In this unusual circumstance of a 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 must 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 if Emory closes?

Changes to Ongoing Studies

- Changes in IRB-approved research must be submitted to the IRB.
- Normally, changes may not be implemented prior to IRB review and approval.

- An exception is when changes are necessary to eliminate apparent immediate hazards to the subject (permitted in both OHRP and FDA regulations)

  - If this happens, the changes must be reported to the IRB as a protocol deviation within 5 days
  - If the changes need to be sustained for multiple visits/subjects, then a Modification to the protocol should also be submitted. (This may come as a revised version of the protocol, or a letter or memo or other document describing the changes.)

Measures to eliminate immediate hazards to research or clinical staff may also be warranted.

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

Specific examples could include:

- cancelling non-essential study visits
- conducting phone visits in lieu of in-person visits
• conducting safety screening (initiated by the Principal Investigator) prior to in-person visits occurring
• shipping investigational products directly to research participants
• other changes as deemed appropriate to eliminate immediate hazards to subjects because of the risk of exposure to this highly communicable disease.

In some cases, changes may include temporarily stopping subject recruitment or placing a temporary hold on all study procedures.
• such holds should be communicated to the funding agency or sponsor (if any) as needed. Additional reporting for VA studies is requested by the VA’s ORD.

Changes that likely need prior IRB approval:

Other changes would not eliminate an immediate hazard, but may still be desired, so consider doing a proactive Modification:
• Changing reimbursement for travel expenses, if travel requirements or modalities change
• Using digital technology to conduct remote visits – think about what types of technology you may wish to use

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. 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. When prioritized, as in past health emergencies, we have reviewed and approved new clinical studies within 3 days; minimal risk research can be faster. We 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.

Emory also has a **Rapid Response policy and procedure** that involves all relevant ORA units in study startup. Use of this workflow requires high-level approval. To request, please contact Sherry Coleman and Robin Ginn.
Impact of Potential 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