In this unusual circumstance of pandemic illness, it may be necessary to rapidly modify research study procedures.

New protocols may also need rapid 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?

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 protocol deviations.
   ▪ At Emory, this must be done within 10 business days, as “Reportable New Information” (RNI). Sponsor and FDA notification may also be required.
   ▪ See specific examples in the table below – and a note about external IRBs.
   ▪ 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.
   ▪ The IRB encourages you to keep careful tracking of all protocol deviations related to the pandemic.
- **Modifications** are required when: (a) there is enough time to obtain IRB approval; (b) the changes do not meet the above criteria, or (c) the changes are urgent but also need to be **sustained** for multiple visits/subjects (with RNI).
  - The **Modification** may 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.

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

<table>
<thead>
<tr>
<th>Modification Description</th>
<th>IRB Approval Requirement</th>
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<tr>
<td>Adding COVID-19 screening before in-person visits, if these visits are not done for research purposes but to ensure subjects’ safety.</td>
<td>No IRB submission needed</td>
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<tr>
<td>Using phone or telehealth instead of in-person visits, or doing home visits</td>
<td>RNI and/or Modification – ensure any software is compliant with Emory policy</td>
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</table>
| Notifying subjects of changes to procedures/visits due to pandemic, via phone or letter (note: if email, must be encrypted) | - No IRB submission needed if communication is limited to scheduling information.  
  - RNI and/or Modification if includes instructions for continuing any procedures at home or other sites. |
| New enrollment via e-Consent or verbal consent                                            | Modification (may not occur without prior IRB approval) and by using current LITS-approved software. Please, also reference this guidance to know if you need LITS review even if using a new software. |
| Shipping investigational products directly to research participants                       | RNI and/or Modification. Consult with IDS for more information about their requirements. |
| Temporarily stopping subject recruitment or placing a temporary hold on all or certain study procedures. | Holds or closure to new enrollment: do NOT need to be reported via RNI; just log a comment.  
  Temporary holds on all or certain study visits/procedures: RNI and/or Modification |
| Other deviations as deemed appropriate to eliminate immediate hazards to subjects due to exposure to COVID-19 | 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. |
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.

External IRBs

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


**Review of New Protocols**

The Emory IRB will seek input from faculty and leadership when prioritizing new COVID-19-related protocols. When prioritized, as in past health emergencies, we have reviewed and approved new clinical studies within 3 days; minimal risk research can be faster.

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.)

Emory also has a **Rapid Response policy and procedure** that involves 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.
Impact of the 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](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
- 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
- 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.