



# Researcher Guidance COVID-19 and IRB Review



## Introduction

**In this unusual circumstance of pandemic illness, it may be necessary to urgently modify research study procedures. New protocols may also need prioritized IRB review.**

### **Addressed in this Guidance:**

- When and how must the Emory IRB be notified of changes to approved research?
- When may prior Emory IRB approval *not* be needed?
- How quickly can the IRB review new COVID-19 protocols?
- Will Emory IRB's review capacity be impacted due to Emory's closures?
- What are my Informed Consent options, electronic and other?
- What if we experience a decrease in the workforce and our approved study team cannot cover study visits?
- What if I need to request an expanded access use for patient treatment?
- Links to additional resources

## Changes to Ongoing Studies

- Changes in IRB-approved research must be submitted to the IRB. Normally, changes may **not** be implemented before IRB review and approval.
- An **exception** is when changes are necessary to **eliminate apparent immediate hazards** to the subject, or the research staff.
  - Complying with Emory's latest policies halting non-essential research and avoiding in-person contact aligns with this exception.

Eliminating immediate hazards may include:

- actions to reduce potential exposure to COVID-19, or
  - to continue to provide medically necessary study care (including study drug) to participants who have been placed in isolation or quarantine, or
  - measures to eliminate immediate hazards to research or clinical staff
- When such urgent changes are necessary: *Most* (not all) must be reported to the IRB as **with a "Reportable New Submission" (RNI)**
    - At Emory, this must be done within **10 business days**. Sponsor and FDA notification may also be required.
    - See *specific examples* in the table below – and a note about external IRBs.





# Emory IRB Guidance

- Consent forms: A revised consent form is not required for urgent changes unless the change fundamentally alters what the participants consented to. You can inform participants via other means.
    - Consent form process changes should be approved by the IRB (e.g. if adding the option to enroll a subject over the phone or with the use of electronic signature)
  - The IRB encourages you to keep *careful tracking of all protocol deviations* related to the pandemic.
- **Modifications** are required whenever: (a) the changes do not meet the above criteria; (b) there is enough time to obtain IRB approval, or (c) the changes are urgent (thus require a protocol deviation), but also need to be **sustained** for multiple visits/subjects.
- The **Modification** can include: a revised version of the protocol, or simply a **letter, memo or other document** describing temporary changes

**External IRB Review:** Studies under review by an **external IRB** must follow the guidelines of that IRB. See the bottom of this webpage for links to major IRB websites. The reviewing IRB’s guidelines may differ.

Contact the analyst or customer service for your IRB of record, and/or see the following webpages for these IRB's:

- NCI CIRB: <https://www.ncicirb.org/announcements/covid-19-and-cirb>
- Western IRB (WIRB): <https://www.wcgclinical.com/changes-to-research-made-in-response-to-covid-19/>
- Advarra: <https://www.advarra.com/about-advarra/news/impact-of-coronavirus-outbreak-on-protocols-under-advarra-irb-review/>

**Specific examples with IRB requirements** (dependent on whether changes must occur before and/or after IRB approval):

Adding COVID-19 screening before in-person visits	<i>No IRB submission needed if data not used for research purposes</i>
Subject infected by COVID-19, unrelated to study participation	<i>No RNI submission needed. You need to inform your sponsor as usual.</i>
Using phone or telehealth instead of in-person visits	<i>RNI or MOD not required if using Emory Zoom account (only telehealth approved software). Study team needs to log a comment letting us know they are starting telehealth.</i>





# Emory IRB Guidance

Using home visits or using a telehealth software <a href="#">not approved by LITS</a> .	<i>RNI if done prior to IRB review, and/or a Modification if planned for future visits – ensure any software is compliant with Emory policy</i>
Notifying subjects of changes to procedures/visits due to pandemic, via phone or letter (note: if email, must be encrypted)	- <i>No IRB submission needed if communication is limited to scheduling information.</i> - <i>Modification if includes instructions for continuing any procedures at home or other sites.</i>
New enrollment via e-Consent or verbal consent	<i>RNI if used prior to IRB approval. Modification if this will be done going forward. Must use <a href="#">current LITS-approved software</a>. Please, also <a href="#">reference this guidance</a> to know if you need LITS review if using different software.</i>
New enrollment or re-consent via encrypted email, mail or fax, with wet signature method (physically signing document and sending copy back)	<i>No IRB submission needed (unless other procedures also moving to remote). Note: You must conduct the consent discussion via phone or videoconference unless the IRB approves an alternative, and obtain a signed copy for your records.</i>
Shipping investigational products directly to research participants	<i>RNI if already shipped prior to IRB approval and/or Modification in planning to ship. Consult with IDS for more information about their requirements.</i>
<b>Temporarily stopping</b> subject recruitment or placing a <b>temporary hold</b> on all or certain study procedures.	<b>Holds or closure to new enrollment:</b> <i>do NOT need to be reported via RNI; just log a comment.</i> <b>Temporary holds on all or certain study visits/procedures:</b> <i>RNI if already taken place and/or Modification if planning a hold on future visits/procedures</i>
Other deviations as deemed appropriate to eliminate immediate hazards to subjects due to exposure to COVID-19	<i>RNI only if deviations increase the risk of harm to participants, or adversely affect the integrity of the data; Modification if changes will be sustained and conflict with the current protocol or IRB smartform.</i>

## Ongoing In-Person Visits

If in-person visits are deemed essential by the Department/Division/School, due to direct benefit to the subject that outweighs the added risk, all possible measures should be taken to maintain as favorable a risk/benefit ratio as possible.

## If Virus Screening Becomes Mandatory:

If COVID-19 **screening** becomes mandatory in your clinical area, then that screening would not be considered part of the research procedures, therefore it does not constitute a change in the IRB-approved protocol. **No Modification is required.** If you wish to incorporate the screening data into your research, however, then you would need to submit a protocol modification.





## Review of New Protocols

The Emory IRB will seek input from faculty and leadership when prioritizing new COVID-19-related protocols. For top priority studies, as in past health emergencies, we have reviewed and approved new clinical studies within 3 days; minimal risk research can be faster. *(Please use a unique study title, not just “COVID-19 study.”)*

The IRB can help with the entire submission process if urgently needed. We also work with central IRB’s to execute reliance agreements as quickly as possible. (For studies under external IRB review, our local administrative review should not be the limiting factor.) Please use [our protocol templates](#) to avoid delays!!!

Emory also has a **Rapid Response policy and procedure** that coordinates all relevant ORA units in study startup. The use of this workflow requires high-level approval. To request, please contact [Sherry Coleman](#) and [Robin Ginn](#).

## Informed Consent and Study Assessment Documentation

**Informed Consent:** We have updated our [guidance on electronic informed consent](#) to help with study activities’ planning during this pandemic. Be sure to note specific requirements for FDA-regulated studies (search for FDA in the document). Only certain eIC platforms are pre-approved by Emory IT, and only one types of DocuSign is compliant with FDA Part 11.

In addition to our guidance, the FDA provides creative options for informed consent during Covid-19 here: [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#). See the Appendix Q&A, Q10-12.

**Reconsent:** Electronic signature, fax, or mail is preferred. If not possible within required timeframe, may do via phone, and send document via encrypted email. Obtain signature at next in-person visit and must submit RNI and/or MOD.

**Real-time assessment of test and safety reports:** The PI or delegated person should still aim to review these documents as promptly as before, especially in these areas:

- Product-related/newly emerging safety issues
- Product problems associated with adverse events



**Remote routing of study documents for review and signature:** Remember that you are always expected to conduct a consent discussion with subjects, unless the IRB approves an alternative.

- Email: If documents contain PHI, can use normal Emory email. Otherwise, **encrypt** and keep replies in same email thread to maintain encryption
- Fax: another preferred method
- Signatures
  - Must be [Part 11 compliant](#) for FDA-regulated studies
  - Scanning wet signatures: Acceptable. Also can send photo of signed document. Must be possible to tell that all pages are part of same document/patient record.
  - eSignature options: currently Emory IT has approved [RedCap](#) and DocuSign as options. Only DocuSign is currently Part 11 compliant (see FAQ's at end of the this [article](#)). In general, we recommend using an electronic signature with a date stamp and an keep the email thread (encrypted if non-Emory addresses)

### Reduction in Workforce to Cover Trial Visits/Procedures

If there is large-scale reduction in on-site workforce, you may not have an IRB-approved, 1572-delegated team member to help with **essential** study visits and real-time AE assessments. Per [FDA guidance](#), qualified clinicians may cover per the following guidelines without being added to the 1572:

- If possible, the clinician should be CITI and GCP certified.
- Log a comment in eIRB study record before or immediately after this visit takes place to inform IRB
- If expected to cover multiple times, add person to the study via a MOD
- Document the coverage in the study records, along with a list of all possible ancillary clinicians
- Clinician should consult afterward with the PI or a Co-I

*Reminder:* This is for essential clinical study visits

### Emergency Use Situations

If you are faced with the need of treating a patient who is gravely ill due to COVID-19, there may be emergency IND's available to treat patients with investigational drugs. (Off-label use of approved drugs is at the discretion of the clinician and unit, and does not require FDA involvement.)







## Emory IRB Guidance

When using the Emergency IND pathway, work with the Sponsor, the FDA, and the IRB: *The Sponsor* will determine if they will release drug for emergency use.

*The IRB* requires:

- Consent form: You are still required to obtain informed consent from these subjects. Use our [consent document for expanded access use](#) to create your document.
- If this is an emergency, and you do not have time to obtain IRB concurrence, submit a new study submission in eIRB *within five days after treatment* was provided to the patient.
- If you have time to provide the required information for IRB concurrence, submit using a fill out an RNI submission [using this guidance](#).

You must also call *the FDA* before the use, to obtain their concurrence:

- Highly time-sensitive requests (<4 hours): obtain verbal authorization from FDA's Office of Emergency Operations (866) 300-4374
- Not highly time-sensitive requests (4-8 hour response time): complete [form 3926](#) and email to [CBER\\_eIND\\_Covid-19@FDA.HHS.gov](mailto:CBER_eIND_Covid-19@FDA.HHS.gov)

### Impact of University Closure

The Emory IRB staff are all capable of working remotely. We are also experienced with holding Committee meetings via teleconference. University closure should not significantly impact our ability to review research, including high-priority studies and modifications.

### Additional Questions

If you have additional questions, please contact our staff leadership at <http://irb.emory.edu/about/staff.html>

### Links to Guidance and Resources

- [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic](#)
- Convalescent Plasma – [FDA Emergency Use Authorization](#)
- [FDA Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency Guidance for Industry and Health Care Professionals](#)
- [Emory Office of Research Administration COVID-19 Guidance Page](#)
- [Emory University COVID-19 Guidance Page](#)





## Emory IRB Guidance

- [Emory Electronic Informed Consent Guidance](#)
- [Current LITS approved apps and software for PHI or IIHI sharing](#) (review the guidance as some apps only allow sharing between Emory personnel)
- [When is a LITS security review needed?](#) Guidance to help you determine if you need a LITS security review when using a software or app for research.
- FDA Guidance-[Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers](#)
- FDA Information Sheet- [Informed Consent](#)
- FDA Guidance: [Post-marketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic](#)