IRBMED Guidance
Reporting Time-Sensitive Modifications

Per federal regulations, IRB review and approval is required before implementing any changes to IRB approved research (an exception exists for an immediate hazard to subjects). To assist study teams with procedures for submitting time-sensitive or urgent changes to research studies, especially as it relates to COVID-19 circumstances, this document consolidates IRBMED guidance in a single location.

I. General Overview

The following framework outlines specific reporting mechanisms based on the type of changes:

- To report **changes that were initiated without IRB approval** (*to eliminate apparent immediate hazards to the subjects*), see IRBMED guidance.
- To report time-sensitive **changes that are study wide and/or permanent**, submit an **Amendment** in eResearch by following the directions provided below (Section II).
- To report time-sensitive **changes that are one-time and/or temporary** to accommodate one or two subjects (e.g., adjustment of enrollment criteria for a single participant), submit an **ORIO** in eResearch by following the directions provided below (Section III).
- All other changes that are NOT time-sensitive should be submitted to IRBMED per the standard amendment process.

Currently, IRBMED is adequately resourced to address the time-sensitive requests promptly when the corresponding eResearch submissions are submitted appropriately (by following the directions provided below). Generally, any submission received by IRBMED will be screened and triaged within 24 hours during normal business hours. During the weekend, these will be checked periodically as necessary.

Once a time-sensitive submission is submitted, the study team can also contact the staff owner of the submission (preferred method) or, the general email ID at irbmed@umich.edu for a status update.

II. eResearch Amendment (study wide and/or permanent changes)

- **Labeling:** Update the Amendment Title to indicate *"Time-Sensitive" or "Urgent" (or as appropriate to reflect the situation) along with any other indicators*
- Include adequate details in the Amendment to minimize the back and forth between IRBMED and the study team. For example:
  - Explain the time-sensitive nature in the Amendment coversheet (Section 01.4 or 01.5). This will allow IRBMED to appropriately triage the submission
  - Describe the proposed changes clearly in the Amendment coversheet
  - Evaluate how the proposed changes will impact the current study procedures and then update the study materials (protocol, recruitment, informed consent, etc.) as applicable.
  - If the consent document is being updated, evaluate, and indicate whether or not subjects will be re-consented. Also, clarify the method of re-consenting (in-person or remote).
- NOTE: See **Section IV** below for an alternative approach that can be utilized under some limited circumstances.

III. eResearch ORIO (one-time and/or temporary changes)

The study teams may encounter situations where the intended change is one-time and impacts only one or two subjects and is not a study wide change. For these situations, the ORIO reporting process can be utilized to obtain IRB approval. The study team should carefully evaluate whether the intended change is a one-time or a permanent study-wide change before using this ORIO process.

Example(s) of scenarios where this is permitted:

- A request to enroll a participant who does not meet the currently approved eligibility criteria:
  - Lab values slightly differ from those stated in the protocol
  - Participant age slightly varies from inclusion criteria (but not adding children and/or other new subject population)
- Making adjustments to the current study drug dosage (but not adding new drugs or devices)

Example(s) of scenarios where this will NOT be accepted:

- Changes to the study procedures that will impact either all or most of the subjects
- Adding a study team member

IV. eResearch ORIO (Special Process for COVID-19 Research Reactivation ONLY)

In the special circumstances associated with COVID-19 research reactivation, IRBMED will accept **time-sensitive** modifications that are **study wide and/or permanent** via the eResearch ORIO reporting mechanism if they meet the following criteria:

The standard eResearch Amendment process permits only one amendment to be in progress at the same time to assure version control of the IRB application/protocol. This may create challenges when two unrelated modifications require evaluation at the same time. When an Amendment is already in-progress and the study team wants to make additional changes that cannot be added to the currently opened Amendment, the ORIO process can be utilized in these unique circumstances, to obtain IRB approval.

Example(s) of scenarios where this is permitted :

- Changing from in-person visits to remote 'visits' for a group of subjects (a minor change) but this change cannot be added to the currently opened Amendment as the Amendment is currently undergoing ancillary review or is already scheduled for a convened board meeting.

Example(s) of scenarios where this will NOT be accepted:

- A standard Amendment is necessary for informed consent updates that require finalization.
- Adding study team members as they require conflict of interest and PEERRS validation.

When Submitting the ORIOs for Section III or Section IV:

- **Labeling:** *When creating the ORIO, if it is Time-Sensitive, update the ORIO title to indicate "Time-Sensitive Change" or "Urgent Change" (or as appropriate to reflect the situation) along with any other indicators*
- Select "Protocol Deviation" sub-type (this selection should be chosen in this work-around)
- Include adequate details in the ORIO submission to minimize the back and forth between IRBMED and the study team. For example:
  - **Describe the intended change(s) AND indicate why the ORIO is being submitted instead of the Amendment.**
  - For One-Time changes, the study team may also need to obtain concurrence from the Sponsor or the coordinating center as applicable. In the ORIO, upload any additional supporting documentation (such as sponsor's approval or other similar documentation)

I. RESOURCES

1. **FDA's 2020 Guidance:** Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency
2. **FDA's 2001 Guidance:** Changes or Modifications During the Conduct of a Clinical Investigation
3. **UMOR COVID-19 Webpage:** https://research.umich.edu/covid-19