EPEX numbers
5/24/2021	Added link to the document as it is no longer hosted on the OCR website

<b>SOP Title:</b>	St. Joseph and John's Creek study site process
<b>SOP Category:</b>	Study Management
<b>Established:</b>	11/27/2013
<b>Last Revision:</b>	1/31/2018

## PURPOSE

The purpose of this document is detailing the steps for handling a study submission including or adding John's Creek and/or St. Joseph (SJHC) as a study site in order to ensure compliance with institutional requirements and ethical and religious directives (ERDs). Per an MOU (created when EHC, St. Joseph's, and Johns Creek became partially owned by a Joint Operating Company [JOC]), Emory IRB is the IRB of record for any studies involving Emory or Emory Healthcare personnel, that have St. Joseph's or Johns Creek as study sites. EHC has set up an Emory Clinic (TEC) location in leased space on the St. Joseph's campus; research studies might take place there, or at the actual hospitals, or both. St. Joseph's does not have an IRB or Research Oversight Committee anymore. Rebecca Heitkam will review protocols and consents to verify compliance with ERDs.

## SCOPE

The SOP applies to all new studies and Modifications including St. Joseph and/ or John's Creek as a study site (other than chart reviews and clinical trials/research conducted at other Emory sites (e.g. EUH) but isolated diagnostic services performed at ESJH for research purposes due to patient convenience or equipment availability).

## DEFINITIONS

- ERDs - [Ethical and Religious Directives](#) for Catholic Health Care Services
- SJHC - St. Joseph Healthcare

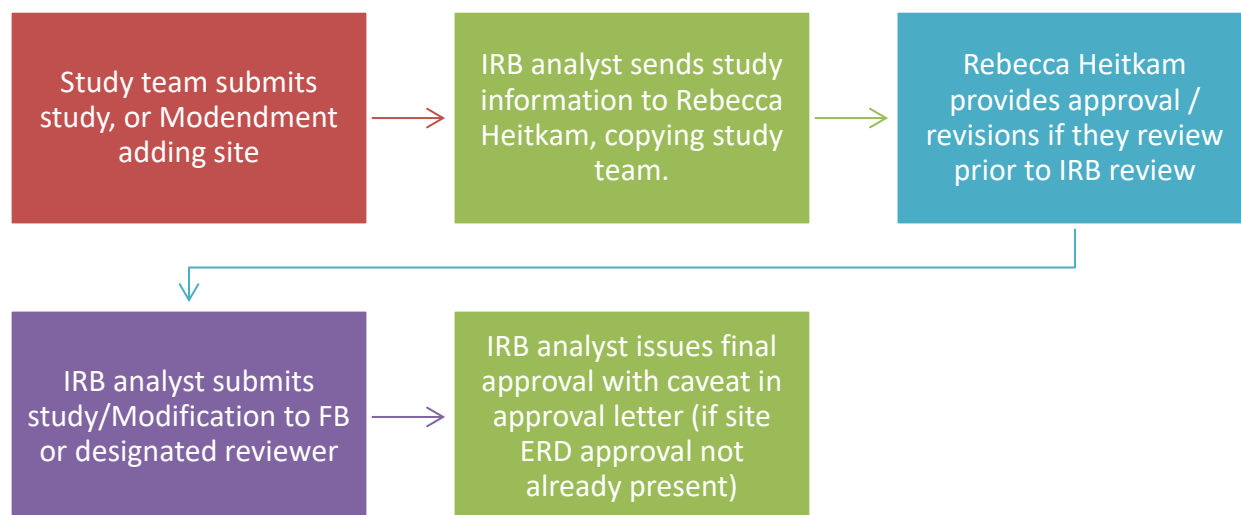
## PROCEDURE

IRB Analyst:

- 1) Review the eIRB submission overall for mention of St. Joseph and/ or John's Creek as a location where study activities will take place.
  - a. Confirm that Emory St. Joseph/Emory Johns Creek is selected as a study site in the Smartform
  - b. Leased space (i.e. TEC) should be reflected using the "other" site selection as well (*See appendix 1 for an example*)
    - i. Confirm with study team whether activities will take place in leased space or not.
  - c. Advise the team (when requesting changes) that they will need at least one physician on the study team is credentialed to practice at SJHC (or Johns Creek, as applicable).
- 2) Determine if SJHC local context (ERD's and credentialing) review is required. If not, the rest of this SOP does not apply
  - a. Chart reviews do not require ERDs review.
  - b. Clinical trials/research conducted at other Emory sites (e.g. EUH) but isolated diagnostic services performed at ESJH for research purposes due to patient convenience or equipment availability do not require ERDs review, though the informed consent should include information about where study procedures will or may take place.
    - c. All other studies taking place at SJHC, TEC at SJHC or Emory Johns Creek require ERD review

- 3) Email the [Rebecca](#) Heitkam (rebecca.heitkam@emoryhealthcare.org) a copy of the study protocol and consent forms. *(See appendix 2 for an example)*
  - a. For an expedited study, email when the study is assigned to you
  - b. For a full board study, email once the study is assigned to a committee. Include the meeting date and a reminder that there still may be changes required by the IRB.
- 4) Confirm that the study used the proper consent form template if St. Joseph/ Johns Creek are engaged.
  - a. Studies taking place only at the St. Joseph’s leased space (TEC) do not need a St. Joseph’s template, as St. Joseph’s is not considered to be “engaged” in that scenario. Note: ERD review is still required, therefore pregnancy prevention language needs to align with their requirements.
  - b. Ensure that the correct terminology for “birth control” is used, per our template, and that no specific birth control methods other than abstinence are listed (e.g. no mention of birth control pills, condoms, etc).
- 5) If SJHC local context approval is not in place (per logged comment from study team) prior to IRB approval of the study or Modification, process IRB approval as usual but add caveat to approval letter stating “Note: No research-related activities may begin at the [St. Joseph’s/Johns Creek] site(s) until the site ERD approval is received from Rebecca Heitkam or her designee. Any changes required by the site must be submitted to the Emory IRB via an (other) Modification.
- 6) Once ERDs approval is received, the analyst will log the information as a comment to study team.

## PROCESS FLOW



## Appendix 1

### Study Sites

- A site is where recruitment will occur
- A site is where the research will take place

- A site is data collection will take place
- A site is where data analysis will take place
- A site is where data will be stored

**1.0 \* Indicate all locations where the Emory Investigator will conduct this study:**

Emory Children's Center  
 Emory Clinic  
**Emory St. Joseph's Hospital**  
 Emory University Hospital Clinical Research Network  
 Winship Cancer Institute  
 Other - In Atlanta metropolitan area

**2.0 If "Other - ", list all other locations where the Emory Investigator will conduct the study:**

Name of the Site	IRB of record for this site
<b>TEC at St. Joseph</b>	

**Appendix 2**

**For expedited studies:**

Hello Ms. Heitkam,  
IRB0000XXX, a new study/Modification, has listed St. Joseph/John's Creek as a study site. Please advise the study team when your approval is granted, replying all to this email

**For Full Board Studies:**

Hello Ms. Heitkam,  
IRB0000XXX has listed St. Joseph/John's Creek as a study site. The study is currently assigned to a committee meeting on X/X/201X. Please note that the committee may request changes to the study. Please advise the study team when your approval is granted, replying all to this email.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
10/14/2021	Added clarification on language requirements even in TEC context & archived log of updates older than 1 year

<b>SOP Title:</b>	REMS study review
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<b>SOP Category:</b>	Study Management
<b>Established:</b>	1/31/2018
<b>Last Revision:</b>	4/11/2019

## **PURPOSE**

The purpose of this document is to explain the process an IRB analyst will follow when reviewing a study under Approved Risk Evaluation and Mitigation Strategies (REMS) requirements.

## **SCOPE**

The SOP applies to studies either reviewed by the Emory IRB or at Emory reviewed by an external IRB under REMS requirements.

## **RESPONSIBILITIES**

- IRB analyst – reviews protocol to identify if drug or biologic is under REMS program & confirms ODP review
- IRB Associate or Assistant Director or Director- initial review of protocol to identify if drug or biologic is under REMS program & flags study as one under REMS
- Office of Compliance Designated Person (ODP)- confirms that protocol/ICF is in compliance with REMS requirements

## **PROCEDURE FOR NEW STUDIES REVIEWED BY THE EMORY IRB**

1. Study will be assigned by IRB Director/designee, indicating that the study is under REMS requirements. It is possible that an analyst will receive a study that was not flagged; in those cases, the analyst should verify with a TL or IRB Director
2. The analyst will contact the ODP and direct the study team to fill out the REMS Investigator Checklist.
3. The ODP will verify that the study protocol and informed consent include all the requirements for that drug under REMS. That information can be found at this [FDA website](#)
4. When the information is complete, the ODP will log a comment under the study history indicating that the REMS requirements are met in the submitted protocol and informed consent
5. The IRB analyst may send the study to full board (FB), before this process is completed. If the ODP review has not been completed before the IRB meeting, the analyst should complete omnibus form accordingly.
6. When forwarding the study for FB review, the analyst will add to the agenda items notes that the study is under REMS requirements.
7. After the study is approved, the approval letter should include the following language:  
“This study utilizes a drug(s) under FDA required REMS. You must ensure your study remains compliant with current requirements as listed in the “REMS Document” and the protocol/informed consent document”

## **PROCEDURE FOR STUDIES REVIEWED BY AN EXTERNAL IRB**

- Follow same steps from 1 to 4 as above.
- The study will not be given an institutional signoff until the REMS requirements are verified.

## **PROCEDURE FOR MODIFICATIONS REVIEWED BY THE EMORY IRB**

1. If the Mod adds a new drug under REMS requirements, follow steps as detailed before, letting the ODP know, and making sure the ODP has reviewed the checklist. The Mod may be placed on FB agenda prior to completion, making sure the omnibus form reflect that this process is still pending.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
2/21/2018	Added process for Mods
4/11/2019	Clarified that REMS process applies to research at Emory or reviewed by our IRB

<b>SOP Title:</b>	Prisoner Studies: Handling of New/Modification/Renewal Submissions when Prisoners are Subjects (Application of Subpart C)
<b>SOP Category:</b>	Study Management
<b>Established:</b>	10/17/2016
<b>Last Revision:</b>	10/14/2021

## **PURPOSE**

The purpose of this document is to describe the review process of new study submissions, continuing reviews, and Modifications by the IRB analyst and prisoner representatives when research involves Prisoners.

## **SCOPE**

This applies to all IRB staff.

## **DEFINITION**

**Prisoner:** an individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial (45 CFR46.303).

## **Important Notes**

- One member of the Emory IRB shall be a Prisoner or a Prisoner Representative. A Prisoner Representative is defined as an IRB member who has appropriate background and experience that includes a close working knowledge, understanding and appreciation of prison conditions from the Prisoner's perspective.
- The fact that the Emory IRB meets the compositional requirements for the review of a Research protocol involving Prisoners will be documented in the meeting minutes at which the Research protocol is reviewed.
- When a prisoner representative completes a review, please contact Carol Corkran, so she can process payments.

## **PROCEDURE**

### **RESEARCH PROTOCOLS THAT *INITIALLY* PLAN TO INCLUDE PRISONERS AS HUMAN SUBJECTS:**

*Note: If a study intends to enroll both prisoners and non-prisoners, and is federally funded (thus requires OHRP certification for involvement of prisoners), study team may be advised to consider omitting Prisoners as a study population at initial submission, and add them via Modification after initial IRB approval is in place, depending on how urgently they wish to begin. This would enable them to begin enrolling non-prisoners immediately.*

### **FEDERALY FUNDED STUDIES**

If the study is federally funded, we need to obtain OHRP certification of subpart C findings before final approval. This means that:

- For expedited studies, you cannot send to a DR until you receive the OHRP certification
- For full board studies, you can put in a FB agenda, but the study has to be pending approval until we receive the OHRP certification

**Exempt studies:**

Not Applicable - Research involving prisoners cannot be reviewed as exempt, **except** for research aimed at involving a broader subject population that only incidentally includes prisoners.

**Expedited new studies:**

- IRB analyst should complete the top portion of the Subpart C Worksheet, and highlight the portion to be completed by the prisoner representative. The IRB analyst should email the prisoner representative to provide their comments and complete the Subpart C Worksheet, as needed. Send the study link in the email. The prisoner rep should document their findings (if any) and upload the worksheet via a private comment. Alternatively, the prisoner rep can email this information to the IRB analyst. This email with the completed worksheet should be logged as a private comment in the study history.
- After this is completed, IRB analyst should send the study to a primary designated reviewer via eIRB. Please alert the primary designated reviewer that the application has been reviewed by the prisoner representative, and if any changes the prisoner rep required.
- Once the primary designated reviewer has completed his/her review, and any requested changes have been made by the study team (including the ones required by the prisoner rep), IRB analyst should send the changes back to the prisoner rep to verify their completion. The study should be sent to the designated reviewer so they can review the adequacy of the changes.
- IRB analyst should upload the completed Subpart C Worksheet using the “Edit Pre-review” function, under question 7 (add supporting documents), so it becomes part of the permanent record.
- **IRB analyst documents Subpart C category in the approval letter.**
- If the study is federally funded, IRB analyst must draft a letter certifying the Subpart C Category findings to OHRP
  - The letter should be drafted for the IRB Director to review (may be reviewed by Associate or Assistant Director in Director’s absence).
  - The OHRP letter will require verification of the Grant number – may be requested from the study team if not in eIRB.
  - A sample OHRP letter can be found at H:\General\Subpart C OHRP Cert

**Expedited new studies not involving interactions with prisoners (i.e. involve only existing data or record reviews):**

Per OHRP, AARHPP, and Emory IRB P&Ps, review by the prisoner representative is not required for minimal risk studies that do not involve interactions with prisoners.

**Full Board new studies**

- For a new study, the prisoner representative must be present, either in-person or by speakerphone, at any meeting of the Emory IRB for FULL Board review of new research protocols involving

Prisoners and Modifications adding Prisoners. Inform the meeting Pod that a prisoner representative is needed for the meeting.

- If a continuing review, IRB analyst must document the participation of the prisoner representative in the review, but the prisoner representative does not have to be present for the full board review of the application.
- If a Modification alters risks/benefits/involvement of Prisoner subjects, the information should be reviewed at the full board. If a Modification is not altering the above, then the information can be reviewed expedited.
- For new studies, or Modifications adding Prisoners as a subject population for the first time (see the following section for more details on the latter case):
  - IRB analyst should pre-fill the Subpart C Worksheet to be filled out at the meeting.
  - After the meeting, IRB analyst should save the Subpart C Worksheet in the Research Design section of the Smart form.
  - IRB analyst needs to document Subpart C category in the approval letter. Final approval should not be granted for federally funded Subpart C studies until we have received confirmation from OHRP about the certification of the Subpart C findings.
  - If the study is federally funded, IRB analyst must draft a prisoner certification letter to OHRP
  - The letter should be drafted for the IRB Director to review (may be reviewed by Associate or Assistant Director in Director's absence).
  - The OHRP letter will require verification of the Grant number – may be requested from study team if not in eIRB.
  - A sample OHRP letter can be found at H:\General\Subpart C OHRP Cert

#### **Continuing Reviews:**

Continuing reviews for studies that required a prisoner representative review must also be reviewed by a prisoner representative. For full board studies, the representative must attend or call in for the review of the renewal. Expedited renewals may use the reviewer assignment procedure listed under “Expedited new studies” above.

#### **Modifications:**

- Any Modifications that are changes to the research require prisoner representative review if such review was required initially.
- Any Modifications that are purely administrative and would not be considered changes to the research requiring IRB review, per OHRP, may be reviewed without a prisoner representative's input.

#### **IF A PARTICIPANT BECOMES A PRISONER WHILE ENROLLED IN A RESEARCH STUDY THAT HAS NOT BEEN REVIEWED ACCORDING TO SUBPART C**

- The study team must immediately notify the IRB (via Modification or other communication) that a participant has become a prisoner, the IRB shall confirm that the participant meets the definition of a “Prisoner.”
- The IRB shall ensure that either:
  - The PI terminates enrollment of the subject OR

- If it is feasible for the participant to remain in the study, cease any research activities until the IRB reviews the research under Subpart C (following the steps outlined above) or not if it meets the “Non-DHHS” criteria per the P&Ps.
- Review the Modification and make one of the following findings:
  - The study is neither DHHS-funded nor considered VA Research, and the “Non-DHHS” criteria below are met, OR
  - The research meets the criteria set forth in Subpart C of the Common Rule. The PI must provide written documentation if he/she feels there are special circumstances that justify why research activities should continue while the IRB reviews the research under Subpart C. The special circumstance should be reviewed by a Vice-Chair.

Non-DHHS Criteria:

- The research is NOT conducted or funded by DHHS or Veterans Administration (VA).
- The subject was not incarcerated at the time of enrollment, and subsequent incarceration was unexpected.
- The incarceration does not put the rights and wellbeing of the subject in jeopardy with respect to the study.
- The prisoner representative has been consulted.
- The terms of the subject’s confinement do not inhibit the ethical conduct of the research.
- There are no other significant issues preventing the research from continuing as approved.
- This approval is limited to the individual subject and does not allow the recruitment of prisoners.
- One of the following is true:
  - The subject will be at increased risk of harm if withdrawn from the research
  - The research presents no more than Minimal Risk and no more than an inconvenience to the subjects

For DHHS-Regulated Research:

The research shall be reviewed per Subpart C

- If some requirements of Subpart C cannot be met:
  - If it is in the best interests of the subject to remain in the study, the subject shall remain enrolled and the IRB shall inform OHRP of the decision along with the justification.
  - Otherwise, the IRB shall advise the PI to remove the participant from the study and to keep the participant on the study intervention under an alternate mechanism as necessary.
- When considering whether to terminate enrollment, the IRB/PI should consider the risks associated with termination of the subject in the study.
  - If the participant cannot be terminated for health or safety reasons, the IRB should advise the PI to keep the subject enrolled in the study and it shall review the research under Subpart C.
  - If some requirements of Subpart C can’t be met, but it’s in the best interest of subject to remain in the study, the subject shall remain enrolled and IRB shall inform OHRP of the decision along with the justification.
  - The IRB shall advise the PI to remove the participant from the study and to keep the participant on the study intervention under an alternate mechanism as necessary.
  - If a participant is incarcerated temporarily while enrolled in a study, and if that incarceration has no effect on the study, the participant shall remain enrolled.

- If the temporary incarceration has an effect on the study, the IRB shall handle the case according to the case set forth above.
- Note: An adolescent (e.g., age 14) detained in a juvenile detention facility is a prisoner therefore; the IRB would need to comply with Subpart C and Subpart D – Children.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
10/14/2021	Replaced Julie's name with Carol in the payment section and archived log of updates over 1 year old

<b>SOP Title:</b>	VA Studies with non-VA Sites – IRB Submission Requirements
<b>SOP Category:</b>	Study Management
<b>Established:</b>	4/11/2019
<b>Last Revision:</b>	4/11/2019

## **PURPOSE**

The purpose of this document is to describe the additional IRB submission requirements for study where the sites include both the Atlanta VA and Emory University or its affiliates, without a PI credentialed at both sites.

## **SCOPE**

The SOP applies to studies with both a site at the Atlanta VA and a site at Emory University or its affiliates, without a PI credentialed at both sites.

## **RESPONSIBILITIES**

- **VA liaison:** IRB analyst in charge of guiding teams through the process of submitting a VA study via the eIRB system
- **Study team:** in charge of making revisions to their submissions and to follow the VA liaison instructions
- **IRB Director:** receives notification from VA liaison and assigns non-VA version of study to RPA with additional instructions
- **Emory RPA:** collaborates with the VA liaison to make sure that both studies are reviewed at the same meeting, if possible

## **PROCEDURE**

- If consulted before approval, the VA liaison will let study teams know that the PI of a study taking place at the Atlanta VA must be credentialed at the VA. If the overall study PI is not so credentialed at VA, there must be a separate VA credentialed PI (local site investigator) for the VA site. In general a separate eIRB submission is preferred for that PI/site; however, if the VA credentialed PI is listed on the grant application and the data is to be combined as part of a collaborative project, an exception can be requested through the VA Research Office and the IRB Director.
- If the VA liaison is assigned a study that, despite the above, takes place at both VA and non-VA sites, and indicates that there two separate PI's, (for example, via listing different PI names in the consent forms) or has a single PI who is not credentialed to serve at the Atlanta VA, he will log the following as a comment in the study history:
  - "Dear study team: My name is X and I will be conducting the initial review of your study. I noticed that this study has [non-VA site(s)] and the Atlanta VA as sites, but does not have a PI credentialed to conduct research at both sites. If this is correct, we require that you submit separate submissions for each site, as the Atlanta VA requires a PI with valid VA credentials. Please confirm if this is your case, and provide the name of the person serving as PI at the VA, and a research coordinator. To prevent additional work on your part, we will clone the study and provide it to you in "pre-submission" status so it can be submitted to the correct department head right away. Make sure you specify in the protocol the work that will be done at each site, so it is clear for both submissions. In the event that this is a collaborative study and you wish to continue with one IRB submission, you will need to request a consult with the VA Human



Research Protection Group. The Group will discuss with the IRB you request and make a determination if the systems are in place to properly manage this as one IRB submission. Let us know if you have any questions”.

- In the event that the study requires two submissions, and after obtaining the names for the PI and coordinator for the VA site, the VA liaison will do the following:
  - Click on “clone study”. The system will ask for a name and they should name the study “Emory-CURRENT\_STUDY\_NAME”.
  - Locate the newly created study. You can locate the newly created study by searching for the short title under the Projects tab using the name assigned to the new study.
  - Once you navigate to the newly created study, click on “Admin View”
  - Put the study back in “Pre-submission” under “Status”, and change the name of the study PI and coordinator.
  - Log a comment in the new study indicating that this study should be reviewed concurrently with the VA version of the study (provide IRB study number)
  - Once the study is submitted to the IRB, the IRB Director will let the new study’s RPA know that this study is similar to one submitted for the VA, and instruct the RPA to communicate with the VA Liaison.
- The RPA will let the VA liaison know the Emory study has been submitted, and to ask him which meeting will review the VA study, if already known, and attempt to assign it to the same meeting. If not already assigned, RPA and VA Liaison should work together to have the studies reviewed at the same future meeting., with Agenda Notes indicating that they are the same protocol at two different sites

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES

<b>SOP Title:</b>	Determinations and Reviews by IRB Staff
<b>SOP Category:</b>	Study Management
<b>Established:</b>	6/26/2012
<b>Last Revision:</b>	2/1/2019

## **PURPOSE**

To detail the type of determinations and reviews that can be made by a qualified IRB staff. The IRB Director shall decide when IRB staff is qualified, based on length of experience and demonstrated expertise.

## **SCOPE**

New studies, continuing reviews, and Modifications submitted to the IRB office for review.

## **PROCEDURES**

Reviews Permitted by IRB Staff (without involving an IRB member):

1. Determining whether a study qualifies as research involving human subjects (NR/NHSR)
2. Determining whether a study should be reviewed as Exempt
3. Approving Exempt reviews that do not involve HIPAA Privacy Rule waivers or authorizations. Only staff authorized by the IRB Director to approve exempt studies can do so. For more information about exempt research that can be reviewed by staff or staff designated reviewers, review [this guidance](#).
  - a. Modifications: similar to new exempt study submissions, Modifications submitted for exempt studies can be reviewed only by staff authorized by the IRB Director to approve exempt studies.
4. Approving certain minor administrative changes.
5. Approving an Modification submitted only to transition a study to the Revised Common Rule-no other changes requested. If the Modification is also updating the consent form to align with the new elements in the Revised Common Rule, that Modification should be reviewed by an IRB member (staff or faculty member).

**Minor Administrative Changes:** Some minor administrative changes may be approved by qualified IRB staff. These changes are exclusively limited to the following:

- Change of contact information
- Addition or deletion of junior level personnel (not co-investigator, principal investigators)
- Addition of co-investigator
- Addition or removal of co-investigator for minimal risk studies
- Title change that does not reflect a change in study
- Corrections of typographical errors
- Reformatting of unchanged text
- Errors in completion of the IRB application, as confirmed with study staff as appropriate (as long as the study was initially reviewed with the correct impression)
- Removal of study sites that were never activated
- Change of funding status from “pending” to “approved” (if federal grant application was previously approved as pending by the IRB, and it is not a new funding source)

**REFERENCES**

- Emory IRB P&Ps, chapter 28 (IRB Protocol Triage and Assignment of Review Category)
- Emory IRB P&Ps, chapter 30 (Exempt Research)
- Emory IRB P&Ps, chapter 40 [Protocol Modifications (Modifications)]

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
5/14/2015	Added a Purpose and Scope sections.
9/16/2016	Added P&P reference
5/5/2017	Clarified the type of changes in funding staff can approve
1/20/2019	Adding that staff can review Mod only requesting the transition of a study to the Revised Common Rule if it does not include any other changes but the transition.
2/1/2019	Added that Mod to exempt studies can be reviewed by staff authorized by the IRB Director

<b>SOP Title:</b>	Categories of Research Reviewable by IRB Staff as IRB Designated Members
<b>SOP Category:</b>	Study Management
<b>Established:</b>	3/29/2013
<b>Last Revision:</b>	6/14/2020

**Background/Policy:** IRB Staff can perform reviews within the scope described below only if they are appointed as IRB members, and have been designated by an IRB Chair as authorized to perform expedited reviews.

Note that all IRB staff, including those appointed as IRB members, can review minor administrative changes as described in the IRB Policies and Procedures, “Modifications” chapter, and the SOP entitled “Determinations and Reviews by IRB Staff”.

#### **A. NEW STUDIES**

1. Minimal risk expeditable studies involving only the following:
  - a. F (5) (e.g. chart reviews or specimen analyses, whether retrospective or prospective)
  - b. F (7), but only as a last resort when faculty DRs are particularly busy or unavailable. Before such an assignment can occur, the study analyst should consult a TL or Director to make sure there are no other available reviewers to help. In addition, the staff DR should have enough expertise to be comfortable with such reviews.  
*If staff IRB member is not comfortable with children populations or sensitive studies, forward to faculty DR.*
2. Exempt Studies: Staff designated reviewers can review all exempt categories except D2 (iii) if the study involves sensitive information or international sites. Sensitive information examples include the use of illicit drugs, mental health issues, sexual preferences, or research that could put participants at any risk of liability (e.g. criminal activities, studies affecting employability, studies conducted at abortion clinics, needle exchange or distribution). **Remember:** Do not use D4 for chart reviews because our HIPAA policy does not cover these type of studies. Use F (5) instead. Also, if you feel uncomfortable reviewing any exempt category, feel free to consult an IRB faculty member or forward the review to them. For more information about exempt research that can be reviewed by staff or staff designated reviewers, review [this guidance](#).
3. Contingency reviews (full board and expedited studies):
  - a. ICF revisions as specifically requested by IRB Committee
  - b. Smartform revisions as specifically requested by IRB Committee
  - c. Confirmation of full board’s stated assumption (i.e. not new information from study staff)

Note that all IRB staff can do contingency reviews for Cost and In Case of Injury options, as well as ancillary committee approvals where no changes were required.

#### **B. MODIFICATIONS**

1. Changes of any kind to studies that Staff DR could have approved at initial review (see the section above), unless the changes move the study outside that scope. For example, F5 studies, moving to other review categories due to the addition of procedures.
2. Changes to informed consent that are made solely to update template language
3. Changes to PI on *minimal risk studies where the PI is NOT the IND/IDE holder*

4. Deletion of Co-Investigators on more-than-minimal risk studies
  - a. Deletion of Co-investigators: inquire about the replacement of expertise
5. Updates of other documents insofar as they are needed to reflect changes 2-4 above
6. Change to ICF, protocol, or other study documents that are limited to corrections or factual updates (i.e. no changes to protocol risk, benefit, design; not clarifications to parts of the protocol that were not clear); simplification for lay-friendlier language, or reflecting completion of a pending issue the IRB knew was in process (such as Cert of Confidentiality, funding). (See “Minor Administrative Changes” list in Emory IRB P&Ps for a subset of corrections/factual/administrative updates that all IRB staff may review.)
7. Use of electronic informed consent when:
  - a. Obtaining an electronic signature using an Emory LITS approved method, if the consent content was already approved by a faculty designated reviewer or the IRB Full board.
  - b. Obtaining verbal consent, when the verbal consent content and verbal consent process has been already approved by a faculty designated reviewer
8. Adding funding sources (but not delete them)
9. Adding Emory-affiliated sites (includes EHC, CHOA if not also adding minors for the first time, St Joseph’s/Johns Creek, Grady)
10. Expeditable increase or decrease of N if the same type of population already approved, OR to allow more consents/screen failures - both on MIN RISK studies only (P&Ps say what levels of increase are expeditable). If new population or more than min risk, send to faculty.
11. Changes in data collection instruments (questionnaires, surveys, chart abstraction forms, CRFs) as long as expertise is not needed to assess risk-level change
12. Advertisements and other recruiting materials
13. Retention materials, newsletters, blasts, reminder cards, health tips related to the disease being studied, participant alert cards, other miscellaneous items that do not involve changes to compensation,
14. Sensitive study determination requests, if not done when the application was initially submitted
15. Translated versions of approved documents, requests to enroll non-English speaking subjects, and the addition of Short Form consents in other languages if the population to be studied (for example, patients with leukemia) are the same.

**C. CONTINUING REVIEWS**

1. All chart reviews, secondary data analyses, and research on existing specimens - F(5)
2. All F(7)
3. Data analysis only (DAO):
  - a. For full board studies (i.e. F8c) – but not the first year that study has entered DAO stage. Those should go to faculty reviewer because there may have been significant new information in the past year before subject interaction ended.
  - b. For all other categories of expedited studies with no restriction on how long the study has been in DAO.

**D. REPORTABLE NEW INFORMATION SUBMISSIONS**

1. Acknowledgments per Associate or Assistant Director review (based on Emory IRB P&Ps)
2. Finalizing decisions made by Compliance Review team or chairs (document)

**STAFF DRS REVIEWING THEIR OWN ITEMS:**

- **CAN review their own:**
  - Continuing Reviews and Modifications that would fall under “minor administrative changes” per P&Ps
  - Truly retrospective F(5) new studies
- **CANNOT review their own:**
  - Exempt studies (need to obtain a second opinion on exempt status)
  - Prospective F(5) new studies (need to get a second opinion on consent/HIPAA waivers)

*In general, all staff should consider the benefit of sending other Modifications to another reviewer but may use their own judgment.*

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
2/11/2015	Clarified when staff DRs should send their own submissions to others instead of reviewing for themselves (end of SOP), clarified what kinds of “data analysis only” Staff DRs can handle (now includes all expeditable studies as well, not just F8c).
2/18/2015	Clarified what Data Analysis Only renewal reviews can be done by staff DR
4/2/2015	Added that Staff DR can approve new Emory-affil study sites. Also CR’s F(5) applies to secondary data analysis in general, not just retro chart reviews. Also reworded Mod’s for increase N to make clearer.
2/18/2015	Changed title (Designated REVIEWERS, instead of Designated MEMBERS) and added Background/Policy. Clarified Modifications section. Removed any listing of items that all IRB staff can actually review. Can now review adding Grady as site. Took off items that actually all IRB staff can approve (minor admin changes).
9/16/2016	Minor corrections
12/20/2016	Clarified that Staff DR’s can review all expedited studies in Data Analysis Only (had been stated already, but not clearly)
1/20/2019	Added information for Exempt Categories review-Revised Common Rule
2/1/2019	Provided more clarification about exempt category review, specifically studies that should be sent to a faculty reviewer instead than to a staff member.
6/14/2020	Adding that staff DRs can approve the use of eConsent in studies, as long as the consent content or consent process (in the case of verbal consent) has been previously approved by the FB or faculty DR

<b>SOP Title:</b>	Assigning New Studies to IRB Analysts
<b>SOP Category:</b>	
<b>Established:</b>	
<b>Last Revision:</b>	02/24/2023

## PURPOSE

The purpose of this document is to detail the steps to follow to assign a new submitted study to an IRB analyst.

## SCOPE

The SOP applies to studies submitted to the Emory IRB.

## ROLES AND RESPONSIBILITIES

Senior RPAs, Assistant/Associate Directors, and Director/AVP – Assign new studies from IRB Inbox to IRB analysts on assigned days. When absent, arrange for others to cover assignments on their day.

## PROCEDURE

- Open current “New Study Assignments [Year]” spreadsheet in [OneDrive](#)
  - Before starting Monday assignments:
    - Create new tab on spreadsheet for the current week by copying the previous week’s spreadsheet, renaming it, and deleting data and formatting from columns A-E.
    - Fill in the “Status” column to note who is on vacation, running a meeting, etc.
    - Copy and paste (Paste *Values* only) the number of study assignments from the prior week’s tab into the “New studies assigned last week” column of the new tab, for all analysts.
    - If new staff have joined the IRB or any other technical questions arise about the spreadsheet: Ask Rebecca
  - Go to “My Inbox” in eIRB, and filter the studies using the following filters:
    - ID: “Study”
    - State: “Pre-review”
    - Sort by “Date Modified”
    - Only work on studies that have no IRB Coordinator listed yet.
  - A shift is from 4:00 pm the day before your scheduled day through 3:59 pm on your scheduled day. The person assigned to Fridays will also assign studies submitted on Saturday and the person assigned to Mondays will assign studies received on Sunday.
  - For each new study that came into the IRB during your shift: Copy and paste the study ID and study title onto the current week’s tab, in the next available row.
  - Open each study from your shift to determine the following. Note: Analysts who handle each type of study are noted in the study assignment spreadsheet.
    - S-I study: Assign to S-I analysts only.
    - VA study: Assign to VA Liaison only.
    - Used an IRB protocol template? If not, assign to analyst and include in your comment to study team that they will need to use our protocol template.
    - Study only involving a chart review and non-clinical data collection methods (surveys, interviews, etc.) involving Children’s records/patients: Falls under CHOA IRB jurisdiction instead.

- Email CHOA IRB director with a link to the study, to ask if they agree it should go to CHOA instead based on the nature of the study.
- Log private comment with the action you've taken.
- If CHOA IRB agrees: Request clarifications with the following comment:

Based on the information in this submission, it should be reviewed by the Children's Healthcare IRB according to the Emory-Children's master research agreement. Please see the following webpage for guidance on submitting to the Children's IRB:  
<https://www.choa.org/research/institutional-review-board>.

If you have any questions, please contact the Children's Healthcare IRB (irb@choa.org). Otherwise, please Discard this submission in eIRB. Thank you!

- Single patient expanded access use of drug/device (may say "treatment use"): Assign to the Q team AD.
- Multisite, industry-sponsored study, smartform indicates Emory IRB will review and there is no apparent investigator COI: Assign to an analyst that handles WCG/Advarra submissions. Add Private Comment saying to follow up with study team about likely need for commercial IRB review.
- XIRB: Assign to appropriate analyst per study assignment spreadsheet
- Chart Reviews (no consent, no surveys/questionnaires, can include AI so long as no plans to submit to FDA): Assign to Tracy Cermak.
  
- In Excel spreadsheet, select the analyst for each study
  - "Assigned To" column: select by last name from the drop down list, must match name of one of the analysts in the "Analysts" column. If the name you need doesn't appear because the team member is new, tell Director.
  - "Notes" column: Note only things you may want to recall as you do your assignments
- In eIRB, use "Assign Coordinator" to assign the study to the chosen analyst.
- "Add Private Comment" only if you need to inform the analyst of something.
- "Add Comment" to the PI/PI Proxy using language directly below.

#### **LOGGED COMMENT TEXT FOR STUDY TEAMS**

- If comment from study team indicates study may be unusually, truly time-sensitive, log following public comment to PI/Proxy:

Greetings, study team! We see that you have asked for prioritized handling of this submission. I have assigned this study to [analyst] to screen per our established turnaround targets. Meanwhile, please reach out to IRB leadership, who will determine if this submission can receive prioritized review. Please see the link to their contact information at this link, under "Requests for Accelerated Handling":  
<https://irb.emory.edu/about/services/irb-target.html>.
- For non-XIRB new submissions using our protocol template(s), log the following comment to the PI/PI Proxy:



Thank you for your submission! I have assigned your study to ANALYST. They will perform a pre-review screening of the study and let you know if any changes are needed before this study is sent for further review.

Our target turnaround time information is here:  
<https://irb.emory.edu/about/services/irb-target.html>

Please reach out to your analyst with any study specific questions.

- For non-XIRB new submissions NOT using our protocol template(s), log the following comment to the PI/PI Proxy:

Thank you for your submission! I have assigned your study to ANALYST. They will perform a pre-review screening of the study and let you know if any changes are needed before this study is sent for further review.

Tip: It appears you have not used our required protocol templates. This will be required before the study goes for final review, so you may wish to start working on that while your analyst does their pre-review screening: <https://irb.emory.edu/forms/protocol-templates.html>. You can upload the revised protocol after the analyst sends the submission back to you.

Our target turnaround time information is here:  
<https://irb.emory.edu/about/services/irb-target.html>

Please reach out to your analyst with any study specific questions...

- For XIRB new submissions, log the following comment to the PI/PI Proxy:

Thank you for your submission! I have assigned this to ANALYST. They will perform a review the submission and let you know if any changes are needed before we can provide institutional sign-off.

**Note: Studies should be assigned each business day.**

#### LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
8/31/2019	Replaced "reliance specialist" with "reliance RPA"
02/24/2023	Extensive updates for evolving process



## DURING STUDY CONDUCT

<b>SOP Title:</b>	Over-Enrollment Via Consent (No Research Activities including during Screening)
<b>SOP Category:</b>	Study Management
<b>Established:</b>	5/15/2012
<b>Last Revision:</b>	6/9/2021

### PURPOSE

The purpose of this SOP is to explain the process to follow if over-enrollment took place in a study, when the subjects enrolled beyond informed consent (hereafter referred to as “over-enrollment via consent”). It may also be used if researchers also did basic screening with those subjects, i.e. reviewed those subjects’ charts or asked them for private information

### SCOPE

This SOP only applies when over-enrollment was due to consenting more subjects than had been approved by the IRB. It does not apply to cases in which the over-enrollment included subjects who completed any study-driven interventions (even if done for screening or if the activities are considered minimal risk), or post-screening study activities. These activities may include fasting for blood test and medication withdrawal before informed consent was obtained.

### RESPONSIBILITIES:

- IRB Analyst: log over-enrollment in log located under the QA folder (see folder name below)
- IRB Team Q designated member: will periodically trend the data in the spreadsheet to identify potential continuing noncompliance and send monthly reports to CoRe.

### PROCEDURE:

Cases should be maintained in a running record sorted by PI. No need for CoRe to review individually unless there is evidence of continuing noncompliance. Team Q is responsible for reviewing records to identify trends of persistent over-enrollment. Persistence of over-enrollment after the issue has already been identified and pointed out to the PI could be continuing noncompliance and should be sent to CoRe. Team Q will review the spreadsheet monthly and report all instances of potential continuing noncompliance to the CoRe team. Other general trends (e.g., departmental patterns) will be reported to the CoRe team and the Associate or Assistant Directors.

### Analyst

If enrollment is close to the cap, but not over it, analyst should recommend a review and, perhaps, an increase in enrollment cap. If an analyst identified a case (e.g. at continuing review), he/she will contact the PI providing:

- A description of the noncompliance (the number approved vs. the number consented)
- A corrective and preventive action plan that includes:
  - The submission of a Modification to increase enrollment (if the study is closed to enrollment, the NC should be acknowledged, but no Modification is necessary).
  - Portfolio-wide audit of enrollment numbers (*See Guidance to PIs Regarding Self-Audits*)

- Education by the analyst about the issue with references to IRB P&Ps (p. 155 defines enrollment in Chapter 43, Informed Consent, under Procedures)

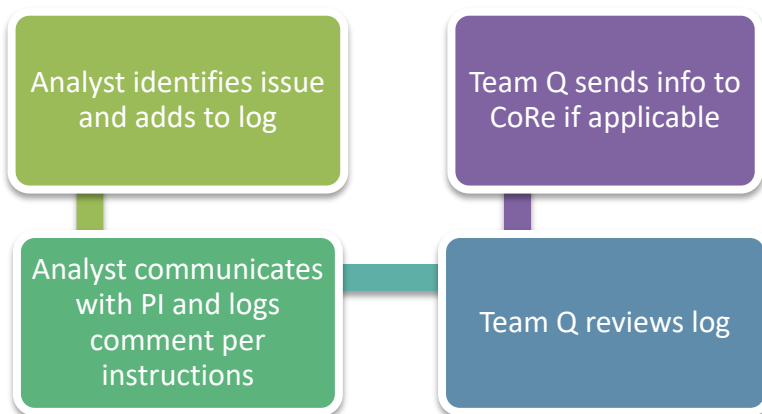
The analyst should follow up to make sure the Modification is submitted (using Outlook calendar or other ticklers). If it is not submitted by the time of review, it becomes a pending issue. The analyst should enter the issue into the over-enrollment tracking sheet. The tracking sheet is in the QA working files main folder. H:\IRB\General\QA Working Files

### Guidance to PI’s Regarding Self-Audits

*Paste as a Logged Comment:*

- If over-enrollment via consent is not present in any other studies, there is no need to report this.
- If over-enrollment via consent is discovered in other active studies, please submit a Modification to increase enrollment and explain why (i.e. discovered as part of audit).
- If over-enrollment is found that was not due to solely to consenting more subjects than had been approved but included exposing subjects to screening or procedures beyond the consent, report the over-enrollment as a protocol deviation in the Reportable new information submissions module for the specific study in eIRB.
  - On the “Protocol Violation/Deviation” page, check yes for question #1, “Is this a substantive deviation from the protocol as approved by the IRB?”
  - For the second question, indicate that the deviation/violation adversely affects: the rights/welfare of subjects and the safety of subjects

### PROCESS FLOW



### LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
9/16/2016	Added clarification about screening procedures
10/26/2017	Clarified purpose of SOP (including title)
6/9/2021	Added additional info to clarify that only active studies are required to be audited for over-enrollment

<b>SOP Title:</b>	Transferring Study Participants Between Study Sites
<b>SOP Category:</b>	Study Management
<b>Established:</b>	11/10/2010
<b>Last Revision:</b>	10/26/2017

## PURPOSE

To explain the steps to be taken if a study is transferring data or patients between sites

## SCOPE

Studies approved by the Emory IRB

## ABBREVIATIONS

- **OTT:** Office of Technology Transfer
- **ORC:** Office of Compliance
- **DTA:** Data transfer agreement

## DEFINITIONS

- **Data transfer agreement:** agreement used when transferring protected health information (PHI), including limited data sets, from one party to another.

## PROCEDURE

### For Patient transfer

- Study team should refer to the OTT/ORC guidance for data transfer agreements. The information can be accessed at <http://www.orc.emory.edu/hipaa/index.html>.
  - Outgoing DTA: To initiate routing and initiation of the appropriate DTA, Emory investigators should complete an Outgoing DTA Questionnaire (provided at <http://www.med.emory.edu/research/resources/index.html> or <http://www.ott.emory.edu/forms/index.html>) and email the questionnaire to [somdta@emory.edu](mailto:somdta@emory.edu).
  - Incoming DTA: OTT manages all DTAs covering receipt by an Emory investigator of human subject data to be used for research purposes not involving a clinical trial or human subject interaction/intervention by the Emory investigator. All OTT-managed incoming DTAs should be forwarded to OTT for approval, along with a completed Incoming DTA Questionnaire (see "Incoming DTA Questionnaire" on the OTT website at <http://www.ott.emory.edu/forms/index.html>). Faculty members should forward these documents via email to [mta@emory.edu](mailto:mta@emory.edu).
  - Note: data must not be transferred until the subjects who are transferring have signed the new HIPAA authorization
  - Any subjects currently on study have to be notified about these changes and offered the option of transfer or study termination, with appropriate referrals if needed.
- Study team should submit an Modification to the Emory IRB for a revised or new HIPAA authorization to cover the transfer of PHI from Emory to the new site for research purposes. The

requirement to complete an appropriate DTA for a transfer of human subject data is in addition to, and not a substitute for, obtaining appropriate applicable informed consent, HIPAA authorization, or IRB approval for any research activity. Contact Kris West and the IRB Director for information about the HIPAA form information.

- Subjects will need to sign both a new ICF and a new HIPAA authorization with the other site.
- Study team should close out the study with the Emory IRB after all the transfer activity has been done and no more activity with PHI is active.

\*This SOP will also apply if subjects transfer to a new site without a study closing at Emory (e.g. because the subjects are moving far away and there is another site closer to their new home)

#### For Data Transfer

- Study team should refer to the OTT/OC guidance for data transfer agreements. The information can be accessed at <http://www.compliance.emory.edu/hipaa/index.html>.
  - Outgoing DTA: To initiate routing and initiation of the appropriate DTA, Emory investigators should complete an Outgoing DTA Questionnaire (provided at <http://www.med.emory.edu/research/resources/index.html> or <http://www.ott.emory.edu/forms/index.html>) and email the questionnaire to [sommdta@emory.edu](mailto:sommdta@emory.edu).
  - Incoming DTA: OTT manages all DTAs covering receipt by an Emory investigator of human subject data to be used for research purposes not involving a clinical trial or human subject interaction/intervention by the Emory investigator. All OTT-managed incoming DTAs should be forwarded to OTT for approval, along with a completed Incoming DTA Questionnaire (see “Incoming DTA Questionnaire” on the OTT website at <http://www.ott.emory.edu/forms/index.html>). Faculty members should forward these documents via email to [mta@emory.edu](mailto:mta@emory.edu).
- Note: the IRB staff should let study team know but the submission process (Modification, new study) should continue.
- The approval letter should indicate that data must not be transferred until the agreement is completed.

#### **LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
10/3/2014	Updated information after OTT/ORC revised guidance
2/15/2017	Changed title and move comment to the end to avoid confusion about subject matter covered by SOP
10/26/2017	Adding information about data transfer, purpose, definitions, etc.

<b>SOP Title:</b>	Fixing Errors in eIRB System
<b>SOP Category:</b>	Study Management
<b>Established:</b>	5/8/2020
<b>Last Revision:</b>	11/3/2020

**PURPOSE**

To explain how to fix errors in the system after a study submission is approved

**SCOPE**

Studies approved by the Emory IRB

**PROCEDURE**

**Studies approved in the new eIRB system**

- As the study owner (or if you have the “Director” role in eIRB) you can make corrections to the record. Make the changes by clicking on “submit designated review” or “submit committee review”, according to the study approval route (DR vs. FB). Taking this action will allow for fixing errors involving approval/expiration dates or when the correct documents were not finalized.

**Approved**

Entered IRB: 4/1/2020 8:45 AM  
Initial approval: 4/6/2020  
Initial effective: 4/6/2020  
Effective: 4/6/2020  
Approval end: 4/5/2021  
Last updated: 4/15/2020 6:55 PM

**Next Steps**

- [View Study](#)
- [Printer Version](#)
- [Report New Information](#)
- [Send Letter](#)
- [Prepare Letter](#)
- [Submit Committee Review](#)
- [Add Participating Sites](#)
- [Assign Coordinator](#)
- [Assign Primary Contact](#)
- [Assign PI Proxy](#)
- [Manage Ancillary Reviews](#)
- [Manage Guest List](#)

### STUDY00000419: Winship4998-20: Tocilizumab for cytokine rel with SARS-CoV-2: An open-labeled, randomized phase 3 trial

Principal investigator: Ajay Nooka  
Submission type: Initial Study  
Primary contact: Kim Nguyen  
PI proxies: Alexandra Hyduk, Kim Nguyen

IRB office: Emory IRB Office  
IRB coordinator: Anisha Easley  
Letter: [Correspondence\\_for\\_STUDY00000419.pdf](#)  
Regulatory authority: 2018 Requirements + FDA

History | Funding | Contacts | Documents | Sites | Follow-on Submissions | Reviews | Snapshots

Filter by **Activity** | Enter text to search for | + Add Filter | X Clear All

Activity	Author	
Comment Added	Rousselle, Rebecca	4/15
Please ignore re-send of letter - I had to resend after editing our review information, but there is no change to the outcome or to the letter. Apologies!		
Letter Sent	Rousselle, Rebecca	4/15
<a href="#">Correspondence_for_STUDY00000419.pdf</a>		
Committee Review Submitted	Rousselle, Rebecca	4/15
Committee Review Submitted	Rousselle, Rebecca	4/15

**Approved**

Entered IRB: 4/29/2020 11:57 AM  
 Initial approval: 5/4/2020  
 Initial effective: 5/4/2020  
 Effective: 5/4/2020  
 Last updated: 5/4/2020 2:50 PM

## STUDY00000659: Orthopedic Trauma Consult Vol

Principal investigator: Mara Schenker  
 Submission type: Initial Study  
 Primary contact: Ndeye Guisse  
 PI proxies:

IRB office: Em  
 IRB coordinator: Re  
 Letter: [icon]  
 Regulatory authority: 20

### Next Steps

- [View Study](#)
- [Printer Version](#)
- [Report New Information](#)

- [Send Letter](#)
- [Prepare Letter](#)
- [Submit Designated Review](#)
- [Assign Coordinator](#)
- [Assign Primary Contact](#)
- [Assign PI Proxy](#)
- [Manage Ancillary Reviews](#)
- [Manage Guest List](#)
- [Add Related Grant](#)



History	Funding	Contacts	Documents	Follow-on Submissions	Reviews	Snapshots
Filter by <input type="text" value="Activity"/> <input type="text" value="Enter text to search for"/> <input type="button" value="Q"/> <input type="button" value="+ Add Filter"/> <input type="button" value="X Clear All"/>						
Activity		Author				
	Comment Added	Taylor, Reonna				
Now that your submission has been approved, please take a few moments to complete the Emory IRB Satisfaction Survey. We will use your responses to improve our service to the Emory research community. We appreciate your feedback!						
	Letter Sent	Taylor, Reonna				
	Correspondence_for_STUDY00000659.pdf					
	Prepared Letter	Taylor, Reonna				
<input checked="" type="checkbox"/>	Designated Review Submitted	Corkran, Carol				

After the “Submit Committee Review” or “Submit Designated Review” options are executed, other errors can be fixed by clicking on “Edit Pre-Review”.

### Studies migrated from RX (old eIRB)

IF THE STUDY SHOWS AS “LAPSED”, THE STUDY TEAM WILL NEED TO SUBMIT A CONTINUING REVIEW SUBMISSION INSTEAD OF A MODIFICATION.

- The preference is to ask the study team to submit a modification submission but, as stated above, a CR may be required to change an incorrect study status.
- If submitting a modification:
  - The study team should select “other parts of the submission”, and should not include any additional changes to the mod.
  - If a study team has a modification already open, we will have to wait until that modification is completed to fix the error if the error would involve re-stamping documents and/or fixing approval dates.
  - If the error would not involve re-stamping documents/fixing dates, then the same modification can be used. If so, make sure the approval letter documents the additional changes made in the submission to fix the error.
- If submitting a continuing review:



- The study team should not worry to include new data in the submission as this is only done for admin purposes.
- Let the team know that this submission is only going to fix the error, and will not be an approval of additional documents, as specified above.
- For modifications or continuing reviews submitted anew to fix errors
  - After the team has submitted the application, you can approve it using the “designated review” route.
  - Select “expedited review” and under the category of review, select “other”.
  - Under question 7 (notes), explain that this submission is not approving any change/renewing the study but it is submitted only to be able to fix an error and specified what is being fixed.
  - When working on the approval letter, select the “Approval of Modification” letter. The title of the approval letter for this submission should read “Administrative Submission to Correct \_\_\_\_”. In the body of the document, if applicable, we should state that the document being stamped was approved on DATE. The document will be stamped with today’s date as the system does not allow for retroactive stamping.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
5/18/2020	Adding that a CR is needed when the study is showing as “Lapsed”.
11/3/2020	Making additional changes to the SOP to reflect the current thought process



<b>SOP Title:</b>	Continuing Review Processing-Preliminary Analysis through Approval
<b>SOP Category:</b>	Study Management
<b>Established:</b>	6/28/2011
<b>Last Revision:</b>	5/5/2021

## PURPOSE

The purpose of this SOP is to describe the process that research protocol analysts (RPAs) will follow when processing continuing review (CR) submissions through approval. It includes the process for transitioning studies to the revised common rule.

## SCOPE

The SOP applies to CRs for single-site studies. (See Collaborative Research SOPs for processing multi-site studies where Emory is the single IRB of record.)

## Menu

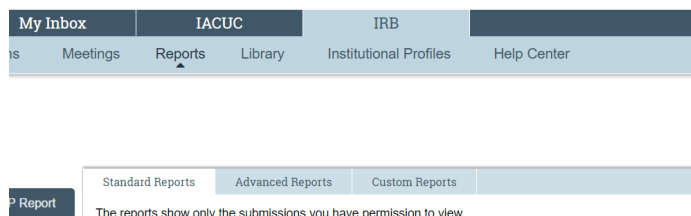
- [Studies wishing to transition to the revised common rule](#)
- [CR Screen Process Pre-review](#)
- [Expedited Review](#)
- [Full Board Committee Review](#)
- [Finalizing Submission](#)

## PROCEDURE

1. Use this SOP and open the Continuing Review Worksheet. Use these documents together when reviewing CRs.
2. For technical issues, refer to the [Huron Staff Quick Reference](#) tool.

## CR Screen Process:

1. Open the CR review worksheet located in [in this folder, H:\General\Admin IRB Documents\Checklists-Staff, Forms, and Templates\1. Staff Screening Checklists and Tip Sheets](#)
2. To see all CRs assigned to you in your inbox, including CRs you have sent back to the study team for clarification, run your CR Report following the steps below. Use the Huron IRB Staff Quick Reference for technical information.
  - a. In eIRB click on “Reports” on the tab at the top of your page.
  - b. Click “Custom Reports”



3. At the bottom of the page change 10/page to 100/page so you can see all options.

4. Page down to ORAIT\_CRs and select this option.
5. When the Search Results window opens, click Pop Out at the bottom of the screen.
6. In the Filter By drop down menu, select "IRB Owner".
7. In the filter box enter your last name.
8. Click the magnifying glass icon.
9. At the bottom of the page change 10/page to 100/page to ensure you see all of your items.
10. You can click Study Date Expiration or Project State to sort items.
11. Review the [Huron Staff Quick Reference](#) for eIRB technical steps starting on sections "Complete a Pre-Review".
12. If clarifications are needed or items are needed from the study team, click on "request pre-review clarification" in the left menu. You can find technical steps on page 15 of the Huron Staff Quick Reference. Use page 16 to compare the documents you are receiving, if any. If the CR will be expedited, all clarifications must be resolved including CITI training and modifications to remove study staff approved before assigning to the reviewer.
13. Follow up with the study team if a response is not received in a timely fashion. If a submission is in requested changes for more than 30 days with no answer from the study team, the analyst should withdraw it. The analyst needs to document their efforts in contacting the study team and email them before withdrawing the study.
14. If the CR will be reviewed by the full board, the CR must be in pre-review (not clarifications requested) before submitting the pre-review. The CR can be assigned to a committee, and CITI certificates and DSMB reports can be uploaded with a comment. If there is a modification to remove study staff, approve it before finalizing the CR.
  - a. **Note: If requesting a current DSMB report, give the study team a deadline to provide it so the committee members have a chance to review it.**
15. To process a modification to remove study team members, follow the SOP titled "Adding/Removing Study Personnel."

**Pre-review:**

1. Click "Submit Pre-review". For technical instructions, review the [Huron Staff Quick Reference](#), on page 14. A new window will open.
  - a. Question 1 - For studies under the pre-2018 common rule, the first question will be the Common Rule Requirements (see below). There is no mechanism to change this answer, so once a study has transitioned to the revised common rule, it cannot be moved back. Confirm the study is not FDA regulated study or under DOJ funding. For more information, see the section of this SOP below titled "Studies wishing to transition to the revised common rule."

1. \* Common Rule regulatory requirements:  
 Pre-2018 Requirements  
 2018 Requirements  
[Clear](#)

  - b. For questions 1-4 (or 2-5 if your first question was about transitioning to the revised common rule),

- confirm the boxes that are checked are correct based on the information you have reviewed about the study. Refer to the SOP titled “Pre-Review Options and Ancillary Review Information.”
  1. If the information is already populated, do not make any changes to the Pre-Review options without confirming with a Director or AD unless this submission is a modification/CR combined.
  2. If there are no boxes checked, check the eIRB record for applicable selection
- Add missing materials and notes, if any.
- 2. Click Yes to the last question to complete the pre-review. (If you know you will need to edit the pre-review later, mark No.) Pre-review must be complete before routing to a designated reviewer or assigning to a committee.
- 3. For information about the required selections under Pre-review or verifying appropriate ancillary reviewers, please review [this SOP](#). If the selections are already made, just leave the selections from the previous review (unless this is a MOD/CR with changes to the study).
- 4. If the study shows as transitioned to the 2018 rule but this is not correct, log a comment to the reviewer explaining this discrepancy, so they do not say the study does not require a CR in the future.

Transitioning studies to the revised common rule:

[Check this information](#) to learn what we mean by the pre-revised common rule and the revised common rule.

Studies required to transition per the guidance found in the link above (under “Emory IRB Transition Plan”) should be transitioned using the CR submission.

1. Review the answers to the CR, ensuring the study is not FDA regulated or DOJ supported.
2. Follow the instructions below under “Pre-review” section 1a.
  - Click “Submit Pre-review”
  - Select 2018 requirement, so the study can transition after the CR is approved.
  - If it is not clear if a study is FDA regulated, consult with the Director. **Remember** that any drug, device, biologic, software or app (considered devices) are FDA regulated even if previously FDA-approved.
3. For studies wishing to transition: The study team needs to submit the [Guidance and Attestation form](#) with the continuing review. If the study is still enrolling subjects, they need to revise the consent to align with the revised common rule requirements by submitting a modification (MOD).
  - If the study requires a MOD (as they are still enrolling subjects), and the MOD has not been submitted yet, ask the team to withdraw the CR and resubmit a MOD/CR application when the changes to the consent are ready. The only way to transition to the revised common rule is via a CR submission, so if the study is close to expiration, we may need to work on the CR submission and ask them to submit a MOD/CR after approval if still wishing to transition.
  - The study owner should be the person in charge of screening the MOD/CR application.

## Expedited Review

1. Select the reviewer based on their specialty, if possible. For example, give cancer, sickle cell, or infectious disease studies to the reviewers who specialize in those areas. If choosing a Staff designated reviewer, make sure you follow the SOP entitled: "Categories of Research Reviewable by IRB Staff as IRB Designated Members". Follow the [Huron Staff Quick Reference](#), page 22 for additional steps.
2. Send the CR to the reviewer at least 3 weeks before expiration (if possible due to CR submission). When assigning, you may suggest review categories based on your review and the prior years' reviews. Make sure that you do not imply that is the category to be used as the member should do their own review. Add this information under question 2 when assigning to a reviewer. If the category from previous years is obviously wrong or not listed, contact your TL or Director.
3. After the CR has been reviewed, follow the post-review activities detailed on Page 25 of the [Huron Staff Quick Reference](#). If the CR is approved (no clarifications are needed) skip to the section of this SOP titled "Finalizing Submission."
4. If clarifications are requested by the designated reviewer, draft a letter to the study team with the required changes.
5. Follow up with the study team if a response is not received in a timely fashion. If a submission is in requested changes for more than 30 days with no answer from the study team, the analyst should withdraw it. The analyst needs to document their efforts in contacting the study team and email them before withdrawing the study.
6. Once a response is received, click on "submit designated review" and send to the original reviewer. Let them know this is an additional review to confirm that the previous changes they requested were completed.
7. The state will change to "Post-Review." Review the dates to confirm they are correct. If not, correct them before proceeding by clicking "Submit Designated Review."
8. You are now able to generate a letter for the approval of the CR application.

## Full Committee Review

1. If the CR requires review at the full board, assign it to the appropriate committee agenda four weeks before expiration (if possible).
  - a. Click "Assign to Meeting" and choose from the options. Choose a committee date that is ideally a couple of weeks before expiration (one week may not be enough, as there may be pending issues) and choose a committee that has appropriate expertise if needed.
  - b. Click on "Edit Pre-review" and add the following information under "Notes":
    - a. Whether enrollment numbers are compliant with IRB approved enrollment numbers in the protocol.
    - b. If there are any CITI/training pending issues that may prevent study reapproval
    - c. If this is a Sponsor-Investigator study:
      - a. Indicate whether the S-I responsibility form is included in the submission with an S-I consult approval (This is required before the CR can be approved) (if not, pending issue)
    - d. If there are any Committee member conflicts you are aware of
    - e. If it is not clear why the CR is going to full board, explain (e.g. list research interventions still ongoing)

**NOTE: You are required to update the pre-review no later than the Monday before the meeting if there are any changes to the above pending items.**

- f. Once the meeting Pod has reconciled the meeting notes and posted in Teams that you can write your letter, review the “Committee Review Submitted” information under the CR history.
2. If the CR is pended or deferred:
- i. Write a letter to the study team, using the appropriate template. Make sure you include all the required changes noted in the “committee review submitted” information. Click “Send letter” to end this part of the process.
  - ii. Follow up with the study team if a response is not received in a timely fashion. If a submission is in requested changes for more than 60 days with no answer from the study team, the analyst should withdraw it. The analyst needs to document their efforts in contacting the study team and email them before withdrawing the study.
  - iii. Once the study team has submitted the requested changes, review materials to assess that the changes have been made.
    - 1. If Deferred issues have been addressed, schedule the Deferred CR to be reviewed by the same committee that conducted the initial review of the CR application (i.e. if CMTE B1 reviewed the CR in January meeting and deferred it, send to the next available meeting for CMTE B1). If the Deferred issues are approved at full board, you may issue the approval letter and release updated consent/HIPAA documents.
    - 2. If pending issues were addressed, email the meeting chair with a link to the study so they

can verify the changes were addressed. Ask them to do not make any changes in the submissions. The vice-chair may document their approval via a private logged comment, or they can email you back with that response.

3. Once you receive the approval, click on “Review Required Modifications” to document the changes made are adequate. The “approval date” would be the date of the meeting. The “effective date” is the date the vicechair confirmed the changes were adequate and the study can receive final approval.

4. Make sure you log a private comment with the email communication from the vice-chair if they did not log a private comment.

## Finalizing Submission

**Note:** Due to the Revised Common Rule, studies in data analysis only and in long term follow up (not under FDA or DOJ regulations), or doing research with secondary data or biospecimens, that were

approved after 1/21/2019 or that transitioned to the Revised Common Rule, will not require continuing review in the future. **In the approval letter, add a reminder that Modifications, reportable new information submissions, and closeout are still required. Also, if the status of the study changes during the year, they need to submit a Modification (for example, if reopening accrual).**

1. Go to page 25 of the [Huron Staff Quick Reference](#) for technical steps for this part of the process.
2. Click “Finalize Documents”
3. Select the protocol and if the study is still enrolling, the consent form(s).
4. Click “Prepare Letter”.
5. Generate the appropriate letter. Remember to include the PI’s post-nominal (degree – MD, Ph.D., MPH, etc.), Principal Investigator (under name), and department name. If this information is not clear in the submission, you can check the last approval letter, or you can search on the [Emory Online Directory](#).
6. Review the letter to make sure all the information added by the system is correct including the dates.
  - If the study migrated to the 2018 Revised Common Rule, add a reminder that Modifications, reportable new information submissions and a close out are still required. In addition, if the status of the study changes during the year, they need to submit a Modification (for example, if reopening accrual).
7. Delete template language that does not apply and put your name and title at the end of the letter.
8. Save a copy on your computer to upload a revision.
9. Click on the ellipses in the Draft letter space to upload the revision and click Ok.
10. Click “Send Letter”, review the letter and dates one more time, and click Ok.

#### LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
12/2/2016	Clarified how to determine expiration date; what to put in CR approval letter (removed some bullets); referred to 30-day window SOP
5/5/2017	Clarified some steps in the process and added required language under FB approval letter
7/14/2017	Formatting and additional guidance on letter writing, comment logging.
5/17/2018	Revamp for readability
11/1/2018	Added location for the over enrollment log excel sheet (link does not work); added information about when is OK to send a study to an expedited reviewer or to full board when finding expired research training
1/18/2019	Adding information for Revised Common Rule. Clarifications and grammatical corrections.
8/31/2019	Updated customer service link.
2/11/2020	Updated CR to align with new eIRB
2/13/2020	Updated links to checklists
3/4/2020	Added that the pre-review note should indicate the enrollment numbers at the time to assign a study to FB
3/13/2020	Updates in the information that needs to be added for CRs going to full board in the pre-review notes
3/23/2020	Updates in the revised common rule transition plan and addition of timelines to send to DR or FB.
4/14/2020	Updates in process for expedited review that were incorrect. More detail provided for contingency review.
5/8/2020	Clarification on the steps after a contingency review changes are received after DR review.
6/14/2020	Updates to the Revised Common Rule transition process
8/21/2020	Instructions added when a study is transitioned to the revised common rule
12/11/2020	Adding additional information for the pre-review process for submissions going to FB
01/20/2021	Clarification of steps
2/25/2021	Adding that the submission can be withdrawn if no response from the team
5/5/2021	Changes in the contingency review process



<b>SOP Title:</b>	Continuing Review: Applying 30-day window
<b>SOP</b>	Study Management
<b>Established:</b>	10/14/2012
<b>Last Revision:</b>	2/11/2020

## GLOSSARY

**Review date:** date on which expedited reviewer finally approved, or full board meeting occurred

**Effective date/Approval date:** first day of an approval period (for purposes of 30-day rule)

**Expiration date:** last day of an approval period (study expires at end of that day, at midnight).

*Note: For stamping ICF/HIPAA documents, this will also apply if the study team requests an expiration date in their documents.*

## SCOPE

All IRB staff may use the 30-day rule in the event of the following:

1. Study is no longer recruiting subjects, so they do not need restamped informed consent/HIPAA documents **and**
2. Approval of the CR happens to occur during the same approval period as the year before (no need to intentionally hold review until 30 day period arrives).

### Scenario using the 30-day rule

- Current approval period: 7/2/2011 – **7/1/2012**
- Renewal approved by the expedited reviewer on 6/26/2012 (within 30 days before **7/1/2012**)
- New effective approval period: 7/2/2012 - 7/1/2013

## PROCEDURE

- Step 1: After the designated reviewer has completed his/her review approving the study, click on “submit designated review” to update the Approval Date and Effective Date.
- After finishing updating the dates, click on OK.
- Be sure to check the approval period granted by the reviewer/full board, if less than one year
- Make sure that the expiration date populated. Revised the letter as usual.
- Add the following language to the letter:

*Because this study was reapproved [with conditions] within 30 days of its expiration date, is closed to new enrollment, and thus consent forms no longer need to be stamped, we are applying guidance from OHRP and FDA (see <http://www.hhs.gov/ohrp/policy/continuingreview2010.html#section-g3> and <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf>) in order to retain the approval and expiration anniversaries from the previous approval period.*

## LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
4/30/2015	Major overhaul, limits scope of when to use 30-day rule
11/1/2017	Revised language to mirror eIRB
1/31/2018	Date fix in example
2/11/2020	Updating to align to new eIRB system



<b>SOP Title:</b>	Continuing Review: REs/PDs/Noncompliance and Monitor Reports
<b>SOP Category:</b>	Study Management
<b>Established:</b>	2/14/2012
<b>Last Revision:</b>	11/1/2017

**PURPOSE:** To explain what safety/compliance-related documents, submitted by the study team with a renewal application, should instead be submitted via the Reportable new information submission (RE) form; and when such documents should be removed from the Continuing Review (CR) application.

**SCOPE:** Continuing Review submissions in eIRB – expedited and full board.

**RESPONSIBILITIES:**

- IRB Analyst: Screen the Continuing Review (CR) application and review the REs/PDs/Noncompliance and Monitor Reports per the guidelines below
- Team Q Lead (QTL): Receive alerts when study teams have been asked to submit REs, and follow up to ensure they are submitted as applicable
- IRB Director: Escalate request for REs with study team as needed

**RATIONALE:** Leaving reports in the renewal application opens the IRB to liability when the IRB member(s) do not adequately review those documents to determine whether they represent unanticipated problems (UPs) or serious or continuing noncompliance.

**OVERVIEW**

<b>Summary of Reporting Timelines</b>	
Unanticipated problems	Promptly reportable
Reportable protocol deviations	Promptly reportable
Internal deaths considered related	Promptly reportable
Internal deaths considered unrelated	Periodically reportable (i.e. at CR)
Internal related events (not UPs)	Periodically reportable (i.e. at CR)
External* SAEs that are not UPs	Never reportable to the IRB
External* deaths not related or UPs	Never reportable to the IRB
Noncompliance	Promptly reportable

*\*Remember that external events under the oversight of an Emory S-I should be assessed as internal events.*

**PROCEDURE:** IRB Analyst screening a CR submission should open every attachment to make sure that only items that are properly reported at CR are remain in the submission, and that they are in the correct form. Any items that required prompt reporting must be reported via a reportable new information submission, if not previously reported. Other attachments should be removed from the submission or modified to comply with IRB requirements of reports at CR.

**What should be reported in the CR?**

- The study team should submit periodic reportable new information submissions in a summary.

If not done, or the information provided was not clear, ask the study team to fill out our summary form (if the information they provided is complete, this is not needed). Use our template at: [http://www.irb.emory.edu/documents/Sample\\_RE\\_summary.xls](http://www.irb.emory.edu/documents/Sample_RE_summary.xls).

- If the study team indicated that events did occur (by checking 'yes' to Questions 3-6 on page 1) and/or submitted descriptions of individual events in the last approval period, check to see if the summary of events contains the following:
  - A list of previously reported UPs
  - A list of internal, expected (anticipated) and related events from the last approval period
  - A list of internal, unrelated deaths
  - List of expected and related events and/or unrelated deaths for any external site under the oversight of an S-I
- For any UPs, make sure that the UPs listed were previously reported to the IRB via a Reportable new information submission. In order to check for previously reported items, go to the "AM-CR-RE-Term" tab in the study record
- If the IRB Analyst is unclear whether events are reportable (promptly vs. periodical) or not, please consult Team Q and the [website guidance](#).

**What should be removed from the CR and submitted as a RNI (unless the event is merely part of a summary of events that were already reported via RE)?**

- 483 reports (FDA inspection findings)
- Any event/death/protocol deviation/noncompliance report that met the criteria for being promptly reportable:
  - Unanticipated problems (including external deaths that are considered a UP)
  - Reportable protocol deviations
  - Internal deaths considered related to the research
  - Noncompliance
  - Any report that indicates an increase in risk for the rights, welfare or safety of subjects
- If the study team submits a spreadsheet with mixed information (SAEs reportable at CR and events that are not reportable), ask them to remove the events that are not required and submit in a reportable new information submission.

**Procedure for handling CRs with items that require a RE:**

- If the study is close to expiration:
  - Remove the promptly reportable items from the submission
  - Email the study team and CC the QTL, asking them to submit in an RNI within 2 weeks
  - Log a private comment in the CR documenting the email.
  - Process the rest of the CR as usual
- If the study is not close to expiration (e.g. more than three weeks for expedited, or longer for full board studies):
  - Send the CR back to the study team asking them to submit the list in a RNI instead of in the CR, and to submit the CR back after they have submitted their RE
  - Email QTL to alert Q
  - Log a private comment in the CR documenting email to QTL
  - If the study team does not respond and the study may expire, check with the QTL for next

steps

**What should be removed from the CR with notification by logged comment to study team, but no RNI required?**

- Any items that are not periodically or promptly reportable
- Minor protocol deviations (per the study team)
  - If the study team needs an acknowledgment for protocol deviations, they need to submit a separate RNI form.
- External deaths: if they are not UPs (per the study team)
- Site Monitor’s Report (not to be confused with a DMC/DSMB report)
  - Monitoring reports should be submitted to CTAC, not IRB. Email the monitoring report(s) to CTAC/Stephanie deRijke at [smickle@emory.edu](mailto:smickle@emory.edu) or [ctcompliance@emory.edu](mailto:ctcompliance@emory.edu), CC the study team.
  - Remove the monitoring report and log a comment to study team saying you removed the monitoring report, and have emailed it to CTAC
- Example language: *“Dear study team, we have removed document(s) X from your submission, as it is not a document required for this review. If you need an acknowledgment, please submit document X as a reportable new information submission”*

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
10/3/2014	Added step of removing monitor report from submission; updated links
8/12/2015	Revamped this SOP to include what to report and what not to report at CR, as well as procedures to deal with events
11/1/2017	Administrative updates and suggested language for notifying teams of information removal of information
10/12/2020	Updated links, corrected typos

<b>SOP Title:</b>	Continuing Review: Processing study staff noncompliance with CITI and Clinical Research Training (formerly Key Concepts/Intro to CR) requirements
<b>SOP Category:</b>	Study Management
<b>Established:</b>	4/30/2015
<b>Last Revision:</b>	4/20/2017

## PURPOSE

The purpose of this document is to outline required actions when IRB staff confirms missing or incomplete training (Clinical Research Training [CRT] for investigators and coordinators) while processing a continuing review. Currently, during screening for a continuing review, the IRB staff check CITI training for all study team members, and check CRT only for researchers who were added within the past approval period via the IRB website's staff-change form.

## SCOPE

The SOP applies to all studies approved by the Emory IRB.

## RESPONSIBILITIES

- IRB analyst – to review CR information and confirm the completion of training requirements. The IRB analyst will forward NC issues to Team Q
- Team Q: - to review any Reportable new information submission that is required

## PROCEDURE

- **Researcher did not have current CRT:** the CR should not be sent to an expedited reviewer while the training is being completed. The study can be placed on a FB committee agenda but this issue should be included in the omnibus form under pending items. The study team could also remove the person with the expired CITI from the submission (if not critical to study and PI agrees). This person may be added back after they certify. Report the person to Bridget Strong at [BSTRONG@emory.edu](mailto:BSTRONG@emory.edu). Have the study submit a RE.
- **Researcher is found to have never had CITI training from Emory or any other institution:** Have the team submit a reportable new information submission. When submitting the event, study team should be asked to clarify whether the staff in question engaged in human subjects' research, and, if the online Staff Change web form was used, to identify who added the uncertified staff person to the study. Follow additional procedures as indicated in the Training Verification SOP.
- **Researcher was added via web-form during the past approval period, but does not have current CRT or/and current Biomedical or Socio-behavioral CITI training:** Have the team submit a reportable new information submission. When submitting the event, the study team should be asked to clarify whether the staff in question is/was engaged in human subjects' research.
- **Researcher had Emory CITI certification but it was expired:** the CR should not be sent to an expedited reviewer while the training is being completed. The study can be placed on a FB committee agenda but this issue should be included in the omnibus form under pending items. The study team could also remove the person with the expired CITI from the submission (if not critical to study and PI agrees). Person may be added back after they certify. A reportable new information submission is not required.

- **Researcher never had Emory CITI certification, but was CITI certified at another institution:** the CR should not be sent to an expedited reviewer while the training is being completed. The study can be placed on a FB committee agenda but this issue should be included in the omnibus form under pending items. The study team could also remove the person with the expired CITI from the submission (if not critical to study and PI agrees). Person may be added back after they certify. A reportable new information submission is not required.
- **Researcher had the wrong Emory CITI training (Biomed/SHB):** the CR should not be sent to an expedited reviewer while the training is being completed. The study can be placed on a FB committee agenda but this issue should be included in the omnibus form under pending items. The study team could also remove the person with the expired CITI from the submission (if not critical to study and PI agrees). Person may be added back after they certify. Review [Step-by-Step Guidance for Selecting Required Courses and Obtaining a CITI Account](#) along with a description of the research activities to determine if they really took the wrong course. No RNI required in any case.
- **Researcher had an incorrect Emory CITI training (GCP or RCR, and never took Biomed/SHB):** Have the team submit a reportable new information submission. When submitting the event, study team should be asked to clarify whether the staff in question engaged in human subjects' research and who added the staff to the study (if the online form was used). The CR should not be sent to an expedited reviewer while the training is being completed. The study can be placed on a FB committee agenda but this issue should be included in the omnibus form under pending items. The study team could also remove the person with the expired CITI from the submission not critical to study and PI agrees). Person may be added back after they certify.

#### LOG OF SIGNIFICANT CHANGES

DATE	SUMMARY OF SIGNIFICANT CHANGES
8/5/2015	Clarified that studies should not be sent to the expedited reviewer if training is not complete. OK to send to FB but study will be pending until training is completed. Added link for guidance on the website
9/16/2016	Updated terminology for the Clinical Research Training (formerly Key Concepts)
4/20/2017	Clarified what "correct" meant

## CLOSE OUT

<b>SOP Title:</b>	Close-Out Process
<b>SOP Category:</b>	Study Management
<b>Established:</b>	7/21/2014
<b>Last Revision:</b>	07/06/2023

### PURPOSE

To outline the processes for closing out a study in eIRB, including:

1. Close-outs initiated by a PI
2. Steps in eIRB to process the close-out

### SCOPE

Applies to all IRB staff personnel responsible for processing close-out requests. *For S-I studies go to SOP entitled: [“Review of Studies Involving an Emory Sponsor/Sponsor-Investigator at Emory Holding an IND/IDE”](#)*

### PROCEDURE

**NOTE:** Closeout applications will start in the form of a Continuing Renewal Application.

1. Review the printer version of the renewal application. If all of the first 4 items in question 4 are checked it indicates that the research is completed, and the study is ready to close out. Log a comment to the study team stating that you have been assigned this closeout for review and that you will be processing it.

The screenshot shows a web browser window with the following content:

- Browser tabs: Brandy Covington, NRG LU005, Continuing Review for Study Ne..., Research Administration Home..., HONORS THESIS: Attachment an...
- Address bar: <https://mpckemystage2.huronick.com>
- Page title: CR004-STUDY0011884
- Page content: Continuing Review / Study Closure Information
- Form questions:
  1. \* Specify enrollment totals at this investigator's sites: 10
  2. \* Specify enrollment totals at this investigator's sites since last approval: 6
  3. \* Specify enrollment totals study-wide: 30
  4. Research milestones: (Select only those that apply, if any)
    - Study is permanently closed to enrollment OR was never open for enrollment
    - All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
    - Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
    - Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
    - Remaining study activities are limited to data analysis
    - Study remains active only for long-term follow-up of subjects
  5. \* Do any investigators or research staff have a financial...

Additional form elements include an "Important!" note about study closure and a "Back To Top" button.



2. Continue reviewing the submission for accuracy:
  - Are the study numbers correct?
  - Did they provide any DSMB reports, etc.? We will not require a summary. If applicable we will need to see the latest DSMB report, unless the study has been in data analysis since the last approval period. AA will review the DSMB document, and if it says anything other than no issues or continue as planned, then consult w/an AD to determine if it needs to be reviewed by faculty.
    - For closeout of S-I studies, look for the S-I closeout SOP.
  - Have all requested reportable events been submitted? If applicable; this applies if the study was still enrolling or doing research activities in the last approval period.
3. Once the submission is ready to be assigned to a reviewer (yourself). Click Submit Pre-Review. The Pop-up window will allow you to capture all of the details of the study as well as make any relevant notes.

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 [Submit Pre-Review](#)

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4. Assign the study for review. Click on “Assign Designated Reviewer”. Analysts can process close-out requests unless the study team is reporting a reportable event issue. If that is the case, the close-out should be reviewed by a vice-chair. Contact a team Q member to assess if an RNI is needed.

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 [Assign Designated Reviewer](#)

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 [Assign to Meeting](#)

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Assign Designated Reviewer

Select a designated reviewer if you believe the submission should follow the non-committee review path.

1. \* Designated reviewer: (select from designated members of all IRB committees)

2. Notes for reviewer:

3. Supporting documents:

Name	Description
There are no items to display	

Clicking OK sends a notification to the reviewer.

OK Cancel

You will need to complete the fields within the reviewer form:

1. \* **Determination:**

Name	Related Worksheet
<input checked="" type="radio"/> Approved	<a href="#">HRP-314 - WORKSHEET - Criteria for Approval</a>

2. \* **Risk level:**

- Greater than minimal risk
  - No greater than minimal risk
  - N/A
- [Clear](#)

3. \* **Review level:**

Name	Related Worksheet
<input checked="" type="radio"/> Expedited	<a href="#">HRP-313 - WORKSHEET - Expedited Review</a>

[Clear](#)

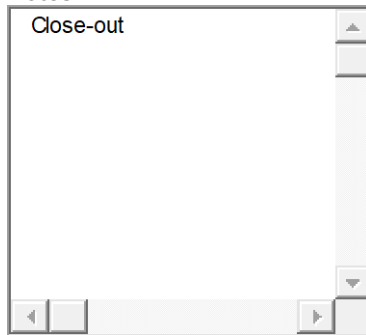
4. \* **Indicate the categories:** Select "Other"

5. \* **Rationale for continuing review requirement:**

N/A Close-out

6. **Dates:** (Don't worry about these pre-populated dates)

7. **Notes:**



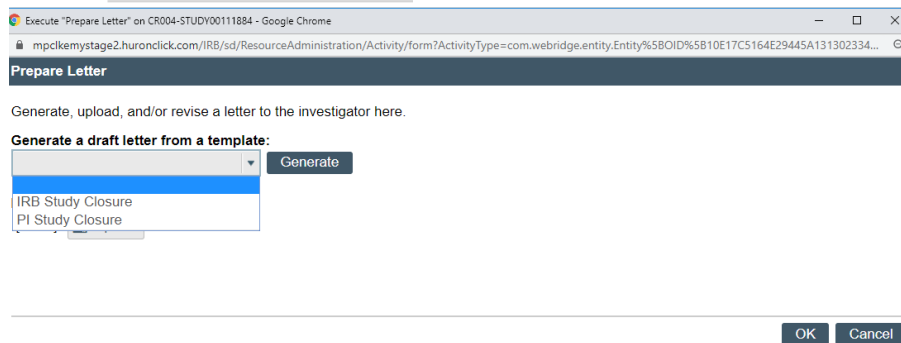
**Supporting documents:** Not applicable

- 8. \* I do NOT have a conflicting interest:
- 9. \* Are you ready to submit this review?

Yes  No [Clear](#)

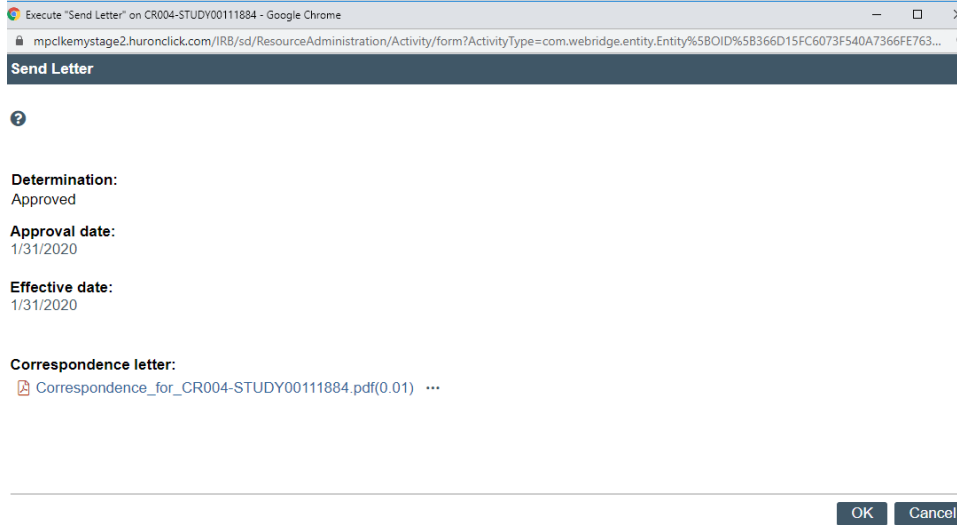
- 5. Click "ok"
- 6. Prepare the letter. From the drop-down menu select the "IRB Study Closure" template letter if the study is being administratively closed by the IRB. Select "PI Study Closure" template letter if the PI is closing the study.

 **Prepare Letter**



- 7. Check the letter that was generated. Add your signature. Re-upload the letter and click Ok. After that step, you will be back in the submission. Click on "Send". A new window will open. Check the letter one last time and then click on OK.

 **Send Letter**



- 8. The Continuing Renewal state will be listed as approved and the main study state should change to closed.

**LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
07/06/2023	Removed reassignment to AAs and archived changes over a year old

<b>SOP Title:</b>	Informing Teams of Study Closure
<b>SOP Category:</b>	Study Management
<b>Established:</b>	7/21/2014
<b>Last Revision:</b>	11/3/2020

## PURPOSE

The purpose of this document is to detail the process of informing study teams that their studies will be closed out.

## SCOPE

The SOP applies to expired studies approved by the Emory IRB.

## RESPONSIBILITIES

- IRB Staff Leadership- have “IRB Director” role.
- IRB analyst: Informs the staff leadership to close a study using the “close Study (Admin)” function.

## PROCEDURE

### Before study expiration

- If a study is identified as one that may expire in the next 2 weeks, the IRB analyst will log the following comment and sent via email:

*Dear team,*

*Your study (IRB#, Short name-INSERT LINK) expires on DATE. Please submit a continuing review application as soon as possible, as we need time to review it before approval. If the study has an approval lapse, you will be required to submit a reportable event for noncompliance. Please, refer to our [timelines](#) for review of studies for additional information.*

*Alternatively, if all human subject research activities are complete, please Indicate in your submission that you would like to close the study.*

*If your study is expired more than two weeks and no action is taken, your study may be closed administratively.*

*If you have any questions, please contact your analyst directly.*

*Best regards,*

*YOUR NAME*

### Less than 90 Days Expired

- If the study expired less than 90 days with a continuing review in pre-submission:
  - Reach out to the study team via email (copying analyst) and logged comment, telling them they have 5 business days to submit the (CR as appropriate) or explain why more time is needed.
    - Here is a suggested text for when a CR has been created but not submitted:  
*Dear study team,*  
*This study expired on [DATE]. Let us know if you have conducted any research during the approval lapse. If so, please submit a reportable event. If this study is FDA regulated, you*

*will need to submit a reportable event even if research activities were not conducted during the lapse. If you plan to continue with this research study, please submit a continuing review application (you created one on [DATE] that has not been submitted yet). If you are no longer conducting research activities, please submit a close out submission. Stop all research, including data analysis until you secure reapproval. If we do not receive a continuing review application, we will close out this study administratively in the next two weeks. If you have questions or concerns, email or call your analyst: [insert analyst name, email, number].*

- Here is a suggested text for when a CR to close out the study has been created but not submitted:

*Dear study team,*

*This study expired on [DATE]. Let us know if you have conducted any research during the approval lapse. If so, please submit a reportable event. If this study is FDA regulated, you will need to submit a reportable event even if research activities were not conducted during the lapse. . If you are no longer conducting research activities, please submit a close out submission (you created one on [DATE] that has not been submitted yet). Stop all research, including data analysis until you secure reapproval. If we do not receive a continuing review application, we will close out this study administratively in the next two weeks. If you have questions or concerns, email or call your analyst: [insert analyst name, email, number].*

- If the study expired less than 90 days without a CR created:
  - Reach out to study team via email, copying the analyst-owner of the study (if not you), and as a logged comment in eIRB, letting them know they have 5 business days to submit a continuing review application.
- If an IRB analyst has a study that has been expired more than 3 months, a staff member with “Director” role can close the study using the “Close Study (Admin)” option.

#### **If a study team wants to reopen the study**

The study team should submit a new submission, that would include using our current templates and checklists and receive approval from any applicable ancillary reviewer

#### **If a study was closed by mistake**

Contact a Director. In general, we will have to ask the team to create a new submission and report the issue to other ORA offices if applicable. The study team will be able to submit their current study documents, and we will just move the study to approved and put today’s date as the expiration date (if the system allows, it is preferable to keep the approval/expiration dates of the closed study). If the study lapsed, the study team will need to submit a new CR application.

#### **LOG OF SIGNIFICANT CHANGES**

DATE	SUMMARY OF SIGNIFICANT CHANGES
2/11/2020	Removed items that cannot be executed in the new IRB system.
11/3/2020	Added additional information about the process