

IRB Review and Researcher Guidance COVID-19

March 12, 2020

**If the University Pandemic Plan is activated,
and during this time of circumstances,
it may be necessary to rapidly modify research study procedures.
New IRB submissions may also need rapid review.**

Guidance Topics:

- When and how must USA IRB must be notified of changes to approved research?
- When may prior USA IRB approval *not* be needed?
- How quickly can the IRB review new COVID-19 protocols?
- Will USA IRB's review capacity be impacted if USA closes?

Modifications to Ongoing Studies:

- **Changes in IRB approved research must be submitted to the IRB**
- Normally, changes may not be implemented prior to IRB review/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 SUBMITTED** to the IRB as a protocol deviation with **5 days**
- If the changes need to be sustained for multiple visits/subjects, then an Amendment to the protocol should also be submitted. This may be initiated as a revised protocol, or memo/other document describing the changes.
- Measures to eliminate immediate hazards to research or clinical **staff** may also be warranted.

Eliminating potential immediate hazards may include:

- actions to reduce potential exposure to COVID-19, or
- continue to provide medically necessary study care (including study drug) to participants who have been placed in isolation or quarantine

Specific examples 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 halting** 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. A temporary hold on study procedures that may impact currently subjects should be evaluated in order to eliminate any immediate hazards to subjects.

- A temporary halt to subject recruitment does not need to be reported to the USA IRB unless the hold is initiated at the request of an external funding agency or the study's Data Safety Monitoring group (if there is one)

Changes that likely need prior IRB approval:

Other changes would not eliminate an immediate hazard, but may still be desired, consider doing a proactive Amendment/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 the clinical area, the screening would not be considered part of the research procedures, therefore it does not constitute a change in the IRB-approved protocol. If the screening data can be incorporated into the research, and amendment to include the screening date must be submitted as a protocol modification.

It is recommended that researchers implement procedures to screen research participants at every encounter and to incorporate telephone screening prior to scheduled visits for potential infectious risk. See the [CDC's Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 \(COVID-19\) in Healthcare Settings.](#)

Review of New Protocols:

The USA IRB will seek input from faculty/leadership when prioritizing new COVID-19-related protocols. When prioritized, review/approval will be conducted within **5 days**, if possible; minimal risk research can be faster. Assistance can be provided for the entire submission process. Reliance submission process to central IRBs to execute reliance agreements will be acknowledged as quickly as possible.

USA also has a Pandemic Preparedness Plan that involves all clinical research operations. For additional information, please contact Windy Blount at wblount@health.southalabama.edu

The procedure for Single Patient Emergency Use of an experimental drug or device remains the same during the pandemic situation. See [IRB SOP 1002: Emergency Use: Investigational Drugs, Biologics and Device](#)

Impact of Potential University Closure:

The USA Office of Research Compliance and Assurance and the IRB Office are all capable of working remotely. If needed, Committee meetings can be conducted via teleconference. University closure should not significantly impact the ability to review research, including high-priority studies and modifications. Provided that Research Compliance staff are not severely impacted by a pandemic, these activities should occur on time and without interruption.

Additional Questions

If you have additional questions, please contact our staff at:

<https://www.southalabama.edu/departments/research/compliance/staff.html>