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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 Staff: Add approved IRB documents to designated H drive area.
- IRB Q Team Lead: Helps with the creation or modification of existing IRB documents.
- IRB Director: Gives final approval of any IRB document added or modified in the designated H drive area.
- IRB SOP Sub-committee: review and approve minor changes to SOPs and review new SOPs before IRB Director review

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 in order to keep it semi-private, but having it under the web documents allows staff to access it at any time from any location; it also allows us to ensure that changes are only made after appropriate review and that the most recent version is always accessible. The direct link to the portfolio is:

For SOP portfolio suggestions (staff)
1. To suggest changes to a SOP, copy the SOP from the SOP portfolio document in word.
2. Track changes and send to IRB Q Team lead for changes/approval. Save copy under H:\General\Admin IRB Documents\SOP Portfolio\SOP Portfolio Source Files\SOPs in process
3. The Q Team Lead will forward to IRB subcommittee for review and approval (in case of minor changes) or review before sending to IRB Director (for major changes or new SOPs)

Instructions for IRB SOP sub-committee
1. The IRB SOP subcommittee will meet at least every two months to review changes to the SOP portfolio
2. Will review changes done after SOP review at staff meeting, suggested changes by staff or new SOP additions.
3. The subcommittee can approve minor and administrative changes to the SOP portfolio. For major changes or new SOPs, the subcommittee will do an initial review and send revised and new SOPs to IRB Director for final approval.
Instructions for SOP Portfolio manager

1. Make the approved changes to the Word document portfolio (H:\General\Admin IRB Documents\SOP Portfolio\SOP Portfolio Source Files\SOP Portfolio.docx)
   a. I found it to be easiest to 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.
   b. After changes, remember to update the table of contents so that the page numbers are accurate. This is done automatically by simply clicking on the table of contents, then click “Update Table” in the top tab, and select “update entire table”
   c. Finally, if applicable, put the separate new/revised SOP into the backup folder: H:\General\Admin IRB Documents\SOP Portfolio\Backup Files

2. Save the updated Word SOP Portfolio as a PDF within the same folder (overwrite the existing one)

3. Update the online SOP portfolio with the revised version:
   a. Log into 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. Go to the “Publish” tab and click Submit (the Publish to Production and Publish to Staging should both be selected by default)

i. 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)

| PROCESS FLOW |
|--------------|---------------------------------|---------------------------------|---------------------------------|
| IRB document is created or modified | Team Lead reviews document for accuracy with current IRB or Emory policies, or federal regulations | Reviewed version is sent to IRB director for final review and approval | Final version is sent to IRB designated person to be added to H Drive |

<table>
<thead>
<tr>
<th>LOG OF SIGNIFICANT CHANGES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DATE</strong></td>
</tr>
<tr>
<td>5/7/2015</td>
</tr>
<tr>
<td>9/16/2016</td>
</tr>
<tr>
<td>2/6/2017</td>
</tr>
</tbody>
</table>
NOTE: Listserv responses MUST be given the same day or at latest the next day, 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 of 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.

<table>
<thead>
<tr>
<th>Required Procedures for Handling Listserv</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>If you send a response to a listserv email</td>
<td>Not required but preferred practice: 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.</td>
</tr>
<tr>
<td>If you forward the email to another analyst</td>
<td>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.</td>
</tr>
<tr>
<td>If you don’t need to respond to the email b/c there is nothing to do</td>
<td>Bcc yourself on the email and indicate that there is nothing to respond to – save in your “Listserv Duties” folder.</td>
</tr>
<tr>
<td>If you cannot cover listserv due to illness or vacation</td>
<td>Communicate with another listserv staff member to ensure coverage (e.g. switch days for that week) and inform the Team Leads and Director</td>
</tr>
<tr>
<td>CITI Completion Reports</td>
<td>Just move to your “CITI Completion Reports” folder under inbox (best to set up a “Rule” so Outlook does this automatically)</td>
</tr>
<tr>
<td>Study Staff change requests</td>
<td>These requests come from the sender <a href="mailto:ORAIT_NO_REPLY@EMORY.EDU">ORAIT_NO_REPLY@EMORY.EDU</a>. Just move these to your “Staff change” folder under inbox (best to set up a “Rule” so Outlook does this automatically). These are handled by designated IRB staff, not the listserver.</td>
</tr>
<tr>
<td>If you handle listserv on a University Holiday</td>
<td>Complete tasks from your assigned day when you return to the office.</td>
</tr>
<tr>
<td>If Maria Wackerly is unavailable during your listserv day</td>
<td>Complete Maria’s tasks.</td>
</tr>
<tr>
<td>Types of Emails</td>
<td>How to respond/Action taken</td>
</tr>
<tr>
<td>-----------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Complaints from participants</td>
<td>Forward to Team Q (Maria Davila and Shara Karlebach); cc Director</td>
</tr>
<tr>
<td>Compliance or UP-related</td>
<td>Send to Team Q (Maria Davila and Shara Karlebach). If a specific study is mentioned, CC the owner of the study.</td>
</tr>
<tr>
<td>Contact IRB Staff Activity</td>
<td>Emails with this Subject line are generated when someone logs a comment in a study before the study is assigned to analyst. 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. 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.</td>
</tr>
<tr>
<td>Corp_IRB_Options.xls from ORA-IT or OSP</td>
<td>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.</td>
</tr>
<tr>
<td>CTRC approvals (*)</td>
<td>Forward to designated person (Maria Wackerly at <a href="mailto:MWACKER@emory.edu">MWACKER@emory.edu</a>). The designated person will upload as a comment in eIRB. In addition, the designated person will upload DSMB plans, when submitted via listserv. The comment should include whether study was approved, pended, or disapproved. Distinguish between DSMB plans and CTRC approval.</td>
</tr>
<tr>
<td>DSMC Plan approvals</td>
<td>Disregard any that are received</td>
</tr>
<tr>
<td>eIRB account requests</td>
<td>Direct to the IRB Website: <a href="http://www.irb.emory.edu/eirb/index.html">http://www.irb.emory.edu/eirb/index.html</a></td>
</tr>
<tr>
<td>eIRB Additional Role Request</td>
<td>Forward to superusers</td>
</tr>
<tr>
<td>Emails containing identifiable health information, like name of study subject.</td>
<td>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).</td>
</tr>
<tr>
<td>Fee/Cost Questions</td>
<td>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, finance supervisor for OCR, has offered to answer any questions about IRB fees or fee schedules.</td>
</tr>
<tr>
<td>FWA, IRB registration questions</td>
<td>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.</td>
</tr>
<tr>
<td>IRB authorization agreements, collaborating with other institutions</td>
<td>Forward to reliance listserv at <a href="mailto:irb-reliance@emory.edu">irb-reliance@emory.edu</a>. If the email is requesting input on a specific collaborative agreement, have the sender fill out a reliance request form and email to the reliance listserv when completed. Emails updating studies for which Emory relies on another institution (e.g. HTVN studies from Hutch): also forward to reliance listserv, copying Director.</td>
</tr>
<tr>
<td>Membership List Requests/Roster Requests</td>
<td>The IRB does not provide rosters generally. Sponsors may use the compliance letter to confirm that no conflicted members take part in IRB reviews. Refer to Contact Us section on 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.</td>
</tr>
<tr>
<td>Need copy of CITI completion report</td>
<td>Give them web address of 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.</td>
</tr>
<tr>
<td>NHSR Determination Requests/Triaging (*)</td>
<td>Refer to <a href="#">SOP on NHSR Determinations</a>.</td>
</tr>
<tr>
<td>Emails stating Costs option chosen for a particular study (*)</td>
<td>Forward to designated person (Maria Wackerly at <a href="mailto:MWACKER@emory.edu">MWACKER@emory.edu</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. If the study is still in pre-submission and no “Private” comment is available, log any kind of comment you can. For WIRB or other external IRB Cost Options, forward to WIRB Listserv.</td>
</tr>
<tr>
<td>CHOA In Case of Injury (icoi) and Cost Options</td>
<td>Forward to designated person (Maria Wackerly at <a href="mailto:MWACKER@emory.edu">MWACKER@emory.edu</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. If the study is still in pre-submission and no “Private” comment is available, log any kind of comment you can. For WIRB or other external IRB Injury Options, forward to WIRB Listserv.</td>
</tr>
</tbody>
</table>
| PowerChart access inquiries from Emory Healthcare IT "Personnel Verifications" (*) | Forward to designated person (Maria Wackerly at MWACKER@emory.edu). The designated person will verify that the person is listed on the study team for the IRB-approved protocol, and that the study itself is not expired. If the study team member is being added via an amendment which has not yet been approved, then do NOT say that the person is authorized for PowerChart. In addition, the designated person should check staff add requests for the person in case they just were not yet added to eIRB. The designated person sure to let the access inquirer know if the person is not affiliated with Emory (i.e. unassigned department or in non-Emory staff section) by adding the following sample text: “Please note, the requested
For WIRB studies, direct personnel to clientservices@wirb.com

<table>
<thead>
<tr>
<th>Research Match emails</th>
<th>Forward to IRB Director</th>
</tr>
</thead>
<tbody>
<tr>
<td>Removal from IRB listserv (&quot;blast&quot;) requests</td>
<td>Forward to Jessica Blackburn</td>
</tr>
<tr>
<td>Request for in-person consultation</td>
<td>Take first one, and then email office about additional requests during the day</td>
</tr>
<tr>
<td>Request name or dept. change</td>
<td>Forward to superusers</td>
</tr>
<tr>
<td>Study staff change questions</td>
<td>Forward to student workers; CC Team Leads and/or Director.</td>
</tr>
<tr>
<td>Study-related questions</td>
<td>Forward to analyst. If analyst isn’t available, forward to Team Lead.</td>
</tr>
<tr>
<td>WIRB questions, notifications, and forms</td>
<td>Do nothing if they come directly from WIRB. If they are emails from a study team, please forward to WIRB Listserv. Also, please forward any WIRB emails regarding Cost, ICI, or OoQ.</td>
</tr>
<tr>
<td>Other</td>
<td>If unsure how to handle requests that are not noted in this chart, forward to Team Lead 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.</td>
</tr>
<tr>
<td>Emails from LITS about security reviews</td>
<td>Email will contain a report that should be uploaded under study history. If there are issues with finding an IRB number, please contact Maria Davila for help. If 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.</td>
</tr>
<tr>
<td>Voicemails from IRB general number received via email</td>
<td>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.</td>
</tr>
</tbody>
</table>

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

**LOG OF SIGNIFICANT CHANGES**

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/6/2014</td>
<td>Updated staff names to reflect new listserv assignments</td>
</tr>
<tr>
<td>5/7/2015</td>
<td>Updated several actions; removed Kevin as a contact</td>
</tr>
<tr>
<td>3/8/2016</td>
<td>Updated to reflect current processes</td>
</tr>
<tr>
<td>5/26/2016</td>
<td>Clarified how to handle holidays; other minor changes to update contacts and processes</td>
</tr>
</tbody>
</table>
9/16/2016  Updated the time the listserv shift starts and ends; clarified that the practice of emailing the listserv monitor back when answering emails can be replaced by saving the sent message under the Listserv Duties folder
10/5/2016  Updated contact people for IIAs and IIAs, as well as contact person for emails in listserv
11/8/2016  Added information about forwarding CTRC, Cost option and CTRC to Adrianne
4/20/2017  Updates about NH/NHSRD process and other clarifications
7/14/2017  Minor changes. Instructions of who is responsible for NHSRD assignment when designated person is out of the office
1/31/2018  Updated SOP replacing designated person for some task and removing Mike Deryck and adding Hanna Allen. Added process if designated person is out of the office
5/17/2018  Added CHOA ICOI email process; other minor changes
6/8/2018  Additional changes including updated to IAA information, and delete of outdated information
7/25/2018  Added more information about LITS security review. Added the requirement of reviewing voicemails.
PURPOSE
Provides steps to 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).

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](http://listserv.cc.emory.edu/cgi-bin/wa?INDEX)
2. If this is your first time – click on the blue text: get a new LISTSERV password.
Creating Email List

1. Run rptSystem: 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/

5. From the top right 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. Components:
   a. Title: Emory IRB Update at Cambria 26, Date at Cambria 12
   b. Table of Contents: Linking to individual sections; Title at Cambria 13 and Items at Calibri 11
   c. Content: Titles linking back to TOC; Titles at Cambria 13, Body Text at Calibri 11
   d. Contact US: Includes IRB email, phone number, website, and physical office; Title at Cambria 16, Body Text at Calibri 11
   e. Unsubscribe instructions: Send unsubscribe email to listserv or request to IRB email; Calibri Italic 10
4. TOC title link to sections
   a. Highlight section title
   b. Right-click and select Hyperlink...
   c. Select Place in this Document
   d. Select the appropriate Heading
5. Content headings link back to the TOC
   a. As above
   b. Select the Things to Know heading
   c. Repeat for each heading
6. To create new headings
   a. Go to the View Tab
   b. Select Outline view
   c. Add desired text
   d. Set as Level 2

**Unsubscribing instructions**

1. Users can unsubscribe via two methods:
a. Send an email to 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 and to the listserv manager(s)
b. Send a request to 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

Sending the Blast

1. Paste the drafted blast into an email
2. Ensure HTML is enabled
3. Send the email to irbresearch-l@listserv.emory.edu

Adding/Removing List Owners

1. Login to the Emory Email List Service
2. From the List Management drop-down, select List Configuration then Manual List Configuration
3. Add/Remove the relevant email from an Owner line
4. Save

LOG OF SIGNIFICANT CHANGES

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/5/2016</td>
<td>Adding graphics to instruction plus instructions if logging in for the first time</td>
</tr>
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</table>
PURPOSE
This SOP and document exchange noted below will serve to ensure that both parties are aware of research related activity associated with their institutions and are afforded the proper oversight of said research efforts.

SCOPE
This SOP applies when providing study information for studies conducted at Grady Health System as reviewed and oversight provided by Emory University Institutional review Board.

PROCEDURE
• Minutes, general study information and other notifications will be exchanged:
  1. **Minutes:** Emory University IRB will provide the approved minutes from the last period for studies that list Grady Health System as a site. The designated analyst assistant will extract the portions of the minutes for these studies and create a new PDF form. These minutes will include personnel participating in the review. See SOP entitled: “Providing Minutes to Grady Health System”
  2. **General Study Information:** The designated analyst assistant will run two searches, one in e-IRB and one in Thicket for Grady Studies. The e-IRB report will include the study ID, name and description of the study, date approved, expiration date, project state, principal investigator’s name, sub investigators’ name, study coordinator’s name, Non-Emory study staff’s name, Sites where study is conducted, Non-Emory sites where study is being conducted and PHI sources. The report should include a list of terminated studies that were conducted at Grady Health System.
  3. **Other notifications:** the QA team lead will provide copies of IRB determinations for Unanticipated Problems and Non-compliance for studies conducted at Grady.
  4. A one-time listing of Emory’s IRB membership and any changes that occur in this membership

• The timeline for document exchange:
  o The documents will be sent every three months.

• Method for document exchange:
  o The documents will be sent via email using Emory’s email exchange. Information should be mailed to Shirley Marshall at smarshall@GMH.EDU.

LOG OF SIGNIFICANT CHANGES

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<tr>
<td>12/20/2016</td>
<td>Updating personnel running reports</td>
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<tr>
<td>1/27/2017</td>
<td>Update to personnel running reports and procedures</td>
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PURPOSE
The purpose of this document is to outline the process of sending relevant excerpts from Emory IRB full board meetings to the Grady Research Oversight Committee (GROC). In particular, minutes affiliated with any protocol that has Grady as a study site will be sent to GROC.

SCOPE
This SOP applies to the designated analyst assistant (AA) responsible for sending excerpts from Emory IRB minutes to the Grady Research Oversight Committee.

RESPONSIBILITIES
• AA – will compile minutes and PHI report and follow the steps below. The reports are due every three months.

PROCESS

PHI REPORT

1. Log into eIRB; click the “Projects” tab in the top right; then click the “All Searches” tab.
2. In the search field: Filter by “Name” and search for “%grady”, then click “rptIRB_Study: Studies At Grady Health System - EMRS conversation.” This will bring up a list of all Emory IRB protocols that have Grady as a study site.
3. Or simply click this direct link to skip the first two steps: rptIRB_Study: Studies At Grady Health System - EMRS conversation

4. Click “Export” in the upper-left area of the report window (see image below). A new window will open to note that the report is pending and a “download link will appear when the export is complete.”

5. Download and then open the spreadsheet by clicking the link.

**REDACTED MINUTES**

1. To open Minutes go to: H:\General\CMTE\Meetings\Minutes
   - Save a copy of the meetings to check on your desktop
   - Check each set of minutes for each meeting to select minutes that have Grady as a study site
   - Delete other minute information for studies not conducted at Grady.
   - Put together one document using Adobe Acrobat for the month to be sent to Grady.
   - If the minutes are not finalized, let IRB Director/Team Lead now and use the omnibus forms contained in each Committee folder under “Notes”.
2. Alternatively, you can use the report you run for the PHI report to find the studies you need to include in the redacted minutes:
   Use the “ID” column in the spreadsheet to cross reference and match Minutes from CMTE meetings from the H: drive folder
   On the excel spreadsheet, click Ctrl-F to search for study ID# from the Omnibus form to locate Grady studies
   Once a match is found copy everything for that study and start a running word document which you’ll later save into a pdf format {similar title}, {Grady Minutes September 24, 2013 - January 8, 2014}.

3. Email these document to Grady staff listed below and CC: Maria Davila, IRB Education and Quality Assurance Team Lead.
   - Chadrick M. Anderson, MHA
     Manager, Office of Research Administration
     Office of Research Administration
     P: 404.616.7349
canderson@gmh.edu
   - Shirley Marshall, MHA
     Research Administration
     404.616.7757
     404.616.0747 – FAX
     smarshall@gmh.edu
   - CC: Maria Davila maria.davila@emory.edu

Process Flow

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<td>1/27/2017</td>
<td>Updating procedures</td>
</tr>
</tbody>
</table>

Page 21 of 299
**SOP Title:** IRB Satisfaction Survey

**SOP Category:** Administrative

**Established:** 8/31/2009

**Last Revision:** 9/16/2016

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**PURPOSE**

The purpose of this SOP is to give IRB staff with the language to be used to log request to study teams for feedback.

**SCOPE**

This SOP applies to new studies, amendments, continuing reviews and reportable events for studies approved by the Emory IRB.

**PROCEDURES**

**IRB Staff**

- **Approved Submission in eIRB:** Once a submission (New, AM, CR, or Close-out) has been approved, log a comment to the study team with the following blurb.
  
  “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. You can access the survey by copying the link below and pasting it into your web browser. We appreciate your feedback! [https://www.surveymonkey.com/s/PY2KYLR](https://www.surveymonkey.com/s/PY2KYLR)”

- **Email Signatures:** add the following blurb to your email signature.
  
  “Please click [here](https://www.surveymonkey.com/s/PY2KYLR) to let us know how we’re doing!” where “here” has the following hyperlink: [https://www.surveymonkey.com/s/Qteamfeedback](https://www.surveymonkey.com/s/Qteamfeedback)

**Team Q for REs**

- **Closing RE:** please log a comment to the RE history with the following blurb. Now that the reportable event has been reviewed, 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. You can access the survey by copying the link below and pasting it into your web browser. We appreciate your feedback! [https://www.surveymonkey.com/s/Qteamfeedback](https://www.surveymonkey.com/s/Qteamfeedback)

- **Email signatures for Team Q (REs):** “Please click [here](https://www.surveymonkey.com/s/Qteamfeedback) to let us know how we’re doing!” where “here” has the following hyperlink: [https://www.surveymonkey.com/s/Qteamfeedback](https://www.surveymonkey.com/s/Qteamfeedback)

**LOG OF SIGNIFICANT CHANGES**

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<tr>
<td>5/13/2015</td>
<td>Added Q language</td>
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<tr>
<td>9/16/2016</td>
<td>Updated blurb to say “copying the link below and pasting it into your web browser” instead of “clicking on the link below”.</td>
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SOP Title: Adding/Removing Study Personnel via a Web Request

SOP Category: Administrative

Established: 4/11/2014

Last Revision: 5/17/2018

PURPOSE
To explain the use of an online form allowing certain changes to study personnel to be done, without using the amendment process in eIRB.

SCOPE
The SOP applies to all approved, non-expired non-AVAMC studies. Changes that may NOT be made to any study via this method are:

- Change of PI.
- Removal of a Co-Investigator on more than minimal risk studies.
- Addition of staff with conflicts of interest.
- Addition or removal of non-Emory study staff, beyond CHOA staff.

PROCEDURE
- Change requests, submitted by study team members via webform on irb.emory.edu, are sent to the IRB listserv by the Apache mail server.
- Listserve monitor forwards request or handles themselves, depending on current assignment of duties.
- Listserve monitor checks to see if the request is eligible for processing per our policies:
  - If adding:
    - The study is not expired (see “Expiration Date,” not study status), closed, or withdrawn
    - The study is non-AVAMC (Check “Study Sites” page of Smartform, and verify Atlanta VA Medical Center is NOT a site)
    - The PI is not being changed.
    - The person making the request is currently listed on the study as a PI, Co-I, or Coordinator.
    - The person to be added has an eIRB account, unless CHOA.
    - The person to be added does not have a conflict of interest.
    - Person has an Emory email address (indicating that they are affiliated with Emory)
    - The person to be added is not a volunteer being added to a SOM study (without acknowledgment of approval from Lisa Carlson at the the SOM, to show it is part of an internship program).
  - If removing:
    - The study is not expired (see “Expiration Date” in study workspace, not study status), closed, or withdrawn
    - The study is non-AVAMC (Check “Study Sites” page of Smartform, and verify Atlanta VA Medical Center is NOT a site)
    - The PI is not being changed.
    - The person making the request is currently listed on the study as a PI, Co-I, or Coordinator.
Coordinator.
  - The person being removed is not a Co-Investigator on a more than minimal risk study.
    - If changing from one role to another:
      - The study is not expired (see “Expiration Date,” not study status), closed, or withdrawn
      - The study is non-AVAMC (Check “Study Sites” page of Smartform, and verify Atlanta VA Medical Center is NOT a site)
      - PI is not being changed
      - The study is more than minimal risk and a co-investigator is not being moved to another role.

- **Replying to ineligible requests**
  - If the request cannot be made due to being ineligible, containing an error, or for any other reason, the listserv monitor must reply back to the requester, and cc’ing the TL and/or Director for documentation purposes, to notify them the change cannot be made, giving the reason why and instructing them to submit an amendment instead, or to obtain additional required information.
  - Examples of common reply messages are:
    - **Based on study status:** Thank you for your add request. Unfortunately, this request cannot be processed because IRB #xxxxx has been deemed to not need IRB oversight/is expired/is closed/is withdrawn. This determination also negates the need to add study staff. If you have questions about this, please contact our office via irb@emory.edu.
    - **VA study:** Thank you for using the online study staff change tool. We do not process staff changes for VA studies because that requires a different process. Please contact Dr. Roysden (droysden@emory.edu) about the process for adding staff to VA studies.”
    - **Volunteer:** Thank you for your add request. You have identified that [NAME] is a volunteer. Since the study is a part of the School of Medicine, please ensure that all steps for internship have been followed; see http://www.med.emory.edu/research/resources/internship_program.html. Please forward confirmation from contact Lisa Carlson at lisa.carlson@emory.edu to ensure that all necessary documentation is verified before the individual can be added. Please submit documentation of acknowledgment of approval from Lisa Carlson to our listserv (irb@emory.edu) in order for the request to be processed.
    - **Unauthorized requestor:** Thank you for using the online study staff change tool. We can only accept add requests made by coordinators, co-investigators, or Principle Investigator’s already on the study. Please have someone from these roles on the study make the add request for you.
    - **Wrong study number?:** Thank you for using the online study staff change tool. It appears that IRB #xxxxx could not be found. Please verify the study number for the intended study.
    - **Remove Co-I from non-Minimal Risk study:** Thank you for your remove request. Unfortunately, [insert name] cannot be removed from his/her role as Co-Investigator because IRB #xxxxx is standard risk study. Removal of Co-Investigators via the online staff change form is only allowed for minimal risk
studies. In order for [insert name] to be removed as Co-Investigator, you must instead submit an amendment. If you have any questions about this particular issue, please contact our office through the listserv (irb@emory.edu). Thank you for your cooperation, and we apologize for any inconvenience.

- **Person not in eIRB**: It appears that [NAME] does not currently have an eIRB account. If s/he is listed under another name, please email me that name so I can search under it. If s/he does not, please have them log into eIRB through https://eresearch.emory.edu/Emory/, in order to gain access to eIRB, then submit a new "Add Staff" request once s/he has created an account.

  - There are a couple of **special cases** in addition to those addressed above. These cases frequently require additional clarification from the study team and/or response from the person receiving documentation of the addition (TL, RR). They are as follows:
    - (a) Someone is adding staff to a more-than-minimal risk clinical trial with the responsibility of consenting subjects, but is seeking to add them as other staff
    - (b) Someone is adding staff to a more-than-minimal risk clinical trial with the responsibility of interacting with subjects **but not consenting**, and is seeking to add them as other staff.

  In these cases, clarification should be sought from the study team, confirming that the staff has appropriate training (i.e. Intro to Clinical Research or Key Concepts training, additional information about these can be found here: http://ocr.emory.edu/training/index.html). Whether they have appropriate training should preferably be documented in the add request (CITI: Yes AND Key: Yes OR CRC: Yes). For a case of (b), additional information should be sought on what activities the person will be participating in, whether they are carrying out protocol driven duties or clinical duties, and whether they are conducting a verbal consenting process. If in doubt, forward to Bridget Strong for clarification.

- **Processing eligible requests**
  - If all necessary criteria are met, use the Edit Study function to make the change(s) in the “Study Personnel” section of the eIRB smartform
    - For Other-Emory staff additions: Answer the subsequent questions as “yes,” “yes,” and “other.”
    - For CHOA personnel, add under Non-Emory staff.
  - Once the change is complete, log the following comment to the study team notifying them of the change(s)
    - Effective [DATE OF SUBMISSION], NAME has been added/removed/changed, per request.
  - If there is an open amendment, repeat the above steps in the amendment workspace, to add/remove/change role of staff accordingly.
    - Log the following comment in the amendment:
      "Effective [DATE OF SUBMISSION], NAME has been added/removed, changed as/to, per request ROLE. Due to a bug in the system, the same change has been processed in this amendment, so that the study change is not erased after its approval."

### LOG OF SIGNIFICANT CHANGES

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<thead>
<tr>
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<tbody>
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<td>5/13/2015</td>
<td>Added purpose and scope and update of information</td>
</tr>
<tr>
<td>Date</td>
<td>Change Description</td>
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<tr>
<td>6/22/2016</td>
<td>Added guidance for incomplete requests</td>
</tr>
<tr>
<td>5/17/2018</td>
<td>Added information to respond to ineligible requests, replaced SOM contact name for volunteer verification, and added VA information</td>
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</table>
SOP Title: Transferring a Phone Call
SOP Category: Administrative
Established: 9/1/2013
Last Revision: 9/1/2013

PURPOSE
To instruct users how to transfer calls to another staff person’s direct line or external number and/or to someone’s voicemail.

SCOPE
Applies to all IRB team members who need to transfer phone calls

PROCEDURE
1.1. **Transfer to Directly to Voicemail**: Unified Messaging (UM) allows you to transfer a caller directly into another person's voicemail. This feature is commonly referred to as Express Messaging.
   1. With the caller on the line, depress Transfer (or equivalent)
   2. Call 87300 (Unified Messaging) and **WAIT** for an answer.
   3. Go to step 4 if you are transferring "From" an extension that does not have UM Voicemail. **Depress *** if you are calling from a phone that has UM voicemail (otherwise, the system prompts you to log in to your own mailbox).
   4. Enter ##, and when prompted enter the **5 digit extension of the mailbox to which you wish to send the caller, then #** (if you do not enter the last #, you will be transferred to the phone instead of directly to the voicemail box).
   5. Depress Complete (or equivalent) to complete the transfer. (On older model phones, depress Transfer or Link again to complete the transfer)

1.2. **Transfer to an internal line**:
   1. Press Transfer
   2. Dial the number to which the call will be transferred
   3. Press Complete and Hang Up
      a. To stop the transfer, press Cancel to return to your original party.
      b. If you make a dialing error, press Clear to re-enter the number

1.3. **Transfer to an external line**:
   4. Press Transfer
   5. Dial the 9+ area code+ number to which the call will be transferred
   6. Press Complete and Hang Up
      c. To stop the transfer, press Cancel to return to your original party.
      d. If you make a dialing error, press Clear to re-enter the number

1.4. **Transfer to a Call & Connect/Conference Parties**:
   1. Press Conf
   2. Dial the number to which the call will be transferred
   3. Wait for the party to answer, announce call
   4. Press Join Introduce Parties and Hang Up
      a. To stop the transfer, press Cancel to return to your original party
b. If you make a dialing error, press Clear to re-enter the number

Additional Reference:

1. Listen to the caller. Let them explain the issue and don’t cut them off. It’s possible you may be able to answer the question without a transfer.
2. Explain why you’ll need to transfer the caller, and give the caller the name and direct line for the extension in case you get disconnected.
3. Ask the caller if they would like voicemail if the extension is not available.
4. If the extension is available, you should give the extension the name of the caller and a brief description of the issue and the study number (this is where step one comes in handy). Make the transfer. This is called a “warm transfer.” A “cold transfer” occurs when you just drop the caller to the extension without first speaking with the extension. Avoid cold transfers at all costs!
5. If the extension is not available, and the caller did not want to be sent to voicemail, go back to the caller, apologize for the inconvenience and take his/her name and number and tell them you will have the relevant person call them back.
6. Go the extra mile...if the extension was not available, follow up with the extension or the caller to make sure the issue was resolved.

Sample script:
After the caller explains the situation...
   Mary is the RPA working on this study and she will be able to answer your question.
   May I connect you to Mary?
If yes, then...
   Mary is in today, but if she is not available at the moment would you like her voicemail?
   (Yes) In case we get disconnected, Mary’s direct line is 712-0216. I’m going to connect you to Mary now.
To Tiesha:
   Hi, Mary. I have Jane Doe on the line and she is calling with a question about changing the inclusion criteria on study 1234. I’m going to put her through. Thanks!
To Mary and the caller:
   Jane you can go ahead, Mary is on the line.

At this point, Mary should summarize Jane’s situation as she understands it and make sure the summary is correct.

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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/)

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
- 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 the desk and the computer for the new employee are set up properly by using the “New Hire Checklist” found on the new staff training website or on the H drive (H:\General\Admin IRB Documents\New Hire Documents).
- 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 IRB Staff so that they can sign-up for the specific days to train the new employee.

New Employee Training Program

- The training program will begin on the start date of the new employee. The training modules found on the training website are to be completed in numerical order. One module is to be completed each day during the training.
- The Analyst Assistant Module is reserved for only new employees that are being hired as Analyst Assistants. This module should be the last module completed during this training program.
• 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 read through the designated module with new employee and follow the directions within the module to complete all of the tasks required for 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.
• Coordinators 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 Team Leads.

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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 current Emory Policy as applicable to IRB staff.

SCOPE
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 corporate credit card. If this is not possible, review 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 in the card that is generally equal to the amount of a day of stay. This hold is released once 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 as personal or corporate card expenses, and tape onto 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 individual or group.
- If a group meal for 10 or less people, list first and last names.
- If a group meal for more than 10 people indicate number served.
• If receipt is missing or lost, list the amount, type, date, and purpose of expense on 8-1/2 x 11 sheet.
• Complete form located at http://ora.emory.edu/docs/orabo_travel_form.pdf
• Deliver documents to ORA Business Operations (ORABO) in 1599 Building, 4th floor, Northwest Corner.

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The turnaround times are listed in **business days**. Study team contributions listed below are considered best case scenario; the IRB cannot control additional delays on their part. Therefore, the overall “total days” are also 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 1:** Staff must log a comment to study team announcing their ownership of new study within 2 business days of being assigned the study (unless OOTO)

**Note 2:** The times below should be decreased if needed due to urgency – discuss with Director or Team Lead if not sure we should act on request for urgent handling.

**Note 3:** 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

**Amendments**
- 90-110 amendments per quarter: less than 1% PQ

**Reportable events**
- 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 Amendments 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 AA’s processing Continuing Reviews, the targets are based on office requirements and alerting Team Lead if other tasks need to be adjusted in order to accomplish this.
For reportable events, 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.

<table>
<thead>
<tr>
<th>Type of Work</th>
<th>Initial Staff Screening</th>
<th>Omnibus Form Deadline and Pinging Schedule</th>
<th>F/up ltr out</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>FB New</td>
<td>Triage when logging comment, then 3-7 d of assignment depending on prioritization</td>
<td>Monday before the meeting (Friday for Tuesday meetings)</td>
<td>2 d of MTG</td>
<td>aim is less than 1 calendar month or less</td>
</tr>
<tr>
<td>FB AM</td>
<td>Triage upon receipt; 3-6 d depending on prioritization</td>
<td>Monday before the weekend (Friday for Tuesday meetings)</td>
<td>2 d of MTG</td>
<td>aim is 3wks or less; PRIORITIZE based on relevance to subject safety</td>
</tr>
<tr>
<td>FB CR (once 45d or less pre-exp date)</td>
<td>Screen no later than 3 weeks from expiration (4 is better); earlier if Grady study; later if submitted less than 30 days before expiration</td>
<td>Monday before the weekend (Friday for Tuesday meetings)</td>
<td>2 d of MTG but lower priority than New and AM – UNLESS Grady, expiring, or study team needs for other reason</td>
<td>Ideal is IRB FB review at least 2 weeks prior to expiration, but 1 week if not possible</td>
</tr>
<tr>
<td>FB Post-Deferral Resubmission</td>
<td>3d – have Chair weigh in on adequacy of response before sending back to Full Board</td>
<td>Monday before the weekend (Friday for Tuesday meetings)</td>
<td>2 d of MTG</td>
<td>Send to same panel if not urgent or submitted near that meeting; if urgent discuss with TL or Director as to whether we can send to different panel.</td>
</tr>
<tr>
<td>Post-Pending Response</td>
<td>2d of receipt</td>
<td></td>
<td>2 d of final approval</td>
<td>If pending response is acceptable, aim for &lt;6d; otherwise aim is 2wks or less</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of Work</th>
<th>Initial Staff Screening</th>
<th>Pinging schedule</th>
<th>F/up ltr out</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple Expedited New</td>
<td>Triage when logging comment, then 3-7 d of assignment depending on prioritization</td>
<td></td>
<td>2 d of decision</td>
<td>aim is 3 wks or less</td>
</tr>
<tr>
<td>Complex Expedited New</td>
<td>Triage when logging comment, then 3-7 d of assignment depending on prioritization</td>
<td></td>
<td>2 d of decision</td>
<td>aim is 4 wks or less; USE PHONE OR EMAIL to resolve issues whenever possible to avoid delays (log notes in study too)</td>
</tr>
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<td>----------------------</td>
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<td>-----------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Expedited AM</td>
<td>Triage upon receipt; 3-5 d depending on prioritization</td>
<td>same day as approval</td>
<td>aim is 1wk or less</td>
<td></td>
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<tr>
<td>by Staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expedited AM</td>
<td>Triage upon receipt; 3-6 d depending on prioritization</td>
<td>2 d of decision</td>
<td>aim is 3wks or less</td>
<td></td>
</tr>
<tr>
<td>by DR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expedited CR</td>
<td>Screen no later than 3 weeks from expiration (4 is better); early if Grady study; later if submitted less than 30 days before expiration</td>
<td>2d of decision</td>
<td>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 expiration</td>
<td></td>
</tr>
<tr>
<td>(once 45d or less pre-exp date)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HSR</td>
<td>Acknowledge immediately; 3d of assignment to screen. For each subsequent response, the IRB staff should reply within 2 days.</td>
<td>same day as determination</td>
<td>aim is &lt; 1wk (*) – we do not wish to hold up projects that do not require any IRB oversight.</td>
<td></td>
</tr>
<tr>
<td>Determination</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exempt</td>
<td>Triage when logging comment, then 3-7 d of assignment depending on prioritization</td>
<td>2 d of decision</td>
<td>aim is 3 wks or less</td>
<td></td>
</tr>
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<td></td>
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</tr>
<tr>
<td>RE case: SNC or CNC</td>
<td>Triage within 1 to 2 days. Sent to CoRE within one week or sooner if having all required case information (**)</td>
<td>If applicable, omnibus form should be added one week before the meeting</td>
<td>Aim is 4 weeks or less</td>
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<tr>
<td></td>
<td>Team Lead will log a comment indicating this is a potential UP case. Send to CoRe within 1 to 2 days</td>
<td>If going to Q, one week before the meeting. If going to other committees, follow facilitator deadlines.</td>
<td>Aim is for 4 weeks or less</td>
<td></td>
</tr>
<tr>
<td>RE case: UP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Triage within 1 to 2 days. Sent to CoRE within one week or sooner if having all required case information, if applicable (**)</td>
<td>N/A</td>
<td>Aim is for 2 weeks or less</td>
<td></td>
</tr>
<tr>
<td>RE case: Not an UP, NC</td>
<td></td>
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</tbody>
</table>

(*) 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

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-28-2016</td>
<td>Complete revamp of targets and columns.</td>
</tr>
<tr>
<td>5/5/2017</td>
<td>Added timeline for comments from study teams</td>
</tr>
<tr>
<td>6/8/18</td>
<td>Revised/added quarterly volume associated with target Performance Quotients</td>
</tr>
</tbody>
</table>
SOP Title: Inquiries & Complaints received about IRB submissions
SOP Category: Administrative
Established: 7/25/2018
Last Revision: 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 Team Leads, 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 Team Lead or Director.
- **IRB Team Lead (TL)** - receives questions/complaints and checks with staff managing study to submit a final response for team when applicable
- **IRB Director (ID)** - receives questions/complaints and checks with team lead and staff member before providing a final response to team when applicable
- **Team Q personnel** - received questions/complaints and responds only if response indicates the IA is following procedure. If not, it will forward question 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.
  o 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 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 procedure, the request will be forwarded to the IA and his/her TL.

**If question/complaint is received by IRB Team Lead**
• 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 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.
    o 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, copying all parties.
    o 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 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.
  o 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 matter is resolved, if ID requests.

**LOG OF SIGNIFICANT CHANGES**

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COLLABORATIVE RESEARCH / CENTRAL IRBS


SOP Category: Collaborative Research / Central IRBs
Established: 9/20/2012
Last Revision: 7/25/2018

PURPOSE
Outline the process an analyst should use for establishing an IRB reliance agreement (IAA/IIA) for a single study where Emory has already approved a study and initiated study activities but submits an amendment or continuing review report which engages another non-Emory site.

For new umbrella single-IRB reliance agreements for groups of studies now and going into the future (e.g. from a research network), please consult with the Director

For more information, please review the following guidance documents:

NOTES
- Before drafting a new IAA or IIA, it is a good idea to check the IAA/IIA tracking sheet on the H Drive under the External IRB Relationships folder>Reliance Agreement Tracking to ensure there isn’t one already (the request may have come in through the listserv or other method previously).
- It’s important to ask your contact at the other institution whether the institution’s policies would consider the other institution “engaged” in the research and would consider the non-Emory study team members to be “agents” of the institution.
- It’s important to note that, where reliance on Emory is not required by the sponsor or by regulation, the other institution can conduct its own IRB review of the non-Emory study team members, and an IAA is not necessary.
- Emory has standing IAAs (or MOUs) with Georgia Tech, CHOA, Morehouse School of Medicine, St. Joseph’s, the Carter Center, UGA, and the American Cancer Society. See http://www.irb.emory.edu/forms/external-irbs/index.html for more information. Study-specific IAA’s are not required with these institutions unless there is a request to override the normal reliance direction for a given study.
- For reference only: Emory also has umbrella reliance agreements in place with the WIRB (Western IRB) and NCI CIRB, and with various institutions for the following research networks: NeuroNEXT, StrokeNet, UAB CIRB, Fast-As and the HVTN, HPTN, and CITN (and possibly others since this SOP was updated). Separate SOP governs handling of studies under those IRB’s.

DEFINITIONS
- Reliance Agreement – Provides a mechanism for an institution or individual engaged in research to delegate institutional review board (IRB) review to an independent IRB or an IRB of another institution. Often referred to as an IAA, IIA, or MOU.
- IIA – Individual or Institutional Investigator Agreement
- MOU – Memorandum of Understanding
RESPONSIBILITIES

- **IRB Analyst (RPA)** – Recognize when another institution may be collaborating in research (often discovered by having a non-Emory study site listed or else the addition of non-Emory study staff). Reviews Reliance Request Form provided by study teams and drafts memo and authorization to present to IRB Director.

- **IRB Q Team Lead (QTL)** - In charge of assigning IAA and IIAs to a designated Analyst Assistant after RPA analysis of the requirement of an IAA/IIA, and memo/authorization review by IRB Director.

- **Institutional Official/IRB Director** – Review all proposed reliance agreements, and provide a signature (Director signs if not federally-funded or if I.O. is not available in a reasonable timeframe).

CONSIDERATIONS

Reliance agreements are governed by the Emory IRB P&Ps, *Emory IRB Relationships with Other Institutions; Reliance Arrangements for IRB Review.*

In general, Emory is open to **relying** on an external IRB when:
- Required by NIH or other funding agency, under discretion of I.O.
- The other institution’s policies and procedures are comparable with Emory’s HRPP policies and procedures
- The bulk of the research activities take place in a geographic area other than that in which Emory University is located (though not international)
- If the study involves greater than minimal risk, it’s much preferred that the reviewing IRB is AAHRPP accredited. If not, consult with Director.
- Emory typically chooses to retain review of a study and not rely on an external IRB when any clinical research *interventions* occur at an Emory site with Emory subjects.

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)
- When the other institution’s or individual investigator’s activities are minimal risk
- When local context is not expected to be a significant factor
- For an individual investigator, when they have 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)

PROCEDURE

- For any AVAMC studies: consult with IRB-VA liaison prior to proceeding
- If request comes from a third party (i.e. not the Emory PI, e.g. other site’s IRB), first step is to verify with Emory PI that he/she is aware of the request and also desires the IAA. If applicable, this must be documented somewhere in the IAA records in case there are later questions about the appropriateness of the IAA.
- If there is a request to use another institution’s agreement template, the IRB Director must decide if we can accept the language in the agreement. Please check with her early in the process.

**Establishing a Reliance Agreement in Which Emory is REVIEWING**

Before anything can be signed, the following steps must be completed:
1. If not done already, the RPA will ask study team to fill the Reliance Request Form to determine whether an IAA/IIA is appropriate or necessary.

2. Using the information provided on the worksheet, the RPA then drafts the Memo to IO and the IAA form (if other institution supplied an agreement to sign, consult with Director as to whether we wish to request use of our own template instead), and saves them on the H: drive in a new folder.

3. Log agreement on the Reliance Agreement Tracking sheet on the H Drive (H:\General\External IRB Relationships\Reliance Agreement Tracking).

4. Determine if the study team should make additional changes to the study submission. Additional changes could include adding the non-Emory study staff, new sites, editing consent form(s) to include other entities who can access study information, requesting a HIPAA waiver to access records from the external site.

5. REQUIRED: RPA presents the drafted memo and reliance agreement to the IRB Director for pre-approval/initials (and signature, if applicable), and then to IO for his/her signature (if not signed by Director).

6. Send the draft IAA, Reliance Request Form, and memo to QTL for delegation.

7. RPA updates Tracking Sheet with status, and corresponds with the relying institution to obtain its signature (unless they already provided a signed agreement (not directly to the other institution’s I.O.). All parties involved should be CC’ed.

   Note: When Emory is the reviewing institution, our IO prefers the relying party to sign the agreement first.

8. Upon receipt of the partially signed agreement, RPA will:
   a. Update Tracking spreadsheet on the H Drive
   b. Note: If IO is not available, leave the packet with his administrative assistant.
   c. If IRB Director is not available to review memo and IAA, have it double-checked by Team Q lead or other Team Lead; if Director would have been signatory (i.e. non-federally-funded), IO can sign instead.
      a. After the final signature is obtained, scan the fully signed and executed document and add to the H: drive folder. Include PDF’s of any important correspondence.
      b. Send a copy of the fully executed agreement to the collaborating institution, and any other interested parties for their records.

9. Finally, update the Reliance Tracking Sheet and ensure that the H: Drive folder complies with the Document Management system outlined below and includes the following:
   a. Memo to IO/Director
   b. Fully executed reliance agreement
   c. Relevant email correspondence

10. The RPA should upload the executed agreement in eIRB as a logged comment in the study workspace along with the following text:

    Dear Study Team,
    
    A reliance agreement (IAA/IIA – choose one) has been executed for INSTITUTION/INVESTIGATOR to rely on Emory's continued review and oversight of this protocol. [If not done already, explain what steps need to be taken in order to include the collaborators – Example, depending on what has already been done:] An amendment should be submitted to add INSTITUTION personnel engaged in research as study team members. If applicable, the amendment should also note INSTITUTION as a study site and include INSTITUTION in the HIPAA Authorization form as an entity with access to identifiable information.
If you have any questions or concerns about the attached agreement, please let me know.

11. Do not add non-Emory personnel to the IRB submission until IRB oversight for the non-Emory personnel/sites is in place (either via IIA, IAA, or realization that an IAA or IIA is not needed), AND any other needed changes are made to the study in eIRB (unless required by relying site IRB, e.g. NIH).
   a. Do not send for expedited review until agreement in place
   b. If FB review is required:
      i. hold from sending to meeting until agreement is in place; or
   c. Advise study team that the sites/personnel will be left off until we review and approve study, then they must be added on via amendment when agreement is ready.
   Note: ensure study is in Changes Requested by IRB while agreement is being worked up and executed. Site Administrator can submit changes for study team upon RPA's request once executed.

PROCESS FLOW

**Establishing a Reliance Agreement in Which Emory is RELYING**

1. Complete steps 1-4 outlined above.
2. The RS will consult with IRB Director or TL as to whether an eIRB submission will be required for local purposes
   - Likely required if Emory will be doing any clinical procedures, but may be required for all studies in the future due to need to obtain COI disclosures, CTRC review even if no clinical procedures but is cancer related, etc.
   - If required, provide study team copy of template eIRB submission, using “Copy Study” activity on IRB protocol # 80101
3. Request a copy of the research protocol if we do not yet have it via eIRB submission; this will be used to verify the information presented in the worksheet, and to keep in our records.

4. Request copy of reviewing IRB’s approval letter.
   • If reviewing IRB determined study is exempt, no IAA should be executed. Inform Emory team that they must submit via eIRB for our own exemption determination. Skip remaining steps.

5. Present the drafted memo and reliance agreement to the IRB Director for pre-approval (and signature, if not federally funded). Provide protocol to Director upon request. Then leave with IO for his/her signature (if federally funded).

   Note: If IO is not available, leave the packet with his administrative assistant with sticky note indicating to contact you once signed. If IRB Director is not available to review memo and IAA, have it double-checked by Team Q lead or other Team Lead; if Director would have been signatory (i.e. non-federally-funded), IO can sign instead.

6. Send the partially executed agreement to the collaborating institution for its signature, either directly or via the Emory study team contact.
   • In the email, be sure to request that a copy of the signed and fully executed agreement be returned to us for our records.
   • Update Tracking spreadsheet
   • Follow-up on obtaining a copy of the executed agreement if it has not been sent within a week (SET OUTLOOK REMINDER).

7. Finally, once duly signed agreement is returned, update the IAA & IIA Tracking sheet and ensure that the H: Drive folder complies with the Document Management system outlined below and includes the following:
   • Memo to IO/Director
   • Fully executed reliance agreement
   • Relevant email correspondence

**Document Management**

- All files related to an IAA/IIA should be stored in a folder at H:\General\External IRB Relationships\Current IAAs (or Current IIAs, depending on the type of agreement) \ according to the type of agreement.
- Memos to IO should be stored in the same folder as the IAA/IIA
- File names follow a specific format
  - Emory Reviewing: EMORY IRB# EMORY PI_RELYING PARTY
  - Emory Relying: EMORY IRB# REVIEWING PARTY_EMORY PI
  - For IIAs: EMORY IRB# EMORY PI_INDIVIDUAL INVESTIGATOR SURNAME

**LOG OF SIGNIFICANT CHANGES**

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
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</thead>
<tbody>
<tr>
<td>3/11/2014</td>
<td>Reformatted and updated the procedures to reflect current practices</td>
</tr>
<tr>
<td>4/26/2016</td>
<td>Revised list of analysts who handle IAA’s and clarified that IRB director should review IO memos; removed name of IO’s admin assistant (since that changes with time).</td>
</tr>
<tr>
<td>9/16/2016</td>
<td>Updated to reflect new process and designated IAA/IIAs analysts.</td>
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<tr>
<td>Date</td>
<td>Change Description</td>
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<tr>
<td>2/6/2017</td>
<td>Updated to reflect new division of duties between RPA and AAs</td>
</tr>
<tr>
<td>7/14/2017</td>
<td>Language clarification; update on process when IAA/IAA is not executed yet</td>
</tr>
<tr>
<td>1/31/2018</td>
<td>Added Hannah Allen (RS) to SOP, replacing Maria Davila</td>
</tr>
<tr>
<td>7/25/2018</td>
<td>Updated SOP to reflect current process</td>
</tr>
</tbody>
</table>
PURPOSE
The purpose of this document is to outline the steps necessary to onboard a new analyst to work with Central IRBs.

SCOPE
The SOP applies to any Emory IRB staff what will be working with Central IRBs (WIRB, NCI CIRB, etc.)

PROCEDURE
WIRB Studies: (see WIRB Study Processing SOP for more information)
• To gain access to the Emory WIRB Listserv: the Listserv owner (Rebecca Rousselle) will need to log onto listserv.cc.emory.edu and add the individual’s email in order to grant access to it.
• To be an authorized Emory IRB representative able to sign off on local context: the IRB Director or delegated staff should email the WIRB Liaison. You can find the current information for the WIRB Liaison at our website at http://www.irb.emory.edu/forms/external-irbs/WIRB.html) requesting the addition of an individual to the list of authorized IRB representatives. Generally, AAs will not need to be an authorized representative to fulfill their functions.
• To gain access to WIRB Connexus: the person requesting access should log on to WIRB Connexus and create an account. This person should let the IRB Director or designee when this process is completed. Once the account is created, the IRB Director or designee should email the WIRB Liaison to grant view access to all current Emory studies.
• To gain access to the Emory WIRB eIRB Shell: Add individual as Co-I to IRB92158
• To gain access to the Emory Box: current owner/editor can add individuals, granting editor access to the IRB CIRB Excel.

NCI CIRB Studies: (see NCI CIRB SOP for more information)
• To gain access to the NCI CIRB IRB Manager:
  o Request a new account from NCI CIRB IRB Manager – https://eapps-ctep.nci.nih.gov/iam/index.jsp
  o The Director or designee should email ncicirbcontact@emmes.com (to update roster to reflect individual as an Institutional Contact
• To gain access to CTSU Registered Member Website: must register with the CTEP-IAM registration system.
• To gain access to the Emory NCI CIRB eIRB Shell: Add individual as Co-I to IRB64666
• To gain access to the Emory NCI CIRB VA eIRB Shell: Add individual as Co-I to IRB88884

CIRB Studies:
• To gain access to the Emory External IRB Shell Short Title eIRB Shell: Add individual as Co-I to IRB80802
• To gain access to the Emory Box: current owner /editor can add individuals, granting editor access to the IRB CIRB Excel.

LOG OF SIGNIFICANT CHANGES

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
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<tr>
<td>11/1/2017</td>
<td>Update to WIRB contact information and minor clarifications</td>
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</table>
**SOP Title:** WIRB Study Processing  
**SOP Category:** Collaborative Research / Central IRBs  
**Established:** 12/9/2014  
**Last Revision:** 5/17/2018

**PURPOSE**
The purpose of this document is to outline the Emory IRB processing of WIRB studies.

**SCOPE**
The SOP applies to all new Phase I-IV drug or analogous device studies that are industry-designed, initiated, and sponsored (with a few exceptions listed on the Form A) that are eligible for WIRB review.

**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 WIRB. There is a link for Form A on the IRB website [http://www.irb.emory.edu/documents/Emory_WIRB_Form_A.pdf](http://www.irb.emory.edu/documents/Emory_WIRB_Form_A.pdf)
- **Institutional Sign-Off** – The process step for which WIRB does not process a study until WIRB receives an email communication from Emory to verify local Emory requirements have been met.
- **Institutional Hold** – The process step for which WIRB holds the approval and consent form documents from the study team until WIRB receives an email communication from Emory to release the Institutional Hold.
- **WIRB eIRB Smartform template** – specialized eIRB smartform for the study team to complete.

**PROCEDURE**

**Part 1: WIRB Form A Processing**
- A study team must submit a Form A via email in order to obtain access to the WIRB eIRB Smartform template.
- Once a Form A is received, the IRB analyst should review each conditional question to make sure the study is WIRB eligible.
  - If the study is not WIRB eligible, direct the study team to submit the study in the eIRB for Emory IRB to review. If there are any push back, contact the IRB Director for next steps.
  - If the study is WIRB eligible, the analyst should generate a WIRB Smartform/study # for the study team:
    1. Log onto eIRB and go to your home page
    2. Locate [IRB00092158 (use link)](http://www.irb.emory.edu/documents/Emory_WIRB_Form_A.pdf), or change your role to study staff and locate the study under Projects/fast find and add the number under “Projects ID”.
    3. Under “My Activities” on the left hand side of the screen, select “Copy Study.”
    4. The following window will pop up.

Submitting this form will copy the current study, and move it to a state of pre-submission.  
You will then be able to edit any and all questions before you submit the study for review. A “Copied Study” is just like a newly “Created” study except all questions have been answered based on the “Original” study.  
You will have to submit this “New” study to the IRB.

* Study Name
5. In the Study Name field, add the following study specific information: “WIRB – [Short title from Form A]” and click OK.

6. Locate the newly created study.
   a. You can locate the newly created study by searching for the short title under the Projects tab or by clicking on the study copied link, Property Changes, IRB Study: IRB000XXXXX.

7. Once you navigate to the newly created study, click the “Edit Study” link on the top left hand side.
   a. Fill in the study name, PI, and coordinator based on the information on the Form A.
   b. Make sure to delete the IRB personnel currently listed on the submission.
   c. Select the Save button (on the top or bottom of the page) to finalize the changes.

8. Log the following template language as a comment to the study team:

   Dear Study Team:
   This submission is now available for your WIRB study. Please see the WIRB Smartform Guidance, available on the IRB website (also attached here-attach with the email), for specific instructions regarding what additional information is necessary to complete this application. Once the study is submitted and the Emory IRB has determined that all local institutional requirements have been met, it will forward the Emory Institutional Sign-Off to WIRB.

   You will also need to submit to WIRB Connexus in parallel to this submission. Note, WIRB will not review the study until they receive notification of Emory Institutional Sign-Off from the Emory IRB.

   In addition, please log a comment note whether you would like for Emory to send the Institutional Sign-Off without waiting for verification of the finalized Cost and In-case of Injury Option numbers. If this is the case, please provide the option number(s) your team prefers in the interim. Please note that the study team may incur a fee from WIRB if the study is submitted with the incorrect Option in the consent forms.

9. Save the Form A in the WIRB Study Documents folder: H:\General\External IRB Relationships\WIRB\WIRB Study Documents.
   a. To create the study-specific folder, you will need to create the folder using the format IRB00XXXXX.

10. Complete the External IRB Tracking Sheet in Emory Box with the study specific information.

11. Email acknowledgment of the creation of the WIRB eIRB Smartform template using the “Notification of creation of WIRB eIRB Smartform WIRB #” email template (found at H:\General\External IRB Relationships\WIRB\Email Templates) top the study team and WIRB LISTSERV.
a. Add WIRB # to the subject line and body of the email  
   i. Attach PDF smartform  

b. Sign email  
c. Click send

That concludes this part of the process. Now you wait for the study team to submit the eIRB study and for them to submit to WIRB directly.

Part 2: WIRB eIRB processing:

- A study team can submit simultaneously to WIRB (via Connexus) and Emory IRB (via the WIRB eIRB template).
- Once the study is assigned, the IRB analyst will review the WIRB eIRB Smartform to ensure:
  a. Log an intro comment according to our current turnaround time requirements  
  b. All study staff have appropriate CITI and Clinical Trials Training (GCP or KC) Certificates  
  c. REMS process has been followed, per our SOP entitled: “REMS study review”  
     i. Study cannot be given the sign-off until the Office of Compliance designated person does not give his/her OK.  
  d. All ancillary committee approval have been received  
     i. i.e. Radiation Safety, IDS, etc.  
     ii. Office of Quality: we don’t need Office of Quality sign off in order to send our institutional sign-off to WIRB. OoQ will need to be in place before we release our post-WIRB-approval institutional hold.  
     iii. In Case of Injury (ICI) and Cost have been determined  
        1. If ICI and/or Cost are pending, study team can submit to WIRB, if they wish. However, any discrepancies would require study team to pay for future amendment, as previously explained in the logged comment.
        a. The analyst is not required to verify the ICI or Cost language in the ICF/HIPAA document during the sign off process. This process is done by WIRB.
- If there is anything missing, send the study back to the study team using the “request changes” function.
- Once all local requirements have been verified:  
  o Use the Institutional Sign-Off email template (found at H:\General\External IRB Relationships\WIRB\Email Templates) to email the study team, WIRB contact, and the WIRB LISTSERV. Copy and paste the template to a new email. Copy the WIRB liaison and any other designated WIRB personnel.  
     a. Upload a copy of the email as a comment to the study staff in the study history.  
  o Change the status of the IRB submission to IRB Chair Correspondence Review  
     a. Select the Admin View button on the left hand side of the study  
     b. Under “Status,” select “IRB Chair Correspondence Review” from the drop-down menu  
     c. Select “Apply” on the top of the page.  
  o Update the Spreadsheet in Box
That concludes this part of the process. WIRB takes over review of the study but might seek some additional information from the study team and/or the IRB. In addition, the study will remain on Institutional Hold with WIRB until Emory removes the hold, as outlined in Part 5.3

Part 3: Emory Input during WIRB Review

- Once study is submitted to WIRB, WIRB analysts begin their review.
- WIRB Listserv gets cc’ed on communications between WIRB and the study team. Scan briefly to make sure there is not an issue that we can help with:
  - Issues that Emory IRB needs to weigh in on:
    - Deviations from our WIRB/Emory consent/HIPAA template (denoted by WIRB as item 12 in WIRB tracking documents). Typically, Emory only really cares about deviations from ICI, Cost, Medical record and HIPAA language.
    - Contact Director to review the changes.
    - No Institutional Sign-Off - look to see if we forgot to email it. Otherwise, are we still waiting on something to sign-off on the study?
    - Ask Director for other issues.

Part 4: Checking the Status of WIRB Studies that have already been Submitted to WIRB:

- Contact WIRB study analyst (if known)
- Call Client Services at 800-562-4789
- Check the status electronically via connexus.wirb.com:
  - Login to WIRB site connexus.wirb.com
  - Select Workspace Sites
  - Sort columns by field you are looking for
  - Click study to view information.
- Contact WIRB Liaison

Part 5: Post WIRB Approval Processing:

5.1 Saving the Regulatory Email and Uploading Docs into eIRB

After the study is approved by WIRB, WIRB will send an email, titled “Regulatory Approval Documents” to the WIRB LISTSERV containing the approval documents.

- 5.1.a. The person handling the WIRB LISTSERV that day will:
  - Open the email and save the attachments under the WIRB Study Document folder (H:\General\External IRB Relationships\WIRB\WIRB Study Documents\IRBXXXXX), only the ones with “initial review notice” in the attachment. Save the ones with the PI name next to the document. Only save the clean, approved version.
  - Update the Spreadsheet in Box
  - Confirm that the Cost Option and ICI Option in the approved consent match the OSP and OCR determinations. Read every word of the Cost and Injury sections and compare to our template for the appropriate Option number determined for the study.

- 5.1.b. If they do not match, send the specific language deviations to the Emory IRB Director (or team lead if she is absent) to see if we can accept the deviation. Copy the Emory analyst who owns the study (“owner analyst”)
  - If we can accept the deviation, WIRB listserv handler performs 5.1.c and
If we cannot accept the deviation, the Owner Analyst does the following steps:

- Send “Need to revise WIRB consents...” email (found at H:\General\External IRB Relationships\WIRB\Email Templates) to the study team, CC’ing WIRB listserv and PI, instructing them to not consent anyone until they amend their consent forms to reflect the negotiated options.
- Log Private Comment in eIRB with the approval documents (so study team cannot access them yet)
- Log comment to Study Team in eIRB with text of the email in the eIRB shell, 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 Amendment notification so that you will see it immediately.
- Set a reminder to check in on the study team weekly to ensure they submit the amendment to WIRB. CC 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 amendment, CC IRB Director and Q Team Lead.
- Once the Amendment approval notification appears in that Outlook folder, review the revised ICF’s to ensure they are now correct, and go to step 5.1.c., then proceed with the rest of this SOP.
- Remove the Outlook rule (leave the folder for future use)

- **5.1.c.** Upload the approved documents (“Certificate of Approval,” Consent Form/HIPAAas, and Revocation) as a private logged comment into eIRB.

### 5.2: Sending Approved Consents to OCR/OTT for new studies

- The person who performed step 5.1.c. above should email the approved consents using the “Emailing W0000 Consent Form” email template (found at H:\General\External IRB Relationships\WIRB\Email Templates) to OCR and the WIRB LISTSERV
  - Add WIRB # to the subject line.
  - Upload approved consent forms (ICF/HIPAA, Rev. Letter).
  - In body of email, add in study title, WIRB #, and PI.
  - Sign email
  - Click send

- In addition, we should email OTT at OTT-ICG@emory.edu (copying the WIRB listserv) by using the “Emailing Consent and WIRB approval letter: EPEX # ADD” email template (found at H:\General\External IRB Relationships\WIRB\Email Templates) following these steps:
  - Upload approved consent forms (ICF/HIPAA, Rev. Letter)
  - Upload WIRB approval letter
  - In body of email, add EPEX Number.
  - Sign email
  - Click send

### 5.3: Removing Institutional Hold

- The Office of Quality will verify either the completion or exemption from the OoQ Checklist within eIRB.
• eIRB will send a notification entitled “Office of Quality Checklist Complete Activity” when there is a change in status.

• Whoever performed step 5.1.c above should look to see if Office of Quality notification has been received from Office of Quality or that the study is exempt from Office of Quality (not taking place at an EHC site).
  o If Office of Quality is done and/or exempt: reply back to WIRB via the regulatory email and state in the body “Please remove institutional hold.” CC the PI, coordinator and WIRB LISTSERV on this email so that they have access to their study documents. WIRB typically takes 1-2 days to update their system to make study docs available to the study team via WIRB Connexus.
  o If waiting on Office of Quality, as a courtesy, send the study team a reminder that this will delay them getting their consents using “On Hold at WIRB” email template (H:\General\External IRB Relationships\WIRB\Email Templates)
    ▪ Note: study teams will sometimes contact you to send the approval letter and/or documents to the sponsor. You can send the approval letter/documents directly to the sponsor but include that they “should not share the consents with the study team due to an institutional hold.”
  o Once the Office of Quality verifies the completion/exemption of the OoQ Checklist, cost, and iCOI option have been verified and amendment submitted (if necessary), send the “Removing Institutional Hold” email template to WIRB.

• In eIRB, change the study status under “Admin View” from “IRB Chair Correspondence Review” to “Approved”

Part 7: Beyond Initial Approval

7.1 Amendments
• WIRB Listserv gets cc’ed on all changes to research and on all approved regulatory documents. No need to save or upload approved Consent/HIPAA forms for already approved studies (however, you will have to check each regulatory document email to confirm this is not an initial approval).

7.2 Continuing Reviews
• WIRB Listserv gets cc’ed on expiration notices between WIRB and the study team. No need for IRB analyst to do anything.

7.3 Reportable Events/ Unanticipated problems
• The WIRB SOP says that the PI should report local adverse events directly to WIRB if they meet the definition of Unanticipated Problem. WIRB will then communicate with our site as needed to resolve. WIRB sets the reporting timelines for the various types of reportable events, which are available on the WIRB website for PI reference. If Emory audit/inspection reveals compliance issues with our local site, then the “institution” must report those findings to WIRB per their reporting guidelines. IRB’s Team Q would be involved in those decisions.
• For REs and Unanticipated Problems that come to us from the PI, Sponsor, or WIRB, Emory IRB (Team Q) will not need to review or re-review, since we are not the IRB of record. However, Team Q should be notified of any WIRB determinations of Serious Non-Compliance and UPs. Refer to Team Q and Director if you are not sure what type of RE it is.
• Save all emails related to REs and Unanticipated Problems under the WIRB Study Document folder (H:\General\External IRB Relationships\WIRB\WIRB Study Documents W00000XXX) after notifying the Q team.
• Update information in NC/UP folder at H:\General\QA Working Files\NC UP Complaints\NC UP tracking sheet.

Part 8: WIRB Close-outs in Current eIRB form

• WIRB close-outs are sent by email to the WIRB Listserv. Save the document in the specific WIRB Study Document folder (H:\General\External IRB Relationships\WIRB\WIRB Study Documents W00000XXX).
• Once a WIRB close-out letter is received, navigate to the specific WIRB study workspace in eIRB.
  - Log as a private comment the Study Close Letter from WIRB.
  - Using Admin view, change the status of the study to Protocol Closed.
• Email the close-out letter using the “Emailing W0000 Close-out” email template (found at H:\General\External IRB Relationships\WIRB\Email Templates) to OCR and the WIRB LISTSERV
  - Add WIRB # to the subject line.
  - Attach close-out letter
  - In body of email, add in study title, WIRB #, and PI.
  - Sign email
  - Click send

WIRB Close-outs for studies that used Form B

• Open attachment from email and copy institutional tracking number (WXXXXX123)
• Open the projects tab in eIRB, under fast find/Project ID and type “IRB_” and paste the tracking number
• Open the workspace, and under “my activities” click on “notification of closure”
• Upload closure notice and enter the date the email came through.
• Email the close-out letter using the “Emailing W0000 Close-out” email template (found at H:\General\External IRB Relationships\WIRB\Email Templates) to OCR and the WIRB LISTSERV
  - Add WIRB # to the subject line.
  - Attach close-out letter
  - In body of email, add in study title, WIRB #, and PI.
  - Sign email
• Click send

For both processes, update the box spreadsheet

Helpful tips:

• When you forward emails, place the WIRB number in your subject line.
• CC the WIRB LISTSERV on ALL email correspondence

LOG OF SIGNIFICANT CHANGES

<table>
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<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
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<td>4/30/2015</td>
<td>Updated close-out section to reflect use of electronic correspondence.</td>
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<tr>
<td>10/27/2016</td>
<td>Updated to reflect use of WIRB Smartform Template via eIRB.</td>
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<tr>
<td>------------</td>
<td>-------------------------------------------------------------------------</td>
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<tr>
<td>4/20/2017</td>
<td>Changes under “removing institutional hold” section, reflecting current process</td>
</tr>
<tr>
<td>11/1/2017</td>
<td>Updates to reflect current process</td>
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<tr>
<td>11/15/2017</td>
<td>Addition of process for amendments after ICF discrepancy</td>
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<tr>
<td>1/31/2018</td>
<td>Updated box link to external IRB spreadsheet</td>
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<tr>
<td>2/21/2018</td>
<td>REMS reference added</td>
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<tr>
<td>5/17/2018</td>
<td>Added process to email OTT after WIRB approval</td>
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**PURPOSE**

The purpose of this document is to outline the steps needed for the IRB staff 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. This SOP includes steps for new studies, continuing reviews, modifications, reportable events, and close-outs.

**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 Assistant):** 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):**

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<tr>
<th></th>
<th>Emory University/Winship Cancer Institute</th>
<th>Emory University</th>
<th>GA005</th>
<th>CIRB Component</th>
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<td>Grady Health System</td>
<td></td>
<td>GA003</td>
<td>CIRB Affiliate</td>
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<td>Saint Joseph's Hospital of Atlanta</td>
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<td>Children's Healthcare of Atlanta - Egleston</td>
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<td>GA035</td>
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<tr>
<td>5</td>
<td>Emory University Hospital Midtown</td>
<td></td>
<td>GA013</td>
<td>CIRB Component</td>
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**PROCEDURE**

The following procedures are included in this SOP:

- **Steps to Provide Study Teams with Access to the NCI CIRB Participants Area**
- **Steps to Obtain Initial NCI and Local Emory Approvals**
- **Responding to “CTSU Inquiry: Site Preference Setting Needed” emails**

**Steps to Provide Study Teams with Access to the NCI CIRB Participants Area**

- NCI uses a platform called [RUMS (Roster Update and Management System)](https://www.ctsu.org/public/default.aspx) to manage our roster of investigators, study staff, and administrative contacts. Only people listed on Emory/CHOA’s roster may work on or be listed on studies at our sites (i.e. access the “Participants Area”)
- Anyone to be added to the Emory/CHOA roster must have an IAM account and a CTEP ID number. The study teams are responsible for doing that part.
- To add, revise, or remove personnel for the Emory/CHOA CIRB Roster, an Emory IRB staff person who has access to and is trained on RUMS (CTSU.org/public/default.aspx) must make the request in that system.
  - If a new IRB staff person needs to be given privileges in RUMS, the IRB Director may make that request to CIRB
Study teams are encouraged to complete the webform at http://www.irb.emory.edu/forms/external-irbs/cirb.html to obtain an account to NCI CIRB’s IRBManager, IAM system. Alternatively, the study team can email the necessary information to WIRB listserv.

Once NCI CIRB processes the request, a separate email with login information will be sent to the new personnel’s email address.

Steps to Obtain Initial NCI and Local Emory Approvals

Step 1: Study Team Identifies an eligible study

Studies and related materials approved by NCI CIRB are made available to participants on the NCI CIRB website.

Step 2A: Beginning the local Emory review process

Note: If the study is under REMS, ask team to contact Margaret Huber and to fill REMS worksheet.

This should be done while preparing the submission to NCI CIRB and our eIRB submission.

Study teams should contact the WIRB listserv / Emory IRB contact to request access to the abbreviated eIRB Smartform template.

The request should include the following information: PI name, study title, coordinator and if the study involves pediatric patients or the VA.

- Emory IRB contact should log into eIRB and select the Study Staff role under the My Roles selection on the top left corner. Depending on the type of Smarform requested, the IRB contact should select the appropriate template (“NCI CIRB Pediatric Template”, IRB #64632, for CHOA studies, “VA CIRB”, IRB #88884, for VA studies, and “NCI CIRB Template”, IRB# 64666, for WCI studies).

- On the left hand side, under My Activities, select “Copy Study” This will create a carbon copy of the original template. Be sure to title the study CIRB: [Short Protocol Title].

- Once the study is copied, return to the Study Staff role to find the new study (search for the short title you gave it), edit the details of the newly created eIRB study to insert the long study title into question 1.0, select the correct PI and coordinator, and remove IRB staff from the personnel list.

- Save the study and, via email, provide a hyperlink to the study team of the newly created CIRB shell along with a link to our website guidance for NCI CIRB studies and how to fill in the smartform: http://irb.emory.edu/documents/NCI-CIRB-guidance.pdf and http://irb.emory.edu/documents/CIRB-smartform-template-guideline.pdf.

  - Copy the WIRB listserve (wirb-l@listserv.cc.emory.edu).

- Log a comment to study staff, in the study, as follows (attaching the NCI CIRB study guidelines, and the smartform template guideline, as attachments to the comment):

  - The IRB created this shell on [date]. Please follow the attached guidelines attached to submit to NCI and fill in this smartform. Remember to uncheck any boxes that are not applicable to your study, and check any new ones that are. Please contact wirb-l@listserv.cc.emory.edu with questions. Please have the PI submit this eIRB form as they would with any other study, once completed. Thank you!

- Once the study team submits the smartform, the IRB Director (or delegate) will assign an owner (the IRB Contact). The IRB Contact goes to Step 4 below and verifies as much as possible, depending on what the study team submitted.

- If items or missing or incorrect, the IRB contact sends the eIRB form back to the study team for changes.

Step 2B: Study team begins the NCI CIRB approval process
• Studies are opened by a Signatory Institution Principal Investigator by submitting the Study-Specific Worksheet to the CIRB for review via IRBManager.

• Note, the Study-Specific Worksheet must include any deviations from Emory/NCI CIRB’s Boilerplate Language (i.e. Radiation Safety Language).

Step 3: Emory IRB Processing of the NCI CIRB approval

• NCI CIRB will email the PI an approval letter, along with the Emory/NCI CIRB’s Boilerplate Language. The study team is responsible for merging the CIRB-approved model consent with the Emory/NCI CIRB’s Boilerplate Language.
  
  o Note: the NCI CIRB may also email the Emory site approval document to IRB staff directly; this should be ignored unless for some reason the study team is unable to provide the approval documents.

• Study team should log a comment to the Emory IRB (initially, if available, or when submitting changes): 1) the merged consent/HIPAA form, 2) the NCI CIRB approval letter for Emory site, and 3) the NCI CIRB expiration date (via overall study approval) for the study via eIRB once available.

Step 4: Processing Emory’s local acknowledgment

• Emory IRB contact will verify:
  
  o All study personnel have the required training (CITI and Key Concepts/Intro to Clinical Research)
    ▪ If study has VA as the only site: VA has their own training requirements. Their accounts should be associated with Emory to see the completion.
  
  o All ancillary reviews have been completed (CTRC, IDS, etc.)
    ▪ If study has VA as the only site
      • IDS, biosafety and Radiation safety: VA has their own pharmacy and it will not go through IDS. The VA Pharmacy does not give exemptions from the R&D process. The same can be said for other sub-committees. In case of questions, contact Jennifer Whelan at Jennifer.Whelan@va.gov
    ▪ If study has both VA and Emory sites: Study team will have to submit one submission for the VA and one for Emory, so the ancillary review requirements are completed without confusion
  
  o The language in the consent matches the required ancillary reviews (Cost, In-Case of Injury, Radiation Safety, etc.). All federally funded studies are assumed to be ICOI option #1, so we don't need confirmation from OSP.
  
  o The study meets the criteria for a partial HIPAA waiver, and then forward to IRB Director; – this waiver must be documented in the eIRB study History.
    ▪ Once IRB Director replies with their approval, the Director will log a comment in the eIRB submission.
  
  o That the appropriate HIPAA language has been incorporated into the consent document(s)
  
  o REMS process has been followed, per our SOP entitled: “REMS study review”

• If any changes are required, or if any training is missing, send the study back to the study team with requested changes, as you would with a normal study.

• To move the submission forward, the IRB Contact changes the Status of the study to “Approved” under the Admin view link in the study. Set the approval date to the date the acknowledgment
letter is dated, and the expiration date to the overall expiration date of the study (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 for a good reason – check with IRB Director - you could set the expiration date to 1 year minus a day from the approval date]. Merge the consent forms to stamp the consent forms using the approval and expiration dates set for the eIRB study.

- Once the requirements have been verified, the IRB Contact will issue an acknowledgment letter via a logged comment to study team attachment. The template acknowledgment letter can be found at H:\General\External IRB Relationships\IRB Auth Agreements\Umbrella IAAAs and FWA Addendums\NCI CIRB\NCI CIRB templates. Stamped ICF/ HIPAA documents can be released only when study teams have obtained approval from CIRB and Office of Quality Checklist (if applicable).

**Responding to “CTSU Inquiry: Site Preference Setting Needed” emails**

NCI needs to know which physical sites will be conducting research activities for studies becoming active at Emory (e.g. Winship, Emory University Hospital, Saint Joseph’s, etc). The email will reference the NCI study number, not an eIRB number.

1. Look up the eIRB shell in the Projects area of eIRB (in case study is still in pre-submission), using a short part of the study protocol name (e.g. if the protocol is referenced as NRG-BA005, search for %BA005 in the “Project” field on the left of the screen).
2. Look in the eIRB shell for the study to see what sites were selected in the Smartform
3. Reply to the CTSU inquiry email with the code names for the sites selected.
   a. If VA is a site, use code number GA002

**PROCESS FLOW**

[Diagram showing the process flow of eIRB submission and approval, including steps such as study team requests an eIRB template shell, IRB analyst copies appropriate template and provides access to study team, study team fills in the designated sections and merges the NCI model consent with the boilerplate language, study team provides the NCI local context approval letter, overall study approval letter, consent, study team verification, and ancillary committee approvals, IRB analyst verifies: study team certification, ancillary reviews, Smartform, and consent forms, IRB analyst changes the status of the IRB submission to "Approved" under the Admin View of the study, IRB analyst stamps the consents with today’s approval date and the overall study expiration date.]
Processing Continuing Review

- Study team must provide Emory IRB with NCI CIRB overall-study the continuing review approval letter so expiration dates can be updated in eIRB (usually attached to logged comment)
- No formal CR submission in eIRB is required.
- IRB contact should update the eIRB expiration date (per NCI reapproval letter) and the approval date (date that the overall studies is reapproved).
- Consent documents should be restamped with the approval date (being the date that you are stamping the consent forms) and expiration date (per NCI reapproval document) (though the consent form may not include Expiration Date in the header).
- Log a comment to the study team letting them know that the renewal has been acknowledged and consents were stamped.

PROCESS FLOW

Processing Modifications

A. Modifications that do not require notice to Emory IRB via an amendment in eIRB:
   - Changes to the overall study that do not include a consent revision (many times a protocol update will require an update to the consent form just to update the version date to match the revised protocol, however, even if there are no content changes in the consent form; we must stamp those revised consent forms for them in these cases, may not require an amendment). If a team submits an amendment for these, we should ask study team to withdraw.

B. Modifications that require approval from NCI CIRB, and also local context review by Emory IRB via eIRB
   - Changes to PI
   - Changes to locally produced advertisements/requirements. If no NCI CIRB letter not provided, send to a staff designated reviewer, as a result of local change only
   - Any translated documents not already approved by NCI CIRB

C. Modifications that require notice to Emory IRB via an amendment in eIRB:
   - Changes to any study personnel
   - Changes to the consent forms

To process modifications under category B or C, have study team submit the amendment. IRB analyst should assign the review to themselves (adding CIRB study in the notes category of assignment.) IRB analyst should complete the review, answering the applicable questions to the sections that are actually
under Emory IRB review [i.e. no need to review the protocol]. Once the review is complete, IRB analyst
should report the expedited amendment review to committee meeting, adding CIRB to the comments.
IRB analyst should write an approval letter making the following type of modifications to the template
letter [no need to add items that were not reviewed by the Emory IRB, i.e. protocol, IB, etc.]

The following changes have been approved:
  Staff changes
    • removed: X
    • added: X
  Changes to consent forms
    • Consent XX, version date XXX

Stamp the consent forms with the date of the Emory IRB review being complete.

PROCESS FLOW

Processing Reportable Events
  • In the event of a local unanticipated problem involving risks to subjects or others, or serious or
    continuing noncompliance, the PI is responsible for reporting to NCI CIRB, according to the NCI CIRB
    reporting requirements.

Processing Close-Outs
Step 1: PI submits a Study Closure to NCI CIRB via IRBManager
Step 2: PI submits a Close-Out in eIRB once NCI CIRB approves the study closure

PROCESS FLOW
**LOG OF SIGNIFICANT CHANGES**

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<tr>
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<td>Change formatting and added information under responsibilities</td>
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<td>2/6/2017</td>
<td>Changes to reflect current process</td>
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<td>11/1/2017</td>
<td>Changes to reflect current process</td>
</tr>
<tr>
<td>2/21/2018</td>
<td>Added reference to REMS process and to ask teams to withdraw unnecessary AMs</td>
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PURPOSE
The purpose of this document is to detail how to process and review notifications of UPs that are received from external IRBs.

RESPONSIBILITIES
- IRB Analyst – identifying and tracking the notification of UPs managed by external IRBs. Reporting selected notifications to the Office of Compliance or Risk Management, as needed.
- Team Q - reviewing the notifications of UPs managed by external IRBs and determining the applicability of the information to the local IRB in consultation with the IRB Director.

PROCEDURE
1. External IRB will notify local contact (via listserv) of UP determinations.
2. IRB Analyst will document the pertinent details of the event on the NC UP tracking sheet found at H:\General\QA Working Files\NC UP Complaints.
3. IRB Analyst will forward the UP notification to Team Q.
4. Team Q, in consultation with the IRB Director, will review if the UP determination (coming from safety event) should be assessed for other studies using the same drug or device.
5. In consultation with Team Q, the IRB Analyst will forward the following notifications to the Office of Compliance and/or risk management as applicable:
   a. If the unanticipated problem indicates a major risk for other subjects e.g. A serious adverse event caused by negligence of the study team.
   b. The unanticipated problem was caused by an error in process that may reoccur without intervention e.g., laboratory process or pharmacy error
   c. If the UP involves a confidentiality breach if Emory is the responsible party for HIPAA waivers or consent.

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<tr>
<td>11/1/2017</td>
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SOP Title: Vetting NIH Single IRB Plans
SOP Category: Collaborative Research / Central IRBs
Established: 5/15/2018
Last Revision: 6/8/2018

PURPOSE
This SOP will detail how to process and review requests for Emory to serve as the Single IRB for a NIH multi-site research at the grant application stage.

RESPONSIBILITIES

• Reliance Specialist/Other IRB Staff Member – processing the request, providing a response to the investigator, providing resources to the investigator, saving all documentation.
• Investigator – filling out the request, putting a single IRB quote in the budget, filling out the single IRB portions of the grant application.

PROCEDURE

• As early as possible, the Emory investigator should send a Single IRB Intake Form to the IRB Reliance Listserv (found at www.irb.emory.edu/forms/external-irbs/index.html at “What if I’m applying for NIH funding?”)
• The IRB staff member will review the Single IRB Intake Form to determine whether Emory may serve as the single IRB or whether the study must be reviewed by an external IRB (another participating institution or a commercial IRB).
  o If Emory IRB is willing to be the IRB of record, let the investigator know they may proceed with the Single IRB Plan stating the same and do not need to get a single IRB quote.
  o If Emory IRB is not willing to be the IRB of record, one of the following should happen:
    ▪ 1) IRB staff member should assist the investigator in identifying another participating institution that will be willing to serve as the single IRB (and add a WIRB quote into the budget)
    ▪ 2) IRB staff member should instruct the investigator to submit the study to WIRB (and add a WIRB quote into the budget)
• When a single IRB is identified, the investigator should use the templates on the website to draft the Single IRB Plan accordingly.
• If Emory is not serving as the Single IRB, IRB staff member should also encourage the investigator to use the Single IRB Quote Request Form on the website to factor the single IRB cost into the budget.
• IRB staff member should save the Single IRB Intake Form and any email correspondence under the H Drive at General>External IRB Relationships>NIH Grant Application Reliance Requests by opening a new folder and naming it as follows: Last Name, First Name – Title.
• Note: Once funding is secured, follow the Processing Reliance Agreements SOP (from reliance request to approval).
## LOG OF SIGNIFICANT CHANGES

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PURPOSE
This SOP will serve to outline the process of collecting information needed to make a determination regarding Emory’s willingness to rely on another institution’s IRB for review or to serve as the IRB of Record for another institution.

SCOPE
This SOP applies to any study which has multiple sites when an Emory PI or IRB administration from another institution comes to you with a request for IRB reliance for a NEW study. To add new sites to a previously-approved Emory study, see the Setting up an IRB Authorization Agreement or Individual Investigator Agreement SOP for IRB analysts.

NOTES

• If you are an analyst who receives a request for reliance that fits within this SOP, direct the requesting individual to email the IRB Reliance Agreement Worksheet to the IRB reliance specialist, Hannah Allen, at Hannah.allen@emory.edu.

• For Emory studies which have been previously reviewed and approved as single-site studies, the analyst assigned to the study shall handle the reliance agreement via the one-page IAA template and shall process the amendment onboarding the new sites where the sites have limited involvement (e.g. one investigator from another institution participating in data analysis at Emory). (See the Setting up an IRB Authorization Agreement or Individual Investigator Agreement and Onboarding a Participating Site via Amendment SOPs for this process)

• Before drafting a new IAA or IIA, ensure we do not already have an MOU in place with the other institution. Emory has standing IAAs (or MOUs) with Georgia Tech, CHOA, Morehouse School of Medicine, St. Joseph’s, the Carter Center, UGA (in progress), and the American Cancer Society.
  - See http://www.irb.emory.edu/forms/external-irbs/index.html for more information.
  - Study-specific IAA’s are not required with these institutions unless there is a request to override the normal reliance direction for a given study.
  - For reference only: Emory also has umbrella reliance agreements in place with the WIRB (Western IRB), NCI CIRB, and Advarra, and with various institutions for the following research networks: NeuroNEXT, StrokeNet, UAB CIRB, Fast-As and the HVTN, HPTN, and CITN (and possibly others since this SOP was updated). Separate SOP governs handling of studies under those IRBs.

• The reliance specialist should create a file for each study under the H Drive (General>External IRB Relationships>IAAs/IIAs>Emory Relying/Reviewing) for each study involving reliance and should save all relevant documents and emails in the file throughout the process.
• The reliance specialist should log all reliance agreements on the Reliance Agreement Tracking spreadsheet found on the H: Drive and create an “IAA Status Checklist” for each study involving reliance, and should continue to update the checklist throughout the process (saved in relevant folder on H: drive)

DEFINITIONS

• Reliance Agreement – Provides a mechanism for an institution or individual engaged in research to delegate institutional review board (IRB) review to an independent IRB or an IRB of another institution. Often referred to as an IAA, IIA, or MOU.
• IIA – Individual or Institutional Investigator Agreement; between Emory and a sole researcher affiliated with another non-FWA-holding entity or without any institution affiliation.
• MOU – Memorandum of Understanding; a longer agreement between two institutions which covers multiple studies under one document.
• POC – Point of Contact; the individual at the other institution who is responsible for handling reliance agreements.

CONSIDERATIONS

• IN GENERAL, Emory is open to relying on an external IRB when/if:
  o Required by NIH or other funding agency, under discretion of I.O.
  o The other institution’s policies and procedures are comparable with Emory’s HRPP policies and procedures.
  o The bulk of the research activities take place in a geographic area other than that in which Emory University is located (though not international).
  o If Emory is the prime awardee and/or lead site, the other institution must be willing to indemnify Emory.
  o If the study involves greater than minimal risk, it’s much preferred that the reviewing IRB is AAHRPP accredited. If not, consult with Director.
• IN GENERAL, Emory is open to reviewing for another institution or investigator when/if:
  o 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).
  o The other institution’s or individual investigator’s activities are minimal risk.
  o Local context is not expected to be a significant factor.

PROCEDURE WHEN EMORY RELYING

• Once a request is received, ask the Emory study team to fill out the Reliance Request Form (found here: http://www.irb.emory.edu/forms/external-irbs/index.html)
  o If the request comes from a third party (i.e. any non-Emory or non-Emory affiliated personnel), first verify with the Emory PI that he or she is aware of the request and also desires the IAA. Please document this desire in IAA file.
  o The IRB staff member (reliance specialist) should NOT take the proposed reliance agreement into consideration until the Reliance Request Form is completed in full and
submitted to the IRB Reliance Listserv and until any follow-up questions are addressed. There are no exceptions.

- Once the Reliance Request Form is completed and received, forward it to the Director to confirm that the IRB is willing to pursue a reliance agreement. If yes, continue to the next step. If no, inform the Emory PI and other relevant individuals that Emory is not willing to enter into a reliance agreement.
  - NOTE: Please make sure the Lead Study Team has received IRB Approval and model study documents back from the Proposed Reviewing IRB before pursuing a reliance agreement. If this has not been done, tell the Emory Study Team to notify you when they have received approved documents back so that you can begin the reliance agreement process at that time.
- Create an eIRB shell by copying the XIRB template study no matter the details of the study.
  - Name the eIRB shell as follows: XIRB: Name of Other Institution – Study Nickname
  - Email the study team to ensure they received the shell.
- Log a comment to the study team in eIRB which states the following:
  - Dear Study Team: The IRB created this template smartform for this study on [DATE]. Please see the guidance at the link below for how to fill in the smartform, then have the PI submit as for a normal IRB submission. You can contact me if you have questions. Remember to uncheck any irrelevant boxes on this template smartform, and check any others that may be applicable. Thank you!
  - Attach the XIRB smartform template guideline document to the comment.
  - Continue to update the IAA Status Checklist with status throughout the process.
- Email the Emory study team and request any and all local context or site submission forms required to be filled out by the Reviewing IRB.
- Email the Reviewing IRB POC to negotiate the Indemnification language (if applicable) and Insurance language (if applicable) and modify IAA form as needed.
  - Use the Reviewing IRB’s system for negotiation to the best of your ability. If the Reviewing IRB does not have a system for negotiating these issues, you may send them our “Division of Responsibilities Table” (on the H: Drive under External IRB Relationships>Online Tools and Aids) and our indemnification language and insurance language (within the “IAA (when Emory reviewing)” template on the H: Drive under External IRB Relationships>Templates>Agreements).
- Draft the Memo to IO using the Reliance Agreement Memo Template in the External IRB Relationships folder under “Templates” and the IAA form (including any negotiated terms) and present to Director for pre-approval initials, and then to IO for his/her signature (if not signed by Director).
- Send the partially executed IAA to the POC for other institution’s IO signature.
- Once the fully executed agreement is received from the other institution, log a comment to the study team in eIRB which states the following (attaching the signed agreement):
  - Dear Study Team,
  Attached, please find a fully-executed reliance agreement between Emory and [ ] for this study. This comment serves as confirmation that the Emory University IRB is relying on the ____ IRB review and oversight of the above-referenced study, pursuant to the
attached agreement, effective [date of last signature]. Based upon Emory’s reliance, independent Emory IRB review is not required.

- At this time, the Emory study team should complete the eIRB local submission as instructed in the first logged comment (See Step 4), ensuring that they have met all of the components in Step 12 below. The Emory study team is ultimately responsible for plugging the Emory-specific provisions (typically cost, injury, and HIPAA authorization language) into the appropriate places on the Reviewing IRB’s approved/model consent form and attaching a redlined copy AND a clean copy to the eIRB submission.
  - Note: In the event the Emory study team has not been provided an approved/model consent form, it is sufficient for the Emory study team use the appropriate Emory consent template in the Consent Toolkit (found here: http://www.irb.emory.edu/forms/consent_toolkit/index.html).
  - Please see the SOP for Customization of Consent Forms for XIRB Studies for more detail.
- Once the study team submits the SmartForm in the eIRB shell, determine if the study team should make additional changes to the study submission.
  - Ensure that all investigator training has been completed and is up-to-date in CITI.
  - Ensure that pdf documents of the protocol and grant (if applicable) are attached and that they are congruent.
  - Ensure that there are no financial conflicts of interest noted.
  - Ensure that all necessary information has been filled out.
  - Check the ICF and HIPAA Authorization for completion and accuracy.
  - Check injury language for completion and accuracy.
  - Ensure that all departmental reviews, ancillary reviews, and OCR involvement have been completed, if applicable.
  - Ensure that Margaret Huber in the Office of Compliance (mhuber@emory.edu) has completed a REMS review of the study, if applicable.
- If changes are needed, click “Changes Requested by IRB Staff” and describe what changes are needed.
- Once you’ve ensured that the eIRB submission and forms to be sent to the other institution are accurate, sign the local context forms if there is a place for a Local Context Representative signature. Scan the forms and place them in the appropriate study file in the External IRB Relationships folder on the H: Drive.
- In the eIRB shell, log a comment to the study team which states the following (and attach the completed local context forms):
  - Dear Study Team,

    Your SmartForm, Investigator Training, Informed Consent and HIPAA Authorization Form(s), and Local Context Form(s) have been reviewed through Emory IRB’s Local Context Review process. All approved Local Context Forms are attached. This comment serves as Emory’s acknowledgment of the Institutional Sign-off for this study. You may now provide the attached forms and make your submission to the external IRB. Please email your approval documents at hannah.allen@emory.edu as soon as you have received them from the external IRB.

PROCEDURE WHEN EMORY REVIEWING
• Once a request is received, the reliance specialist will ask the Emory study team to fill out the Reliance Request Form.
  o If the request comes from a third party (i.e. any non-Emory or non-Emory affiliated personnel), first verify with the Emory PI that he or she is aware of the request and also desires the IAA. Please document this desire in IAA file.
• Once the Reliance Request Form is completed and received, the reliance specialist will forward it to the Director to confirm that the IRB is willing to pursue a reliance agreement, if necessary. If yes, continue to the next step. If no, inform the Emory PI and other relevant individuals that Emory is not willing to enter into a reliance agreement.
• If Emory IRB is willing to enter into a reliance agreement, the reliance specialist will instruct the Emory study team to submit the study to the Emory IRB as they normally would as if Emory was the ONLY site involved in the study, including only Emory study materials and leaving out any information or personnel for other participating sites. Instruct the Emory study team to notify you as soon as they have submitted to Emory IRB.
  o NOTE: If an Emory study team knows that a study is going to be multi-site and will need a reliance agreement, they should NOT submit until they have confirmed that Emory IRB is willing to be the IRB of record.
• Once the submission has made, the study will be assigned to an analyst to undergo the Emory IRB review process. Once the study has been approved, the study team will be responsible for forwarding the approval letter and approved consent and assent form(s) as well as any approved study materials to the reliance specialist so that the “site activation” process can begin and will also be responsible for providing the approved consent and assent form(s) as well as any study materials to the Relying Study Team(s).
• Once the reliance specialist receives the approval documents, the reliance specialist should pursue a reliance agreement with the participating site(s). The reliance specialist should email the Relying IRB and Relying Study Team contacts a copy of the Initial Review Local Context Worksheet, PI Responsibilities document, and IAA template to complete and have signed. If Emory has not served as the IRB of Record for the Institution before, the reliance specialist should also send an Institution Information Sheet for the Relying IRB to fill out and save the form under the External IRB Relationships folder under “Other Institutions.”
  o If the Relying Site has any requested changes to the insurance language, send the changes to Danielle Britton in the Office of Quality and Risk for approval (Danielle.carr@emoryhealthcare.org)
  o If the Relying Site has any requested changes to the indemnification language, send the changes to Robin Everhart in the Office of General Counsel for approval (robin.everhart@emory.edu)
• Once the reliance specialist has received the signed IAA back, the reliance specialist should draft the Memo to IO and the IAA and present to Director for pre-approval/initials, and then to IO for his/her signature (if not signed by Director).
• The reliance specialist should then send the partially executed IAA to the POC for other institution’s IO signature.
• Once the IAA has been fully-executed, the reliance specialist should send the fully-executed IAA to the Relying IRB and Relying Study Team contacts.
• The reliance specialist should then instruct the Emory/Lead Study Team to have each Relying Study Team create site-specific consent and assent form(s) by plugging provisions for cost, in case of injury, and HIPAA authorization as well as any site or study team contact information into the approved model consent/assent documents previously provided.

• The Emory/Lead Study Team will then be responsible for submitting an amendment to Emory IRB adding each participating site and uploading each site’s informed consent/assent/HIPAA authorization documents as a separate document to the Informed Consent Process section of the submission. The Emory/Lead Study Team will also be responsible for adding the fully-executed IAAs and completed Local Context Worksheets as Miscellaneous Documents in the submission. (See guidance for this on the website)
  
  o NOTE: THE AMENDMENTS ADDING NEW SITES SHOULD ONLY BE USED FOR THE PURPOSE OF ADDING SITES FOR THE RELIANCE SPECIALIST TO PROCESS. ANY CHANGES IN STUDY STAFF/PROTOCOL FOR EMORY AS A SITE WILL HAVE TO SUBMITTED IN A SEPARATE AMENDMENT FOR THE ANALYST ASSIGNED TO THE STUDY TO PROCESS.
  
  o The Reliance Specialist should ensure she is given the IRB number for the main study to include on the Reliance Tracking Spreadsheet.

• Once the amendment has been submitted, the amendment will be assigned to the reliance specialist for processing. The reliance specialist should cross-check the informed consent forms/HIPAA authorizations with the uploaded Local Context Worksheets to ensure 1) that the site-specific provisions are correct, and 2) that no other provisions except for the ones mentioned in step 23 are changed from the approved/model forms.

• Once the amendment has been approved, the reliance specialist will be responsible for sending an approval letter and any other approved documents to the Emory/Lead Study Team and changing the state in eIRB. The Emory/Lead Study Team will be responsible for sending the approval documents to the Relying Study Teams (who should then forward them to the Relying IRBs).

LOG OF SIGNIFICANT CHANGES

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PURPOSE

This SOP will outline the process of negotiating an institutional authorization agreement (IAA)/reliance agreement using the SMART IRB agreement.

SCOPE

This SOP applies to any study which has multiple sites when an Emory PI or IRB administration from another institution comes to you with a request and the other institution’s IRB (or proposed commercial IRB) has signed onto the SMART IRB Master Agreement.

FOR DEFINITIONS AND CONSIDERATIONS, SEE THE SOP ENTITLED “PROCESSING XIRB RELIANCE REQUESTS/REQUESTS FOR IAAs (NOT USING SMART IRB)”

NOTES

- SEE THE NOTES IN THE SOP ENTITLED “PROCESSING XIRB RELIANCE REQUESTS/REQUESTS FOR IAAs (NOT USING SMART IRB)”
- The SMART IRB Agreement is a master agreement with fully-fleshed out terms and a division of responsibilities for institutions. Institutions that have signed onto the SMART IRB Agreement can choose to use that Agreement for any given study in lieu of negotiating the terms and division of responsibilities with the other IRB from scratch. The agreement can be found here: https://smartirb.org/agreement/. A visual aid of the division of responsibilities can be found here: https://smartirb.org/harmonization/.
- Although the SMART IRB Agreement covers most of the necessary terms and responsibilities, some terms and responsibilities are flexible, and it is the job of the institutions to determine how to handle them. SMART IRB has tools available to facilitate the process. You can find those tools here: https://smartirb.org/resources/.
- Some institutions process SMART IRB reliance requests using the SMART IRB Online Reliance System (https://smartirb.org/reliance/). Other institutions use the Smart IRB Exchange (https://sirb.trialinnovationnetwork.org/auth). The remainder handle the requests manually through email. This SOP covers all three of these scenarios.

PROCEDURE WHEN EMORY RELYING

- Using the Online Reliance System (a video of this process can be found at https://vimeo.com/226008270):
1. Note: Designated Emory IRB staff members (Emory IRB POCs) needing access to the Online Reliance System for the first time should send an email (subject line: SMART IRB Reliance access request) to help@smartirb.org and cc Rebecca.rousselle@emory.edu.

2. Once a Proposed Reviewing IRB has indicated its willingness to be the Reviewing IRB for the study (see step 10 of the PROCEDURE WHEN EMORY REVIEWING), the designated staff member at the Emory IRB (Emory IRB Point of Contact/POC) will receive a notification via email that Emory IRB has a reliance request.

3. The Emory IRB POC will log into the Online Reliance System by going to https://smartirb.org/reliance/ and clicking “Log In” listed under the Get Started box on the right side of the webpage.

4. Once logged in, the Emory IRB POC will see a “Requests for Reliance” table on his/her home page. The new reliance request will be listed under the “Action Required” tab.

5. The Emory IRB POC will click on the listing to be taken to the “Request Details” page. The Emory IRB POC will then see a yellow box with “Action Required” at the top.

6. The Emory IRB POC will click “Review the Request” inside of the yellow box to review the study details and analyze whether Emory IRB is willing to rely.

7. The Emory IRB POC should then contact the Emory study team and/or the Proposed Reviewing IRB POC (listed in the second bullet of the yellow “Action Required” box) in order to gather any additional information needed to conduct the analysis and to request any local context or other site submission forms which the Proposed Reviewing IRB will require Emory to fill out.

8. If the Proposed Reviewing IRB is a private institution, the Emory IRB POC should also request via email that the Proposed Reviewing IRB sign the “MOU on Indemnification and Insurance - XIRBs When Emory Relying” document on the H: Drive under External IRB Relationships>Smart IRB. Emory will generally not agree to rely on an institution unless this MOU is signed. Public institutions will not undergo this step due to governmental immunity.

9. Once the Proposed Reviewing IRB has agreed to sign the MOU (see step 7), the Emory IRB POC will create an XIRB shell for the Emory study team in eIRB and complete the eIRB submission review process (see the SOP entitled “PROCESSING XIRB RELIANCE REQUESTS/REQUESTS FOR IAAs (NOT USING SMART IRB)”). The local context and site submission forms should NOT be returned to the Emory study team for submission to the Proposed Reviewing IRB until the eIRB administrative review process is complete.

10. Once the eIRB administrative review process is complete, the Emory IRB POC will click the “Enter Decision” button in the SMART IRB online system to indicate “Yes” or “No” regarding Emory’s ability and willingness to rely on the Proposed Reviewing IRB. The Emory IRB POC will then be prompted to fill out “institutional requirements and local context concerns” and may choose to fill those out, depending upon what information they have already or will be provided the Proposed Reviewing IRB via site submission forms. Once complete, the Emory IRB POC will click the “Submit” button.

11. The Emory study team can then submit to the external IRB.

- Using the SMART IRB Exchange (applicable for Trial Innovation Network studies):
  1. Note: Designated Emory IRB staff members (Emory IRB POCs) needing access to the SMART IRB Exchange for the first time should notify Rebecca Rousselle.
2. The Emory Study Team POC will email a completed copy of the Reliance Agreement Worksheet and Central IRB Decision Checklist (found on http://www.irb.emory.edu/forms/external-irbs/index.html) to the Emory IRB POC Hannah.allen@emory.edu. The email should mention that the Proposed Reviewing IRB will be using the SMART IRB Exchange as a platform.
   ▪ Alternatively, the Emory IRB POC might receive an email from the SMART IRB Exchange indicating that Emory “has been listed as a participating site” for the study. The Emory IRB POC should reach out to the Emory PI and have him/her complete the Reliance Agreement Worksheet and Central IRB Decision Checklist as noted above.
3. The Emory IRB POC should go to https://sirb.trialinnovationnetwork.org/auth and log into the Smart IRB Exchange. The Emory IRB POC will then use the “Find A Study” feature on the main page to go to the study’s page. The Emory IRB POC can then register for the study by selecting Emory from the drop-down menu and clicking the “Register” button.
   ▪ If the Emory IRB POC received the email notification from SMART IRB Exchange, he/she can access the study via the Study Link in the email and then register as explained above.
4. The Emory IRB POC will analyze whether Emory IRB is willing to rely and contact the Emory study team and/or the Proposed Reviewing IRB POC as needed to gather additional information pertinent to the analysis.
5. If the Proposed Reviewing IRB is a private institution, the Emory IRB POC should also request via email that the Proposed Reviewing IRB sign the “MOU on Indemnification and Insurance - XIRBs When Emory Relying” document on the H: Drive under External IRB Relationships>Smart IRB. Emory will generally not agree to rely on an institution unless this MOU is signed.
6. Once it has been determined that Emory is willing to rely and that the Proposed Reviewing IRB is willing to sign the MOU (if applicable), the Emory IRB POC will return to the study in the Smart IRB Exchange and click the “Edit Review” button. A window will pop up prompting the Emory IRB POC to fill out additional information about the site and asking him/her to review and accept the Study-Specific Reliance Plan (SSRP). The Emory IRB POC should accept the plan as-is or click “Request Changes” as needed.
7. When the SSRP has been accepted, the Emory IRB POC and Reviewing IRB POC will receive a confirmation email that a reliance agreement has been reached. The Emory IRB POC should save the determination letter attached to the email (as well as any other documents for the study) in a designated study file on the H: Drive under the External IRB Relationships folder.
   ▪ At this time, the Emory study team will also receive a confirmation email and can access the study via a Study Link provided in the email.
8. The Emory IRB POC will then create an XIRB shell for the Emory study team in eIRB and complete the eIRB submission review process (see the SOP entitled “PROCESSING XIRB RELIANCE REQUESTS/REQUESTS FOR IAA (NOT USING SMART IRB)”).
9. Once the eIRB submission review process is complete and the MOU has been signed, the Emory IRB POC, the Emory Study Team POC should complete the PI survey on the
SMART IRB Exchange by going to the study and clicking the “Complete PI Survey” button on the top left side of the webpage. The Emory IRB POC should also complete the local context process on the SMART IRB Exchange by going to the study and clicking the “Complete Local Context” and “PI Completes Survey” buttons and filling out the information as prompted. The Emory IRB POC should download the completed forms and place them in the appropriate folder on the H: Drive.

10. The Emory study team can then submit to the external IRB.

- Using SMART IRB without an online platform:
  1. The Emory Study Team POC will email a completed copy of the Reliance Agreement Worksheet and Central IRB Decision Checklist (found on http://www.irb.emory.edu/forms/external-irbs/index.html) to the Emory IRB POC Hannah.allen@emory.edu. The email should mention that the Proposed Reviewing IRB intends to use the SMART IRB Agreement.
  2. The Emory IRB POC will analyze whether Emory IRB is willing to rely and contact the Emory study team and/or the Proposed Reviewing IRB POC as needed to gather additional information pertinent to the analysis.
  3. Once it has been determined that Emory is willing to rely, the Emory IRB POC should reach out to the Proposed Reviewing IRB POC to request a copy of their SMART IRB Cede Letter (also called a SMART IRB Letter of Acknowledgment) and the completed SMART IRB Communication Plan and/or Implementation Checklist, and any other local context or site submission forms which are required for Emory’s review (unless the Emory study team has already provided these documents to us).
    - If Emory would require changes or additions to the Communication Plan and/or Implementation Checklist, negotiate those changes with the Proposed Reviewing IRB POC at this time.
  4. If the Proposed Reviewing IRB is a private institution, the Emory IRB POC should also ask the Proposed Reviewing IRB if they have any indemnification or insurance language which could be added. If they have a supplemental document with this language which is acceptable to Emory, have the appropriate institutional official (IO) sign the document along with the SMART IRB Cede Letter (and be sure to include a memo with the document explaining the study and the agreement).
    - If they do not have a supplemental form but do have language acceptable to Emory, plug their language into the “MOU on Indemnification and Insurance - XIRBs When Emory Relying” document on the H: Drive under External IRB Relationships>Smart IRB.
    - If they do not have language at all, request that they sign our “MOU on Indemnification and Insurance - XIRBs When Emory Relying” document on the H: Drive under External IRB Relationships>Smart IRB. Emory will generally not agree to rely unless some form including this language is signed.
  5. When the documents from Step 4 are signed, the Emory IRB POC will send them to the Proposed Reviewing IRB POC for full execution.
  6. The Emory IRB POC will then create an XIRB shell for the Emory study team in eIRB and complete the eIRB submission review process (see the SOP entitled “PROCESSING XIRB RELIANCE REQUESTS/REQUESTS FOR IAAs (NOT USING SMART IRB)”.

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7. Once the eIRB submission review process is complete, the Emory IRB POC will complete the local context worksheet and any other site submission forms and send them to the Emory study team for submission to the Proposed Reviewing IRB.

8. The Emory study team can then submit to the external IRB.

PROCEDURE WHEN EMORY REVIEWING

- Using the Online Reliance System (a video of this process can be found at https://vimeo.com/22600827):
  9. The Emory PI or other designated member of the study team (Study Team Point of Contact/POC) will go to https://smartirb.org/reliance/ and click “Request Investigator Access” listed under the Get Started box on the right side of the webpage.
  10. The Study Team POC will fill out the Request Investigator Access smartform and hit “submit.”
  11. Once the Study Team POC has access to the Online Reliance System, he will log in by going to https://smartirb.org/reliance/ and clicking “Log In” listed under the Get Started box on the right side of the webpage.
  12. Once logged in, the Study Team POC will click “New Request” at the top of the webpage and fill out the Reliance Request Form by providing key information about the study.
  13. At the bottom of the page, the Study Team POC will use the drop-down menu to select which IRB will be the Proposed Reviewing IRB from the list of institutions which have joined SMART IRB before clicking to the next page.
  14. Once on the next page, the Study Team POC will click the “Add New Site” button to identify each site engaged in the study and provide information about the activities and personnel involved at each engaged site before clicking to the next page.
  15. The Study Team POC will add a .pdf document of the Research Protocol, Consent Templates, and any other relevant documentation before submitting the form.
  16. Once the form is submitted, the Online Reliance System will notify the designated Emory IRB staff member (Emory IRB Point of Contact/POC) that a Reliance Request form has been submitted.
  17. The Emory IRB POC will log into the system as described in step 3 to review the request.
  18. The Emory IRB POC will complete a “pre-check,” analyzing whether reliance for the study is appropriate and asking the Study Team POC for any additional information needed in order to complete the analysis.
     - Emory IRB will have “the right of first refusal” to be the Reviewing IRB if it determines that it is not willing to review for the other sites for the study.
  19. The Emory IRB POC will click the “Enter Decision” button on the summary page of the Reliance Request form to indicate “Yes” or “No” regarding its ability and willingness to review for the other sites. If the Emory IRB POC indicates “Yes,” the Overall Status of the Reliance Request will switch to “Reviewing IRB Identified.”
     - Note: If the Emory IRB POC indicates “No,” the Emory IRB POC will select another Proposed Reviewing IRB for the study. The system will automatically notify the POC for the Proposed Reviewing IRB so that steps 8-11 can be completed by that POC.
20. The Emory IRB POC will then wait for all proposed relying sites to review the reliance request and enter a decision regarding their willingness to rely on Emory. The Emory IRB POC can regularly check the “Request Details” page for the study to stay up-to-date on which sites have entered their decisions. The decisions will be listed in the “Sites Involved” box.

21. The Emory IRB POC should send each site PI and relying IRB point of contact via email a copy of the SMART IRB Communication Plan and Emory’s local context worksheet to fill out and send back. Emory’s IRB POC should save all documents and emails in a file for the study under the External IRB Relationships folder on the H Drive.

22. If the site is a private institution, the Emory IRB POC should also request via email that the Proposed Reviewing IRB sign the “MOU on Indemnification and Insurance - XIRBs When Emory Reviewing” document on the H: Drive under External IRB Relationships>Smart IRB. Emory will generally not review for a private institution unless this MOU is signed.

23. Once each site has indicated “Yes” regarding its willingness to rely and has returned the necessary forms (completed and signed), the Emory IRB POC will click the “Enter Decision” button again on the “Request Details” page and will be taken to a screen where the reliance agreements will be recorded. On this screen, the Emory IRB POC can review each site’s comments and directly address any questions or concerns and, based upon those comments, can record whether Emory is ultimately willing or unwilling to review. Once complete, the Emory IRB POC will click “Next” at the bottom of the screen.

24. The Emory IRB POC will then be prompted to review the draft determination letter documenting the reliance arrangement for the study and “submit” the determination to the sites.

25. Emory study team should then do a normal submission to Emory’s IRB system, adding each relying site as a sub-site on the SmartForm.

- **NOTE:** Emory does not use the SMART IRB Exchange when it serves as the Reviewing IRB for studies using the SMART IRB Agreement.

- **Using SMART IRB without an online platform:**
  1. The Emory Study Team POC will email a completed copy of the Reliance Agreement Worksheet and Central IRB Decision Checklist (found on [http://www.irb.emory.edu/forms/external-irbs/index.html](http://www.irb.emory.edu/forms/external-irbs/index.html)) to the Emory IRB POC Hannah.allen@emory.edu.
  2. The Emory IRB POC will analyze whether Emory IRB is willing to review and contact the Emory study team and/or the Proposed Reviewing IRB POC as needed to gather additional information pertinent to the analysis. The Emory IRB POC should confirm that the Proposed Relying Site has signed on to the SMART IRB Agreement.
  3. Once it has been determined that Emory is willing to review and that the Proposed Relying Site uses SMART IRB, the Emory IRB POC should send an email to the Proposed Relying Site POC attaching a copy of the SMART IRB Letter of Acknowledgment and completed SMART IRB Communication Plan (which are on the H: Drive under External IRB Relationships>SMART IRB). The Emory IRB POC should also attach the Initial Review
Local Context Worksheet (which is on the H: Drive under External IRB Relationships>IRB Tools>Other Forms).

4. If the Proposed Relying Site is a private institution, the Emory IRB POC should also request via email that they sign the “MOU on Indemnification and Insurance - XIRBs When Emory Reviewing” document on the H: Drive under External IRB Relationships>Smart IRB. Emory will generally not agree to review for an institution unless this MOU is signed.

5. When the documents from Steps 3 and 4 have been signed by the Proposed Relying Site, the Emory IRB POC should have the Emory IO sign the document along with the SMART IRB Letter of Acknowledgment (and be sure to include a memo with the document explaining the study and agreement).

6. Once the documents have been signed, send the fully-executed versions back to the Relying Site.

7. Emory study team should then do a normal submission to Emory’s IRB system, adding each relying site as a sub-site on the SmartForm.

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SOP Title: Reportable Event Notification Process When Study is Subject to External IRB Review
SOP Category: Collaborative Research / Central IRBs
Established: 1/23/2018
Last Revision: 6/8/2018

PURPOSE
This SOP will detail how to process and review notifications of UPs that are received from external IRBs.

RESPONSIBILITIES

- Reliance Specialist – identifying and tracking the notification of UPs managed by external IRBs and reporting notifications to the appropriate institutional officials.
- Team Q – reviewing the notification of UPs managed by the external IRBs and determining the applicability of the information to the local IRB in consultation with the IRB Director.

TIMEFRAME

Once you receive notice of an RE from an Emory researcher, you have 24 hours to review it and forward it to the appropriate Emory IOs as detailed below. Once you receive the RE determination letter from the external IRB, you must complete the below procedure within 5 business days of the receipt.

PROCEDURE

- When negotiating a reliance agreement, the reliance specialist should negotiate a term into the Division of Responsibilities which requires the external IRB to notify Emory IRB when they receive a report or complaint against the Emory study team which involves wrong side surgery, wrong drug, wrong dose, UPs/deaths related to research, or falsification/fabrication of data.
- Any Emory researcher who reports a reportable event to the external IRB must either 1) cc Hannah Allen at Hannah.allen@emory.edu and Maria Davila at maria.davila@emory.edu on your email reporting the event to the external IRB or 2) if reporting via online platform, screenshot or save a copy of the online report and email to Hannah and Maria.
  - Emory researchers must follow this procedure for every event that you would have been required to report to our IRB had we reviewed the research, and if the external IRB’s rules go beyond our requirements, you must follow this procedure for those additional events you are required to report to the external IRB.
- When Hannah receives the reportable event via email from the Emory researcher, she will review the report to determine whether it falls into one of the following categories: wrong side surgery, wrong drug, wrong dose, UPs/deaths related to research, or falsification/fabrication of data.
- If it does fall into one of the above categories, Hannah will create a file under on the H: drive in the QA Working Files\RE Notifications from External IRBs folder with study title and PI name, using the following format (1234 Jones) and save all necessary documentation in it.
- She will forward the report to the Director of Compliance Kristin West at kwest02@emory.edu, Compliance Manager Margaret Huber at mhuber@emory.edu, and Director of Claims Management Laura Deane at laura.deane@emoryhealthcare.org.
The external IRB should send notice of its determination and the determination letter to the reliance specialist Hannah Allen at Hannah.allen@emory.edu.

The reliance specialist will add the determination to the NC UP spreadsheet located under the QA working files main folder. H:\General\QA Working Files\NC UP Complaints.

The reliance specialist will create a folder on the H: drive in the QA Working Files\RE Notifications from External IRBs folder with study title and PI name, using the following format (1234 Jones) and put all necessary documentation in it OR, if the RE already has a file, she will save the all documentation in the already-existing file.

The reliance specialist will forward the UP notification to Team Q.

Upon receiving the notification, Team Q will consult with the IRB Director and review if the UP determination should be assessed for other studies using the same drug, device, or study intervention.

The reliance specialist will draft an email to the Emory PI with the IRB # and Study Nickname in the subject line stating the following:

Dear Dr. __________:

We have received notification from [Reviewing IRB] that a reportable event during the course of the above-referenced study constitutes a [type of determination]. Attached, please find the determination letter from [Reviewing IRB]. This determination will be reported to the sponsor and federal oversight agencies.

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.

CC the following individuals on the email:
- Team Q Lead
- IRB Director
- Department head (Department Name)
- David Wynes, PhD (Office of Research Administration)
- Kris West, JD, MS (Office of Compliance)
- Margaret Huber, RN (Office of Compliance)
- If the study is funded....
  - For grants: Holly Sommers (Office of Sponsored Programs)
  - For Industry-sponsored: J. Cale Lennon III, PhD, MBA, CLP (Office of Technology Transfer).
- Anne Adams, JD (Clinical Trials Audit and Compliance)
- Stephanie DeRijke, RN, MSN (Clinical Trials Audit and Compliance)
- If a COI exists, also copy Brenda Seiton, JD (Conflict of interest)
- If Winship, also copy the following people:
- Bassel El-Rayes, MD
- Walter Curran, MD
- Sagar Lonial, MD
- Kathleen Rodger, BSN, MS, CCRP
- Kim Nguyen
  - If related to the Investigational Drug Service, copy Susan Rogers, RPh (IDS)
  - If involving research at CHOA, copy Sarah Marie Huban, MA, BS (Children’s Healthcare of Atlanta IRB)
  - If involving research at Marcus, also copy:
    - Ami Klin, PhD
    - Lynn Perez MHSA
  - If involving research at Grady, also copy:
    - Chadrick Anderson, MHA
    - Shirley Marshall, MHA
  - If involving research at St. Josephs, copy Kristi McGinnis, CIM

- Once sent, save a copy of the determination letter and the email in the study folder under QA Working Files.

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SOP Title: Approval Lapse When Study is Subject to External IRB Review
SOP Category: Collaborative Research / Central IRBs
Established: 3/16/2018
Last Revision: 6/8/2018

PURPOSE
This SOP will detail how to process notifications from external IRBs that IRB approval has lapsed.

TIMEFRAME
Once you receive the notification from the external IRB, you must complete the below procedure within 5 business days of the receipt.

PROCEDURE
• Notification should be sent from the external IRB to the reliance specialist at Hannah.allen@emory.edu.
• The reliance specialist will forward the notification via email to the PI and study coordinator and confirm that they are aware of the approval lapse and remind them that all enrollment, data analysis, and study interventions must stop until re-approval. Confirm whether the study is still in the enrollment stage; whether subjects are receiving treatment; and whether any subjects will be harmed by the lapse.
• When the PI and/or study coordinator respond, save their response in the study’s folder on the H drive.
• Log a comment in the study’s eIRB shell attaching the email and the notification and state the following:
  o  Dear Study Team: We have received notification from [Reviewing IRB] that IRB approval for this study has lapsed. Please be aware that all study activities must stop until the study is re-approved by the external IRB. Please see attached.

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PURPOSE
This SOP will detail 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 specialist- 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
Where Emory is the IRB of Record:
- Where only one site is closing down although the greater study is remaining open....
  - The Emory study team would submit an amendment in eIRB stating which site is closing, providing a study summary detailing why the site is closing as well as any other pertinent details and also giving assurance that no other study activities (whether enrollment, data collection, data analysis, study interventions, or investigator involvement) will be taking place either at the site or which engages the site.
  - Upon approval of the amendment, the Emory IRB analyst assigned to the study would send an amendment approval/close-out letter to the Emory study team, including in the letter a statement that the site has been closed out and that no other study activities are allowed to take place there.
  - The Emory study team would be responsible for providing the amendment approval/close-out letter to the relying site study team. The relying site study team would then be responsible for providing that letter to their institution’s IRB so that the institution could close out the study locally.
- Where the whole study needs to be closed out....
  - The Emory study team would follow the normal non-multi-site process for study close-out, processed by their Emory IRB analyst.
  - The Emory study team would be responsible for providing the close-out letter to all relying site study teams. The relying site study teams would then be responsible for providing the letter to their institutions’ IRB(s) so that the institutions could close out the study locally.

Where Emory is relying on an external IRB (both when Emory is closing as a site and when the whole study is closing):
- Emory’s study team would be responsible for providing any necessary information and documents to the lead study team to pursue the close-out process at the Reviewing IRB and/or would follow the Reviewing IRB’s close-out process.
• Upon receiving a close-out/amendment approval letter, the Emory study team would be responsible for submitting the letter to their RAS administrator, OCR contact, and any other ORA offices that need notification. The Emory study team would also need to email the letter to the reliance specialist at Hannah.allen@emory.edu.
• The reliance specialist would switch the state to “Closed” in the eIRB local submission.
• The reliance specialist would log a comment, attaching the letter, which states the following:

  Dear Study Team:
  [This study has been/Emory as a site has been] closed out by the external IRB. Please see the attached close-out letter. Please ensure that this letter has been provided to any ORA office that need notification. You are prohibited from continuing with any study activities at this time.

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SOP Title: Processing A Reliance Amendment (to Onboard a Participating Site)

SOP Category: Collaborative Research / Central IRBs

Established: 4/5/2018

Last Revision: 6/8/2018

PURPOSE
This SOP outlines how the IRB Analyst/Reliance Specialist should process an amendment to obtain IRB approval for participating sites to begin multi-site research post-Emory IRB approval of the main protocol, consent form, and other study documents.

SCOPE
This SOP applies to any study which has multiple sites engaged in human subjects’ research, where Emory is serving as IRB of record. It applies to new multi-site studies being handled by the IRB Reliance Specialist as well as Emory studies which were previously approved as single-site studies but are now onboarding new sites, and Emory has agreed to be the IRB of record.

ASSIGNMENT
• For new multi-site studies, the main Emory study submission (approving the main protocol and model consent template) and any Emory amendments making substantive changes to the study should be assigned to a designated Emory IRB Analyst. Any amendments governed by this SOP, specifically on-boarding participating sites for a new study, should be assigned to the IRB Reliance Specialist.
• For previously-approved Emory studies now onboarding new sites, the IRB Analyst assigned to the study should handle the reliance agreement and amendment.

RELIANCE SPECIALIST/ANALYST RESPONSIBILITIES
• Processing amendment and assigning for review
• Cross-checking the site-specific consent documents with institutional language provided in Local Context Worksheet
• Sending approval letter and any other approved documents to the Emory/Lead Study Team
• Setting up reliance agreement(s)
• Updating reliance tracking checklist and reliance agreement tracking spreadsheet during this process

PROCEDURE
1. Processing the Amendment:
   a. Reliance Specialist or Analyst checks that all questions have been answered and all documents uploaded as instructed in the Amendment Request section of this SOP and processes the amendment as described in the SOP entitled Amendment: AM Applications IRB Processing from Preliminary Analysis through Approval.
   b. He/she opens Local Context Worksheet and checks that site-specific sections of Relying Site consent documents are correct and ensures that no changes have been made.
outside of the costs, in case of injury, HIPAA authorization, site name, and PI contact information.
c. If changes needed, he/she clicks “Changes Requested by IRB Staff” and informs the Emory/Lead Study Team of the requested changes in the text box.
d. When/if no changes needed, he/she clicks the “Assign Expedited Reviewer” tab and selects the appropriate designated reviewer from the dropdown menu (will be an IRB Staff Designated Reviewer).
e. Under Comments, he/she specifies that this is a Reliance Amendment submitted to onboard a new site to the multi-site study and includes the Emory/Lead Study Team’s response to Question 2.0 of the Amendment Request, stating also that the Relying IRB has confirmed that all site requirements have been completed and listing which new documents have been uploaded then presses ok.
f. The current state changes from “IRB Staff Review” to “Expedited Review.”
g. Once Review completed, Reliance Specialist/Analyst opens the IRB reviews tab for the AM application and clicks on “Review of” and accesses the Printer Version to view comments, determinations, and changes requested.
i. If changes requested:
   1. Click Draft Letter and choose Pending – Expedited template. Remember to include: PI’s post-nominal, letter date spelled out, requested changes in a bullet list (noted in the Reviewer’s notes in eIRB), and your name and title. Then click OK.
      a. If there was a numbered protocol AM insert the highlighted text into the third line of the “RE” section: “IRB Amendment (#) for IRB Study #xxx (Protocol Amendment XX) (this is because Sponsors often get confused about the difference between our AM numbering system and their protocol AM numbering).
      b. Reset and resize the font of the CC: section at the bottom of the letter if needed
      c. Delete any language that doesn’t apply to the current AM and remove rows that state “No Items to Display.”
   2. Once requested changes have been submitted, the state changes to “Expedited Review.”
      a. Review submitted materials to assess correctness. If any further changes needed, click “Request Changes by IRB Staff” and describe changes. If none, send AM for contingency review by selecting Forward to Contingency Reviewer – EX” and the appropriate reviewer. Send reviewer an email about the review with a link to the AM. Once contingencies approved, move to step ii.
ii. If no changes requested:
   1. Click Draft Letter and choose the Approved template. See i(1)(a), (b), and (c) for letter drafting.
   2. Select GENERATE OFFLINE DOCUMENT in main workspace BEFORE sending letter for signature and to PI. Click Obtain Signature and select your name in the pop-up window. Click OK. Click Send Letter to PI and click OK.
a. Please ensure that revised approved documents have been listed correctly.
   i. – Examples: i) Changes to Study Team members: Added Steve Smith... Removed Tom Jones... ii) Changes to Protocol Document(s): Revised Protocol Version 2.0 dated 01/17/2007 iii) Changes to Consent Form(s): Revised Consent Form Version 2.0 dated 01/17/2007

3. *IF AM included site-specific consent forms (if no site-specific consent forms, skip to next step):
   a. Go to main workspace and click Edit Consent Forms.
   b. Under Approved Consent Forms, remove tracked changes versions of the RELYING SITE-SPECIFIC consent documents and click OK.
   c. Click Consent Form Merge and only select the relying site-specific consent documents.
   d. Ensure that the approval date and expiration date are correct (and if not, put the correct dates). Click OK.

4. Log a comment to the study team that states the following:

   Dear Study Team:
   The amendment to onboard [list of relying sites] has now been approved. These sites are now permitted to begin research activities for this study. Please provide the approval letter to your contact for each Relying Site Study Team. [If consent forms: The stamped-approved informed consent documents for each Relying Site included are available under the Documents tab in the main workspace. It is your responsibility to provide each Relying Site with their site-specific consent document(s)]. The Relying Site Study Team is responsible for providing these documents to the appropriate offices at their institution. 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. You can access the survey by copying the link below and pasting it into your web browser. We appreciate your feedback!
   https://www.surveymonkey.com/s/PY2KYLR

5. Select Report to Committee Meeting> Report to Committee – Amendments Approved by Designated Reviewer > Select Meeting.
   a. The meeting should have a one-week lead time. Add to CMTE C if SHB study, and add to A or B if a Biomed study. It’s ok to add it to a “closed” meeting.

LOG OF SIGNIFICANT CHANGES

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PURPOSE
This SOP will detail how to process and review notifications of approval (Initial Review, Amendments, and Continuing Review) that are received from external IRBs.

RESPONSIBILITIES
- Reliance Specialist – identifying and making a record of the notification of approval sent by external IRBs and/or Study Teams.

PROCEDURE
- The external IRB or Emory study team should send any and all approval letters and approved study documents (at the time of Initial Review, Amendment, and Continuing Review) to the reliance specialist, Hannah Allen, at Hannah.allen@emory.edu and to their RAS administrator via email with the eIRB number, the EPEX number, the PI name, and the short study title in the subject line.
- The reliance specialist will add the documents to the study file on the H: Drive under General>External IRB Relationships>IAAs>Emory Relying.
- The reliance specialist will switch the stage to “Approved” in eIRB but SHALL NOT include an expiration date.
- The reliance specialist will log a comment in the study’s XIRB eIRB submission (attaching the documents) which states the following:

> Dear Study Team:

> Emory has been approved as a site through the [amendment review/continuing review] process by the external IRB, and no further action is required with respect to Emory IRB. The next expiration date is [date]. Please see the attached approval letter and approved study documents. Please ensure that you have sent these approval documents to your RAS administrator so that other Emory departments are notified of this approval.

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PURPOSE
To correct listed department approver

SCOPE
Applies to all IRB team members who need to correct the department approver

PROCEDURE
1. One correct AND one incorrect department are selected for Departmental Approval; only the correct one was necessary.

   1.1. Go to the “Contacts” Fast Find in “Projects,” find yourself, then add the role of Dept/Div Approver to your profile if you don't have it already (You do this by going to the “Account” tab, and clicking the “Edit” button for the “Assigned Roles” section.) Once you do this once, it will be good for all future activities.

   1.1.1. Go to “Projects” screen, select “Organization” under Fast Find, and select the organization (aka Department) that you have to “reapprove” for. Add yourself as one of that department’s approvers. (You do this by going to the “Properties” tab for that organization, and clicking “Add” to add yourself in the “Dept Approvers” section.)

   1.1.2. Remove erroneous department from approver list (done within Admin View – remove from “Required Departmental Approvals,” if not done already, and from “Pending Departmental Approvals”).

   1.1.3. Re-approve for the correct department (eIRB is expecting two Dept Approvals to be submitted, so we have to give it two, even if they are both from the same dept), then log comment in the main study workspace. (This will move the study to the proper state.)

1.2. Incorrect department selected for Departmental Approval, need to remove and replace with different Department

   1.2.1. Go to the “Contacts” Fast Find in “Projects,” find yourself, then add the role of Dept/Div Approver to your profile if you don't have it already (You do this by going to the “Account” tab, and clicking the “Edit” button for the “Assigned Roles” section.) Once you do this once, it will be good for all future activities.

   1.2.2. Remove erroneous department from approver list and add the correct Department, if it’s not there already (the IRB analyst may have already done this via editing the study's "Required Approvals" page). Need to check both Pending and Required departmental approvals sections.

   1.2.3. Place the study back into "Pre-submission" state

   1.2.4. Click "Submit for Dept/FA Approval"
1.3. One correct and one incorrect department selected for Departmental Approval, need to remove the incorrect one AND replace with different Department (so two approvals still needed)

1.3.1. Go to the “Contacts” Fast Find in “Projects,” find yourself, then add the role of Dept/Div Approver to your profile if you don’t have it already (You do this by going to the “Account” tab, and clicking the “Edit” button for the “Assigned Roles” section.) Once you do this once, it will be good for all future activities.

1.3.2. Go to “Projects” screen, select “Organization” under Fast Find, and select the organization (aka Department) that you have to “reapprove” for. Add yourself as one of that department’s approvers. (You do this by going to the “Properties” tab for that organization, and clicking “Add” to add yourself in the “Dept Approvers” section.)

1.3.3. Remove erroneous department from approver list (done within Admin View – remove from “Required Departmental Approvals,” if not done already, and from “Pending Departmental Approvals”).

1.3.4. Re-approve for the correct department (eIRB is expecting two Dept Approvals to be submitted, so we have to give it two, even if they are both from the same dept), then log comment in the main study workspace. (This will move the study to the proper state.)

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PURPOSE
Explain the steps necessary to run a report in eIRB for finding studies that have lingered in the departmental review state.

SCOPE
This applies to any staff member assigned with the weekly task of checking on studies that have lingered in the departmental review state.

Frequency of running above reports
Complete each Thursday or more frequently if instructed

Other tools to have handy
“Department Approvers” spreadsheet which can be found in two places – either on our website or on the H-drive. Displays which departments have active reviewers.

http://www.irb.emory.edu/documents/Department%20Approvers.xlsx
H:\General\Department-Faculty Review\Department Approvers_for_Website_with_emails_FINAL

Procedure:

1. Run report in eIRB
   o Click on “Projects”
2. **Determine cause of delay for each study:**
   - For each study listed, click on the study link to review the “History”
     - There may be comments from one or more Approvers explaining that their review is not necessary; or, discussion from others in the IRB – in which case consult those IRB staffers before taking action.
   - Click on “Submit study to Dept or FA for approval” to view which Faculty Advisor or departments were selected for Departmental Approval/Faculty Advisor Approval
     - If **Faculty Advisor** review was selected: Email to alert the student PI and the Faculty Advisor that the submission is still awaiting FA approval, including a link to the study.
     - If **Departmental Review** was selected:
       - If you see any “Department Name” that does not have an “*” in front of it, you can automatically assume that the study team has selected the incorrect department.
If two departments are selected and one appears to be the “parent” of the other, you can assume that the “parent” is not required UNLESS some member of the study team is also the only Department Approver for the “child” department (in which case ONLY the “parent” department should have been selected and the other should be removed).

3. Possible Causes – Remedies described in sections below
   - Multiple departments selected and not all needed
   - The incorrect department was selected?
   - There no approvers affiliated with this department (even though it has an asterisk)
   - The department has an asterisk, but approvers simply have not acted on the request
   - The researcher chose wrong type of review (faculty advisor vs departmental review)

   ****NOTE: please pay attention to any comments already logged in the history of the submission. If the irb director or a team lead has already been in communication with the study team, do not follow the rest of this sop. Consult the irb director or a team lead for further instruction.

4. Were multiple departments selected and not needed?
   - A study needing more than one department selected in the “Required Reviews” section should only happens rarely. Winship is the one known example
   - Generally, the only department that needs to review the study is the one that the PI is affiliated with, per Emory director/website. If the PI is also the approver for that dept/division, then the parent department should be selected instead (not in addition). As noted in #2 above, the correct department should have an “*” in front of it.
   - We have found that there are a few schools at Emory whose “Required Reviews” section automatically pre-populates two different departmental reviews:
     - *ECAS – all Emory College of Arts and Sciences departments will also be pre-populated with *ECAS: Dean of College. This department is almost never needed. Move forward by removing that “Required Review” and then ask an eIRB Super User to re-issue the correct departmental approval if already granted.
     - *SPH – all School of Public Health departments will also be pre-populated with *SPH: Dean’s Office DeptApproval. Move forward by removing that “Required Review” and then ask an eIRB Super User to re-issue the correct departmental approval if already granted.
     - *SON – all School of Nursing departments will also be pre-populated with *SON: Dean’s Office. Move forward by removing that “Required Review” and then ask an eIRB Super User to re-issue the correct departmental approval if already granted.

   ACTION: Use “Edit Study” to remove the unnecessary required review in “Required Reviews” section, log private comment explaining what you did, and email SuperUser to reissue approval for the remaining department (this moves the study along).
   IF both departments are incorrect, move to (B) below.

5. Was the incorrect department selected?
   - Check the Emory Online Directory or conduct a web search using the PI’s name + Emory.
If you are unable to find the department that the PI is affiliated with, review what departments the Co-investigators listed in the smartform are affiliated with.

Refer to the Department Approvals list once you have a good idea of what the appropriate department review should be. Remember to look for the department with the “*” in front of it. [http://www.irb.emory.edu/documents/Department%20Approvers.xlsx](http://www.irb.emory.edu/documents/Department%20Approvers.xlsx)

If you can determine the correct department, use ‘Edit Study’ to revise the “Required Reviews” page and save, log a private comment explaining what was done, then alert a superuser to resubmit the study.

If you cannot determine the correct department, send the first email of the two below, and set a tickler for yourself to check in every 2 days if no response.

**SAMPLE EMAIL TEXT:**

Dear Dr. Warren,

We have noticed that IRB00050823 (FMR1 iPS cells_blood) has been awaiting departmental approval for a while now. It appears that the department selected for review is incorrect as it does not have any associated reviewers. Please let us know which department should review this submission (see matrix here: [http://www.irb.emory.edu/documents/Department%20Approvers.xlsx](http://www.irb.emory.edu/documents/Department%20Approvers.xlsx)) so we may properly re-route it.

**OR**

We have noticed that IRB00050823 (FMR1 iPS cells_blood) has been awaiting departmental approval for a while now. It appears that the department selected for review is incorrect as it does not have any associated reviewers. We have changed the required departmental review to XXXX and rerouted the study for their review.

If you have any questions or concerns, please feel free to email me directly for assistance. Thank you,

---

6. **Are there no approvers affiliated with this department, despite having an asterisk (*)?**

   - First, ensure that this is the correct department for this PI (and that it does not instead require Faculty Advisor review – see (E) below) by one of the above steps noted in A-C.
   - If there are no approvers for this department, despite the asterisk, alert Carol Corkran and Rebecca Rousselle.
   - Carol and/or Rebecca will determine if study should be routed to parent department instead. If so, determine what the Parent Department is (found in the spreadsheet [http://www.irb.emory.edu/documents/Department%20Approvers.xlsx](http://www.irb.emory.edu/documents/Department%20Approvers.xlsx)) and use “Edit Study” to change “Required Reviews” section accordingly, then alert superuser of need to resubmit.
   - It may be possible that the approvers listed for the correct departmental review are no longer at Emory University and we may need the department chair to appoint new approvers. See IRB Director or Team Lead for further instruction on this.

7. **Have the Approvers simply not acted on the request?**
If the correct department has been selected for review/approval and the approvers simply have not acted on the request (and nothing in History to indicate prior communication), provide the study team with the email addresses for the departmental approvers so they may contact them directly to alert them of the pending review.

SAMPLE TEXT:  Include email addresses of all of the departmental approvers listed in the spreadsheet for the correct department:  http://www.irb.emory.edu/documents/Department%20Approvers.xlsx

- Remember that Stuart Lipkin & Christine Gomez were IT staff. Their names should not be included in lists of approvers sent to PIs.
- Department Administrators cannot approve studies.

Dear Department Approvers,

We have noticed that IRB00050823 (FMR1 iPS cells_blood) has been awaiting *SOM: Ophthalmology: Admin departmental approval for a while now. Please have one of the following departmental approvers login to eIRB to approve the submission on behalf of your department:

- [list names]

8. Is the individual listed as the PI a student who should instead receive Faculty Advisor review? If the type of review should change, place study back in “Presubmission”, email student PI, and have them edit the study accordingly. See below for guidelines:

Please refer to Chapter 82 of the Emory IRB Policies & Procedures for further explanation of Investigator Qualifications:
http://www.irb.emory.edu/documents/PoliciesandProcedures.pdf

- How would I know this? In general, on the main workspace of the submission, the PI’s department will be listed below his/her name. If the nomenclature of the department does not appear to follow our formula that includes the “*” and the pre-fix of the school, you may be able to assume that this person is not a faculty member. Here is an example:
Check the Emory Online Directory to assess the individual’s status at the university:

The above directory listing indicates that the PI is a Doctoral Student. If the student is an undergraduate, it may say “Undergrad Student employee/BW.” If you are unable to verify this information here, you can also open the smartform and check to see if the PI indicated that this is student research in the “Required Reviews” section or you can open the research protocol to see if the terms “Honors Thesis,” “Dissertation,” “Capstone Project,” or the like have been used to describe the project.

- Medical students and residents cannot be PI
  - Ask Superuser to place study back in Pre-Submission state
  - Advise study team via logged comment AND EMAIL to change the PI, and to revise the Departmental Review to reflect the new PI’s department, and resubmit
- Other Graduate Student submissions should be reviewed by the students’ faculty advisor, with the student being listed as PI.
  - Use “Edit Study” to revise Q2 in the “Required Reviews” section of the smartform to indicate that the project is student research and a Faculty Advisor should be listed.
  - Ask a superuser to place the study back into Pre-Submission state
  - Alert the study team via logged comment AND EMAIL that the study is back in their inbox, and must be resubmitted for the appropriate faculty advisor review.
- Undergraduate projects must list the Faculty Advisor as PI, the student as Co-I, and be routed for departmental review (not Faculty Advisor review). If this was done incorrectly,
  - Revise Q2 in the “Required Reviews” section of the smartform to indicate that the project is NOT student research and add the appropriate Department for approval.
  - Ask a superuser to place the study back into Pre-Submission state
  - Alert the study team via logged comment AND EMAIL that the study must be resubmitted for the appropriate review.

SAMPLE TEXT FOR LOGGED COMMENTS FOR FACULTY ADVISOR APPROVAL ISSUES

COMMENT TO RESEARCH TEAM IN eIRB
We have noticed that your study has been awaiting Faculty Advisor Approval for a while now. Please check with your Faculty Advisor about this study. Once it is approved in the eIRB system and sent to our office we will be able to begin processing.

For faculty advisor review, the advisor should:
- Log into eResearch
- Click "My Home" in the top right corner
- Look at the left side, verify active role is Faculty Advisor
- If not, click "Faculty Advisor" under the Roles section
- The study should appear in the Inbox
- Click on title of the study, review the study by clicking Printer Version on left side
- Request changes or issue approval by clicking on appropriate activity on the left side

Please feel free to contact me directly with any questions or concerns. Thank you.

EMAIL TO STUDENT PI (COPY FACULTY ADVISOR)
We have noticed that IRB000____ has been awaiting Faculty Advisor Approval for a while now. Please check with your Faculty Advisor about this study. Once it is approved in the eIRB system and sent to our office we will be able to begin processing.

For faculty advisor review, the advisor should:
- Log into eResearch
- Click "My Home" in the top right corner
- Look at the left side, verify active role is Faculty Advisor
- If not, click "Faculty Advisor" under the Roles section
- The study should appear in the Inbox
- Click on the title of the study, review the study by clicking Printer Version on the left side
- Request changes or issue approval by clicking on the appropriate activity on the left side

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<td>2/5/2015</td>
<td>Changed title slightly and updated the formatting; NO content changes were made</td>
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<tr>
<td>1/30/2017</td>
<td>After AA meeting, procedure and email text changes were made</td>
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<tr>
<td>4/20/2017</td>
<td>Added timeline for sending reports to study teams</td>
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<tr>
<td>2/21/2018</td>
<td>Overall changes to clarify process</td>
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SOP Title: Converting from Sponsored Accounts to NetId (Super Users Only)
SOP Category: eIRB Technical Processes
Established: 9/1/2013
Last Revision: 9/1/2013

PURPOSE
Occasionally, someone will switch from having a sponsored account to having an account tied to their University netID. If they obtained an eIRB account using their netID (or it was automatically given to them because of their Sponsored account status), they may not be able to log in with their NetID or their old Sponsored account ID.

SCOPE
Applies to all Super Users who need to convert an eIRB account tied to a sponsored ID to one tied to a University netID.

Before proceeding with this process, have the person check ENID to verify they don’t have the option to add an eIRB account (which means they already have an account tied to their netID). See "How to get an eIRB account" instructions on our website.

PROCEDURE
Emory/CHOA Verifications

1.1. Login to eIRB
1.2. Select Projects
1.3. rptSystem: Verify Person ID
1.4. Enter Last Name
1.5. Select the hour glass next to person you need to update
1.6. Select Account tab
1.7. Enter their netID in the User ID field

After following these instructions, the user should be able to log in to eIRB using their University netID and password.

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SuperUser: What Super Users Do in eIRB

1. Appointing roles
2. Triggering CTRC (or other ancillary committee reviews)
3. Clearing unnecessary ancillary reviews
4. Resetting/adjusting departmental and FA approvals
5. Adjusting study states as needed
6. Submitting close outs when PI has left Emory
7. Facilitating change from exempt to expedited review and vice versa
8. Static text changes to smartforms (hopefully, in future)
9. Changes to letter templates (hopefully, in future)

SuperUser: New eIRB Account Creation

Usually a new eIRB user will go to ENID, request eIRB access, then the system sends Karen Cotter (Rsch-Health Sciences IT) a spreadsheet each night with all the new user requests. She then does a "bulk import" to create the new Contacts in eIRB.

If we have an urgent account need for a non-Emory person, then we can do this manually, using the information in the fields included in the spreadsheet called “NewPersonRecs_20110925” in Admin SOPs/SOPs folder (or more fields, if we want, but these are the fields that the automated system would use).

For an Emory person, who would login via LDAP, we'd need to use the bulk Import, making a copy of the spreadsheet with just one row for that person. But Karen or Helpdesk would have to give you their ID number to use (it’s something from PeopleSoft, but different from their Employee ID number).

The button for creating a new user record in eIRB is on the Projects screen, near the top. Looks like:

Create: Organization | Contact

SuperUser: Appointing Roles for People in eIRB, and what to assign to IRB staff

Look up Person record by last or first name, in Projects window. Go to “Account” tab. Under “Assigned Roles” click “Edit” button at right. Look up roles to add, then click “OK”. No need to then click “Apply” or anything, the changes will be complete.

IRB Staff need the following roles:

IRB Administrator (not sure exactly what this gets you, but we guess it's a lot)
Registered User (the basic eIRB role)
IRB Designated Reviewer (for doing exempt reviews and signing letters)
Study Staff (for seeing what the study staff see, for troubleshooting)
IRB Director (for doing aging reports)
IRB Sr. RPA (allows you to edit studies at any stage of their lifecycle)

Not sure if needed or not:

IRB Staff
IRB Committee Member [maybe needed if the staff person is a designated reviewer]

Only SuperUsers Need/should have:

Site Manager
Dept/Div Approvers
CTRC (Human Cancer Studies)
EHSO - Biosafety
EHSO - Radiation Safety

OSP and OCR people can have CTO role or OSP role. Occasionally other research oversight personnel request roles similar to OCR and OSP (e.g. people working for the RAS Units, CTAC personnel, IRB colleagues from CHOA or St. Joseph’s, etc). For these, please consult the IRB Director for approval to give them this access. Once approval is obtained, they can be given either role. Do not give them the more generic “External Organization” role (the “parent” role for CTO and OSP roles), since for some reason that doesn’t have full functionality.

**SuperUser: Issuing Ancillary Approvals**

If EHSO-Biosafety Committee or EHSO-Radiation Safety Committee convey their approval of a study via email or logged comment, but for some reason are not able to issue approval in eIRB, then Super Users can do this. A Super User must be listed as a member of the relevant committee first.

Maria Davila, Carol Corkran and Rebecca Rousselle are currently "members" (in eIRB) of RSC and Biosafety. To add another person to those committees, go to "Site Administration" in eIRB (link near top of screen next to Home, IRB, Committees). Then click "User Role" link (under "Useful Shortcuts"). Find the relevant committee in the list that appears. In the LAST column to the right, you'll see a number of members. That is also a link - click on it. A pop-up window will appear that lets you add new members.

Back in the study, click the "Issue Ancillary Committee Approval" button on the left side of the screen, and check the appropriate Committee before hitting 'OK'. Log a comment to explain why you are issuing the approval. Make sure evidence of the real approval is also logged in the History.

**SuperUser: Departmental and FA Approval Tasks**

Scenario:
One correct AND one incorrect department are selected for Departmental Approval; only the correct one was necessary

What to Do:
1. Go to the “Contacts” Fast Find in “Projects,” find yourself, then add the role of Dept/Div Approver to your profile if you don't have it already (You do this by going to the “Account” tab, and clicking the “Edit” button for the “Assigned Roles” section.) Once you do this once, it will be good for all future activities.

2. Go to "Projects" screen, select “Organization” under Fast Find, and select the organization (aka Department) that you have to “reapprove” for. Add yourself as one of that department’s approvers. (You do this by going to the “Properties” tab for that organization, and clicking “Add” to add yourself in the “Dept Approvers” section.)

3. Remove erroneous department from approver list (done within Admin View – remove from “Required Departmental Approvals,” if not done already, and from “Pending Departmental Approvals”)

4. Re-approve for the correct department (eIRB is expecting two Dept Approvals to be submitted, so we have to give it two, even if they are both from the same dept), then log comment in the main study workspace

5. This would move the study to the proper state.

Scenario:
Incorrect department selected for Departmental Approval, need to remove and replace with different Department

What to Do:
1. Go to “Contacts” Fast Find in “Projects,” find yourself, then add the role of Dept/Div Approver to your profile if you don't have it already (You do this by going to the “Account” tab, and clicking the “Edit” button for the “Assigned Roles” section.) Once you do this once, it will be good for all future activities.

2. Remove erroneous department from approver list and add the correct Department, if it's not there already (the IRB analyst may have already done this via editing the study's “Required Approvals” page). Need to check both Pending and Required departmental approvals sections.

3. Place the study back into "Presubmission" state

4. Click "Submit for Dept/FA Approval"

Scenario:
One correct and one incorrect department selected for Departmental Approval, need to remove the incorrect one AND replace with different Department (so two approvals still needed)

What to Do:
Not sure about this one - how to avoid triggering a new email to the correct department that had already submitted its approval? Seems unavoidable. Oh well. But SuperUser can reapprove on their
behalf right away. The Departmental Approver for that department might just be confused when they
go to eIRB and see that it's already been approved by someone they don't recognize. Maybe log
comment to study team so they can see?

SuperUser: Bulk Study Edits (e.g. to reassign many studies from one analyst to another)

STEP 1 – Identify projects to be moved

Projects (top right hand corner)
All Searches (middle of page)
Filter by Name “rptIRB%IRB Staff%” without the quotes (this provides a list of preset queries)

Click on Name of preset query – rptIRB_Study: IRB Staff Study Assignment
Click Change Search Parameters
Click on ellipse next to Owner field
Choose IRB staff name
Click OK
Click OK (this will rerun the query for the specified staff name)
Click Export (this will present a dialogue box that will provide a link once the export is complete)
Click on the “Click here to download” link
Save .csv file

Repeat the above for AM, CR and RE
Attached .csv files
Provide to IRB
END STEP 1

IRB to note name or person id of staff member to transfer items to in the .csv file then return
Not all items will need to be transferred, only active items (REMEMBER that the text in all the columns
except "ID" needs to be preceded by a single apostrophe!!! See template file at top of this page)

STEP 2

NOTE: we have a template Excel spreadsheet for this part, in the Admin SOPs/SOPs folder, called
“Template for Staff Reassignment.xls.” Please use that, but ensure that the “MyData” range is correct
once you have copied in your data from STEP 1.

Open or create spreadsheet for Staff Reassignment
Fields: | Action | Type | ID | owner |
Action = Update
Type = _Protocol (or _Amendment, _Continuing Review, _IRB WIRB, or _Adverse Event)
ID = IRBxxxxxxx (or AM1_IRBxxxxxxx, CR4_IRBxxxxxxx, etc)
Owner = ####### (person id of the person you’re assigning the studies TO. Use search “rptSystem: Verify
Person ID” custom search, to find the person ID)

Update fields with information needed (See sample file at top of this page)
Name the range “MYDATA” without the quotes (if you start with the sample file at top, the range is
already there, but if your data is larger than what’s in the sample, you may have to expand the
"MYDATA" range. Name info can be found in the "Formulas" tab of the MS Excel ribbon, under "Name Manager". Click on the "MYDATA" name, then click 'Edit...' to add more cells to the range.)

Click on Site Administration on the top left side
Click on Bulk Import under the Useful Shortcuts
On the Active tab, name the job (something logical)
Browse to the spreadsheet, choose the spreadsheet
Check "Report ID's in Feed Back"
Click Import
Once complete, click on the Completed tab to verify
END STEP 2

**SuperUser: Sponsored-to-NetID**

If someone has had a Sponsored account in the past, they may have that ID number in our eIRB system in their Account page. If they now have a netID and got an eResearch account through that (or it was automatically given to them because of their Sponsored account), then they may not be able to log in with their NetID or their old Sponsored ID. I've had one case of this so far.

To fix, I brought up the person's Account tab in eIRB's Projects screen. I edited their "Log In" information, to update their "User ID" to be their netID. After this, they were able to log in to eIRB using their netID and Password.
Before doing this, I had them log into ENID (per the "How to get an account" instructions on our website), and verify that they didn't have the option to add eIRB account (which means they must have already had the account via their netID)

**SuperUser: CTRC Troubleshooting in eIRB**

Scenario:
CTRC approval is required but the request for CTRC review is not generated in eIRB.

What to Do:
If "Cancer Related Research" has not been selected, the analyst should follow these steps if changes will be requested by the analyst:
1. Include a note for the study team to check “Cancer Related Research" in the list of changes to be requested.
2. When the study team submits the revisions, the analyst will verify that “Cancer Related Research” has been selected and that CTRC is listed under question 3 of the Required Reviews section.
3. Contact Lydia Cox at 8-5569 or lydia.g.cox@emory.edu to verify that she can see the study in her inbox.
If “Cancer Related Research” has not been selected, the analyst should follow these steps if changes will not be requested by the analyst:
4. The analyst should click “Edit Study” and select “Cancer Related Research” in the Biomedical Research Section.
5. The analyst should verify that CTRC is now listed under question 3 of the Required Reviews section.
6. Contact Lydia Cox at 8-5569 or lydia.g.cox@emory.edu to verify that she can see the study in her inbox.
## LOG OF SIGNIFICANT CHANGES

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<thead>
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MEETING FACILITATION

<table>
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<th>SOP Title:</th>
<th>Meeting Facilitator Responsibilities</th>
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<td>Meeting Facilitation</td>
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Meeting Facilitator Responsibilities

This SOP provides an overview for the steps to be taken to effectively prepare for, facilitate, and perform tasks for a convened IRB Full Committee meeting.

**Two Weeks Prior to the Meeting:**

1. The Meeting Facilitator (also called “facilitator”) sends an email to all regular and alternate members of the committee panel. The invitation email template may be found [here](#). Lists of regular and alternate panel members are on the [All Committee Roster by Chair](#).

   As responses are received, the facilitator files the emails into a folder and tracks the members who will be in attendance, those who will not attend, but will do secondary reviews and those who will not attend and will not do secondary reviews.

2. 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).

3. Reviews the meeting agenda periodically to assess what expertise will be required for new studies and other agenda items.

   a. When mandatory expertise (oncology, pediatric or cardiology on a new study) is not available among the members attending the meeting, the facilitator must decide how best to acquire the required expertise. The facilitator may coordinate with other facilitators to move the item to another agenda where that expertise will be present. The facilitator must inform the IRB staff analyst-owner if the agenda item is transferred to another agenda.

   b. The facilitator may also inquire if a member expert from another panel will attend or call (*in addition to his or her responsibilities to their primary panel that month.*) It is recommended to first try members whose primary meeting is farthest from the meeting requiring assistance. **NOTE:** The facilitator has discretion to move an agenda item with notification to the analyst-owner.
c. Assesses the size of the agenda. If it appears that the agenda will be too light, the facilitator will send an email to IRB staff to ask them to add agenda items.

d. Ensures that agenda items are listed under the correct agenda item type.

One Week (or more) Prior to the Meeting

1. The facilitator may close the meeting agenda to additional items by editing the agenda title in eIRB so that “[CLOSED]” precedes the agenda name. Other informational iterations may be used such as “[CLOSED to Peds NS]”.

Emails IRB staff that the meeting has closed with a reminder to upload missing omnibus forms to the meeting folder no later than the day before the meeting.

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

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

Additions to a Closed Agenda or Closed Category may include:

- Team Q and/or other emergencies where a patient is waiting for treatment, or, there are 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 prior to the next meeting when there is sufficient time for a proper review.

Note: The meeting facilitator must be contacted prior to any addition to a closed agenda. If the facilitator is not available, the Operations Manager should be contacted.

2. Creates the reviewer assignment sheet (RAS) from the panel’s reviewer assignment template: <<H: General\CMTE\Meetings\Committee A or B or C\Panel\Reviewer Assignments\(Year\)Reviewer Assignment Template>>.

Names the RAS with the date of the meeting (eg. 8-10-2017 reviewer assignment).
Saves the RAS to <<H: General\CMTE\Meetings\Committee A or B\CMTE (Panel \Review Assignments\(Year\)>>.

3. Populates the RAS with the meeting date and initial version date. The version date should be updated for any change made on subsequent dates.
The following information is populated for each item on the agenda:
• Study ID. AM/CR Number if applicable
• Department/VA/Grady/CHOA
• P.I. Name
• Analyst-Owner Name
• Date of IRB Expiration for CRs
• Member Conflicts of Interest
  • Members who will attend the meeting in the RAS member grid with the member’s classification (PS, NPS, A-NS or UA-NS).
  • Identifies members who will be calling in via the conference bridge.
  • Identifies members who will not attend the meeting but will complete secondary reviews.

The facilitator assesses the numbers 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), contact the last member(s) confirming attendance in that category and asks them to attend next month’s meeting.

NOTE: Members will be shown as available to attend when category limits prohibit attendance as a voting member.

4. Populates the member conflicts of interest (COI) for each item on the RAS, noting any member listed on the study team or with a previously established conflict of interest made known to the IRB (such as marriage, supervisory relationship or collaborators).

Assesses the impact of all conflicts of interest on quorum and the recommended order of the agenda when the member will be in attendance.

5. Assigns members to review agenda items on the RAS based on required expertise and review experience and/or ability.

**Assignment Considerations:**

• Try to limit reviews for members who are not VCs/CCs or community members if possible.
• The maximum amount of reviews for a given member who is not serving in a VC/CC or community number capacity should not exceed 4-5; depending on the agenda load.
• 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.
• See Item 3 under “Two Weeks Before the Meeting.”

NOTE: The facilitator has discretion to move an agenda item with notification to the analyst-owner.

6. Advises the IRB Staff Liaison to the VA when the required IRB member affiliated with the VA will not be present at the meeting if there are any VA agenda items to be reviewed.

7. Ensures that a prisoner representative is available at the meeting in person or by conference if a prisoner study is on the agenda.

8. Assigns members to the agenda in the electronic system from the information on the RAS.
9. 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.

10. Distributes the meeting agenda to members at least one week prior to the meeting date with copies to the meeting driver and back-up note-taker if identified. The email template may be found at <<H: General\CMTE\Meetings\Meeting Facilitator Prep Kit\Meeting Invite Email Template - UPDATED\Meeting Material email for all CMTEs.

   Email attachments include:
   - Finalized meeting agenda including draft minutes from the previous meeting
   - Reviewer presentation tools
   - Pertinent guidance or worksheet materials
   - Other information related to the upcoming meeting

11. Notifies the Chairperson and any affected members of an addition or change to an agenda occurring after distribution to members.

12. Emails individual reminders to Chairs of other panels who have been assigned a secondary or tertiary review for the meeting with a link to each study assigned. Title the email “Secondary Reviewer Assignment for IRB Committee (Panel Letter/Number) on (Meeting Date) and sends high priority.

13. Periodically updates the RAS to document the reviewer’s recommendation (vote) on an agenda item (Approval, Pending Approval, Deferral etc.) as recommendations are received.

14. For a deferral recommendation, contacts the assigned analyst-owner to see if deferrable issue(s) can be resolved prior to the meeting with sufficient time to return and review the information. The decision to remove a deferral from the agenda prior to the meeting should be escalated to the IRB Director and Meeting Chair for approval.

   NOTE: The facilitator must be informed of any item removed from an agenda and the reason if reviewers have been assigned and the agenda distributed to the Committee.

15. If the agenda includes VA agenda items, the facilitator may consider adjusting the order of the agenda to accommodate the VA liaison.

Two Days before Meeting Day

1. The facilitator emails a reviewer assignment reminder to those members who have not yet completed all of their reviews in eIRB.

2. 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)>>.
3. Emails IRB analyst-owners for missing, inconsistent, or unclear information on the omnibus form to resolve issues before the meeting.

4. The facilitator will create a OneNote page for the meeting under the specific Committee section. The facilitator will create a subpage for each new study on the agenda and a subpage for all other agenda items for the purpose of notetaking outside of the omnibus forms.

5. For unanticipated problems (UPs) cases: the case manager (Q team member) will contact the facilitator 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 will occur in cases where the next available meeting is not CMTE Q. The facilitator should email attending members the “Guidance on How IRB Makes Determinations of Serious or Continuing Noncompliance and UPs” found on the IRB website when sending the revised agenda.

   a. The case manager will attend the meeting and assist with the minutes notes for the case and email those to the facilitator after the meeting and before the minute draft deadline.

   b. The case manager will guide the meeting driver to prepare for checking omnibus form boxes

Meeting Day

1. The facilitator checks the study history for missing cost option information and other information for new studies on the agenda. Checks the OSP ICOI Database Daily Spreadsheet for missing injury option information.

2. Updates the RAS as reviews come in or new information is obtained.

3. Captures the pending administrative items for each new study.

4. Checks AMs for current accrual for the purpose of identifying if the Committee needs to make a reconsent determination.

5. Checks CRs for logged comments regarding missing DSM and study progress reports so that the facilitator may mention these during the discussion of the CR.

6. Finalizes the Pre-Meeting Huddle information. The Pre-Huddle template may be found at here.

7. The ORA Event Coordinator places drinks and snacks for the meeting in the conference room by 3:30 pm (see ORA Event Coordinator SOP for details).

8. The assigned Analyst Assistant completes meeting set-up responsibilities no later than 3:45 pm. (Analyst Assistant Meeting Preparation and Cleaning up SOP)

   NOTE: The facilitator must check that meeting set-up is complete and advise the assigned AA.

9. The facilitator sets up his or her laptop and attaches the microphone system used to record the meeting. This should occur around 3:30pm in order for the facilitator to ensure that the microphone and polycom are set up correctly and are operational.

10. The assigned Driver for the meeting should be prepared to conduct driver responsibilities before, during and after the meeting (See Drivers for IRB Meetings SOP)

11. The facilitator conducts the Pre-Meeting Huddle at 3:45 pm or when the Meeting Chair arrives.
12. The facilitator will greet meeting guests. Confidentiality Agreements 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.
   a. Ensures that confidentiality agreements have been signed before the meeting convenes. Guests arriving after the meeting has started may not enter and may reschedule their observation.
   b. Member candidates attending a meeting as part of the appointment process have already signed a member confidentiality form. The facilitator arranging the candidate’s visit, will email the meeting date scheduled for observation to the meeting facilitator. The meeting facilitator should send the candidate a courtesy reminder or notification of any change of date, time or place.

13. The facilitator will make sure doors are closed for privacy and confidentiality when the meeting convenes.

14. 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.

15. Takes the meeting minutes and includes:
   - Controverted issues during Committee discussion on an item and how they were resolved
   - Comments on the submission whether positive or negative (e.g. the protocol was well-written. The consent form used too many medical terms).
   - Information from the discussion on science relative to the study.
   - 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.
   - The recusals and other departures, returns and permanent departures by individual members to and from the meeting.
   - Compliments to the study team on the submission.

NOTE: 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.

NOTE: An experienced Back-Up Note Taker, usually the IRB Director or her representative, will 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.
Closing Activities after the Meeting

1. The facilitator, as well as all other staff present, are responsible for shutting down, disconnecting and plugging laptops into the laptop cart, disconnecting and storing other electronic devices in the containers provided, turning off the projector, retracting the large screen, returning the conference room furniture to the standard setting when applicable, turn off the lights, disconnecting the conference bridge, and returning it to its container.
2. The laptop cart, mice, laptop chargers, and large power strip must be returned to the IT offices on the 4th floor by staff closing the meeting. The laptop cart must be plugged in to the source provided in the IT office so that the equipment may charge overnight.
   a. The keys that opens the laptop cart and the IT office must be left in the Lock Box on the 4th floor outside the IT office. The Lock Box requires an ID issued by IT and a unique passcode to access and return keys.
   b. The conference bridge equipment is returned to the Operation Manager’s office.
3. Remaining chips, sodas and water are returned to the pantry closet within the meeting room. The chips are left 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 insure a proper count for the IRB account.
   a. Sodas should be left in the refrigerator in the pantry on the shelfs labeled IRB.
   b. Candy is returned to the locked Member File Cabinets in the IRB area outside Jennifer Truell’s office.
   c. IRB Keys (pantry closet and IRB member file cabinets) should be returned to the Lock-Box in the IRB Director’s office.
4. The facilitator ensures that the meeting area does not have any documents left behind. Any meeting-related documents must be discarded in the “CONFIDENTIAL” bin outside the conference room. Ensures all loaned portable meeting equipment has been removed from the meeting room or properly secured.

The Day After the Meeting

1. The facilitator changes the status on the meeting from “Meeting Scheduled” to “Pending IRB Approval”.
2. The facilitator reconciles the notes and total votes by the Committee with the information from the back-up notes and recording if necessary to resolve any discrepancies.
3. Completes and adds the minutes front and back bookends to the meeting notes. Bookends are found on the shared drive here.
4. Sends an email to pertinent staff and copies all team leads when reconciliation is complete and letters to the study teams may be created unless otherwise noted on the omnibus form.
5. The facilitator will update the Attendance Log with the Committee designator (B1, B2, etc.) in the cell in the column for the month of the meeting and row of the name of the members who attended.
6. If minutes were approved at the meeting, the facilitator will move the draft version(s) of approved minutes from the Minutes -- drafts folder to the [approved] Minutes folder. In this action the facilitator will remove “DRAFT” from the title of the draft minutes document.
a. The facilitator will change the status of the meeting from “Pending IRB Approval” to “Minutes Approved”.

7. If the Committee approves the draft minutes pending edits, the edits indicated must be made to the draft version and returned to the panel the next month for a second review. If the edits are purely administrative, the draft minutes may be considered to be approved once the edits are completed.

By the Second Friday after the Meeting Day

1. The facilitator prepares minutes for review by the Team Leads and emails them when ready. When the minutes have been reviewed and edits made if any, the facilitator combines the minutes into a draft PDF document with a set footer that indicates the meeting panel, the date of the meeting and the page number.

2. Names the document, “(Panel (Meeting Month).(Day). (Year). DRAFT” and saves it at <H: General\CMTE\Meetings\Minutes-drafts\((Year)\(Month)>>.

3. The document should also be attached to the next month’s meeting agenda for that panel.

Semi-annual Tasks:

1. Go through the OneNote for the IRB Committee meetings and delete any recordings that are older than 6 months. Prior to deletion, check to see if any items for that meeting were deferred.
   a. If the deferred item is in an approved state, proceed with the deletion of the recording.
   b. If the deferred item is in a non-deferred but not approved state, e.g. Contingencies Pending, do not delete the recording.

LOG OF SIGNIFICANT CHANGES

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<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
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<td>Overhauled to indicate current job requirements.</td>
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<tr>
<td>11/1/2017</td>
<td>Major changes to align with current process</td>
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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.

RESPONSIBILITIES
- **Meeting driver (MD)** – will drive during the meeting, assists the MF as needed, assists with meeting breakdown whenever possible. The MD pool consists of all Senior RPAs, RPAs, and AAs. MFs, Team Q members, and the VA liaison are exempt from driving. Finds a substitute if unable to fulfill their duties for a given meeting and communicates that to the TL and MF.
- **Meeting facilitator (MF)** – facilitates the meeting.
- **IRB Team Lead (TL)** – Ensures that the bi-monthly MD announcement is made to all eligible staff, that all eligible staff volunteer to drive for a meeting, checks weekly for MD coverage for that week, and makes accommodations if an MD is not available.

PROCEDURE

**TL Duties**
- The TL will announce to all IRB staff the onset of a 2-day MD sign-up period. During this period, the eligible drivers will be asked to go into a OneNote section on the IRB shared drive, Drivers and AA functions for meetings, and sign up for the meeting of their choice.

**MD Duties**
- Prior to meeting
  - Record their chosen meeting date(s) in their Outlook calendar, with an alert, and if unable to attend the meeting, arranges for a substitute and informs the TL and MF.
- The day of the meeting:
  - Arrives to the meeting room at approximately 3:30 pm to prepare the MD laptop:
    - Maps to the IRB shared work drive on the Driver laptop (if the AA has not done so already).
    - 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 study on agenda if desired
    - Opens “Words to PI” file, located in the CMTE folder
    - Opens the omnibus forms for the new studies
- During the meeting:
  - Note: Responsible for Omnibus Forms for NEW studies only
First display the item being presented. Display the History in case there are important notes (both main study, and AM or CR being discussed.

- Omnibus forms: When the discussion begins for each new study, the MD fills out the section of the omnibus form “Findings by the Board”, including checkboxes and adding and protocol specific comments. The MD 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 MD will follow the MF and vice-chair instructions when filling out the forms.

- When not completing 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 vote on each item: log a determination comment to Study Team in the Study History for each item on the agenda using language in “Words to PI” file (if advanced MD; may be done after meeting if novice MD)

- The MD may leave the meeting after 5 pm if all the new studies have been reviewed already. The MD should leave the computer on.

### LOG OF SIGNIFICANT CHANGES

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<td>6/8/2018</td>
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**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**
- **Meeting Facilitator (MF)** - will draft minutes after FB meeting.
- **IRB Team Lead** - will review minutes draft for final approval

**PROCEDURE**
The expectation is that the Meeting Facilitator (MF) will create a draft copy of the minutes after his/her meeting has occurred and before the second Friday (*) after the meeting.

On the H drive are 2 Minutes folders:
- 1. Minutes – Draft (H:\General\CMTE) – for draft minutes
- 2. Minutes (H:\General\CMTE) – for approved minutes

**Draft Minutes**
When the MF creates the draft version of the minutes, they will do the following:

- Conduct a thorough review of the omnibus form for content, regulatory requirements, and administrative clarity.
- Put them in the order that they were voted upon at the meeting, via initial numbering convention
- Create the front and back bookends for the minutes using the Omnibus Minutes template that is located in the H:\General\CMTE\Meetings\Minutes.
- Combine the draft minutes into a single PDF document using Adobe Acrobat Pro. The naming convention for the draft minutes will be CMTE-Minutes-Meeting Date-DRAFT. (i.e. A1 Minutes 1.14.2015 DRAFT)
- Place a copy in the Minutes-draft folder on the H drive in the appropriate Year/ Month folder (e.g. 2015/01 January).
- The Team Lead should be sent a notice when the draft minutes are available for review.
- The Team Lead will review the draft minutes and provide the revisions, if any, to the Meeting Facilitator by the 3rd Friday. The MF will make the revisions prior to finalizing the draft version. This ensures that the final draft minutes will be able to be sent to IRB Committee members when all meeting materials are sent to them one week prior to the meeting.
After the Team Lead has reviewed and cleared the draft minutes, the MF will combine and then attach the draft minutes to the committee agenda for the next month. The minutes are then assigned to the committee for review/approval. Should a committee request that changes be made, the MF will make those changes to the Word document in the appropriate Minutes - Draft folder and delete the old one.

Final Approval

Once the minutes have been approved, the MF will copy the draft version of the approved minutes into the Minutes folder (H:\General\CMTE\Minutes) in the appropriate folder by Year/Month (i.e. H:\General\CMTE\Minutes/2015/01 January). The MF will modify the title of the minutes document to remove the word “DRAFT”, thus signifying that the minutes are approved and are no longer a draft version. The MF will remove the term “DRAFT” from the footer of the draft version if it is in the footer. Approved minutes will always be saved in PDF format.

*There will be exceptions to this policy in cases where IRB Committee meetings were rescheduled due to holidays, lack of/loss of quorum, or natural phenomena. (i.e. adverse weather conditions)

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<td>Added purpose and Scope change of title and other updated to reflect current process. Combined with previous SOP entitled “Combining Omnibus Forms for Minutes”</td>
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<tr>
<td>11/1/2017</td>
<td>Revised to update this SOP with current process</td>
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**SOP Title:** Analyst Assistant Meeting Preparation and Cleaning up

**SOP Category:** Meeting Facilitation

**Established:** 1/30/2017

**Last Revision:** 11/1/2017

**PURPOSE**
The purpose of this document is to explain the tasks analyst assistants (AAs) are responsible for when setting up and cleaning up for a full board meeting.

**SCOPE**
The SOP applies to the analyst assistants’ functions in preparation and closing for a full board meeting.

**RESPONSIBILITIES**
- AA: to perform all activities assigned to them in preparation and closing for the assigned full board meeting

**PROCEDURE**

**PRIOR TO MEETING**
- Set up recurrent meetings for laptop pick up, involving Enid Sullivan (or replacement). 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 the following information:
    - To: Enid Sullivan (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 the review assignment spreadsheet that is emailed by the facilitator before the meeting. Alternatively, you can find the spreadsheet under H:\General\CMTE\Meetings\Committee CMTENAME\Cmte N\Reviewer Assignments
- 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 facilitator or driver 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 (facilitator, driver and backup note taker)
  - Map the chair and driver laptops to the H drive.
- 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:** sometimes the meeting facilitator, backup note taker will bring their own computers. 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.

**Setup the Phone:**
Check with facilitator or person who set up laptops the last time.

**Before leaving:**
Talk to meeting facilitator before leaving to ensure that all the required steps have been completed.

**AFTER THE MEETING (IF DRIVING)**

- Put up Snack/drinks:
  - An ORA person will setup the drinks, chips, cups and ice for us. At the end of the meeting we are responsible for putting all drinks/snack back in to the pantry cabinet.
- If the AA is not driving at the meeting, the meeting facilitator and driver should do the following:
  - Put Drinks in the refrigerator
  - Chips go in the IRB closet right outside 5C (main office key should work)
  - Ice bucket goes on the snack shelf
  - Breakdown the phone
  - Place in the Computer closet in 5C
  - Recycle any extra agenda, paper, etc. that are left at the meeting. This room is reserved very early sometimes and we want to make sure it's tidy for the next team.
- If an AA is the meeting driver, the laptops should be taken down. Otherwise, an AA who set up for the meeting will take the laptops in the morning.

**LOG OF SIGNIFICANT CHANGES**

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<th>SUMMARY OF SIGNIFICANT CHANGES</th>
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<tr>
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<td>7/14/2017</td>
<td>Adding step before leaving meeting</td>
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<tr>
<td>11/1/2017</td>
<td>Changes made to align to current procedures</td>
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SOP Title: Using the Roster Ultimata
SOP Category: Meeting Facilitation
Established: 11/10/2017
Last Revision: 6/8/2018

PURPOSE
The purpose of this document is to explain how to manipulate the Roster Ultimata, track member attendance, how to add members, remove members, and archive the spreadsheet when changes are made.

SCOPE
The SOP applies to any staff who edit the the Roster Ultimata.

RESPONSIBILITIES
• IRB Meeting Facilitator(s): track member attendance, keep CITI certification dates updated, add new members, remove old members, and archive spreadsheet when changes are made.
• IRB Staff: view the Roster Ultimata for guidance when assigning reviews or full board meeting items.

DEFINITIONS
Attendance Record: the attendance record is the percentage of meetings attended since the date of appointment. The appointment date is vital in interpreting this statistic.

PROCEDURE
RPAs who need view-only access can review all of the pages in the workbook by clicking the tabs at the bottom of the page. They can also search the workbook for a specific member by typing ctrl+f and using the dropdown menu next to “Within” to search the entire workbook.

A copy of the Roster Ultimata workbook should be saved as an archived version BEFORE making changes to the document. These changes include adding new members, removing members, changing members to a different committee permanently (temporary changes do not need to be archived).

1. Archiving the workbook:
   a. Click File, Save As, and select this file path: H:\General\CMTE\Members (and VCs)\Rosters\Archived
   b. Save the copy as “Roster DATE-DAY”. (Dates should be listed in MM-DD-YYYY format).
      i. The first DATE is the date of the last roster archival and the second DATE is today’s date

To add new members:
Members must be added in two sheets of the document: the Attendance sheet and the All Members Sheet.
1. First add the new member(s) to the attendance sheet.
   a. Insert a row for the new member alphabetically
   b. Input the Member Name.
c. For the Attendance Record column, copy and paste the formula from the cell above your new row. Once the formula has been copied, select the \( \int x \) text box at the top of the screen, in the tool bar, and change ONLY the parenthetical information after “DATE”. This should be located in two different places in the formula (the numerator and the denominator). Enter the appointment letter date to accurately calculate attendance for the new member since the appointment date. The date should be entered like this: (YYYY,MM,DD).

2. Navigate to the All Members sheet
   a. Insert a row where your new member(s) should be added
   b. Fill out all fields accordingly.
      i. Enter the committee where the new member will be serving in the appropriate column (for example “A1” in the A1 column).
      ii. If the new member serves as a backup on a committee, enter the committee with the “-A” suffix.
      iii. If the new member is a prisoner rep on a committee, enter the committee with the “-P” suffix.
      iv. Continue entering the rest of the information on the row, ensuring that all fields are filled out (this seems tedious, but helps inform the separate committee-specific spreadsheets with the appropriate information).
   v. Save the Document. Note that the committee-specific sheets are designed to pull information off the All Members sheet to display. There is no need to update those sheets specifically.
   vi. If the data needs to be refreshed in a sheet, click on Data at the top of the screen. Click Manage in the Data Model tab, and click the arrow under Refresh in the toolbar. Select Refresh All to update all of the tables in the workbook (which will update all of the committee-specific sheets with newly entered information). You can close the Data window once this is complete. Resave the document.

To remove old members:
Members must be removed from two sheets of the document: the Attendance sheet and the All Members Sheet.
1. In the Attendance sheet, hover your cursor over the row number that you will remove and click. This should highlight the entire row.
2. Right click and select “Delete”. This should remove the entire row from the document.
3. Navigate to the All Members sheet, hover your cursor over the row number you will remove and click. This should highlight the entire row.
4. Right click and select “Delete”. This should remove the entire row from the document.
5. Save the Document. Note that the committee-specific sheets are designed to pull information off the All Members sheet to display. There is no need to update those sheets specifically.
   a. If the data needs to be refreshed in a sheet, click on Power Pivot at the top of the screen. Click Manage in the Data Model tab, and click the arrow under
Refresh in the toolbar. Select Refresh All to update all of the tables in the workbook (which will update all of the committee-specific sheets with newly entered information). You can close the Power Pivot window once this is complete. Resave the document.

**To track attendance:**
Enter the committee meeting the board member attended in the appropriate row and column for each member. Note that this activity must be completed as soon after the meeting as possible to ensure that community members are paid correctly based on attendance.

**LOG OF SIGNIFICANT CHANGES**

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QA AND EDUCATION

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<th>Acknowledgments &amp; Noncompliance Determinations Made by Senior Team Q Staff</th>
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<td>QA and Education</td>
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<td>Established:</td>
<td>10/19/2011</td>
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PURPOSE
The purpose of this document is to specify in which circumstances a designated senior Team Q staff may acknowledge reportable event submitted to the Emory IRB.

SCOPE OF SOP
The SOP applies to the reportable events submitted for studies reviewed by the Emory IRB.

RESPONSIBILITIES
- **Senior team Q staff**: Reviews and triages reportable events submitted to the Emory IRB. Under this SOP, the staff will also acknowledge certain type of events as explained below. “Senior” is defined as Team Lead, 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 serious 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.
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 event 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**

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<td>7/14/2017</td>
<td>Changes to procedure section</td>
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**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 been in compliance with 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 IRB Director, the Emory IO, and Emory Office of Compliance (OC) Director 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 Emory IRB Committee and/or its administrative office.

**DEFINITIONS**
- **Minor IRB NC**: NC with Emory IRB P&Ps or federal regulations that does not impact the rights, welfare, safety of subjects, or the integrity of the research data.
- **More than Minor IRB NC**: IRB NC, or identification of a repeated pattern of IRB NC, with Emory IRB P&Ps or federal regulations that could negatively impact the rights, welfare, safety of subjects, or the integrity of the research data.
- **Findings**: information or a fact that is discovered during the IRB internal QA/QI process.

**RESPONSIBILITIES**
- **OC Director** – reviews quarterly reports of IRB NC to identify potential patterns and immediate reporting needs.
- **IRB Director** - reviews More than Minor IRB NC issues to determine if they should be routed to the CoRe team.
- **IRB Q Team**: Compiles information to be sent to the CoRe Team
- **CoRe Team**: reviews issues coming from ORC representative or IRB Director. If they find the issue to be More than Minor IRB NC, the event will be routed to the IO.
- **IRB Director and Team Leads**: 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 CAPA plan.

**PROCEDURE**
1. IRB noncompliance issues may be identified during monthly routine internal review or during incident-based reviews by IRB staff, researcher or other members of the HRPP.
2. Director and TLs will go through the findings identified during the monthly QA/QI review in a later meeting. The IRB Director will review events identified outside the QA/QI review.

3. After Team Q has finished with the monthly internal QA/QI review, the Director and TLs will meet to review the findings and determine which findings are minor and which are potentially serious or continuing. A CAPA plan will be drawn up. The Director will do the same for events identified outside the QA/QI review.

4. The TLs will communicate the CAPA plan to the staff. The TLs will follow CAPA plans until completion. Some minor findings may not have a CAPA plan if already fixed or if it is considered unnecessary.

5. Minor IRB NC will be logged in a spreadsheet, and sent monthly to the OC Director or his/her designee. The information will be cumulative. If the OC Director/designee finds any concerning trends that might represent More than Minor IRB NC, he/she will email the IRB Director with his/her concerns.

6. Findings considered More than Minor will be sent by a member of Team Q to CoRe for review. Team Q will send a summary of the finding in question in the CoRe email.

7. If CoRe finds the information to be More than Minor IRB NC, it will be sent to the IO. If the CoRe finds the information to be Minor IRB NC, the determination will be logged in the spreadsheet.

8. The IO will review the information to assess reporting requirements and adequacy of CAPA plan.

9. If IO deems appropriate, the NC will be reported to OHRP.

**PROCESS FLOW**

**LOG OF SIGNIFICANT CHANGES**

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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.

SCOPE
CAPA plans from studies reviewed during Committee Q meetings for possible serious and/or continuing non-compliance, and unanticipated problems 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.

PROCEDURE
The process will start after Committee Q reviews and approves the CAPA plan for a specific case. The CAPA plan will be included in the determination letter sent to the principal investigator after the meeting. The study team may request a deadline extension. This extension may be reviewed and granted or denied at the CoRe team discretion. Every case manager will follow up with the study team about the CAPA plan completion and the deadline. When the CAPA plan is completed, the case
manager will email the details to the Team Q designated member. If the CAPA plan has not been completed in the allowed period, the case manager will notify the study team that non-completion on 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.

PROCESS FLOW

REFERENCES

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

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SOP Title: CMTE Q Meeting Facilitation
SOP Category: QA and Education
Established: 6/11/2013
Last Revision: 5/13/2015

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

SCOPE
Applies to Team Q, meeting facilitator, and administrative staff who help conduct Committee Q meetings.

PROCEDURE

Before the Meeting

1. Create 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 worksheet in PDF format should be under the “Meeting Materials” folder. Additional documents to present to the FB should be added to the same PDF document. The Omnibus forms, containing case information, should be saved under “Omnibus Forms”.

3. Each meeting folder should include subfolders for PI letters, Fed Letters, Investigator slot spreadsheet, Meeting Notes, Meeting Materials, and Omnibus forms. The Recap Spreadsheet is located under the YYYY folder.

4. On the first week of the month, an email invitation should be sent 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). A VA member must be present if any VA cases are reviewed. Any identified conflicts of interest should be taken into account when ensuring quorum.

5. The agenda should be finalized and materials sent no later than the Friday before the meeting, if possible. The VA Compliance Officer should receive an invitation to the meeting, and a copy of the VA materials to be reviewed. Guest arrivals should be noted in 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 in the agenda.

6. If any items are added or removed after the agenda and materials are emailed, the members should be notified as soon as possible via email 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.
7. Ensure that members have access to the meeting materials. The folder will include the agenda, any last minute additions (if applicable) and NC/UP guidance.

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. The number for the Conference line is 404-727-1109 (access code 302014#).

Day of the Meeting

1. The administrative staff will set up drinks and snacks about 30 minutes before the meeting.

2. The meeting facilitator will place a sign near the elevator to indicate PIs attending the meeting to wait in room 5A.

3. The meeting facilitator will make available name cards and copy of the agenda for all committee members and staff at the meeting.

4. The meeting facilitator will ensure that laptops are set up for members and staff. The meeting facilitator will save a copy of all meeting materials in each laptop before the meeting.

5. If necessary, the meeting facilitator 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 locked in 5C. The next morning, the laptop cart 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, amendment 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 consider of great urgency, the letter should be sent earlier. 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 Team Lead for review at least one week prior to the next meeting.
6. Every Team Q member will be responsible for follow-up with the study PI regarding CAPA completion. The meeting facilitator should remind Q team to add outstanding CAPA items to the CAPA report worksheet in the meeting materials folder.

LOG OF SIGNIFICANT CHANGES

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<tr>
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<td>Update to follow current practices</td>
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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 risk for participant s or others. This SOP is intended to guide the IRB in communicating to 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 he knows 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 consider 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. David Wynes, VP for Research Administration
      ii. Kris West, ORC
      iii. David Stephens, VP for Research
      iv. Jeffrey Lennox, Associate Dean for Clinical Research
      v. If Winship: Curran, Waller, El-Rayes, Rodger, and PI
      vi. Katie Lewis (OGC)
      vii. Cheryl Ritchie (Risk Management)
      viii. Anne Adams and Stephanie deRijke (CTAC)
      ix. Laura Deane (Office of Quality)
      x. William Bornstein (Office of Quality)
xi. Susan Rogers (IDS) – if it is a drug trial (Non-VA)

xii. IRB analyst owner of the study

xiii. Chair of IRB meeting that will be reviewing the possible UP

xiv. Anyone else it makes sense to alert (check with IRB Director first)

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**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. 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 description of 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 was not consented 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 FB, 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:

- 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 a similar use of the device occurring again at Emory, and if such future is likely, begin steps to obtain a new IDE or amend 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 description of 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.

The Team Q member will create a submission using [IRB00077369](#) by cloning this study. The “cloned” study should be named using the following nomenclature:

YEAR-MONTH-DAY (of concurrence)-IDE/IND compassionate use-PI: Name. For example, for a concurrence given on 12/19/17 to Dr. Shervin Oskouei for an IDE, the study should be named as follows: “2017-December-19-IDE compassionate use-PI:Oskouei”. The Team Q member will also create a folder with the IRB number of the cloned study and will save the information received from the treatment team. Note: Do not upload information to eIRB that has identifiers, including dates of treatment and clinic numbers.

In order to find the study that was cloned:
- Select “study staff” from your IRB roles
- Find the study under the “IRB” tab
- Fill out the form using the information obtained during the IRB concurrence process
- Place study on Completed status. Do not put an expiration date, unless use is ongoing and will last more than one year.

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 device via email. This concurrence will be sent to the study team. 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:
- 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.

Once the study has been reviewed and approved, the study may be reassigned to an IRB analyst after discussion with Biomedical Team Lead.

**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 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 an amendment 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
- Documentation of FDA approval for the Expanded Access Use request, including waiver of IRB approval

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 submission using IRB00077369 by cloning this study. The “cloned” study should be named using the following nomenclature:
YEAR-MONTH-DAY (of concurrence)-IDE/IND compassionate use-PI: Name. For example, for a concurrence given on 12/19/17 to Dr. Shervin Oskouei for an IDE, the study should be named as follows: “2017-December-19-IDE compassionate use-PI: Oskouei”. The Team Q member will also create a folder with the IRB number of the cloned study and will save the information received from the treatment team. Note: Do not upload information to eIRB that has identifiers, including dates of treatment and clinic numbers.

In order to find the study that was cloned:

- Select “study staff” from your IRB roles
- Find the study under the “IRB” tab
- Fill out the form using the information obtained during the IRB concurrence process
- Place study on Completed status. Do not put an expiration date, unless use is ongoing and will last more than one year.

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 email. 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.

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.

**PROCESS FLOW**

**Compassionate use of unapproved device:**

![Flowchart showing the process of compassionate use of unapproved device]

**Emergency use of unapproved device:**

![Flowchart showing the process of emergency use of unapproved device]
Compassionate use of device:

- Use may start before IRB/FDA approval
- Team Q will review information from physician and request submission
- Team Q member sends application to FB, assigning IRB chair, Meeting VC as reviewers
- Once approved, the IRB member assigns study to IRB Analyst

Emergency use of unapproved drug:

- Drug requires FDA review (not IRB approval). Needs submission to FDA within 15 days and IRB submission within 5 days of use
- Team Q member reviews information and sends to FB
- Acknowledged per normal procedure
- IRB member reviews information and alerts IRB chair
- Team Q creates shell or reviews submission

REFERENCES

FDA webpage: Expanded Access (Compassionate Use) at https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm#Investigational_Drugs

FDA Expanded Access for Medical Devices Guidance at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm


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<tr>
<td>1/31/2018</td>
<td>Revamp of process per FDA changes; adding drugs to SOP</td>
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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 – make sure to obtain 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 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. The room information will be emailed to the attendees. This list may include other IRB staff, IRB members, or staff from other divisions (at director’s request). The email should contain:
  - Link to adobe connect if the IRB staff is required to attend and the webinar takes place on a day other than Monday.
  - 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.
- In addition, the same room should be reserved from 15 to 30 minutes prior to 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 the webinar is being broadcasted via adobe connect, the QA IRB analyst will do a “screen grab” to capture attendees via adobe connect.
- After the webinar if finalized:
  - 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 power point presentation (if not sent earlier), and an attendance certificate/survey if applicable.
PROCESS FLOW

IRB Director/Team Q supervisor purchase webinar

Team Q supervisor purchases webinar and emails attendees

Team Q member creates sign in, and after webinar, scans completed form to H drive folder

Team Q supervisor emails attendees certificate of attendance and slides as applicable

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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:
    o 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.
    o The Team Q designee will also ask the study team to submit a reportable event if any procedure took place before the subject reconsented.
    o 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).
    o 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:
    o 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 event 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**

1. OCR emails study team and Q designee
2. Q designee emails back with reconsenting instructions, ask study team to submit RE if procedures took place and sends letter for OCR
3. OCR will upload either expired ICF in eEMR with the IRB letter, or unexpired consent if reconsent was possible
4. If procedures took place before reconsent, the Q designee will send event to designated reviewer

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

1. OCR emails study team and Q designee
2. Q designee emails back asking study team to reconsent and to indicate if procedures took place prior to reconsent
3. OCR will not upload ICF in eEMR and will wait to receive correct ICF version after reconsent
4. The Q case manager sends letter to OCR indicating the CoRe (FB) findings, final determination, and CAPA plan for the study, if OCR did not receive the subject reconsent form
5. If activities took place, Q designee asks study team to submit a RE. The RE case manager sends event to CoRe.
6. If OCR receives the correct ICF from the study team, they will inform the Q designee

**Attachment 1**

*Use IRB letterhead for this letter. Delete instructions in red.*
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 reconsent the subject for documentation purposes, and to submit a reportable event if any research activities took place before the subject was reconsented.

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

Sincerely,

NAME
TITLE

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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)

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SOP Title: Internal QA/QI review of documents after IRB Review

SOP QA and Education

Established: 6/1/2012

Last Revision: 11/1/2017

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 team lead 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

PROCEDURE
Note: Studies reviewed at full board are audited by the minute reviewers. Effective on 8/29/2017, Team Q will only audited studies reviewed using the expedited review process.

Monthly, team Q will review a sample of new studies, amendments and continuing reviews submitted to the IRB office during the past month. The review will include 3 items per staff member. The Team Q member will populate a dedicated excel document for this purpose. The findings will be reviewed by the Team Lead and/or IRB director. Once the findings are verified, the IRB Team Lead 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
For Non-human subject research determinations: folder with information pertinent to review
- 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.

**PROCESS FLOW**

- IRB Team Q Member reviews 3 items per study analyst
- After audit, the findings (if any) are shared with the Team Lead and IRB Director
- If findings are confirmed, the IRB director or Team Lead will meet with the IRB staff to discuss study.
- If necessary, the study team will be contacted to correct further.

**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

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<td>5/13/2015</td>
<td>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.</td>
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<tr>
<td>11/1/2017</td>
<td>Changes to the subject matter reviewed, as TLs are reviewing FB studies at the moment of auditing the FB minutes</td>
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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 SCN, CNC or UP determinations should be reviewed by the IRB Director 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 in the IRB chair behaves. For notifications to OHRP, the IRB Director should sign the letter. In case the IRB Director is absent, the IRB chair or the Institutional Official could sign the letter.

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

The case manager should give the hardcopy of the letter to the meeting facilitation for archiving. The meeting facilitator will save the letter under the corresponding meeting section in the binder.

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. This guidance includes information of which Institutional Official should be copied in the letter and current email addresses for FDA and OHRP officials. When sending the email to the federal agencies:

- Email the FDA/OHRP 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, forward the email to the meeting facilitator and the study PI, if not copied before.

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PURPOSE
The purpose of this document is to describe the review process of reportable events (REs) submitted to the Emory IRB office.

SCOPE OF SOP
This SOP scope is all REs submitted to the Emory IRB. The RE may report an issue involving a study reviewed by the Emory IRB or from a site under an Emory S-I oversight.

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 and/or qualified compliance staff from the AVAMC (for VA cases only) to investigate cases of 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 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 because it does not represent a noncompliance issue, a reportable protocol deviation, an unanticipated problem (or any information that may increase a risk in the research) or a research-related death.

PROCEDURE
For cases sent to designated reviewer or acknowledged by Team Q Lead or senior Team Q member:
- The Team Q Lead or senior Team Q member will screen the submission.
  - If the case reported is determined to be potentially noncompliance, a reportable protocol deviation, or an unanticipated problem, it will be assigned to a Team Q member (see next section on Expedited Review).
  - If the case is considered as a minor protocol deviation, the Team Lead may send the event to a designated reviewer.
  - If the case is a non-reportable matter, the event may be acknowledged by a designated member

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or Team Q Lead/senior Team Q member per SOP (see in references).

- Expedited Review: If there is precedent for a case, via CoRe and/or FB, that indicates that the reportable event is potentially noncompliance, but neither serious nor continuing, the Q Team Lead may send the reportable event for expedited review. The following specific precedents are already in place for sending to expedited review:
  - A review by the study team of more charts than what was approved by the Emory IRB. Because this deviation constitutes a HIPAA matter, the Team Lead will also notify the Emory Privacy office via email. A copy of the email and the privacy officer’s response will be logged under the RE history.
  - 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 enrolling few subjects or the study’s overall risk is considered high, the reportable event should be sent instead to the CoRe Team. In either case, because this deviation also constitutes a HIPAA matter, the Team Lead will also notify the Emory Privacy office via email. A copy of the email and the privacy officer’s response will be logged under the RE history.
  - The case should be added to the NC UP spreadsheet. The spreadsheet is in the QA working files main folder. H:\General\QA Working Files\NC UP Complaints.

For cases sent to the CoRe team:

- After the RE is assigned to the Team Q member, the case should be added to the NC UP spreadsheet. The spreadsheet is located at the QA working files main folder. H:\General\QA Working Files\NC UP Complaints.
- 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 (1234 Jones). When the case is under review, it should be located under the Pending folder. If closed, the case should be moved to the Close folder. Every case (inside the study folder) should be named after the RE number used to report it. For example, if a NC event was reported with RE 2, and it is currently closed, it should be located at H:\General\QA Working Files\NC UP Complaints\Non Compliance\Closed\1234 Jones\RE2. The cases under the pending folder should be named after the study number, PI name and RE number.
- The Team Q member should contact the PI and study team for the input and clarification of data, and for a corrective and preventive action plan. Use current SOP Ed & QA Team Mission and Process
- The information obtained is added to the Omnibus form. The worksheet part of the form should be completed. The form can be located at: H:\General\QA Working Files\Forms, templates and Guidance\Omnibus Forms\ RE Omnibus-Worksheet form
- The team Q member emails the 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 March 1, 2014 is composed by Carlton Dampier, Maria Davila, Cliff Gunthel, Shara Karlebach, Rebecca Rousselle, Aryeh Stein, and Larry Tune.
- The CoRe team will “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, and at least one Vice-chair or Co-Chair, the case can be closed and you can prepare the letter. In addition, if any member of the CoRe has a conflict, they should recuse him/herself from the review of the event. For VA cases, the VA compliance representative should be copied as well.

- The cases will be divided in Clinical CoRe cases and Procedural CoRe cases. Clinical CoRe cases will be those involving a missing clinical test or any other matter involving clinical care or safety events. The Procedural CoRe cases will be those involving 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. 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 event represents no noncompliance, not serious or continuing noncompliance or not an unanticipated problem, the event will be closed. The Omnibus form should be completed and non-applicable sections should be deleted. The RE should be closed in eIRB by sending a letter to the study team. If the RE was reported outside eIRB, the letter should be created in word, signed, converted to PDF file, saved under study history and also emailed to the PI and study team. A copy of the letter sent to the PI should be saved in the RE folder. Once the case is considered closed, the RE folder should be archived in the closed folder.
  - If CoRe has determined that a safety report submitted in a RE is not an UP, the following report received containing the same information can be send 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 in lieu of a worksheet. The RE letter should also be saved in the same folder.

- If the case has a CAPA pending item, the case should be moved from the “pending” folder to the “working on CAPA” folder. In addition, the case manager will log the CAPA item in the NC/UP log and in the CAPA shared calendar. When the CAPA issue is completed, the case can be moved to the “closed” folder. The CAPA item should be deleted from the NC/UP log (but kept in the done tab)

- 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: CoRe determination on DATE
  - Completed Omnibus form

**Cases sent to Committee Q:**

- If the CoRe assesses the event as potentially SNC or CNC, the event should be forwarded to committee Q for review. If the CoRe assesses the event as a potential UP, the event should be sent to the next available full board meeting or CMTE Q if the event does not represent an immediate safety issue for subjects. The following actions should be completed:
  - The case manager is also required to inform the Children’s’ Healthcare of Atlanta IRB manager of any cases going to CMTE Q involving CHOA facilities.
Complete the Omnibus form and delete non-applicable sections. Do not include CoRe correspondence with the materials.

Email materials to all IRB members to be present at the meeting, including primary and secondary reviewers. The materials include the case worksheet, CAPA information to be approved by the Full Board, information from the sponsor (Medwatch reports, safety information, etc) and any other applicable information. All members will have access to the study record via eIRB. If the items to review include a new study, amendment or continuing review, these materials will be accessible via e-IRB as well. Primary and secondary reviewers will present their findings during the meeting.

Contact the PI to schedule the SNC/CNC/UP review for a Committee Q meeting. The PI must be invited (both by in-person and by phone). The PI may submit a response in writing or may be available to call in if they prefer. 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 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. VA cases are required to be reviewed within 30 days. Notify VA RCO representative that a VA case is going to Q and invite him/her to the meeting.

If the board determines that an event constitutes an unanticipated problem or serious or continuing noncompliance, the following actions may be taken:

- 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.
- Optional actions might include:
  - 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, the PI should receive a determination letter within 24 hours. Follow available templates, and make sure institutional officials are copied if the issue was determined to represent an UP, SNC or CNC by the convened IRB.

If applicable (after an UP, SNC or CNC determination), a letter to OHRP and FDA should be drafted and sent to the Director for review (refer to SOP). Specifically:

- For studies funded with federal funds: report to OHRP
- For studies using a FDA regulated product: report to FDA

The RE is closed in eIRB by sending the letter to the study PI. If the RE was reported outside eIRB, the letter should be created in word, signed, converted to PDF file, saved under study history and...
also emailed to the PI and study team. A copy of the letter sent to the PI should be saved in the RE folder. Once the case is considered closed, the RE folder should be archived in the closed folder. If the case was considered serious noncompliance, continuing noncompliance or an unanticipated problem, the institutional officials should be copied. Follow available templates to determine who should be copied in this communication to the PI and/or federal oversight agencies.

- Once the FDA/OHRP letters have been reviewed by the Director, they can be emailed as a PDF to the study PI, federal oversight offices and university officials.
- The letters to OHRP and FDA should be logged in a comment under the RE history, and saved in the study folder. These letters should also be saved under the CMTE meeting folder entitled “Letter to Feds”. The hardcopies should be given to the meeting facilitator for archiving.
- If the case has a CAPA pending item, the case should be moved from the “pending” folder to the “working on CAPA” folder. In addition, the case manager will log the CAPA item in the NC/UP log and in the CAPA shared calendar. When the CAPA issue is completed, the case can be moved to the “closed” folder. The CAPA item should be deleted from the NC/UP log (but kept in the done tab)
- Save a copy of the sent email correspondence under the “PI letter” folder or “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)

For AVAMC Research:
- The medical center director must report the problem or event to the appropriate Office of Research Oversight research officer within five business days after receiving such notification.
- If the convened IRB or the IRB reviewer 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.
- 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.

For Cases involving an UP decision that affects multiple studies
• During the meeting, the board will make an UP determination. If the determination affects studies using the same drug or device, the board will make a note on the meeting minutes stating one or more of the following options:
  o Studies should submit a RE, as this UP applies to the studies
    ▪ The study team may disagree, and if so, they should explain why this UP does not affect their study
  o Studies should submit an amendment, as the new risks should be documented in the study informed consent form
    ▪ Studies should reconsent subjects with the approved amendment
    ▪ The RE and AM submission can be reviewed via 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, including facilitators, letting them know that this UP may affect several studies, and that the RE and AM 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 a RE. If the original RE 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 event involving a different IRB study using the same investigational agent than your study. The reportable event 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 affects your study. As such, you are required to submit a reportable event. Please review the attached document, and submit a reportable event with your assessment of this risk. If you do not agree with the submission of the reportable event, please let us know why this event does not apply to your study population. If you agree with the UP determination, you are also 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 event 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 RE and AM or provide your assessment of why this event does not apply to your study.

  Let us know if you have any questions,

• The case manager is responsible to check that the REs and AMs have been submitted. The AMs will be process by the study owner.
• When the RE is submitted, the information can be send 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:
  o Determination was made during CMTE X on DATE
  o Assess if the UP determination also affects this study
  o 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. 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 hear from you,

NAME of TEAM MEMBER

PD: See attached documents from the Q meeting for your reference

- After the DR reviews the RE, the RE 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 RE will follow the CoRe review process as outlined before.
- If the RE was confirmed as an Unanticipated Problem by the DR, the case manager will close the RE with a letter to the study team. See letter example under QA Team Letter templates.

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

<table>
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<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
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<tbody>
<tr>
<td>11/19/2014</td>
<td>Addition of designated review process. Update of CoRe Information.</td>
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<tr>
<td>2/27/2015</td>
<td>Added step of “Emailing materials to all IRB members...”</td>
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<tr>
<td>4/30/2015</td>
<td>Added language to clarify sections, but not changes in process</td>
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<tr>
<td>6/3/2015</td>
<td>Added the information that is normally sent to the IRB members</td>
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<tr>
<td>6/8/2015</td>
<td>Added actions than may be taken by FB after a SNC, CNC or UP determinations.</td>
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<tr>
<td>2/8/2016</td>
<td>CAPA process reflected</td>
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<tr>
<td>10/18/2016</td>
<td>Revisions to CAPA plan</td>
</tr>
<tr>
<td>4/20/2017</td>
<td>Adding process of reviewing UP determinations affecting multiple studies</td>
</tr>
<tr>
<td>5/17/2018</td>
<td>Added process for when a safety event is called not an UP by CoRe, and there are multiple submissions with the same information for other studies</td>
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**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.

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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.

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 RE in 10 business days. If the study team do not comply with the request, the Team Q member will create the RE 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

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<tr>
<td>8/5/2016</td>
<td>Adding RE requirements if findings need CoRe review.</td>
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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 Team Lead** – 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 Team Lead.

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 Team lead 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**

IRB receives progress report from sponsor holding an IDE → If progress report does not contain new information, the Team Q Lead will be forward it to Admin staff to be scanned. If the report contains new information, it will be routed to the CoRe team → Once scanned, the Team Q lead will attach their report to the study electronic record with a comment indicating that no new information was identified

**REFERENCES**

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

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SOP Title: Team Q Communications with Other IRB Staff
SOP Category: QA and Education
Established: 10/18/2010
Last Revision: 10/18/2010

PURPOSE
To describe the communication methods Team Q staff will use when approaching other staff for:

- Further information regarding an issue reported to Team Q
- Clarification of a staff member’s actions
- Solicitation of the staff member’s assistance with an issue

PROCEDURE

1. When approaching a staff member for further information regarding a noncompliance issue, Team Q staff will begin the email/conversation with language similar to the following:

   “Hello, (name of staff member). I was wondering if you would be able to give me some further information regarding (issue reported to Team Q).”

2. When contacting a staff member for clarification of his or her actions, Team Q staff will make sure to approach him/her with the intent of understanding his/her actions, not accusing him/her of doing something wrong. Team Q staff will begin the email/conversation with language similar to the following:

   “Hello, (name of staff member). I was wondering if you could explain (action of the staff member). I’m not as familiar with the (process/SOP/etc.) as you, so I would really appreciate your insight.”

   Team Q staff will acknowledge the co-workers explanation to show that he/she heard it and understood it. Team Q staff will take extreme care to give the impression that they are trying to understand the situation, not point out the errors of others.

3. When soliciting the assistance of a staff member, Team Q staff will begin the email/conversation with language similar to the following:

   “Hello, (name of staff member). I’ve come across (something Team Q staff member needs help with). I understand you have a lot of experience with (the issues/topic). Can we talk about this later?”

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**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;
o 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
o 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 event (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 RE (and AM if necessary).
  o If event does not merit changes via AM (e.g. study is closed for enrollment without active subjects), Team Lead will send event to DR.
  o 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.
  o 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 amendment, the IRB analyst will request the submission of a RE as well.

The IRB analyst will contact Team Q lead to notify about the AM. Team Q only needs to know about AM involving increased risk (e.g. changes to the ICF involving new adverse event).

• Team Q lead will assign the RE 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:
  o The IRB acknowledges the UP determination, and determines that changes as submitted are appropriate.
  o 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

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<thead>
<tr>
<th>DATE</th>
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STUDY MANAGEMENT
AMENDMENTS

<table>
<thead>
<tr>
<th>SOP Title:</th>
<th>Amendment: AM Applications IRB Processing from Preliminary Analysis through Approval</th>
</tr>
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<tr>
<td>SOP Category:</td>
<td>Study Management</td>
</tr>
<tr>
<td>Established:</td>
<td>8/9/2013</td>
</tr>
<tr>
<td>Last Revision:</td>
<td>5/17/2018</td>
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PURPOSE
The purpose of this SOP is to outline the step by step procedures for processing an amendment from submission to approval.

SCOPE
This SOP applies to amendments that need both expedited and full board reviews.

DEFINITION
- **Amendment**: 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), CTRC etc., that would need to review an amendment based on any additional procedures being added that would trigger their departments review.

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

PROCEDURES

I. **Analysis of Amendment Application**

NOTES:
- Have the **AM Checklist** accessible while analyzing the AM application H:\General\Admin IRB Documents\Checklists, Forms, and Templates
- If the AM includes a 483 report after a FDA inspection to the study or sponsor, ask the study to remove this report and to submit via RE.
- If this AM adds a drug under REMS, please review REMS SOP and talk to a TL or IRB Director about following steps

1) **Verify that the proposed modifications have been made in the revised eIRB smartform and AM application.**
   a) Due to some quirks in eIRB, certain changes do not appear in “View Differences”
i) To review a change to an IB, IFU or package inserts, click on “View Study History” and “Jump To: Drug Section” or “Jump To: Device Section”

ii) To review protocol changes when the study team utilizes the upload revision rather than add function, click on “View Study History” and “Jump To: Research Design”

iii) To review enrollment changes, click on “Printer-Friendly Version”

iv) To review consent form changes when the study team makes subsequent changes, do not review the documents listed under the difference tab, but rather the latest modified consent form.

2) If changes are needed, click the “Changes Requested by IRB Staff” and inform the study team of the requested changes.
   a) The state of the AM will change to “PI Changes Requested”
   b) The study team will need to hit the “submit changes” button to return the AM 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 and logged comments to catch these AMs,

3) If no further changes are needed, determine the appropriate routing of the review (i.e expedited or full board) below.
   Reference the following SOPs to determine the appropriate route and reviewer of the AM:
   a) Determinations and Reviews by IRB Staff: for minor administrative changes that can be approved by the analyst assigned to review the AM
   b) Categories of research reviewable by IRB staff as IRB designated members: for selected AM that could be reviewed by Team leads or other Sr. RPAs.
   c) Amendments Indicating Increased Risk: for AM that may require Full Board review

II. Expedited Reviewed AM
IIA. Steps to Assign an AM to Expedited Reviewer
   1) Click the “Assign Expedited Reviewer” tab
   2) Select the appropriate Designated Reviewer from the dropdown menu
      As a general rule of thumb 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.
   3) Under the Comments section, include a brief description of the proposed AM when assigning the AM for review. The description should allow a reviewer to quickly ascertain the contents of the AM.
   4) Press “OK”
   5) The current state of the AM should change from “IRB Staff Review” to “Expedited Review.”
      • At this point you wait for the expedited reviewer to complete their review

IIB. Steps to Check the Expedited Reviewer’s Review (Draft Letter –EX state)
   1) Open the “IRB reviews” tab for this AM application and click on the “Review of” link.
   2) Select the “Printer Version” to view the Expedited Designated Reviewer’s comments, determinations and changes requested.
      a) If changes are requested, move to step IIC, Post Expedited AM Review Steps – PENDING.
      b) If no changes are requested, skip to step IIE, Post Expedited AM Review Steps – APPROVED.

IIC. Post Expedited AM Review Steps – PENDING
   1) Click ‘Draft Letter,” choose letter template (Pending – Expedited) from the dropdown menu, and make the following edits:
      a) Remember to include the PI’s post-nominal (degree – MD, PhD, MPH, etc.)
b) Insert the letter date, spelled out (e.g. April 15, 2015) – the date the letter is being composed.

c) If there was a numbered protocol AM as part of this AM insert the highlighted text into the third line of the “RE” section: “IRB Amendment (#) for IRB Study #xxx (Protocol Amendment XX) (this is because Sponsors often get confused about the difference between our AM numbering system and their protocol AM numbering).

d) List the changes requested – these issues will be noted in the reviewers’ notes in eIRB.

e) Delete the template letter language that does not apply to the current AM and remove rows that state “No Items to Display.”

f) Edit the “ENTER NAME OF LETTER SIGNATORY” and “title’ fields to add your own name and title.

D) Highlight the entire letter and select the same font name and size.

g) Click “OK”

2) You can review the draft letter by clicking on “View Draft Letter.”

3) Click “Obtain Signature” and find your name from the dropdown menu and click “OK”

4) Click “Send Letter to PI” and click “OK.”

5) The current state of the AM should change to “PI Changes Requested- EX”

II.D. Expedited Pending Contingency Review

1) Once the study team has submitted the requested changes and the state of the AM changes to “Expedited Review,” review submitted materials to assess that all the requested changes have been made.

a) If Pending Contingencies have not been completed, send back to the study team for more changes by clicking “Request Changes by IRB Staff” and inform the study team of the outstanding requested changes.

b) If Pending Contingencies have been completed

i) Send the AM for contingency review by selecting “Forward to Contingency Reviewer –EX” and selecting the appropriate reviewer from the dropdown menu, either

(1) the Expedited Designated Reviewer that originally reviewed the AM application, OR

(2) a Staff Reviewer if the contingency review is allowed by Categories of research reviewable by IRB staff as IRB designated members SOP

ii) Send an email to the Contingency Reviewer to notify him/her of the contingency review with a link to the specific AM.

(1) Due to a glitch in eIRB, the contingency review is not assigned to the reviewer’s inbox.

c) Review the decision of the contingency reviewer:

i) If contingencies are approved, move to step IIE, Post Expedited AM Review Steps – APPROVED.

ii) If the reviewer finds outstanding contingencies, repeat steps IIC, Post Expedited AM Review Steps – PENDING.

iii) If the reviewer recommends sending the AM to Full Board, skip to step IIIA, Scheduling a Full Board Committee Reviewed AM

II.E. Post Expedited AM Review Steps – APPROVED

1) Select “GENERATE OFFLINE DOCUMENT” in the main workspace BEFORE you begin drafting the letter.

2) Determine if the AM was approved at the same time as a CR. If so, process the CR first, and then process the AM.
3) Click “Draft Letter,” choose the letter template (Approved) from the dropdown menu and make
the following edits:
   a. Remember to include the PI’s post-nominal (degree – MD, PhD, MPH, etc).
   b. Insert the letter date, spelled out (e.g. April 15, 2015) – the date the letter is being
      composed.
   c. If there was a numbered protocol AM as part of this AM, insert the highlighted text into
      the third line of the “RE” section: “IRB Amendment (#) for IRB Study #xxx (Protocol
      Amendment XX) (this is because Sponsors often get confused about the difference
      between our AM numbering system and their protocol AM numbering).
   d. Enter the AM Changes to Study. Please ensure that the revised documents approved
      with this AM have been listed in the letter correctly. The version date of a protocol is
      usually on the cover-page of a protocol. Please use that date and not the date that it
      was uploaded. Consent version dates should be in the footer of the revised document.
      – Examples:
         i. Changes to Study Team members: Added Steve Smith... Removed Tom Jones...
         ii. Changes to Protocol Document(s): Revised Protocol Version 2.0 dated
             01/17/2007
         iii. Changes to Consent Form(s): Revised Consent Form Version 2.0 dated
             01/17/2007
   e. Use formatting tools to add bullets to the list of changes made.
   f. Delete the template letter language that does not apply to the current AM and remove
      rows that state “No Items to Display.”
   g. Edit the “ENTER NAME OF LETTER SIGNATORY” and “title’ fields to add your own name
      and title.
   h. Highlight the entire letter and select the same font name and size.
   i. Click “OK”
4) Click ‘Obtain Signature’ and make sure to select your own name in the pop-up window and
   select “OK.”
5) Click ‘Send Letter to PI’ and select “OK.”
6) Select “Report to Committee Meeting”
   a. Select “Report to Committee - Amendments Approved by Designated Reviewer”
   b. Select Meeting – that is at least two weeks away; report to CMTE C if C member
      reviewed the SHB study, report to A or B if biomed (doesn’t matter which one). If an IRB
      Staff Designated Reviewer completed the review, add to meeting agenda based on type
      of study (SHB or BIO). Ok to add to a “closed” meeting.
7) Determine if the AM modified consent forms:
   a. If the AM did not modify consent forms:
      i. Log a comment to the study team to let them know the AM was approved and
         include the Customer Service Satisfaction survey link:
         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. You can access the survey by copying the link below and pasting
         it into your web browser. We appreciate your feedback!
         https://www.surveymonkey.com/s/PY2KYLR
      ii. The AM processing is complete.
   b. If the AM did include changes to Consent(s)/Authorization(s)
i. Go to the main study workspace by clicking the main study link in the breadcrumb trail (shown below)

![Main Study Link]

ii. Click “Edit Consent Forms”
   1. Under ‘Approved consent forms:’ Select only the document(s) that is/are being replaced or are no longer in use.
   2. Click ‘Delete’ – this action will permanently remove the documents from the study but they will be accessible to the IRB if Generate Offline Document was appropriately selected.
   3. Under “Draft consent forms” remove any outdated versions of consents and any tracked change versions of the new consents. (Or rename the outdated versions as [ARCHIVED]...)
   4. Click ‘OK’

iii. Click “Consent Form Merge”
   iv. Only select the box(es) of the document(s) that were amended (modified)
   v. Ensure that the approval date and expiration date are correct; meaning that they match the approval date on the approval letter, and expiration date of the overall study.
   vi. Click ‘OK’

c. Ensure that all merged documents were merged appropriately by opening them from the “Documents” tab.
   i. eIRB may fail to stamp the consent if the stamping header has been altered and/or the document was saved as a .docx file.

d. Log a comment to the study team to let them know stamped-approved amended informed consent documents are available under the “Documents” tab in main workspace and include the Customer Service Satisfaction survey link:

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. You can access the survey by copying the link below and pasting it into your web browser. We appreciate your feedback!

https://www.surveymonkey.com/s/PY2KYLR

III. Full Board Committee AM
IIIA. Scheduling a Full Board Committee Reviewed AM

1) Click “Schedule for IRB Meeting” and select the next open meeting that includes a reviewer with the specialty needed for this amendment (A or B for Biomedical/ C for Social Behavioral). Select that this is a “Full Board – Amendment”. In the “Agenda Item Notes” section of the window, enter
   a) Study Title
   b) PI’s name,
c) Reason why the AM should be reviewed by the full board if not obvious.
   i) changes/additions, applicable subparts, changes in risk: benefit etc.

d) Special population

e) Potential IRB Member COIs

2) Complete the AM Omnibus form, along with any new Subpart forms that may be needed due to the addition of a vulnerable population.

3) Upload the completed Omnibus and Subpart worksheets in the applicable CMTE meeting folder by the day reviewer assignments are announced.

IIIB. Steps to Check the Full Board Committee’s Decisions Reviewer’s Review

1) Once the meeting facilitator has reconciled the meeting notes and omnibus forms and releases the agenda for letter writing via email, review the applicable omnibus forms to obtain committee decision.
   a) If changes are requested, move to step IIIC, Post FB AM Review Steps – PENDING OR DEFERRED.
   b) If no changes are requested, skip to step IIIE, Post FB AM Review Steps -APPROVED.

IIIC. Post FB AM Review Steps – PENDING OR DEFERRED

1) Review the applicable omnibus forms to obtain pending contingencies or deferred items.

2) Select “GENERATE OFFLINE DOCUMENT” in the main workspace BEFORE you begin drafting the letter.

3) Click “Record Meeting Minutes”
   a) Select the motion (approved, pending or deferral)
   b) Enter the vote numbers
   c) In the notes to PI section (not actually seen by the PI), add in the risk level, approval period (1 yr, 6 months), subparts, parental signature requirements for peds studies, waivers granted if any and whether it is AVAMC study. (Do not record the actual meeting notes. Just any facts that would be useful to refer to in the future).
   d) Click “OK”

4) Click ‘Draft Letter,’ choose the appropriate letter template (Pending – Full Board or Deferred – Full Board), and make the following edits:
   a) Remember to include the PI’s post-nominal (degree – MD, PhD, MPH, etc).
   b) Insert the letter date, spelled out (e.g. April 15, 2015) – the date the letter is being composed.
   c) If there was a numbered protocol amendment as part of this AM, insert the highlighted text into the third line of the “RE” section: “IRB Amendment (#) for IRB Study #xxx (Protocol Amendment XX) (this is because Sponsors often get confused about the difference between our AM numbering system and their protocol AM numbering).
   d) List the changes requested – these issues will be noted in the omnibus forms and may also reference the reviewers’ notes in eIRB for more details. If the changes requested are more complex, please have the vice-chair of that meeting review the pending contingencies or deferred items via email to ensure that the information has been accurately interpreted and conveyed.
   e) Use formatting tools to add bullets to the list of changes requested. Remember to reset & resize the font of the “CC:” section at the bottom of AM letter if needed.
   f) Delete the template letter language that does not apply to the current AM and remove rows that state “No Items to Display.”
   g) Edit the “ENTER NAME OF LETTER SIGNATORY” and “title’ fields to add your own name and title.
h)  
5) Click “Obtain Signature” and make sure to select your own name in the pop-up window  
6) Click “Send Letter to PI”  
7) The state of the AM should change to “PI Changes Required - Cont.”

IIIC. Full Board Pending Contingency Review of Changes Requested or Review of Deferred Items by FB  
1) Once the study team has submitted the requested changes, review materials to assess that the changes have been made.  
   a) If Pending Contingencies have not been completed, send back to the study team for more changes by clicking “Request Changes by IRB Staff” and inform the study team of the outstanding requested changes.  
   b) If Pending Contingencies have been completed  
      i) Send the AM for contingency review by selecting “Forward to Contingency Reviewer” and selecting the appropriate reviewer from the dropdown menu, either  
         (1) the Vice Chair of the committee that originally reviewed the AM, OR  
         (2) a Staff Reviewer if the contingency review is allowed by Categories of research reviewable by IRB staff as IRB designated members SOP  
      ii) Send an email to the Contingency Reviewer to notify him/her of the contingency review with a link to the specific AM.  
         Due to a glitch in eIRB, the contingency review is not assigned to the reviewer’s inbox.  
   c) Review the decision of the contingency reviewer:  
      i) If contingencies are approved, move to step IIID, ‘Post FB AM Review Steps - APPROVED.’  
      ii) If the reviewer finds outstanding contingencies, send back to study team the requested changes.  
      iii) If the reviewer recommends sending the AM to Full Board, skip to step IIIA, Scheduling a Full Board Committee Reviewed AM  
   d) If Deferred issues have been addressed, schedule the Deferred AM to be reviewed by the same committee that conducted the initial review of the AM application (i.e. if CMTE B1 reviewed the AM in January meeting and deferred it, send to the next available meeting for CMTE B1). After the meeting, if the Deferred issues are approved, move to step IID, ‘Post FB AM Review Steps – APPROVED.’

IIID. Post FB AM Review Steps - APPROVED  
1) Review the applicable omnibus forms to obtain any amended risk determinations, waiver approvals, Subpart determinations, etc.  
2) Select “GENERATE OFFLINE DOCUMENT” in the main workspace BEFORE you send the approval letter for signature and to the PI. Determine if the AM was approved at the same time as a CR. If so, process the CR first, and then process the AM.  
3) Click “Record Meeting Minutes”  
   a) Select the motion (approved, pending or deferral)  
   b) Enter the vote numbers  
   c) In the notes to PI section (not actually seen by the PI), add in the risk level, approval period (1 yr, 6 months), subparts, parental signature requirements for peds studies, waivers granted if any and whether it is an AVAMC study. (Do not record the actual meeting notes. Just any facts that would be useful to refer to in the future).  
   d) Click “OK”  
4) Click “Set Expiration Date” and enter the date the AM was approved (do NOT alter expiration date)
5) Click ‘Draft Letter,’ choose the appropriate letter template (Approved) and make the following edits:
   a) Remember to include the PI’s post-nominal (degree – MD, PhD, MPH, etc).
   b) Insert the letter date, spelled out (e.g. April 15, 2015) – the date the letter is being composed.
   c) If there was a numbered protocol AM as part of this AM, insert the highlighted text into the third line of the “RE” section: “IRB Amendment (#) for IRB Study #xxx  (Protocol Amendment XX) (this is because Sponsors often get confused about the difference between our AM numbering system and their protocol AM numbering).
   d) Enter the AM Changes to Study. Please ensure that the revised documents approved with this AM have been listed in the letter correctly. The version date of a protocol is usually on the cover-page of a protocol. Please use that date and not the date that it was uploaded. Consent version dates should be in the footer of the revised document. – *Examples*:
      1. Changes to Study Team members: *Added Steve Smith*… *Removed Tom Jones*…
      3. Changes to Consent Form(s): *Revised Consent Form Version 2.0 dated 01/17/2007*
   e) If the AM was previously ‘Approved – Pending’ by the Full Board, edit text so it reads, “The Emory IRB reviewed and approved this amendment at a convened meeting on [ENTER DATE of meeting]. This approval became effective on 3/25/2015 after all pending issues were addressed.” This text is prepopulated in the letter template.
      i) If the AM was previously ‘Deferred’ by the Full Board, no text edits are required because the approval date will be the date of the meeting that the deferred issues are approved.
   f) Use formatting tools to add bullets to the list of changes made.
   g) Delete the template letter language that does not apply to the current AM and remove rows that state “No Items to Display.”
6) Edit the “ENTER NAME OF LETTER SIGNATORY” and “title” fields to add your own name and title.
7) Highlight the entire letter and select the same font name and size.
8) Click ‘Obtain Signature’ and make sure to select your own name in the pop-up window
9) Click ‘Send Letter to PI’
10) Determine if the AM modified consent forms:
    a) If the AM **did not** include changes to Consent(s)/Authorization(s)
      i. Log a comment to the study team to let them know the AM was approved and include the Customer Service Satisfaction survey link:
         *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. You can access the survey by copying the link below and pasting it into your web browser. We appreciate your feedback!*
         [https://www.surveymonkey.com/s/PY2KYLR](https://www.surveymonkey.com/s/PY2KYLR)
    b) If the AM **did** include changes to Consent(s)/Authorization(s)
      i) Go to the main study workspace by clicking the main study link in the breadcrumb trail (shown below)
      ![Main Study Link]
      [Development of MyoviewTM (99mTc-Tetrofosmin) for CFR > Amendment 1 for IRB Study #R900000541]
      ii) Click “Edit Consent Forms”
1) Under ‘Approved consent forms:’ Select only the document(s) that is/are being replaced or are no longer in use.
2) Click ‘Delete’ – this action will permanently remove the documents from the study although they will be available to the IRB if Generate Offline Document was appropriately selected.
3) Under “Draft consent forms” remove any outdated versions of consents and any tracked change versions of the new consents. (Or rename the outdated versions as [ARCHIVED]...)
4) Click ‘OK’
   iii) Click “Consent Form Merge”
       1) Only select the box(es) of the document(s) that were amended (modified)
       2) Ensure that the approval date and expiration date are correct; i.e., matches the effective approval date of the approved AM, and expiration date of the overall study. If they don’t, enter the correct date(s).
       3) Click ‘OK’
   iv) Ensure that all merged documents were merged appropriately by opening them from the “Documents” tab.
       (1) eIRB may fail to stamp the consent if the stamping header has been altered and/or the document was saved as a .docx file.
   v) Log a comment to the study team to let them know stamped-approved amended informed consent documents are available under the “Documents” tab in main workspace and include the Customer Service Satisfaction survey link: 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. You can access the survey by copying the link below and pasting it into your web browser. We appreciate your feedback! https://www.surveymonkey.com/s/PY2KYLR

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<tr>
<td>5/13/2015</td>
<td>Major overhauled of this SOP, with combination of previous SOPs involving AM information.</td>
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<tr>
<td>8/11/2016</td>
<td>Clarify process for handling issue with consent merge following AM processing</td>
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<tr>
<td>11/11/2016</td>
<td>Slightly revised suggested letter text for amendments given approval after being pended by full board</td>
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<tr>
<td>4/20/2017</td>
<td>Deleted the step of setting expiration date under IIE (Post-expedited AM review steps-APPROVED)</td>
</tr>
<tr>
<td>5/17/2018</td>
<td>Rearranged document for readability, added purpose, scope and definitions</td>
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SOP Title: Amendments: AMs Indicating Increased Risk

SOP Category: Study Management

Established: 7/18/2012

Last Revision: 11/1/2017

PURPOSE
To explain the process of reviewing amendments (AM) that indicate an increase in risk, and to describe when a reportable event (RE) 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 AM may need a RE submission.
IRB Team Q member – will assist analyst in determining if an AM needs a concurrent RE submission.

PROCEDURE
1. Determine if a reportable event should be submitted along with the amendment:
   a. If this AM 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 event is required.
      i. For example: the AM states that, after reviewing data from all sites, they have discovered an increased frequency of event X, and they have decided to amend the protocol, ICF or IB. Such sponsor-prompted AMs 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 event.
   b. If the AM information includes a safety memo about an event involving an individual subject or subjects, a reportable event may be required.
      i. For example, the AM 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 amendment. Team Q will verify if a RE is required or not. If Team Q received a RE that requires the submission of an AM (if not already submitted), Team Q will log a comment into the study history to alert the study analyst.

2. Determine mode of review for Amendment: When receiving a new risk via an amendment, check Onenote to verify if the information in the AM was previously reviewed at FB and can go expedited in subsequent studies. The Onenote is called “One Note IRB Full Board Meeting Operations”, section “AM risk changes FB determined can be expedited for other studies (without RE).” 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 AM.
3. Handling of Amendment with respect to Reportable Event (when required)

a. If a reportable event 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 event for more information. Case manager should also log a comment in AM and communicate with study owner about RE disposition.

b. If the CoRe determines that the reportable event is not a potential UP, and determines that there is no change to the overall risk/benefit ratio of the research study, then the amendment may go to expedited review.

c. If the CoRe determines that the reportable event 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 amendment to the same meeting’s agenda where the reportable event will be reviewed, if possible. In general, amendments 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 event is a potential UP that does not represent an immediate safety concern, then it will be reviewed at the next Committee Q meeting. The amendment can also be reviewed at the Committee Q meeting if the only changes relate to the reportable event and/or other changes do not need to be reviewed sooner (discuss with your Team Lead or Director if not sure).

   i. Let the Team Q case manager and Q meeting facilitator know that the amendment 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 amendment history detailing if the amendment was approved as it is or if it has pending issues.

   ii. If the amendment was approved, the analyst should assign the review to him/herself for completion. This does not mean the analyst is making a determination; the amendment was approved at the Committee Q. The analyst is simply completing the review to move the amendment to the draft letter state.

   iii. If the amendment has pending issues, the amendment should be assigned to the Q chair (Dr. Stein) for review and final approval.

LOG OF SIGNIFICANT CHANGES

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<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
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<tr>
<td>12/11/2015</td>
<td>Clarification of steps and updating to match current process</td>
</tr>
<tr>
<td>2/27/17</td>
<td>Minor administrative edits</td>
</tr>
<tr>
<td>11/1/2017</td>
<td>Reformatting to improve readability and clarifications</td>
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NEW STUDIES

SOP Title: eIRB Processing of New Study Applications: Preliminary Analysis through Approval
SOP Study Management
Established: 03/12/2015
Last Revision: 6/8/2018

IRB Staff Initial Analysis/Screening

1. In your Main Inbox, click on the next new study application in your queue for processing.
2. Have the applicable New Study Worksheet (from H drive) open for completion while analyzing the new study application. (i.e. for a New Study Worksheet for Biomedical vs. Socio-Behavioral vs Exempt Study Worksheet vs worksheet for Retro Chart Review studies).
   a. Upload completed worksheet as Private IRB Comment for all new studies, regardless if reviewed at full board, expedited or exempt.
   b. Based on issues noted in the New Study Worksheet, click on ‘Changes Requested by IRB Staff” and include the requested changes to be addressed. Either enter the requested changes directly into the text box of the window or attach a separate document that includes the changes requested. Attaching whole worksheet is not ideal.
   c. If no changes are needed or study team makes the requested changes, move to next section.

Preparing for Review

1. If the new study requires full committee review,
   a. Click ‘Schedule for IRB Meeting’ and select the next available meeting with an open agenda.
   b. Log comment to study team requesting contact info for PI during meeting time.
   c. In the ‘Agenda Item Notes’ section of the window, enter the following information:
      i. Study Title
      ii. PI
      iii. Contact number * also wanted for deferred studies *
      iv. Special Populations
      v. VA Study (Yes/No)
      vi. (AM’s only) Reason why AM came to full board
      vii. IRB member COI’s
      viii. Any other pertinent comments
   d. Complete the New Study Omnibus form found in the H drive along with any Subpart forms that may be needed.
   e. Make reviewer assignments the day the meeting facilitator announces the assignments and if not done by then, also upload the completed Omnibus and Subpart worksheets in the applicable CMTE meeting folder.
   f. Check the study a day or two before the meeting to read through any received reviews to identify any pending or deferrable issues. Consult with meeting facilitator, TL, or Director as needed to determine if you should ask study team to address any issues prior to meeting. Also ensure that PI contact info has been provided (if not, ask again).
      i. If there are possible deferrable issues that the study team is not able to address prior to the meeting, consult the meeting facilitators, team lead analyst or IRB
director for further instruction about keeping the study on the meeting agenda or removing it.

2. If study requires expedited or exempt review,
   a. Click ‘Assign Exempt/Expedited’ and select if the study should go through Exempt or Expedited Review and type (biomed or SHB)
   b. IMPORTANT: Click ‘Forward to Reviewer’ and select reviewer (can be experienced analyst if exempt). Use weekly reviewer workload report and reviewer status spreadsheet to select reviewer.
   c. Enter a comment in the text box to provide the reviewer with recommended exempt/expedited category, info to support the review category recommendation, waivers requested, type of consent to be obtained, and inclusion of vulnerable populations/Subpart considerations.
   d. Check on status – target turnaround is 5 business days. Ping reviewer as needed or reassign.
   e. Await notification of review completion

AFTER Review

1. FULL BOARD first steps
   a. Open study’s omnibus form meeting minutes and backup meeting notes
   b. Click ‘Record Meeting Minutes.’ Record the motion (approved, pending or deferral), votes, risk level, approval period, subpart findings, parental signature requirements for peds studies, waivers granted if any, device and drug determinations, and whether it is AVAMC study. (Do not record the actual meeting discussion.)
      i. If study was previously deferred, add new meeting minutes as noted above, inserting a comment and separation between the new and old minutes. Change the vote from ‘Deferred’ to ‘Approved’ and use most recent vote counts.

2. EXPEDITED/EXEMPT first step
   a. LOOK AT REVIEWER FORM to verify determination (pending or approved) and any subpart findings

3. If FULL APPROVAL (any type of review):
   a. Set approval period and risk level. If pending or deferred (only full board can defer), do not do this yet.
      i. Full Board: The Approval Date is the date the study review was initially completed (for approved or pending); or the date a deferred study was finally given pending or full approval.
      ii. Expedited or Exempt: The Approval Date is the date the study was fully approved by the Designated Reviewer (or determined exempt by IRB staff). Do not use the date of initial review if changes were requested at that time.
      iii. Expiration date: The Expiration Date is determined by the reviewer or Committee, and does not necessarily relate to risk level (but the default for minimal or moderate risk studies is one year, if the reviewer does not specify). Check meeting notes/minutes/expedited review form. Exempt studies do not have an expiration date so leave blank.
   b. Expedited/Exempt only: click “Report to IRB Committee Meeting” to report this action to a full committee agenda. Select an agenda that is still not finalized.
   c. Choose the panel to report to, based on the membership of the Designated Reviewer (A or B doesn’t matter, but only report to C Committee those studies approved by a member of C Committee).
i. If IRB staff reviewed, report based on whether Biomed or Sociobehavioral (IRB staff 
Designated Reviewers are all on both committees)

4. Click ‘Draft Letter,’ choose the appropriate letter template from the drop-down menu, and make the 
following edits:
   a) Delete any rows that say “There are no Items to Display” (right-click within the row, scroll to 
   “Rows”, and click “Delete Row”).
   b) Remember to include the PI’s post-nominal (degree – MD, PhD, MPH, etc).
   c) Letter date is spelled out (e.g. April 15, 2015); review/approval/expiration dates (as applicable) 
can be in mm/dd/yyyy format
   d) If a Pediatric study, ensure that the approval category is listed in the body of the approval letter 
for new and renewed studies per the New Study approval letter template language available on 
the IRB shared drive.
   e) Ensure that the approval and expiration dates are correct (no expiration date for Exempt).
   f) For new studies, state if PHW or other consent/HIPAA waivers/alterations have been granted 
and why, (for all) vulnerable pops categories, insert explanation and bullets for all approved 
documents (incl. CIB versions, survey and questionnaire versions if unique to this study [i.e. not 
standard tools], protocol version/date, consent form version/date, anything else that might have a version). Use language from the official New Study approval letter template language 
document on the IRB’s shared drive. In the next para, “The following documents were included 
in this review:” [followed by bulleted list]. Include any other relevant instructions/qualifications 
for the approval. For renewals, you can just list the current protocol and consent form versions.
   g) Refer to our letter template language document for additional information of required HIPAA 
language, waivers of consent/HIPAA and other special scenarios.
   h) IF PENDING OR DEFERRED: List the changes requested – these issues will be noted in the 
omnibus forms and backup notes for FB studies, or reviewers’ notes in eIRB for expedited 
studies. If not clear, please have the vice-chair of meeting or expedited reviewer clarify the 
pending contingencies or deferred items via email to ensure that the information has been 
accurately interpreted and conveyed. Note: Sometimes the Vice-Chair is not available to quickly 
review letter text. If necessary, you can ask the primary/secondary reviewer, or facilitator or TL 
who was at the meeting. If in doubt, ask IRB Director for advice.
   a. Use formatting tools to add bullets to the list of changes requested.
   i) ENTER NAME OF LETTER SIGNATORY (Do NOT Bold) –this should be your own name and title.
   a) Click “OK” button at bottom right

5. Click “View Letter” for quality assurance. If revision needed, click “Draft Letter” again to revise.

6. Click “Send Correspondence Letter” and make sure to select your own name in the pop-up window

7. Click ‘Send Letter to PI’

8. If Exempt or Expedited: click “Report to IRB Committee Meeting” to report this action to a full 
committee agenda. Select an agenda that is still not finalized. Choose the Committee to report to 
based on the membership of the Designated Reviewer (A or B doesn’t matter, but only report to C 
Committee those studies approved by a member of C Committee)
9. If this is final approval and there are consent forms to stamp, go to **Merge Consent** (see below) and log a comment to the study team to let them know stamped-approved informed consent documents are available under the “Documents” tab in main workspace. Include the Customer Service Satisfaction survey link:

   *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. You can access the survey by copying the link below and pasting it into your web browser. We appreciate your feedback!*
   
   https://www.surveymonkey.com/s/PY2KYLR

### Contingency Review (after pending approval)/Review of Deferred Studies

1. **Pending studies**: Once the study team has submitted the requested changes, IRB analyst must review materials to confirm that the changes have been made.
   
   a. If yes, choose Forward to Contingency Reviewer or Forward to Designated Reviewer (do not forward for expedited review again – that would require another whole expedited review).
   
   b. Send email to reviewer to notify him/her with a link to the study (no notifications are sent by eIRB for contingency review – so this is crucial).
   
   c. Reviewer might request more changes, in which case another letter may need to be drafted per instructions above. Once contingencies are approved, follow the steps above for **FULL APPROVAL**
   
   d. Check on status. Target turnaround is 3-5 business days for contingency review. Ping reviewer as needed.

2. **Deferred studies**: if the analyst, in consultation with Chair of meeting, determines issues seem to have been addressed, schedule the Previously Deferred New Study to be reviewed by the same panel (e.g. B1) that conducted the initial review of the new application, unless there is urgent need for exception (consult TL or Director). See instructions at top of this SOP for assigning to meeting.

   **Set Approval Period**: For approval date, enter the date the new study was reviewed and first pended or approved at full board (not contingency approval date) OR given final approval by expedited review. Set expiration date based on full board meeting date or expedited full approval date, per review outcome (e.g. 1-year, 6 months). Also set the Risk Level to ‘Standard Risk’ (for more than minimal risk) or “No more than Minimal Risk”.

   a. Approval Date – The Approval Date is the date the study review was initially completed (for approved or pending); or the date a deferred study was finally given pending or full approval. OR If using 30-day rule, see “Continuing Review: 30-day rule” SOP.

   b. Expiration Date – The Expiration Date is determined by the reviewer or Committee (default is one year, if the reviewer does not specify). Check the study’s Omnibus form and/or meeting notes. NO expiration date for exempt studies.

### Merge Consent

1. Click ‘**Edit Consent Forms**’
a. Delete unnecessary forms
   i. Click “Generate Offline Document” first
   ii. Under ‘Approved consent forms:’ select only the document(s) that will NOT be used.
   iii. Click ‘Delete’ – this action will permanently remove the documents from the study
   iv. Click ‘OK’

2. Click ‘Consent Form Merge’
   a. Only select the documents that were approved.
   b. Ensure that the approval date and expiration date are correct; i.e., matches the effective approval date of the new study. If they don’t, enter the correct date(s).
   c. FOR FULL BOARD STUDIES THAT WERE ORIGINALLY PENDING: insert the final approval date (effective date contingencies approved) as the approval date on the consent form only. FOR EXEMPT STUDIES: No need to enter Expiration Date.
   d. Click ‘OK.’

3. Ensure that all merged documents are merged appropriately by opening them from the “Documents” tab. (Problems with this are a common source of QA findings.)

4. Log a comment to the study team to let them know stamped-approved informed consent documents are available under the “Documents” tab in main workspace and include the Customer Service Satisfaction survey link:

   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. You can access the survey by copying the link below and pasting it into your web browser. We appreciate your feedback!

   https://www.surveymonkey.com/s/PY2KYLR

5. See appendix 1 for the eIRB new study process Map

LOG OF SIGNIFICANT CHANGES

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<td>10/18/2016</td>
<td>Under “After Review”, Step 6, change “obtain signature” with “Send Correspondence letter”</td>
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<tr>
<td>6/8/2018</td>
<td>Removed need for VA liaison to have VC sign letters to investigators in eIRB; merged with SOP “Process of New Approved or Pending Studies or Continuing Reviews” ;</td>
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PURPOSE
The purpose of this document is to describe the naming conventions used to signify special study designations in the short title the study.

DEFINITIONS / NOMENCLATURES
- Emory Sponsor Investigator study – [SI]
- External IRB shell – [XIRB]
- NCI Central IRB – [CIRB]
- Grady and/or Ponce studies – [Grady]
- National Cancer Institute IRB – [NCI]
- Prisoner studies – [Subpart C]
- Department of Defense – [DoD]
- Radioactive Drug Research Committee – [RDRC]
- Veteran Affairs – [VA]
- Western IRB – [WIRB]
- REMS- [REMS]

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.

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<tr>
<td>2/21/2018</td>
<td>Added REMS as a nomenclature to use</td>
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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.

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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 amendment.
• 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:
  o Current, valid certification of translator’s credentials along with an invoice or memo stating the specific document that was translated.
o Other: Consult with your Team Lead 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**

6. An analyst receives a new study or an amendment 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.

7. The analyst reviews the new study or amendment to see if documentation of one of the
appropriate translation methods has already been provided.

8. 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 amendment.

9. The analyst assigns new study or amendment 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 amendment 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 amendment will be required to submit
documentation of translation.

10. Once the new study or amendment 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.

**Amendments revising approved, translated ICFs**

1. Amendments 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 amendments 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 amendment 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. Amendments 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 amendments to update the study and the translated ICF. One amendment 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.

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SOP Title: Research Projects led by Non-Emory students
SOP Category: Study Management
Established: 8/28/2013
Last Revision: 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:
   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

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<tr>
<td>9/16/2016</td>
<td>Added clarification to align with current process</td>
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SOP Title: Not Research/ Not-Human-Subjects/Not-Human-Subjects-Research
SOP Category: Study Management
Established: 6/28/2013
Last Revision: 5/17/2018

PURPOSE

Outline the necessary steps for processing a determination of not research (NR), not-human-subjects (NHS), or not-human-subjects research (NHSR). Determinations are made in response to:
- Requests for a determination via email (typically using the form on the website)
- eIRB submissions which upon initial review are determined NR/NHSR

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: Assigns requests from listserv to IRB staff member recipients
- IRB Analysts: Conduct initial review of eIRB submissions and determine if the project is NR/NHS/NHSR. Receive NHSR requests from listserver monitor and determine whether the project is NR/NHS/NHSR, or if it requires a formal submission in eIRB. Compose NR/NHS/NHSR letters 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

LISTSERVER FUNCTIONS
1. The Listserv Monitor will check the listserv mail folder to identify NH/NHRD requests during the assigned listserv day
2. The request will be assigned to staff members (excluding IRB director) using the rotation dictated by the "NHSR Determination Rotation" spreadsheet. The spreadsheet can be found here.
3. The Listserv Monitor will document the date of receipt and requestor’s name in each new cell in the spreadsheet. Every row in the spreadsheet corresponds to an IRB staff member. The staff member whose row corresponds with an entry dictates that person as the recipient of the request.
4. The Listserv Monitor will reply to the requestor and CC: the staff member recipient with a notification to the requestor that the request has been assigned to that staff member for review.
5. The Listserv Monitor may also forward the request to the staff member recipient with a note about the Listserv Monitor’s impressions of the request (if time permits).
6. In case the Listserv Monitor is out of the office on the assigned listserv day, this function will be done by the person doing listserv that day(s)
   a. The Listserv Monitor will email the TLs on the eve of any vacation days, and on the morning of any days for which the Listserv Monitor may call out sick

REVIEW OF NR/NHSR DETERMINATIONS
NR/NHSR determinations are typically made in response to either email requests or upon initial review of eIRB submission. These scenarios are separated into respective sections below:

Email Requests for NR/NHS/HSR Determinations
1. Take a preliminary review of the information submitted about the project; determine whether additional information is required
   a. The website form (“Does My Project Need IRB Review”) 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 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. 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.” (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)
   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.
4. 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.
   d. If you determine that an IRB submission is required, please copy the listserv when emailing the study team

eIRB Submissions Determined NR/NHS/NHSR
1. If determined NR/NHS/NHSR, log a comment to the study team in the study history to note the determination and attach a determination letter
   a. Draft a letter based on the most recent template: \H:\General\Admin IRB Documents\Checklists, Forms, and Templates\Letter templates and suggested language\NHS NR Letter Template.doc
   b. PDF the letter and attach it to the logged comment in eIRB
c. Note: when a determination is made in eIRB a separate determination letter is necessary so that the study team has a document they can easily print for their records. A logged comment can be harder to print, and may not be as readily accepted as proof for sponsors or journals.

2. Administratively withdraw the submission, noting in the reasoning that it was determined NR/NHSR
a. If the “withdraw” option is not available given the current state of the protocol, refer to the “Administrative Close-out and Withdraw” SOP.

3. Document the determination on the H: Drive
a. eIRB retains the information in the submission, but to track/audit these determinations it is necessary to document outside of eIRB on the H: Drive.
   b. Create a folder under H:\General\NR-NHS Letters\[eIRB# PI-Last-Name]
      1) Copy the PDF determination letter into the new folder. The protocol and other study information will remain in eIRB; the study number in the folder title will direct to the submission.

How to make a determination
1. Review the eIRB submission and determine whether the project constitutes 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.

LOG OF SIGNIFICANT CHANGES

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/13/2015</td>
<td>Large overhaul of SOP: rearranged the information, added procedures for processing requests submitted via the web-form, clarified how to handle determination via email vs eIRB, added the step to forward VA determinations to Emory/VA liaison.</td>
</tr>
<tr>
<td>2/6/2017</td>
<td>Changed title</td>
</tr>
<tr>
<td>4/20/2017</td>
<td>Added new process of NH/NHSR determination assignments</td>
</tr>
<tr>
<td>7/14/2017</td>
<td>Minor changes and removed requirement to receive a preliminary determination by IDP</td>
</tr>
<tr>
<td>5/17/2018</td>
<td>Updated the process as Listerver will assign the review of these requests</td>
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</table>
PURPOSE
The purpose of this document is to guide IRB personnel in the use of the applicable websites 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, formerly Key Concepts training), Clinical Research Coordinator training in CITI or Introduction to Clinical Research 2-day course completion. Specifically, the SOP will provide guidance on accessing the CITI to confirm research staff course completion from logging into the system to obtaining the information. In addition, it will clarify the required Modules per Emory University IRB office. For Clinical Research Training and Clinical Research Coordinator training, it will outline steps for obtaining proof of completion.

SCOPE
It applies to new clinical trials and amendments to add personnel to clinical trials, which are submitted on or after 7/16/2012 for all Emory PI’s, Co-I’s, or Sub-I’s, and coordinators on Clinical Trials.

DEFINITIONS
• CITI – or the Collaborative Institutional Training Initiative. It is valid for three years.
• CITI Good Clinical Practice and ICF (GCP), as part of the Training for investigators (formerly Key Concepts in Clinical Research for Investigators Course) - A mandatory CITI GCP course to be completed by any investigator (PI, Co-I, or Sub-I) on a federally funded or FDA-regulated clinical trial. Course completion is valid for three years for federally funded studies and recertification is via the CITI biomedical refresher course.
• CITI Clinical Research Coordinator course (formerly Introduction to Clinical Research): A mandatory CITI or class-based course to be completed by research coordinators or other staff assisting the study PI (including residents and fellows). Course completion is valid for three years.

RESPONSIBILITIES
• IRB analyst: responsible for checking that the research team staff has received the required training for new submissions, amendments (adding new staff) and continuing reviews (CITI and all training for people added within the last approval period).

PROCEDURE
Procedures for Emory/CHOA or VA CITI

For searching users’ completion records
1. For Emory/CHOA: Login to www.citiprogram.org using your own personal login. If you are a new employee, please contact the IRB staffer in charge of CITI so they can request institutional access for
you to Emory and CHOA CITI’s. Make sure you have a CITI account that is associated with Emory and CHOA.
a. For VA CITI: Checked with VA liaison or staff designated person for access to this information.
2. Scroll down until reaching “Institutional Administrator’s Menu” and click on “Emory University”
3. Scroll down the page until reaching the “Members” section.
4. If you need to verify the record completion for a small number of users, click on “Member profile for a single member.” For checking the status of large numbers of users, please go to step 9.
5. After clicking the single member selection, a new page will open. Click on the drop-down list and start typing the user’s last name. Select the desired name. After selecting the name, click submit
6. A new page will open. Click on “Course completion history” to get the most up-to-date information (do not rely on what appears on the user’s first summary page)
7. The new page will show the user’s entire CITI course history and each course’s expiration date.
8. To search on another user, use the “Back” button on your browser to return to member lookup page. Otherwise, if you are finished, log out of CITI.

**For Viewing Emory’s Required Modules**
- Login and access the Emory University page as above
- Under “Active Courses Being Used”, select the type of course you desire.
- A new page will open indicating the “Required” and “Optional” modules for Emory University.

**Clinical Research Training for investigators (formerly Key Concepts and Introduction to Research):**

On all new studies and amendments (adding new staff) submitted on or after 7/16/2012, check “Type of Research” section question 2.0 to see if the study is a Clinical Trial. If blank, ask study team or read study information to determine whether the study is a clinical trial. In addition, check if the study is FDA-regulated. For information about what constitutes an FDA-regulated trial, check our website at [http://www.irb.emory.edu/forms/faqs.html](http://www.irb.emory.edu/forms/faqs.html). If the answer is yes for both:
- Identify the PI, Emory co-investigators, and Emory sub-investigators and Emory personnel listed in the “Coordinators” category.
- Definition of “co-investigator” for course purposes: a co-investigator (co-I) is "an individual involved with the PI in the scientific development or execution of a project. The co-I (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-I typically devotes a specified percentage of time to the project and is considered senior/key personnel. The designation of a co-I, if applicable, does not affect the PI’s roles and responsibilities as specified in the NIH grants policy statement nor is it a role implying multiple PI."
- For more information, please check this website from the Office for Clinical Research: [http://www.ocr.emory.edu/training/index.html](http://www.ocr.emory.edu/training/index.html)
- Ensure that there is proof of completion of the appropriate course for each of the above personnel. It should be uploaded in Miscellaneous Documents.
- If any proof of completion is missing, please ask the study team to provide or to contact Bridget Strong for assistance.
- If the PI has not completed the course, the study may not be given final approval until they have completed it.
If a Co-I, Sub-I, or Coordinator has not completed the appropriate course, then the study may receive full approval as long as that person is removed temporarily from the list of study personnel. That person may later be added back on, via amendment, once they have completed the course.

Be sure to confirm dates on any certificate provided by the team.

If the team requires assistance with this process, please have them contact the Office of Clinical Research.

The IRB will accept CITI GCP or CITI Clinical Coordinators training certificates from research staff who took the training after June 1, 2016. For people who did not take GCP after June 1, 2016, or never took Key concepts training/certification has expired, they may provide an older GCP training certificate.

Steps to follow if CITI and/or Key Concepts/Introduction to Research are not up to date:
If study team members do not have up-to-date CITI or Key Concepts (whether new submission, CR, or AM to add new people), do not send to expedited reviewer until those are completed (except CR for Key Concepts; the IRB still hasn’t agreed to check that, except for people who were added via the new web form in the past year). Study team can opt to remove the offending study team members temporarily, instead of waiting on them.

Reference our Continuing Review: Processing study staff noncompliance with CITI and Clinical Research Training (formerly Key Concepts/Intro to CR) SOP for handling noncompliance.

Note to Analyst: You can send to full board, but the lack of training should be a pending issue, though the study team can always address the pending issue by removing those folks from the study team. That couldn’t apply to the PI, of course, and if it involves removing Co-I’s from a full board study that should be reviewed by a DR or the Chair of the meeting.

REFERENCES

- Emory Required Training for Investigators, Clinical Research Nurses, and Coordinators Chart.
- CITI Program modules: 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

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/16/2016</td>
<td>Updated to reflect changes in policy and IRB procedure</td>
</tr>
<tr>
<td>10/18/2016</td>
<td>Clarification about certificates accepted by the IRB as proof of training</td>
</tr>
<tr>
<td>2/6/2017</td>
<td>Removing the GCP expiration.</td>
</tr>
<tr>
<td>1/31/2018</td>
<td>Clarifying that GCP training is also required in federally funded CTs</td>
</tr>
</tbody>
</table>
PURPOSE
The purpose of this document is to explain the current available options Emory researchers have to use electronic informed consent documentation (eICD). 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. Note that HIPAA authorization may be obtained via electronic signature as well, when in compliance with the below SOP and federal guidance.

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 current 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 current approved options
• QA/QI team lead- facilitates the discussion with LITS representatives and investigators

FEDERAL GUIDANCE (OHRP and FDA)

PROCEDURE
• Review our guidance document (When is a LITS security review needed?) to review the current software approved at Emory to create eICD.
• Electronic documentation of consent is not permitted by CHOA or the AVAMC (though they do allow online consent with waiver of signature when regulatory criteria are met).
• 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)).
  o 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.)
  o 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 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 accepts 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. In addition, use of security questions to confirm an individual’s identity can also be considered.

- If using Redcap to obtain electronic signature for informed consent:
  - Note: The investigator 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. Instead, 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 signature of the person obtaining consent at a later time. Here is an example:

<table>
<thead>
<tr>
<th>Name of Person Conducting IC discussion</th>
<th>Date when IC discussion took place</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature of Person Conducting IC discussion</td>
<td>Date when IC was signed by person obtaining consent</td>
</tr>
</tbody>
</table>

- It is important that the Redcap system captures the signature of the subject in a way that it can be electronically audited. The ideal format is as follows:

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1)</td>
<td>Name of Patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* must provide value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2)</td>
<td>Name of Legally Authorized Representative with authority for research decisions</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* must provide value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3)</td>
<td>Relationship to Patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* must provide value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4)</td>
<td>* must provide value</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Add signature</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5)</td>
<td>Current Date and Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* must provide value</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Please press the NOW button</td>
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</tbody>
</table>
If the study team should later submit, via amendment, 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. The study team cannot enroll anyone with the electronic method until this amendment is approved.

The study analyst should include in the approval letter the following:

- The IRB approved use of electronic informed consent via Redcap is contingent upon the submission of an amendment showing the final version of the electronic informed consent as it will be seen by subjects
- Do not use the eICF until this amendment 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

NOTE: The amendment can be sent for expedited review.

If **not** using Redcap

- Study team should go to this link: 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) 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.
- 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”.

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<tbody>
<tr>
<td>1/20/2017</td>
<td>Updated process when not using Redcap</td>
</tr>
<tr>
<td>4/20/2017</td>
<td>Updated broken links</td>
</tr>
<tr>
<td>5/17/2018</td>
<td>Remove need for study team to send email to Derek or Maria</td>
</tr>
<tr>
<td>7/25/2018</td>
<td>Added that we should let OSP know if the study is under a security review when the study is funded</td>
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</tbody>
</table>
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. 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. 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): 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.

WHAT SHOULD YOU DO WITH THE INFORMATION GATHERED PER THIS SOP?
The following procedures involve gathering information from the study team that may not have already been part of the submission.
- If this is an investigator-initiated, local study, the information may be added to the protocol document (and consent form, as needed).
• If this is a multisite study and Emory is not the lead site, the information may be provided in a second document, and/or throughout the eIRB smartform and consent form.
• If the use involves the collection of individually identifiable health information (IIHI)
• If study is conducted at Grady: email this information to the Grady privacy officer at djmoring@GMH.EDU for her review and approval. Save the email with her review to the study records.
• If the study is conducted at CHOA: email this information to Annabel Biwott at Annabel.biwott@choa.org or (404) 785-7175
• If the study is funded, let OSP know (at 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.

PROCEDURE FOR MOBILE MEDICAL APPS USED IN RESEARCH STUDIES
1. Review our information chart, to make sure the app/software needs to go to LITS for review
2. Determine whether a study involves mobile medical devices / apps
   a. Review the protocol and Smartform for mention of mobile platforms / apps
   b. Review if the proposed use involves the collection or storing of IIHI
      • If not, the medical device/app does not need to be vetted by LITS.
      • If yes, the study analyst should ask the study team to put an IT ticket through this link: https://emory.service-now.com/sp?id=kb_article&sys_id=e5c2cd88f5c6f1c055c77bd8604896c2 The form has the information to provide under “more information”
   c. Determine whether the mobile platform+app is a medical device per FDA definition (aka intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; see References and Definitions above)
      • 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.
   d. For mobile medical devices/apps:
      • Check to see that the device is listed in the protocol and consent form:
         o If the protocol is sponsor generated, a separate addendum in the Research Design of the Smartform may be acceptable.
      • Check to see that the device is listed in the Device Section of the Smartform.
      • Review whether the device is likely to be a 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.
         o For studies with enforcement discretion (see FDA guidance)
            a. The study team should select the following options when filling out the device section of the Smartform:
               i. “This is not an FDA approved use of the device” should be selected under Q2.0
               ii. Holder of the IDE number should be “N/A” under Q4.
               iii. Q5 should be “Non-significant Risk” device, with “Mobile Medical app” included in the text box for justification of risk classification.
               iv. Q6 should be selected as “Yes” for reusable device.
v. For Q8, if there is not device manual, PI should provide clarification for why there is not a device manual.

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 will 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.

PROCEDURE FOR USE OF MOBILE PLATFORMS IN A RESEARCH STUDY (NOT MOBILE MEDICAL APP)

1. Review our information chart, to make sure the app/software needs to go to LITS for review
2. Determine ownership/possession of the mobile device/app (whether a medical device or not):
   a. Review if the proposed use involves the collection or storing of IIHI
      i. If not, the mobile platform does not need to be vetted by LITS.
         • If yes, the study analyst should ask the study team to put an IT ticket through this link: https://emory.service-now.com/sp?id=kb_article&sys_id=e5c2cd88f5cdf1c055c77bd8604896c2. The form has the information to provide under “more information”
   b. 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.
      i. 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?
            o 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.
      ii. 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
             o Is the subject responsible for paying for the device (the device itself)?
             o 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 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:

- Body Mass Index (BMI)
- Total Body Water / Urea Volume of Distribution
- Mean arterial pressure
- Glasgow Coma Scale score
- APGAR score
- NIH Stroke Scale
- 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.


LITS report review

After the LITS review occurred, the LITS security 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:
<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Description</th>
<th>Mitigation Timeline</th>
<th>Risk Acceptance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Critical</strong></td>
<td>The Security Review has determined that the current level of risk associated with the finding is critical (severe) in its current state.</td>
<td>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.</td>
<td>Critical risks can only be accepted by VP/Dean level leadership with the consent of Emory’s Chief Information Security Officer.</td>
</tr>
<tr>
<td><strong>High</strong></td>
<td>The Security Review has determined that the current level of risk associated with the finding is high (substantial) in its current state.</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Medium</strong></td>
<td>The Security Review has determined that the current level of risk associated with the finding is medium (moderate) in its current state.</td>
<td>The risk must be fully remediated or mitigated to an acceptable level within 90 days.</td>
<td>Medium risks may be accepted by study team department Director/Chair level leadership.</td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>The Security Review has determined that the current level of risk associated with the finding is low (tolerable) in its current state.</td>
<td>Risk remediation is recommended, but not required at present.</td>
<td>Low risks do not need to be explicitly accepted.</td>
</tr>
</tbody>
</table>

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/downloads/MedicalDevices/.../UCM263366.pdf

LOG OF SIGNIFICANT CHANGES

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/20/2017</td>
<td>Updated broken links</td>
</tr>
<tr>
<td>1/31/2018</td>
<td>Added information about Grady Privacy officer</td>
</tr>
<tr>
<td>2/7/2018</td>
<td>Clarifying that mobile medical apps under enforcement discretion do not have to go to FB for risk determination.</td>
</tr>
<tr>
<td>5/17/2018</td>
<td>Removed need to email Derek or Maria; added information from CHOA IT person and the link to our information chart</td>
</tr>
<tr>
<td>7/25/2018</td>
<td>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.</td>
</tr>
</tbody>
</table>
SOP Title: Certificate of Confidentiality Process in non-federal studies
SOP Category: Study Management
Established: 6/26/2012
Last Revision: 11/1/2017

PURPOSE
NIH grants Certificates of Confidentiality (CoCs) for all federally funded studies and for studies that will collect sensitive information from participants. The CoC protects the research record from forced disclosure, such as subpoena.

For federally funded studies that automatically receive a CoC, please ensure that the template CoC language is in the ICF and process as usual. The remainder of this SOP applies only to non-federally funded studies obtaining sensitive information from subjects.

- 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.

Please note: our Institutional Official (I.O.), who needs to sign off on these applications, may push back even if the study seems to meet NIH’s guidance on what qualifies for a CoC. We do not want study subjects to get an inflated or false sense of security from the CoC language. 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. We would prefer only to sign off on CoC’s that protect information that may not appear anywhere else in a subject’s records. The IRB Director can help you determine whether the I.O. is likely to push back, as well as how to make sure the memo contains the information the I.O. will be looking for.

SCOPE
The SOP applies to all non-federally funded human subject research where the research activities are likely to solicit information considered to be sensitive per the NIH definition above. See here for information about CoCs: http://irb.emory.edu/forms/coc.html

RESPONSIBILITIES
- IRB Study Analyst – Owner of the study to which the CoC applies or will apply; can also acknowledge own amendments that simply upload approved CoCs; delays stamping of consent forms until CoC is in place, if applicable
- Institutional Official (I.O.) – signs CoC applications before they are sent to NIH
- IRB Director – Reviews CoC cover memos before they are sent to I.O.
- 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 amendments)

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.

Charted Procedure:

New Study/ AM received by analyst. CoC document uploaded in DSMP?

Yes.
Continue Processing the study/AM until approval. (note in the letter that enrollment cannot begin until CoC is in place) then process CoC application per chart 2 below.

No.
Give the team two options:

Move toward approval w/o CoC to enroll earlier.
- Team submits 2 ICF versions (1 with CoC language and 1 without)
*it will be up to a reviewer/FB to determine if this is appropriate for the study

Wait for CoC before enrolling.
- Keep CoC language in ICF and move forward with review.
- Write approval letter and state that enrollment cannot begin until CoC in place. Do not stamp consents.
- After approval, continue processing CoC application per chart 2 below.

Final outcome: approved.
- Write approval letter and state that consent form version (insert version with CoC language) may not be used until an amendment is submitted with the approved CoC.
- Stamp consents w/o CoC language for immediate use and process CoC application per chart 2 below.

Final outcome: team needs CoC before enrolling.
- The team can remove the ICF without CoC language and send changes back.
- Continue processing. Write approval letter and state that enrollment cannot begin until CoC in place. Do not stamp consents.
- After approval, continue processing per chart 2 below.

AM with CoC in DSMP section is submitted
- Analyst processes the memo as per chart 2 instructions but can administratively approve the AM and stamp the CoC language ICF
* be sure to remove the non-CoC language ICF from the documents tab!
Written Procedure:
1. If consent form states that there is a CoC for the study, and/or if approved CoC is uploaded in DSMP section:
   a. Is the consent form language consistent with the presence - or absence - of CoC in SmartForm DSMP section? (Both has the required language describing the CoC, and also does NOT have the language about records being disclosed subject to subpoena [since CoC prevents disclosure based on subpoena])
      i. If yes, proceed with screening as normal with no further consideration to the CoC.
      ii. If there is a CoC uploaded in DSMP section or elsewhere but no CoC language in consent form, request that the study team insert our required CoC language into the consent form.
      iii. If consent has CoC language, but no evidence of a CoC in DSMP section or elsewhere:
          1. Have study team confirm that they have or will be applying for a CoC;
             a. If study team will not be applying for a CoC: request that study team remove the erroneous CoC language, and process the study as a regular non-CoC study. (Note: IRB reviewer(s) may still request CoC in their review, if they feel it is necessarily in order to minimize risk, and this would be a pending issue.)
             b. If study team does have an NIH-approved CoC that they neglected to attach, ask them to upload now and process as per (1)(a)(i) above.
             c. If study team does not yet have approved CoC but will be applying for one, there are two choices, depending on whether the study team wants to enroll subjects prior to obtaining a CoC:
                i. If the study team agrees to not enroll any subjects until a CoC is granted, then they will submit only the CoC-version of the consent form.
                OR
                ii. If the study team requests enrollment of subjects prior to the approval of the CoC:
                   1. The study team should request IRB approval of two versions of the consent form(s) – one with the CoC language, and one without any reference to CoC (to be used until the CoC is approved by the NIH; because NIH advises against using language like “we plan to obtain a CoC”).
2. For full board studies, put a note in the omnibus form “Pending Issues” section asking IRB to determine if study team can start enrolling prior to CoC being approved despite potential exposure of sensitive data to subpoena; if members feel CoC is necessary for study, then the no-CoC version should be removed from the smartform and not stamped.

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)

2. Post-approval processing instructions (for study that has CoC language in consent but does not yet have approved CoC):
   a. Lack of approved CoC from NIH is not a pending issue, but any consent form(s) that have the CoC language in them must NOT BE STAMPED until the CoC is approved by the NIH.
   b. In approval letter (whether full board or expedited) state that the consent form version [insert version with CoC language] may not be used until an amendment is submitted with the approved CoC
   c. Once amendment is submitted to upload the approved CoC, IRB Study Analyst may “approve” (really just acknowledge) the amendment.
   d. Once amendment is approved with NIH-approved CoC (to be placed in DSMP section of Smartform), use “Edit Consent Forms” to remove any stamped non-CoC versions of the ICF (if applicable), and then stamp the CoC version of the ICF.

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 forwards application to IRB analyst. (*Note, the assurance page of the application must be on the study team’s department letterhead, and be signed by the PI prior to coming to us for institutional official signature).
   a. The study team may have trouble figuring out how to create an electronic copy of the overall CoC application for us to review. They should consult with the NIH or their own IT resources since we are unable to access the NIH’s system to assist.

2. Print out copy of the PDF of the signed CoC application, along with the most recently approved informed consent form and corresponding approval letter (e.g. if the CoC was planned from the start of study, this will be the initial approval letter and the initially approved consent document; if the CoC was requested after the initial approval of the study and consent modified through an amendment, print out the amendment approval letter and approved, amended consent form).

3. Update the CoC Tracker file Under H:\IRB\General\Certs of Confidentiality
Draft memo for IO to sign using “Template MEMO to IO re COC” in the same folder, and save the draft memo in a folder for the COC study. **If the study does not already have a folder, create one.

Provide the memo, consents, and application to the Director for review. After Director approves the memo, place sticky tabs on the packet pages to indicate where the I.O. must sign and where the CoC language is printed in the ICF. Hand-deliver the entire packet to Dr. Wynes’ assistant.

Receive IO signed packet from Dr. Wynes’ assistant.

Scan the packet and save the electronic file in the appropriate study folder at H:\IRB\General\Certs of Confidentiality.

Notify the PI/study team that the packet is completed and Email the signed packet to the PI and study team. The hard copy of the packet should be made available for pick up, if requested by the study team. Otherwise, the packet may be

Attach the scanned file to a logged comment to study team in eIRB.

Once the study team has received the approved CoC, update the CoC Tracker file and ensure that a copy of the CoC approval letter is uploaded in the study history.

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”.

LOG OF SIGNIFICANT CHANGES

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>5/13/2015</td>
<td>Clarification of process</td>
</tr>
<tr>
<td>12/23/2015</td>
<td>Revamping of SOP following current NIH requirements.</td>
</tr>
<tr>
<td>3/1/2016</td>
<td>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.</td>
</tr>
<tr>
<td>11/22/2016</td>
<td>Updated name of template Memo to IO</td>
</tr>
<tr>
<td>5/5/2017</td>
<td>Addition of section: handling CoC assurances; other minor clarifications</td>
</tr>
<tr>
<td>11/1/2017</td>
<td>Added charts, clarified SOP for new NIH CoC policy from 10/1/2017; other minor clarifications</td>
</tr>
</tbody>
</table>
PURPOSE
The purpose of this document is to detail the steps necessary for the IRB to review all studies that have 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 in accordance with this SOP; verifying adoption of management plan in studies; escalating when study teams do not comply with management plan within required timeframe.
- **COI Program 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 deadline, by requiring submission of Reportable Event 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.
- **IRB Full Committee** - responsible for re-reviewing management plan when the investigator objects to any additional requirements recommended by IRB CoRe.

TARGET TURNAROUND TIMES

**Time 0 (Zero)** = When COI Office receives notification from conflicted party that they have accepted the COI management plan, or when the timeframe for objection has elapsed.

**Targets**

When 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.
- 2 business days for Director to send plan to conflicted party and PI.
- 10 calendar days for study team to make necessary changes in eIRB, 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 conflicted party via email.
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

POV of IRB Study Analyst

1) Disclosure via New study/Amendment in eIRB (for disclosures that come initially from COI office, please see (3) below)
   a. If the Smartform or logged comment indicates a COI:
      i. Ask study team if they have disclosed to the COI office (unless this has clearly been done, based on content of comments), and if so, what the status of COI review is. If this takes place outside of eIRB, document the exchange in the History.
      ii. Contact COI Program Specialist, copying IRB Director, informing them of disclosure and study number and what is known of COI review status. Await feedback as you continue processing the submission as follows...
      iii. Depending on the nature of the study:
          1. 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 in a logged comment in the History.**
          2. For expedited items, do not send to 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.
      iv. Upon receipt of an IRB CoRe-approved management plan from the COI Program 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.
      v. 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 Agenda Item 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 Investigator COI box is checked, look at main study workspace Smartform to see if this is being disclosed for the first time. If already disclosed, there is no need to take further action regarding COI (unless you do not see evidence that there ever was COI review or a management plan, in which case contact the COIPS and IRB Director).

b. If the disclosure is new, ask study team if they have submitted to the COI office (unless this has clearly been done). If far in advance of expiration, send back to study team to get their response; otherwise can obtain response via call/email/logged comment as needed, but document the exchange in study History.

c. Contact COI Program 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. Note, eIRB currently does not send notification to the COI office if selected during the CR process.

d. Process the CR as usual; this is not a pending issue (though an amendment may need to be submitted once a management plan is approved, per section (3) below). Alternatively, if the conflict was incorrectly identified, you may need to deselect the option for the study team.

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 an amendment with that information in eIRB. Therefore you may hear about it first from the COI Office or Program Specialist, as follows:

   a. COI Program Specialist will send an email and log a private comment to the analyst informing them that the study team has been given 10 business days to submit an amendment to implement the COI management plan and check the “COI” box in the eIRB Smartform.

   b. IRB Study Analyst should set calendar reminder for 10 business days to double-check that study team complies with updating the study to implement COI management plan and check the COI box.

   c. If no amendment is submitted within the timeframe, log a comment to the study team reminding them. Also email the IRB Director Team Q for escalation, and log a comment in the History stating that you have done this.

   d. Hand off responsibility for monitoring management plan completion to the Team Q and IRB Director.

POV of COI Program Specialist
1) Notification of Investigator or Study COI is sent to you by IRB Analyst, due to disclosure in eIRB:

   a. Reply to analyst to acknowledge receipt, and estimated turnaround for next steps (if not able to complete remaining steps immediately)
      i. If COI Committee has already determined a management plan, follow step 2 below and inform the IRB Analyst of current IRB approval status (e.g. whether IRB CoRe has reviewed and approved yet).
      ii. If COI management plan has not been determined by the COI Committee, ensure they are aware of the disclosure, and CC the IRB Analyst.
      iii. If COI Committee determined there was no conflict or plan needed, inform the IRB Analyst that eIRB form should be edited to remove disclosure.
   b. 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/Wynes Review Period has Elapsed

a. Save 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) For AM or CR, if required changes not submitted w/in 10 bus days, alert Team Q and IRBD and require study team to submit RE

**POV of IRB Director:**

- As member of CoRe, submit opinions re: COI management plans on a timely basis (14 calendar day total turnaround for CoRe determination)
- When COI Program 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 amendment within 10 calendar days, and if the amendment is not submitted within that timeframe a Reportable Event may be required. “Please let me know if you have any questions or concerns and thank you for your work to manage this conflict.”
  - Copy IRBA and COI Program Specialist
  - Update COI tracking spreadsheet when email sent

For flow chart on next page:

**IRBA: IRB Analyst**
**IRBD: IRB Director**
**COIPS: COI Program Specialist**
COI Disclosure (New study, AM, or CR)

If IRBA aware first via eIRB, IRBA notifies appropriate parties per SOP

If COIPS receives inquiry from IRBA, COIPS checks status at COI Office; responds with status to IRBA

COI Management Plan Required and Finalized by COI Office
("No COI" determinations handled differently, see written SOP (in progress))

IRBA continues processing CR through review (not pending); may send Full Board AM or New study to meeting with COI as pending issue (add to Agenda Item Note and History); but must delay sending expedited AM or New study for review until COI mgt plan approved and adopted

COIPS sends plan through IRB CoRE per SOP using templates; sets reminder to ensure votes received in timely manner; saves determination form once vote complete; once approved update COI Office records; email approved plan and Letter to PI to IRBD, copying IRBA; upload approved mgt plan and letter in eIRB History as PRIVATE comment with deadline if applicable; log comment to Study Team saying a mgt plan has been approved by IRB and IRBD will be emailing shortly.

COI Management Plan Approved by IRB

IRBA receives IRB-approved management plan from COIPS (email or History comment), then reviews IRB submission to see if any requirements are outstanding; notes findings in History; holds final review of AM or New study until all changes are made. For AM or CR: IRBA reminds study team in 10 business days; if not complete email IRBD for escalation with note to History.

COIPS updates COI tracking sheet to reflect CoRE approval and deadline; IRBD emails investigators with plan. If AM/CR, also include deadline; IRBA and IRBD each set reminders to follow up with study team in 10 bus days; for AM or CR, if required changes not submitted w/in 10 bus days, alert Team Q and require study team to submit RE.
## LOG OF SIGNIFICANT CHANGES

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<tr>
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<tr>
<td>5/7/2015</td>
<td>Replaced the SOP titled “Conflict of Interest Management Plan Process” with all new procedures</td>
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<tr>
<td>8/17/2015</td>
<td>Added to IRB COI Liaison Analyst’s responsibility to keep IRB analyst informed of plan status.</td>
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<tr>
<td>5/18/2016</td>
<td>Updating the number and composition of CoRE needed for acceptance. Also updated responsibilities between IRB and COI.</td>
</tr>
<tr>
<td>12/20/2016</td>
<td>Major overhaul of entire SOP. Removal of IRB COI Liaison role.</td>
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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

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1. OCR pre-award staff identifies the COST OPTION for a clinical study, checks it on a worksheet, signs it, scans it, and emails it to OSP/Contracts listserv AND IRB listserv. This PDF or word document has the IRB File # on it.

2. 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.”

3. The study IRB analyst checks the selected Cost Option against the draft ICF.

4. 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. As above, the CHOA IRB Manager or the RAS pre-award specialist will email the IRB listserv with a PDF or word document containing a study cost option.

2. After the information is posted under the study history, the study analyst checks the selected Cost Option against the draft ICF.

3. 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.)

4. Contact the following people for additional questions:
   a. **Sarah Marie Huban** (CHOA IRB Manager) for COG studies
   b. **Xiayang “Chloe” Xie “Shay”** (RAS pediatrics) for other Pediatric studies

*Note: the Monday report to the IRB listserv is about the In Case of Injury option, not the Cost Option.*

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<td>2/6/2017</td>
<td>Addition of CHOA process</td>
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The Winship Cancer Institute’s Clinical and Translational Review Committee must review all studies related to cancer at Emory, regardless of the nature of the studies. This includes chart reviews, as well as epidemiological studies and sociobehavioral studies. Studies do not need to be done at Winship Cancer Institute in order to require CTRC review.

The checkbox “Cancer Related Research” in question 2 of the Biomedical Research section of the eIRB application is what triggers the CTRC ancillary review requirement in eIRB. The IRB analyst assigned to the study must verify during initial screening that the study team has checked this box if the study is related to cancer.

If “Cancer Related Research” has not been selected, the analyst should follow these steps:

1. Use “Edit Study” function to check the “Cancer Related Research” checkbox in the “Biomedical Research” section (even if the Biomedical Research section does not appear in the “Printer Version” of the study, e.g. when the study is a chart review).

2. When you send the study back to the team for changes, inform the study team that CTRC approval must be in place before they submit the study back to you for further review. Direct them to the CTRC website to access the application form. The analyst should confirm that CTRC review is showing up in the reviews tab. Follow up with a team lead if the review isn’t there. Keep sending the study back to the study team if needed, until the study team or CTRC provide documentation of approval.

3. Contact Melissa Hwang at 404-778-5714 or melissa.l.hwang@emory.edu or Lydia Cox at 404-778-5569 Winshipctrctr@EMORY.EDU to verify that the study is in the CTRC team’s inbox.

**FAST TRACK STUDIES:** For time-sensitive multi-site pharmaceutical studies, the CTRC and the IRB may review the study at the same time, as an exception to the rule that CTRC review precedes IRB review. Usually this will be documented in the study History via WCI Regulatory Lead and/or IRB Team Lead. If not, and the analyst requests CTRC approval prior to sending the study for review, the study team may reply that this is a “fast track” study. The analyst should consult with the IRB Ops Manager or Director to determine if this is study meets the criteria for that process, and if so, the study can go to full board review with CTRC approval as a pending issue.

You may see CTRC approval come in via logged comment or via listserv. Have a superuser issue CTRC approval in eIRB if not done by the CTRC.

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<tr>
<td>8/5/2015</td>
<td>Updated CTRC contact information and also correct tab in eIRB</td>
</tr>
<tr>
<td>7/14/2017</td>
<td>Updated based on analyst-requested administrative changes</td>
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1. Log Comment to PI indicating the change in Study Status and attach the re-determination letter in the main study workspace. Ask the PI to withdraw the continuing review if a continuing review is currently in process.

2. Log a similar private comment indicating the change in the continuing review workspace.

3. Request that a SuperUser change the study status of the study to Exempt (and if the PI doesn’t withdraw the Continuing Review have them do it).

4. Remove the Expiration date and (if applicable) merge the consent forms with the new Exempt Determination and no expiration date.

5. Log Comment to the PI attaching the new stamped consent documents.

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PURPOSE
To delineate the steps to change review type from Exempt to Expedited status

SCOPE
Applicable studies approved by Emory IRB

RESPONSIBILITIES
- IRB Analyst: process changes as described below
- Super User: change study status

PROCEDURE
1. Log Comment to PI indicating the change in Study Status and attach/draft the redetermination letter.
   a. Drafting a redetermination letter - we will use the intro from the "Exempt Clarification" letter to indicate that we have reviewed the proposed changes and based on "x" change, there is an increase in risk that raises the status to expedited review based on "y" procedures/risks.
   b. The letter will also include the effective/approval date and an expiration date, reminder that a renewal will need to be submitted and that amendments should be submitted before any changes are made to the study procedures.
2. In the main study workspace log a similar private comment indicating the change in the continuing review workspace.
3. Request that a Super User change the study status of the study from "Exempt Approved" to "Expedited Approved".
4. Set the Expiration date and (if applicable) merge the consent forms with the new Expedited Determination and expiration date.
   a. Make sure the expiration date is populated in the main workspace.
   b. Make sure that the stamping template no longer says "Determined Exempt on" and it should have the regular stamping template in place.
5. Log Comment to the PI attaching the new stamped consent documents.

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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. OCR takes the “Clinical Research Key Points” Smartform pages and the consent/HIPAA form from eIRB and/or the study team, and uploads them into the ERMS research management system. 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/Amendments
  1. Study team should request “Sensitive Study Determination” by selecting yes to Q2.0 under the Emory Healthcare Office of Quality section of the Smartform.
     a. For studies where the Office of Quality section of the Smartform does not auto-populate, study teams should be directed to http://www.irb.emory.edu/forms/clinical.html to fill out and upload the paper versions of the forms in “Miscellaneous Documents.”
  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.

- 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 an amendment and RE to correct the discrepancy. Follow steps for “Amendment” above.
     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.
  b. For studies utilizing an external IRB seeking sensitive study status:
     1. Study teams should be directed to http://www.irb.emory.edu/forms/clinical.html to fill out and upload the paper versions of the forms.
     2. The request should be sent to a Vice-Chair or FB for review.
     3. IRB Analyst should include the reviewer’s determination of sensitive study status in an acknowledgment letter.
     4. For studies with sensitive study status, the IRB Analyst should forward the acknowledgment letter to OCR@emory.edu.

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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](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*)
o 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.

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<td>11/6/2014</td>
<td>Expanded the scope from just fMRI and MRI to cover all studies where imaging is done for research</td>
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<tr>
<td>2/18/2015</td>
<td>Adding information about other imaging that may require referral to RSC and review by FB</td>
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<tr>
<td>4/27/15</td>
<td>Adding note about the potential for HIPAA requirement based on study staff.</td>
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<tr>
<td>12/10/2015</td>
<td>Administrative changes made for clarity and note about clinical trials with research scans.</td>
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<tr>
<td>6/8/2018</td>
<td>Minor clarifications</td>
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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 a Team Lead 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

- You may also obtain more information at [http://gds.nih.gov/](http://gds.nih.gov/)

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<td>9/16/2016</td>
<td>Updated with information about 1/25/15 policy change</td>
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SOP Title: Humanitarian Device Exemption (HDE) Studies
SOP Category: Study Management
Established: 8/8/2013
Last Revision: 9/16/2016

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 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 will review the HUD submission.

- Non-research HUD
  - 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-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.

- 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. This information should be reviewed and approved by the IRB, and all regular IRB P&Ps should apply.

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 Event 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 RE 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**

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
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<tr>
<td>1/5/2015</td>
<td>Replaced “should” with “must” to state Chair/Co-Chair <em>must</em> be a clinician; added HUD definition</td>
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<tr>
<td>5/14/2015</td>
<td>Added New Study and Reportable event sections.</td>
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<tr>
<td>6/29/2015</td>
<td>Added close out section and information for template letter.</td>
</tr>
<tr>
<td>9/16/2016</td>
<td>Added links to current tools and clarified Emory IRB position on reviewing HUDs for community physicians.</td>
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PURPOSE
The purpose of this document is to 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 amendment, registration with RM should be done after the amendment 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.

Process Flow

- Study team submits new study or amendment to use ResearchMatch.
- IRB Analyst reviews submission for completeness.
- IRB Reviewer reviews and approves submission.
- Study team follows the ResearchMatch Registration Instructions to register in RM.
- Emory’s ResearchMatch Liaison logs in and confirms ResearchMatch’s request.
LOG OF SIGNIFICANT CHANGES

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<tbody>
<tr>
<td>10/22/2015</td>
<td>Addition of links for template language and instructions. Modification of Process flow</td>
</tr>
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</table>
HIPAA Waiver and Informed Consent Waiver Worksheets

HIPAA Waiver and Informed Consent waiver worksheets must be filled out any time researchers request a HIPAA waiver or alteration, or any waiver or alteration of the consent process (unless it is an exempt study; exempt studies do not need formal consent waivers but do require a HIPAA waiver worksheet if applicable). The waiver of documentation of consent worksheet is required when a study wishes to waive signed consent.

NOTE: HIPAA alteration worksheets are not necessary for Partial HIPAA Waiver requests unless it is for a VA study. (The Atlanta VA requires a HIPAA Waiver worksheet for any study requesting a partial or full HIPAA waiver. The worksheet content is based on the responses in eIRB, and the worksheet should be uploaded in the Research Design section.

Analyst steps:

1. Fill out the relevant HIPAA and/or consent worksheets with protocol-specific information for all elements. (If the study team has already filled out the worksheets, verify that they are complete; if not, start over).
2. Upload the waiver form(s) into the Research Design section (for secondary data studies where the Informed Consent section does not appear) or in the “Informed Consent Process” section (for all other studies). If you upload in “Miscellaneous Documents,” the reviewer is less likely to see it.
3. The form thus becomes part of the IRB submission and included in what the reviewer approves.
4. Include the waiver(s) explicitly in the study approval letter. For HIPAA waivers, include what PHI will be accessed under the waiver (based on study team’s responses in the eIRB smartform’s HIPAA sections).

Vulnerable Population Worksheets

Worksheets only need to be completed by the analyst for expedited studies, not for full board studies. For full board studies, the Subpart omnibus forms need to be prepared with basic study information, but will be completed at the meeting.

Subpart B (pregnant women/fetuses/neonates) Worksheets

These must be used if these populations are a specific target of the research. If the study excludes pregnant women or if pregnant women are just incidental to the research and would incur no special or additional risks because they are pregnant, the Worksheet does not need to be completed. Upload in the Research Design section.

Subpart D Worksheets

These should be filled out by the IRB analyst if any minors are involved in the research, whether incidental or specifically targeted. There is an additional page of the worksheet for minors who are Wards. Upload in the Research Design section.
Subpart C Worksheets
These likewise must be filled out by the IRB analyst if any prisoners will be study subjects, or if a subject becomes a prisoner during the research study. The reviewer(s) can then require changes if they disagree. Please see the Subpart C Prisoner Study SOP. Upload in the Research Design section.

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<tr>
<td>10/22/2015</td>
<td>Clarification in the worksheet requirements and process</td>
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</table>
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 a team lead/ 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.

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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 Team Lead and/or Director - Serve a resource for analysts in cases where appropriate process of review in 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 Team Lead or IRB Director to determine whether Full Board review is appropriate.

PROCESS FLOW
Determine whether study involves deception and/or incomplete disclosure

Incomplete Disclosure?

If study meets the criteria for Exempt review, may be an option. If Exempt categories do not apply, may go Expedited.

Incomplete Disclosure, Mild Deception, or both?

If mild deception & topic is not sensitive or participants are not vulnerable, analyst should consult with the Committee C Chair or Director.

Significant Deception?

Analyst should consult with the Committee C Chair or Director.

Not Expeditable?

Assign to CMTE C for review

If possible, expedite. If not expeditable, assign to CMTE C for review

*Adapted from University of North Dakota IRB’s “Guidance on the Use of Deception or Incomplete Disclosure in Research”

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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 Team Lead or Director must write to ora-it@emory.edu and request access to “Contract

PROCEDURE

1. Click on 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:

![Login](https://oraws2.emory.edu/shared_web/secured_apps/login.png)

3. Once logged in, navigate to “IT Resources” tab:
4. Click on “ORA Reporting Export” tab:

5. Click on “OSP Contract Tracking Data Peoplesoft/COMPASS merged data”:

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).

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PURPOSE
The purpose of this document is to detail 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 amendments 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.
   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 amendment, 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)
it 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) amendment.

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
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:

<table>
<thead>
<tr>
<th>Name of the Site</th>
<th>IRB of record for this site</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEC at St. Joseph</td>
<td>IRB of record for this site</td>
</tr>
</tbody>
</table>

Appendix 2

For expedited studies:

Hello Ms. Heitkam,
IRB0000XXX, a new study/amendment, 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

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<td>Update to purpose and procedures to align with current MOU</td>
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<tr>
<td>11/12/2015</td>
<td>Update to indicate that chart reviews and trials where only isolated diagnostic services performed at ESJH for research purposes due to patient convenience or equipment availability no longer need ROC/ERDs review.</td>
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<tr>
<td>03/08/2016</td>
<td>Minor changes to clarify that The Emory Clinic in the leased space at SJHC still requires ROC review.</td>
</tr>
<tr>
<td>11/15/2017</td>
<td>Revised to reflect that Kris McGinnis is no longer at Saint Joseph’s and there is no longer an ROC.</td>
</tr>
<tr>
<td>1/31/2018</td>
<td>Clarification on process as Rebecca H needs to be emailed with protocol and ICF information</td>
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PURPOSE
The purpose of this SOP is to outline the procedures after a study is tabled at a full board meeting.

SCOPE
This SOP applies to studies being tabled at a full board meeting due to the following:
- The primary and secondary reviewers are not present at the meeting and no other committee member has reviewed the study.
- Quorum is lost
- The committee decided that the necessary elements weren’t present at the meeting (i.e. reviewer specialty, expertise)

DEFINITION
Tabling - Rescheduling a full board committee assigned submission to another meeting due to the committee's decision that the submission falls under one of the conditions noted above.

PROCEDURES
Once you receive notification that your study has been Tabled:
1. Record Meeting Minutes vote as “tabled” (including vote numbers is not a requirement).
2. Request a SuperUser change status back to “IRB staff review” so the study can be sent back to the team for changes and/or be added to a new agenda.
3. Log the following comment to the study team in the history:

   Dear X:

   The IRB reviewed and discussed the above-referenced submission at its convened meeting on DATE. Unfortunately, the review was tabled, we will send it to the next available convened meeting. Thank you for your patience and understanding.

4. Once the submission is sent back, assign it to a new agenda per usual practices. Note: A “tabled” study functions like a new submission in eIRB and can be assigned without additional assistance from a SuperUser

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<td>11/1/2017</td>
<td>Substantive changes, adding purpose, scope and additional information</td>
</tr>
<tr>
<td>1/31/2018</td>
<td>Revisions to comment to post under study history</td>
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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 conducted at Emory (either reviewed by the Emory IRB or external IRB) under REMS requirements.

RESPONSIBILITIES
- **IRB analyst** – reviews protocol to identify if drug or biologic is under REMS program & confirms ODP review
- **IRB Team Lead 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 EMMORY 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](https://www.fda.gov)
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 AMENDMENTS REVIEWED BY THE EMORY IRB

1. If the AM 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 AM 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

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<tbody>
<tr>
<td>2/21/2018</td>
<td>Added process for AMs</td>
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PURPOSE
The purpose of this document is to describe the review process of new study submissions, continuing reviews, and amendments 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 Regina Drake 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 amendment 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.
Exempt studies:

Not Applicable - Research involving prisoners cannot be reviewed as exempt.

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. Upload this document in the “Research Design” section of the eIRB Smart Form.
- IRB analyst should first send the study to a primary designated reviewer via eIRB. Please alert the primary designated reviewer that the application will then be reviewed by the prisoner representative.
- Once the primary designated reviewer has completed his/her review, and any requested changes have been made by the study team, IRB analyst should contact IRB Super user to change the state of the study to allow for the review to be assigned to the prisoner representative.
- The IRB analyst should work with the prisoner representative to complete the eIRB review and Subpart C Worksheet, as needed.
- IRB analyst should upload the completed Subpart C Worksheet in the “Research Design” section of the Smart form so it becomes part of the permanent record.
- IRB analyst documents Subpart C category in the approval letter. Final approval letter should not be issued 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 letter certifying the Subpart C Category findings to OHRP
  - The letter should be drafted for the IRB Director to review (may be reviewed by Team Lead 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

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 amendments adding Prisoners. Inform the meeting facilitator that a prisoner representative is needed for the meeting.
• If a continuing review, IRB analyst must document 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 an amendment alter risks/benefits/involvement of Prisoner subjects, the information should be reviewed at full board. If an amendment is not altering the above, then the information can be reviewed expedited.
• For new studies, or amendments adding Prisoners as subject population for first time (see following section for more details on the latter case):
  o IRB analyst should pre-fill the Subpart C Omnibus form to be filled out at the meeting.
  o After the meeting, IRB analyst should save the Subpart C Omnibus form in the Research Design section of the Smart form.
  o 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.
  o If the study is federally funded, IRB analyst must draft a prisoner certification letter to OHRP.
  o The letter should be drafted for the IRB Director to review (may be reviewed by Team Lead in Director’s absence).
  o The OHRP letter will require verification of the Grant number – may be requested from study team if not in eIRB.
  o 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, 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.

Amendments:
• Any amendments that are changes to the research require prisoner representative review, if such review was required initially.
• Any amendments 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 amendment 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:
  o 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).

• 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.

• When considering whether to terminate enrollment, the IRB/PI should consider the risks associated with termination of the subject in the study.
  o 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.
  o 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.
  o 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.
  o 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.
  o If the temporary incarceration has an effect on the study, the IRB shall handle the case according to the case set forth above.
  o 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.

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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 amendments 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
4. Approving certain minor administrative changes.

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 (Amendments)]
LOG OF SIGNIFICANT CHANGES

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<tr>
<td>5/14/2015</td>
<td>Added a Purpose and Scope sections.</td>
</tr>
<tr>
<td>9/16/2016</td>
<td>Added P&amp;P reference</td>
</tr>
<tr>
<td>5/5/2017</td>
<td>Clarified the type of changes in funding staff can approve</td>
</tr>
</tbody>
</table>
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. Those types of changes are not listed in this SOP. All IRB staff may also review certain contingency responses, as well as any close-out request.

A. NEW STUDIES
   1. Minimal risk expeditable studies involving only the following, and including advertisements:
      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 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. 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. AMENDMENTS
   1. Changes of any kind to studies that Staff DR could have approved at initial review (see section
      above), unless the changes move the study outside that scope. For example, FS studies.
   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 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. not changes to protocol risk, benefit, design; not clarifications to parts of 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 subset of corrections/factual/administrative
      updates that all IRB staff may review.)
7. Adding funding sources (but not deleting them)
8. Adding Emory-affiliated sites (includes EHC, CHOA if not also adding minors for first time, St Joseph’s/Johns Creek, Grady)
9. Expeditable increase or decrease of N if 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.
10. Changes in data collection instruments (questionnaires, surveys, chart abstraction forms, CRFs) as long as expertise is not needed to assess risk-level change
11. Advertisements and other recruiting materials
12. Retention materials, newsletters, blasts, reminder cards, health tips related to disease being studied, participant alert cards, other miscellaneous items that do not involve changes to compensation,
13. Sensitive study determination requests, if not done when application was initially submitted
14. 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) is 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 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 EVENTS
   1. Acknowledgements per Maria Davila’s 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 Amendments 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 second opinion on exempt status)
  - Prospective F(5) new studies (need to get second opinion on consent/HIPAA waivers)

*In general, all staff should consider the benefit of sending other amendments to another reviewer, but may use their own judgment.*
## LOG OF SIGNIFICANT CHANGES

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<td>2/11/2015</td>
<td>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).</td>
</tr>
<tr>
<td>2/18/2015</td>
<td>Clarified what Data Analysis Only renewal reviews can be done by staff DR</td>
</tr>
<tr>
<td>4/2/2015</td>
<td>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 AM’s for increase N to make clearer.</td>
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<tr>
<td>2/18/2015</td>
<td>Changed title (Designated REVIEWERS, instead of Designated MEMBERS) and added Background/Policy. Clarified amendments 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).</td>
</tr>
<tr>
<td>9/16/2016</td>
<td>Minor corrections</td>
</tr>
<tr>
<td>12/2016</td>
<td>Clarified that Staff DR’s can review all expedited studies in Data Analysis Only (had been stated already, but not clearly)</td>
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SOP Title: Study assignment by Director or designee
SOP Category: Study Management
Established: 2/9/2018
Last Revision: 2/21/2018

PURPOSE
The purpose of this document is to detail the steps to follow before assigning a new submitted study to an IRB analyst.

SCOPE
The SOP applies to studies submitted to the Emory IRB

PROCEDURE

- Log in under “IRB Director” role
- Open “New Study Assignments [Year]” spreadsheet in “H:/Management/ Studies Assignments” folder
  - If not yet created, create new sheet on spreadsheet for the current week, by copying the previous week’s spreadsheet and renaming it, and deleting study titles and previous assignments
- Open each new study in the Director’s Inbox
- Copy and paste the study title hyperlink onto the Excel spreadsheet starting at the top row (and if desired, enter IRB study number)
- Use data in the “# assigned” column and the columns further to the right (which, if updated, display the volume of submissions each analyst received the preceding week) to decide how many items to assign each analyst. Also fill in and/or refer to “Status” column to note who is on vacation etc. and should not receive new assignments.
- Open each study to determine basic information, including:
  - Whether VA is a site: assign to VA liaison
  - Whether it is a CHOA-only medical record review: ask study team to withdraw and submit to CHOA IRB instead
  - Whether is an expanded access: assign to Team Leads for Q
  - Whether is an expanded access taking place at CHOA (even with Emory physicians): ask study team to withdraw and submit to CHOA IRB instead
  - WIRB studies: assign to analyst assistants in rotation
    - If it looks like an industry-sponsored trial without investigator COI, likely should have gone to WIRB instead. Assign to Analyst Assistant and log comment to study team alerting them that we are determining if it should go to WIRB and ask if they had a reason for not WIRB-ing.
  - CIRB studies: assign to analyst assistants in rotation
  - XIRB: assign to Reliance Specialist per Director instructions
  - If this is an Sponsor-Investigator study: needs to be assigned to an S-I specialist
  - If study involves REMS: alert the analyst who will be reviewing the study via private comment.
  - If study involves ICH-GCP: alert study analyst, and let OSP and Director (if not the one assigning) know
In Excel spreadsheet, write down very short note about the type of study if you have time (e.g. “MCCT” for Multi-center clinical trial, “Observational Peds Study”, “VA study”, “Chart review”…)

If the study is an investigator-initiated clinical intervention study, write “Y” in the column titled ‘Refer to MH/SD?’ (this is to alert the right people that the study team may benefit from an education session before starting the study; no further action is needed on our part as MH/SD can view the spreadsheet)

One you have chosen the analyst to assign the study to, enter their name in the “Assigned To” column (this column is coded to accept only the names in the “RPA” column, so names must be entered accurately).

- Check the time-off calendar or right-hand columns to see if an analyst is OOTO or on sick leave.

In eIRB, use “Assign Owner” to assign the study to an analyst.

Then do “Log Private IRB Comment” to inform the analyst that the study has been assigned to them, perhaps with a brief reference to the type of submission, and any other items you wish to alert them based on your scanning of the smartform prior to assignment.

If the study submission is in drastically bad shape, you may choose to assign the study to an analyst but then immediately request changes to have major revisions made before the IRB starts their real screening.

Note: Studies should be assigned each business day.

**PROCESS FLOW**

**LOG OF SIGNIFICANT CHANGES**

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DURING STUDY CONDUCTION

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<tr>
<th>SOP Title:</th>
<th>Chart Over-enrollment</th>
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<tr>
<td>SOP Category:</td>
<td>Study Management</td>
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<tr>
<td>Established:</td>
<td>March 2, 2016</td>
</tr>
<tr>
<td>Last Revision:</td>
<td>March 2, 2016</td>
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PURPOSE

The purpose of this document is to explain the process to follow when a study reports that they have accessed more charts than previously approved in the study protocol/IRB submission.

SCOPE

The SOP applies to chart-review studies approved by the Emory IRB.

RESPONSIBILITIES

- IRB analyst – screens chart review submissions initially to ensure compliance with current guidelines; requires changes to ongoing chart review protocols if they do not comply with current guidelines; determines (with study team) if there has been noncompliance due to accessing more charts than IRB originally approved, and referring case to Team Q.
- Study team – may be required to submit an amendment (AM) and/or reportable event (RE) under specific circumstances detailed below.

PROCEDURE

When screening or reviewing a renewal application for a chart review study, IRB analyst will note whether the application reflects “over-enrollment” of charts accessed for the study. If numbers of charts accessed are not provided in the application, application may be sent back to study team.

If a study team reports that they have accessed more charts than previously approved in the eIRB submission:

- If the study protocol does not have a number of charts to be reviewed, and this is only stated in the eIRB smartform (under Study Population section):
  - Verify that the dates of the chart review with the study team.
    - If the review period is the same, remove the number of charts from the submission, and log a comment to the study history documenting the process. The study analyst can do this administratively and a RE is not required.
    - If the review period is not the same (e.g., they have extended the review period without an AM), ask the study team to submit an AM to change the review period, and an RE to document the NC.
- If the study protocol document states the number of charts to be reviewed:
  - Verify the approved period for the chart review with the study team, and ask them to submit an AM to remove the chart number from the protocol.
    - If the review period is the same, a RE is not required. No additional actions are required.
    - If the review period is not the same (e.g., they have extended the review period without an AM), not only ask the study team to submit an AM to change the
review period and delete the number of charts from the protocol, but also ask for the submission of a RE to document the NC.

PROCESS FLOW

Report of excess of charts reviewed per eIRB submission
• If protocol does not have number of charts, remove number administratively
• If protocol have number of charts, ask for the submission of an AM.

Check if access period is the same approved by the IRB
• If period is the same, no additional actions are needed
• If period is not the same, a RE is required

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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 Team Leads.

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 an amendment to increase enrollment (if the study is closed to enrollment, the NC should be acknowledged, but no amendment 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 amendment 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 studies, please submit an amendment 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 Events 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**

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
</tr>
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<tr>
<td>9/16/2016</td>
<td>Added clarification about screening procedures</td>
</tr>
<tr>
<td>10/26/2017</td>
<td>Clarified purpose of SOP (including title)</td>
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SOP Title: Transferring Study Participants Between Study Sites

SOP Category: Study Management

Established: 11/10/2010

Last Revision: 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](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](http://www.med.emory.edu/research/resources/index.html) or [http://www.ott.emory.edu/forms/index.html](http://www.ott.emory.edu/forms/index.html)) and email the questionnaire to 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](http://www.ott.emory.edu/forms/index.html)). Faculty members should forward these documents via email to 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 amendment 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](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](http://www.med.emory.edu/research/resources/index.html) or [http://www.ott.emory.edu/forms/index.html](http://www.ott.emory.edu/forms/index.html)) and email the questionnaire to 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](http://www.ott.emory.edu/forms/index.html)). Faculty members should forward these documents via email to mta@emory.edu.

- Note: the IRB staff should let study team know but the submission process (amendment, new study) should continue.
- The approval letter should indicate that data must not be transferred until the agreement is completed.

**LOG OF SIGNIFICANT CHANGES**

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<td>10/3/2014</td>
<td>Updated information after OTT/ORC revised guidance</td>
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<tr>
<td>2/15/2017</td>
<td>Changed title and move comment to the end to avoid confusion about subject matter covered by SOP</td>
</tr>
<tr>
<td>10/26/2017</td>
<td>Adding information about data transfer, purpose, definitions, etc.</td>
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CONTINUING REVIEW

SOP Title: Continuing Review: CR reassignment
SOP Category: Study Management
Established: 9/22/2016
Last Revision: 5/29/2018

PURPOSE
The purpose of this SOP is to describe the process that research protocol analysts (RPAs) will follow when assigning continuing review (CR) submissions to their designated analyst assistants (AAs). In addition, this SOP will also cover the overall timeline for the process of these submissions.

SCOPE
The SOP applies to CRs assigned to AAs.

RESPONSIBILITIES
- AA – will review and process CRs assigned by an RPA
- RPA – will assign CRs to AAs following this SOP

PROCEDURE

CR Assignments
- RPAs will assign CRs to the AAs in succession, one CR per analyst until all the CRs has been reassigned. We require that the RPA keeps a tally of the reassignment to make sure all the AAs receive a similar amount of CRs per week.
- Every day, RPAs will go through their inboxes to assign CRs to the AAs. RPAs should aim for 2 business days to accomplish this task. If an RPA is out of the office for any reason, the RPA will contact their Team Lead for CR assignment before the leave.
- After re-assigning the CR, the RPA will log a comments to the study submission (if applicable):
  - Private comment: In this comment, the RPA will notify the AA if the study is conducted at Grady (because the ROC deadline would apply). They analyst may include any additional or urgent detail that seems important for the review as they see fit.
  - Comment to Study Team: with this comment, the AA may notify the study team that the CR was received and it is in process. Suggested language: Thanks for your submission. The continuing review application has been reassigned to me for further handling, and I will contact you if any questions arise during the review of your submission. If there are any urgent items that need addressing, please list them in a logged comment to the IRB staff.
- The AA will make sure CRs are reviewed under the following timelines, when CR’s are submitted to the IRB at least a month prior to expiration (if CR’s are submitted late, timeframes may be shifted accordingly):
  - For Full board CRs: The CR should be screened no later than 3 to 4 weeks of expiration and assigned to a committee meeting accordingly. Please choose a CR meeting no later than 2 weeks before expiration unless not possible.
  - For Expedited CRs: The CR should be screened and assigned to a reviewer no later than 2 weeks before expiration.
For studies conducted at Grady: Because Grady studies need a subsequent approval by the Grady Research Oversight Committee, which meets once a month, these submissions should be screened and sent for review as soon as they are received (even if far in advance of expiration).

- FDA regulated studies, which are also actively enrolling subjects, submitted after expiration or 5 business days before expiration cannot be reassigned.

Procedure for when an AA is on a planned leave (e.g. vacation leave)

- One week before the vacation leave, the AA will email the RPAs to let them know.
- The RPA should not reassign CRs that would expire between the vacation leave to one week after the person is back to the office. For example, if an AA is going on vacation between May 12 to 16 (Monday-Friday) and the CR arrived on May 12 and would expire on a date between May 12 to 23 (M-F), the CR should not be reassigned to the AA.
- AAs will reassign back to the RPAs CRs that were already processed but that will be reviewed at a FB meeting on the week of the vacation leave. In addition, AAs will reassign back CRs waiting for DR review if the review was not completed before the vacation leave. If the RPA is unable to release an approval letter during the vacation time or a CR was not reviewed by the DR during the vacation leave, the CR submissions can be reassigned back to the AA.
- This procedure is designed to prevent approval lapses and to provide approval letters in a timely manner.

PROCESS FLOW FOR CR ASSIGNMENT

RPA assigns CR to AA in 2 business days

RPA logs private comment if Grady Study

AA reviews CR per designated time

LOG OF SIGNIFICANT CHANGES

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<td>Revisions after RPA-TL meeting</td>
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<tr>
<td>2/6/2017</td>
<td>Revisions to reflect current re-assignment process</td>
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</table>
CR Screen Process

1. You can find the CRs assigned to you in your inbox. For CRs that required PI changes, click on the “AM-CR-RE-Term” tab:

   - AM-CR-RE-Term
   - CR Reviews
   - Documents
   - Change Log

2. Have the Continuing Review Worksheet accessible while reviewing a CR application.
   a. If the study is using a humanitarian use device, review the HUD studies SOP.
   b. If applying the 30-day rule, please reference the CR: 30-day rule SOP. As a reminder, the 30-day rule cannot be use if the study is still enrolling subjects.

3. Review the last two CR applications to reconcile:
   a. Enrollment status: review past years to make sure the selection is correct. For example, we should inquire if the study team selected “only in data analysis” one year and changes to “long term follow up” in another.
   b. Enrollment totals: if there are number discrepancies, we need to ask the study team to provide an explanation. If there is an over-enrollment over the IRB approved number (that information will populate from the IRB submission in question 5.0), the study team will need to submit a reportable event (RE) if the subjects underwent study procedures (including fasting before medical procedures or surveys). Accessing data (approved under a partial HIPAA waiver) is not considered study participation. If the subjects were screen failures, with no research participation (only consent signature), use this excel sheet to document the over enrollment (a RE will not be required). The use of the excel sheet is only required when a RE will not be submitted as explained before. Review the SOP entitled: Over-Enrollment Via Consent (No Research Activities including during Screening) for more information.
   c. Review category: check AMs in the last approval period in case there has been any changes requiring a new risk change. For example, if via an AM a study added an activity considered more than minimal risk, the study will need to go to full board even if it was previously considered expeditable.

4. Reportable events: check this chart to verify that the study team is only reporting appropriate events at continuing review. If the information the study team is sending do not include information about relatedness to study participation, or it is confusing, ask them to complete this excel form. If the study team is reporting events that are not required, ask them to withdraw from the application.
If the study team is asking for an acknowledgment of those events, they should submit a reportable event.

5. **DSMB reports:** check study submission and protocol to verify if the study has a DSMB and how often they meet. If the study meets more than once a year, they will need to submit the same amount of reports per meeting.

6. **CITI certification and other training:** check the study submission to check that all study personnel is CITI certified or have completed additional required training. Check specially study staff added through our online tool as CITI or additional training was not verified for that process. For more information about this process, check the SOP entitled: *Training Verification.* If not adequately trained, refer to Team Q and request a RE.
   a. Ask the study team to let you know if any member listed in the initial submission is no longer working in the study. This may help with the amount of CITI verifications you may need to do.
   b. We suggest to run a report in the CITI website, if the study staff number is numerous. Click [here](#) for instructions.

**Full Board Committee Review**

1. If a study requires review at full board, fill out the “**CR xx Study xxxxx**” Omnibus Form. Complete and upload the CR Omnibus form under the meeting notes folder as soon as possible, but not later than required my meeting facilitator per their email.

2. If an AM is also open at the same time:
   a. Minor amendments (like staff changes other than PI) can be processed right away – see IRB P&P’s for the kinds of amendments you can approve yourself.
   b. Others can be processed with the CR. Any amendment that alters consent form should wait to be processed with the renewal, unless study team requests otherwise. Use the “**AM/CR Pair for study**” omnibus form in these cases. If the AM and CR are owned by different IRB staff, you would need to collaborate so you add one form to the committee meeting.

3. Click “Schedule for Full Committee.” Choose a committee date that is ideally a of couple weeks before expiration (one week may not be enough, as there may be pending issues). Screen CR upon receipt to avoid delays in review or missing items (such as required reports).

4. Indicate that it is a “Full Board - Continuing Review.” Also keep in mind specialties, though that’s not as important for CR’s.

5. For the Agenda Item Notes include:
   - Title:
   - PI:
   - Special Population:
   - VA: Yes/No
   - Pertinent Comments:
   - FDA Regulated
   - Risk at last review (*including AMs in the same approval period*):
   - Previous approval period

6. If changes are required after assigning to committee, consider the following:
   i. If changes are minor or only require the attachment of documents, you may do the changes/additions for study team
ii. If changes are substantive, take study out of committee and ask study team to do the changes. Inform the study facilitator to ask to keep spot on CMTE while the study team works on changes. Inform the study team that the changes need to be submitted 7 working days before CMTE meeting, to avoid delays in review/expiration.

7. Once the meeting facilitator has reconciled the meeting notes and omnibus forms and releases the agenda for letter writing, review the applicable omnibus forms to obtain pending contingencies or deferred items.

8. Click “Record Meeting Minutes” and insert the following information:
   a. Motion (approved, pending or deferral)
   b. Vote
   c. Risk level
   d. Approval period
   e. Subparts and waivers if new
   f. Whether it is AVAMC study.
   g. Click “OK.”

9. After the meeting, the CR could be approved as is, or pending/deferred changes may be needed.
   a. If the CR is pended or deferred:
      i. Write letter to study team, using the appropriate template. Make sure you include all the required changes noted in the omnibus form after the meeting under the “pending/deferral issues” in the CR omnibus form
      ii. Once the study team has submitted the requested changes, review materials to assess that the changes have been made.
         1. If Pending Contingencies have been met, send to the Vice Chair of the committee that originally reviewed the CR application to complete the Contingency Review. Send email to Vice Chair to notify him/her of the contingency review with a link to the specific CR. If contingencies are approved, you may issue approval letter and release updated consent/HIPAA documents as indicated below
         2. 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 FB, you may issue the approval letter and release updated consent/HIPAA documents
   b. If the study was approved during FB meeting or all pending/deferred items have been reviewed and approved as applicable
      i. Click “Set Expiration Date” and enter the date the CR was approved and the expiration date based on committee decision (e.g. 1-year, 6 months, “after X numbers of patients have been enrolled”). Also set the Risk Level “No more than Minimal Risk” if determined to be minimal risk.
      ii. Approval Date – The Approval Date is the date the study was reviewed at full board (for approved, pending or deferred);
      iii. Expiration Date – If using the 30 day rule (see “Continuing Review: Applying 30-day window” SOP), Expiration Date will be the same date, plus one year, as the prior Expiration Date. Otherwise: the Expiration Date is based on the approval period determined by the
Committee (which does not necessarily relate to the risk level, but default for minimal or standard risk studies is one year, if the reviewer does not specify). See omnibus form from meeting. Set Expiration Date based on the meeting date (i.e. “Approval Date”), not the effective approval date.

iv. Click “Draft Letter,” and follow steps under “Drafting letter” section below.

v. Do NOT Merge consent forms in the CR workspace.

vi. Log a comment to the study team to let them know stamped-approved renewed informed consent documents are available under the “Documents” tab in main workspace and include the Customer Service Satisfaction survey link:

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. You can access the survey by copying the link below and pasting it into your web browser. We appreciate your feedback!
https://www.suremonkey.com/s/PY2KYLR

Expedited Review
1. Assign a reviewer by clicking on “Assign Expedited Reviewer”

2. Select a reviewer from the drop down menu. You may assign some CRs to a staff reviewer; make sure you follow the SOP entitled: “Categories of Research Reviewable by IRB Staff as IRB Designated Members”. In addition, review OHRP guidance for expedited review before assigning to a reviewer.

3. When assigning, you may suggest review categories based on your review. Make sure that you do not imply that is the category to be used as the member should do their own review. If the category is obviously wrong, or not listed, contact your TL or Director about this.

4. After the CR has been reviewed, in the CR workspace, follow steps below when approval is pending:
   a. Review the designated reviewer’s comments, determinations and changes requested.
   b. If there are changes requested by the designated reviewer, and the review was submitted, you will need to issue a letter so the study team can correct the submission
   c. Once the study team has submitted the requested changes, review the submission to assess that the changes have been made.
   d. If pending contingencies have been met, send to the designated reviewer that originally reviewed the CR application to complete the Contingency Review. Send an email to designated reviewer to notify him/her of the contingency review with a link to the specific CR.

5. If the study was approved by the DR/or contingencies were submitted:
   a. Click “Set Expiration Date” and enter the date the CR was approved by designated reviewer. For contingencies, use the date last date when the designated reviewer approved the changes requested.
   b. Report to Committee - Select Meeting – use a meeting that will take place in the future (not past meetings); report to CMTE C if designated reviewer approved a SHB study, or report to any A or B committee for biomedical studies.

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c. Draft letter. Follow Drafting letter section in this SOP.
d. Click “Obtain Signature” and make sure to select your own name in the pop-up window
e. Click “Send Letter to PI”
f. Do NOT Merge consent forms in the CR workspace.
g. Log a comment to the study team to let them know stamped-approved renewed informed consent documents are available under the “Documents” tab in main workspace and include the Customer Service Satisfaction survey link:

   *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. You can access the survey by copying the link below and pasting it into your web browser. We appreciate your feedback!* [https://www.surveymonkey.com/s/PY2KYL](https://www.surveymonkey.com/s/PY2KYL)

**Drafting letter (after FB or DR review)**

1. Choose the appropriate letter template (approved/pending/deferred) and make the following edits:
   a) Remember to include the PI’s post-nominal (degree – MD, PhD, MPH, etc.). 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](https://www.emory.edu).
   b) Insert the letter date, spelled out (e.g. April 15, 2015) – the date the letter is being composed.
   c) If using the 30 day rule, see the “Continuing Review: Applying 30-day window” SOP for letter content.
   d) If you are issuing a pending/deferred letter, make sure you include the information requested in the DR review or omnibus form and jump to step “g”.
   e) If the CR was previously approved pending changes by the Full Board, edit text so it reads, “The above referenced renewal was reviewed and given pending approval under the Full Board review process by Committee___ on **3/11/2015**. This approval became effective on **3/25/2015** after all pending issues were addressed…”
   f) If the CR was previously deferred by the Full Board, no text edits are required because the approval date will be the date of the meeting that the deferred issues are approved (unless it was thereafter given pending approval, at the subsequent meeting, and then final approval)
   g) Insert the letter date, spelled out (e.g. April 15, 2015) – the date the letter is being composed. Revise the list of template letter items and only include the following issues that were determined:
      a. Specific document versions and approval dates: protocol and informed consent
      b. Any other specified requirements by the board or reviewer (e.g. DSMB report was not reviewed because the DSMB has not met yet, and the FB requires the submission of an amendment at a later date)
   h) Use formatting tools to add bullets to the list of changes made. Remember to reset & resize the font of the “CC:” section at the bottom of CR letter if needed.
   i) Delete the template letter language that does not apply to the current CR and remove rows that state “No Items to Display.”
   j) ENTER NAME OF LETTER SIGNATORY (Do **NOT** Bold) – again, this should be your own name and title.
   k) Click “Obtain Signature” and make sure to select your own name in the pop-up window
   l) Click “Send Letter to PI”
Consent Form Release (if applicable)

1. After sending the approval letter, go to the main study workspace by clicking the main study link in the breadcrumb trail (shown below)

2. Delete previous consent versions by clicking on “Edit Consent Forms”
   a. Under “Approved consent forms”, select the document(s) that is/are being replaced or are no longer in use.
   b. Click “Delete” – this action will remove the documents from the study documents tab
   c. Under “Draft consent forms” remove any outdated versions of consents, and any highlighted versions of the new consents.
   d. Click “OK”

3. Click “Consent Form Merge”
   a. Only select the documents that are to be renewed or were amended (modified) – if applicable
   b. Ensure that the approval date and expiration date are correct; i.e., matches the approval date of the approved CR, and expiration date of the overall study. If they don’t, enter the correct date(s).
   c. FOR FULL BOARD STUDIES THAT WERE ORIGINAL PENDING: insert the final approval date (effective date contingencies approved) as the approval date on the consent form only.
   d. Click “OK”

4. Ensure that all merged documents are merged appropriately by opening them from the “Documents” tab.

5. Log a comment to the study team to let them know stamped-approved amended informed consent documents are available under the “Documents” tab in main workspace and include the Customer Service Satisfaction survey link:
   Your submission has been approved. [if applicable, add “Your stamped-approved, renewed informed consent forms are under the "Documents" tab to the right of the "History" tab on the main study page. Feel free to contact me if you have difficulty accessing the files”.]

   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. You can access the survey by copying the link below and pasting it into your web browser. We appreciate your feedback! [link]

If an AM is opened and approved while a CR is still in process
If an AM was approved at the same time as a continuing review, process the continuing review first (skipping the “consent form merge” step until after the AM is approved too), then process the AM.

If an AM is opened while a CR is still in process, the system may revert any stamps made in documents. To avoid any issues, the CR should be processed first, then you may proceed with the process of the AM.

**LOG OF SIGNIFICANT CHANGES**

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<td>12/2/2016</td>
<td>Clarified how to determine expiration date; what to put in CR approval letter (removed some bullets); referred to 30-day window SOP</td>
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<tr>
<td>5/5/2017</td>
<td>Clarified some steps in process and added required language under FB approval letter</td>
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<tr>
<td>7/14/2017</td>
<td>Formatting and additional guidance on letter writing, comment logging.</td>
</tr>
<tr>
<td>5/17/2018</td>
<td>Revamp for readability</td>
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Appendix 1. Process Map
**SOP Title:** Continuing Review: Applying 30-day window

**SOP**

Study Management

**Established:** 10/14/2012

**Last Revision:** 1/31/2018

**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: Set approval date and expiration date after CR is approved**

![Set Approval Period](image)

Please provide an Approval and Expiration date for this study.

* Approval Date:
  
  6/26/2012

  The approval date should be the:
  Meeting Date for Full Board
  The date reviewed by the Designated Reviewer for Expedited and Exempt

* Expiration Date:
  
  7/1/2013

  The expiration date should be:
  One Year minus 1 Day for Full Board (not High Risk)
  One Year minus 1 Day for Expedited
  (EXAMPLE: Approval Date = 02/05/06 Expiration Date = 02/04/07)

No expiration date for Exempt
As set by the committee by Full Board High Risk

* Select the Research Risk:
  - No more than minimal risk
  - Standard risk
  - HIGH RISK
“Set approval period”
(1) “Approval date:” Key in the date the **review date**, which in this scenario is **6/26/2012**.
(2) “Expiration date:” Key in the new **expiration date** (7/1/2013 in our scenario)

Be sure to check the approval period granted by the reviewer/full board, if less than one year.

**Step 2: The approval letter**
1. Start a new paragraph where the template letter starts to refer to the review date and approval period.
2. Begin the new paragraph with the language at bottom.
3. Enter the review date as well as the new effective approval period, which would be **7/2/2012 - 7/1/2013** in our scenario above.

Language for 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.*

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<td>Major overhaul, limits scope of when to use 30-day rule</td>
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<tr>
<td>11/1/2017</td>
<td>Revised language to mirror eIRB</td>
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<tr>
<td>1/31/2018</td>
<td>Date fix in example</td>
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SOP Title: Continuing Review: REs/PDs/Noncompliance and Monitor Reports
SOP Category: Study Management
Established: 2/14/2012
Last Revision: 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 Event (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**

<table>
<thead>
<tr>
<th>Summary of Reporting Timelines</th>
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</thead>
<tbody>
<tr>
<td>Unanticipated problems</td>
</tr>
<tr>
<td>Reportable protocol deviations</td>
</tr>
<tr>
<td>Internal deaths considered related</td>
</tr>
<tr>
<td>Internal deaths considered unrelated</td>
</tr>
<tr>
<td>Internal related events (not UPs)</td>
</tr>
<tr>
<td>External* SAEs that are not UPs</td>
</tr>
<tr>
<td>External* deaths not related or UPs</td>
</tr>
<tr>
<td>Noncompliance</td>
</tr>
</tbody>
</table>

*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 event, 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 events 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.

- 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 Event. 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 the QTL and the website guidance

What should be removed from the CR and submitted as a RE (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 event.

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 RE 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 RE 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 RE 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 RE 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 or 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 event submission”

LOG OF SIGNIFICANT CHANGES

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/3/2014</td>
<td>Added step of removing monitor report from submission; updated links</td>
</tr>
<tr>
<td>8/12/2015</td>
<td>Revamped this SOP to include what to report and what not to report at CR, as well as procedures to deal with events</td>
</tr>
<tr>
<td>11/1/2017</td>
<td>Administrative updates and suggested language for notifying teams of information removal of information</td>
</tr>
</tbody>
</table>
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 Event 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. 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 event. 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 event. When submitting the event, the study team should be asked to clarify whether the staff in question 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 event 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 event 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 RE 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 event. 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**

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</thead>
<tbody>
<tr>
<td>8/5/2015</td>
<td>Clarified that studies should not be sent to 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 website</td>
</tr>
<tr>
<td>9/16/2016</td>
<td>Updated terminology for the Clinical Research Training (formerly Key Concepts)</td>
</tr>
<tr>
<td>4/20/2017</td>
<td>Clarified what “correct” meant</td>
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</table>
SOP Title: Sponsor/Sponsor-Investigator at Emory Holding an IND/IDE: Review of Studies Involving Emory University

SOP Study Management

Established: 7/26/2012

Last Revision: 2/21/2018

PURPOSE
The purpose of this document is to describe the review process of 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.

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

DEFINITIONS
- **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].

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 Form, 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 Form is complete and accurate, according to the
study protocol submitted to the FDA.

PROCEDURE FOR NEW STUDIES
Once a new study has been identified as one having an IND or significant risk IDE (held by an Emory
investigator as Sponsor or S-I), the IRB analyst will contact the ODP via email, alerting him/her about the
new study while logging a comment in the study history to document this communication. The IRB
analyst will notify the Sponsor/S-I to contact the ODP for training, and to provide additional information
about the study IND/IDE. The ODP will provide training about specific Sponsor/S-I responsibilities, and
will request that the Sponsor/S-I complete the Emory S-I IND or IDE Responsibility Form. The IRB analyst
will notify the ODP if the study involves an expanded access IND or IDE, the IRB analyst will notify the
ODP, but will not need to notify the S-I to contact the ODP to receive training, as the requirements are
minimal, and hence additional training by the ODP is not necessary.

If the study team received an IND 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 on a full board agenda until we receive all requested updates from FDA. These changes
should be uploaded under the drug section (except for protocol/ICF that have a section in eIRB).

When the study is ready for Full Board (FB), the IRB analyst will forward it to the FB, adding in the
omnibus meeting materials the following information: 1) S-I has/has not received training; 2) The IND or
significant risk IDE holder has/has not completed the Emory S-I Responsibility Form; 3) the Emory S-I
Responsibility Form has /has not been uploaded into the study record. The study can still be assigned
to a FB committee meeting without ODP notification of the completion of the Emory S-I Responsibility
Form and/or training; however, this will be a pending issue by the committee, barring mitigating
circumstances.

Once S-I training and the Emory S-I Responsibility Form are completed, the ODP will notify the IRB
analyst via email and will attach the completed Emory S-I Responsibility Form in eIRB under section 6.0
in the Drug section or section 8 in the Device section as applicable. The ODP will also log a comment in
the study history regarding completion of the form and status of S-I training before Full Board review, if
possible.

For studies with an Emory investigator as Sponsor that include non-Emory sites, the Emory sponsor will
complete the appropriate multi-site Responsibility Form(s). If the non-Emory sites include international
sites, the Emory sponsor must provide the IRB with assurance that they are aware of international
regulations and have appropriate processes in place. For interventional clinical studies, specifically studies with investigational drugs, the IRB should stipulate that the sponsor will need a CRO or legal counsel review prior to initiating the study at the international site. Moreover, clinical studies require international site IRB/EC review. The Emory IRB will ask the international site IRB/EC for a list of considerations regarding the use of investigational drugs along with applicable laws. The IRB analyst should contact Kris West in OC before sending the study to full board, as a CRO and/or consult with the general counsel may be necessary. The IRB analyst will work with the ODP to obtain the required documentation. The ODP will also log a comment in the study history regarding completion of the S-I Responsibility Form and status of S-I training before Full Board review, if possible.

**PROCESS FLOW (NEW STUDIES)**

1. **Emory investigator holding IND or significant risk IDE submits new study to IRB for review**
2. IRB analyst notifies ODP about study, and Emory Sponsor/S-I to contact ODP
3. ODP provides training, forms to complete
4. ODP uploads forms to study record

**PROCEDURE FOR CONTINUING REVIEWS**

At continuing review, the IRB analyst will request that the Emory Sponsor/S-I holding an IND or significant risk IDE complete the appropriate Emory Sponsor-Investigator Responsibility Form Continuing Review Update and forward to the ODP. The ODP will review the form to confirm that processes are in place so that Sponsor/S-I responsibilities are being met. 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 DSMB report. Once the Emory Sponsor-Investigator Responsibility Continuing Review Update is complete and the ODP has confirmed that the processes are in place to meet S-I responsibilities, the ODP will notify the IRB analyst via email and will attach the completed Responsibility Form in eIRB under section 7.0 in the Research Findings section and log a comment in the continuing review workspace in eIRB. If the study is in data analysis only, the Sponsor-Investigator Responsibilities form is not required.

At continuing review, 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 omnibus meeting materials: 1) S-I has/has not completed the Emory Sponsor-Investigator Responsibility Form Continuing Review update if required; 2) ODP has/has not confirmed that processes are place to meet S-I responsibilities, and 3) the status of the IND/IDE annual report submission.

**PROCESS FLOW FOR CONTINUING REVIEW**

1. **Emory investigator holding IND or significant risk IDE submits continuing review to IRB for review**
2. **IRB analyst will ensure IND/IDE annual report is included in the CR submission, requests Emory S-I Responsibility Form Continuing Review Update and forwards to ODP**
3. **ODP reviews and confirms processes are in place and that S-I responsibilities are being met**
4. **ODP notifies IRB analyst via email and upload completed form as a logged comment in CR workspace in eIRB**
5. **IRB analyst forwards to FB, adding information in omnibus meeting materials**

**PROCEDURE FOR AMENDMENT 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.*

- **ADDING NON-EMORY STUDY SITES**

The IRB analyst will request that the Emory Sponsor/S-I holding an IND or significant risk IDE complete the appropriate Multi-Site trials information form(s) and forward it to the ODP. The IRB analyst will ensure that any non-Emory study sites, for which the Emory sponsor has oversight, are listed in the eIRB submission Study Site section (with documentation of the non-Emory study site’s IRB approval, if available) and that the protocol and DSMP are modified appropriately. The IRB analyst will also request that the Emory sponsor confirm that the submission of an IND amendment or IDE supplement to the FDA for the additional investigator/site.

Amendments that include international sites require that the Emory sponsor provide the IRB with assurance that they are aware of applicable international regulations and have appropriate processes in place. For interventional clinical studies, specifically studies with investigational drugs, the IRB will stipulate that the site will need a CRO or legal counsel prior to initiating the study at that site. Clinical studies require international site IRB/EC review. The Emory IRB will ask the international site IRB/EC for a list of considerations regarding the use of investigational drugs along with applicable laws. The IRB
analyst should contact Kris West in OC before sending the amendment to Full Board, as a CRO and or consult with the general counsel may be necessary. The IRB analyst will work with the ODP to obtain the required documentation.

The ODP will review the Responsibility Form 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 Emory Sponsor and make the IRB analyst aware of any significant concerns. Once the Multi-site trials Responsibility form(s) is complete and it is evident that processes are in place to meet Sponsor responsibilities, the ODP will notify the IRB analyst via email and will edit the amendment in eIRB to include the completed Responsibility form(s) under section 6.0 in the Drug section or section 8 in the Device section, as applicable. If the ODP does not have editing capabilities in the amendment, the IRB analyst will complete this task. The ODP will also log a comment in the amendment study history regarding the completed form(s) before Full Board or designated review.

For amendments that are ready for Full Board review, the IRB analyst will add it to a meeting agenda and include the following information in the omnibus meeting materials: 1) S-I has/has not completed the Multi-site trials information form(s) noting if international sites are involved. If this is not in place prior to the Full Board committee meeting, this may be deemed a pending issue.

- **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 Form (if changing Sponsor) and forward to the ODP.

The ODP will review to confirm that processes are in place so that S-I 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 Form 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 amendment in eIRB to include the completed form(s) under section 6.0 in the Drug section or section 8 in the Device section, as applicable. If the ODP does not have editing capabilities in the amendment, the IRB analyst will complete this task. The ODP will also log a comment in the amendment 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 the change in 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 a 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:
    1. 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.
    2. Any significant change in the design of a protocol (such as the addition or dropping of a control group).
    3. 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... prior to implementing a change to an investigational plan, unless the change does not affect:
    1. 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;
    2. The scientific soundness of the investigational plan; or
    3. The rights, safety, or welfare of the human subjects involved in the investigation.

**PROCESS FLOW (AMs)**
PROCEDURE FOR CLOSE-OUTS

- 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 prior to 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, RE 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)

| Emory investigator holding IND or significant risk IDE submits close-out for acknowledgment | IRB analyst will request final FDA report and close-out of IND/IDE. | If no report available, study held open an CR is submitted. If study has lapsed, CR is accompanied by RE for lapse. | Once report is received, close-out is processed as normal (see Close-Out Processes) |

REFERENCES

- 21 CFR § 312
- 21 CFR § 812
- IRB policies and procedures
- Emory Sponsor-Investigator IND Responsibility Form
- Emory Sponsor-Investigator IDE Responsibility Form
- Emory Sponsor-Investigator Responsibility Form Continuing Review Update
- Emory Sponsor-Investigator Responsibility Form Multi-site trials information form

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<tr>
<td>6/1/2015</td>
<td>Update in definition and process to reflect current practices</td>
</tr>
<tr>
<td>9/16/2016</td>
<td>Updated to include close-out process</td>
</tr>
<tr>
<td>5/5/2017</td>
<td>Clarified that changes of PI/SI do not need to go to FB</td>
</tr>
<tr>
<td>2/21/2018</td>
<td>Adding the need to ask for additional information when we are provided with an IND letter pending contingencies. Adding a clarification that a DSMB report is required at CR, if applicable</td>
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CLOSE OUT

SOP Title: Close-Out Processes
SOP Category: Study Management
Established: 7/21/2014
Last Revision: 11/1/2017

PURPOSE
To outline the processes for closing out a study in eIRB, including:
1. Initially determining eligibility
2. Close-outs initiated by a PI
3. Close-outs processed administratively
4. 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: please do not call close-outs “terminations” as the latter term has a precise regulatory meaning that involves reporting to OHRP. Disregard how eIRB occasionally refers to them as terminations.

Determine Eligibility
- If it appears that a study should be closed out, you first want to determine:
  - Are they still following up with subjects?
  - Are they only analyzing de-identified data?
- If they are still analyzing data, email or log a comment to the PI to determine whether the data includes identifiers:
  - If it does NOT include identifiers (completely deidentified), they can choose to close out the study and continue data analysis.
- They should submit a Close-Out in eIRB and attach a brief summary to indicate that the data is de-identified, all links are destroyed, and there will be no follow-up with subjects.
  - If the data DOES include identifiers, and they are continuing to analyze the data, then the study must remain open and be renewed.
- Sample email/logged comment to the PI:
  - Non-FDA regulated: “Thank you for submitting a renewal application for this study. It appears that this study is in the data analysis and publications phase. Can you please let me know if the study data has been anonymized at this time, such that you do not retain any links to identifiers, and whether all subject follow-up is complete? If the identifiers have been completely destroyed and follow-up with the subjects is complete, then you can likely close out the study, even if you are still preparing manuscripts for publication. Consider Emory retention policy when making plans for data storing. You can find more information at http://records.emory.edu/retention-schedules/categories/research.html. Once a study is closed, it may not be reopened except under very special circumstances. Thank you!”

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FDA-regulated: “Thank you for submitting a renewal application for this study. It appears that this study is in the data analysis and publications phase. Can you please let me know if all subject follow-up is complete? If the data has been stored (and it is not being accessed) and follow-up with the subjects is complete, then you can likely close out the study, even if you are still preparing manuscripts for publication. Be aware that for FDA trials, you should not destroy collected data. Also, consider Emory retention policy when making plans for data storing. You can find more information at [http://records.emory.edu/retention-schedules/categories/research.html](http://records.emory.edu/retention-schedules/categories/research.html). Once a study is closed, it may not be reopened except under very special circumstances. Thank you!”

- Check on the main page to confirm if there are any open submissions for Continuing Review, Amendment, Reportable Events, or a duplicate close-out. If there are open submissions, these must be completed before the Close-out can be processed. For a duplicate submission, you will select “Withdraw Close-out Request” from the activities and select “Duplicate” for the reason for withdrawal. Also, check to ensure that the study has not lapsed in approval. If it has, confirm with the PI if any HSR activities have taken place since the lapse.

**Close-Out Initiated by the PI**

- Close-Outs should be reviewed and feedback sent to PI within 5 business days.
  1. Review data in smartform.
  2. Has the PI given a reason for the close-out?
     a. If not, request it. Acceptable replies include, for example: data analysis with identifiable data is finished; funding not secured; PI moving.
  3. Copies of manuscripts/articles are fine but not required.
  4. If the PI submits manuscripts/articles, check the following:
     a. Approved N versus number of enrolled subjects described in article
     b. Approved study design/procedures versus study described in article
  5. If you find discrepancies, ask PI to clarify. If it appears that noncompliance may have occurred, consult the Education/QA team.
     a. QA consultant may reassign study to him or herself depending on complexity of review.
  6. If no discrepancies exist and/or all issues are resolved, complete close-out according to the steps outlined below under “Close-Out Process in eIRB.”

- If the PI is unresponsive, see the “Close-Out Administratively” section below.

**Close-Out Administratively**

- Before administratively closing out an eIRB study, every effort should be made to contact the PI and have them a) respond to pending issues, b) renew an expired study, or c) close out an expired study. If, after several attempts, you have been unable to get any response from the PI, then proceed to administratively close (not withdraw) the study.
- This process should also be used when a study team can create a close-out form, but the PI has departed and cannot submit it.
- Efforts to contact the PI / study staff should be evident in the history of the study.
• Provide the PI/study staff with a date by which they must respond/take action. Let them know that if response/action has not happened by that date that the study will be administratively closed out.

• To administratively close out a study:
  1. Log a comment to the PI that “Effective today, this study has been administratively closed out due to lack of response from the PI/study team.”
  2. Forward a link to the study to a Super User so they can create (if needed) and submit the close-out request on behalf of the PI.
  3. Continue with the normal close-out processing steps outlined below.

**Close-Out Process in eIRB**

1. Log into eIRB
2. Click on the name of the IRB Close-Out
3. Click Printer Version - Verify that uploaded documents have been uploaded

4. If documents are incomplete, click Requested Changes by IRB Staff

5. If documents are complete, click Forward for Expedited Review

6. Assign Expedited Reviewer (normally, the IRB Staff member who owns the study)

7. There will not be a Review Project created. Close-outs are processed like contingency reviews.

8. The reviewer will Submit Review. Select “Approved- no changes needed”

9. Once the review has been completed, finish processing

   a. Click on “Draft Letter”. You will select from the drop-down menu either “IRB Close-out by PI” if the PI has submitted the report or “IRB Close-out Administratively” for administrative close-out’s. The letter only needs to include the close-out day (the day you process approval) and your name.
b. Click on “Obtain Signature”, once the letter has been drafted, select your own name, and click “OK”.

c. Click “Send Letter to PI”.

d. Click “Report to IRB Committee Meeting” and select “Report to Committee – Close Out.”

10. If the IRBA is signing the letter click Send Letter to PI

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUMMARY OF SIGNIFICANT CHANGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/15/2014</td>
<td>Merged 3 separate close-out related SOPs into one single SOP, but no significant content changes</td>
</tr>
<tr>
<td>11/1/2017</td>
<td>Adding FDA and Non FDA studies, and other administrative changes</td>
</tr>
</tbody>
</table>