Modifications

Overview:

This guidance is specific to making changes to an IRB approved research project. This guidance is intended to describe the following:

- When the submission of a modification is necessary
- The procedures for submitting modifications to Exempt, Expedited and Full Board protocols

Definitions:

Modification refers to any change.

Modifications:

All changes to a research study require the submission of a Modification to the IRB. The following are the only exceptions to this requirement:

- a change is necessary to eliminate an immediate hazard to one or more of the participants
- the change is limited to updating contact info on approved flyers or letters, or
- correcting typographical errors that do not alter the original meaning of the text

Due to the fact that Modifications and Renewals are two separate functions in OSIRIS, the IRB generally does not permit Modifications and Renewals to be submitted at the same time. The following are the only exceptions to this requirement:

- Changes that relate to a safety issue
- Changes at the IRB's request

Given that the majority of Modifications and Renewals cannot be submitted at the same time, the study team needs to be mindful of their Renewal date when determining their timeline for submitting a Modification. If the study is due to expire shortly and there are no safety issues, the Renewal should be submitted first. Once the IRB approves the Renewal, a Modification can be created and submitted.

Rarely, situations occur when a Modification needs to be submitted and the Renewal date is quickly approaching. In this case, please send an email to askirb@pitt.edu to request that the IRB administratively open a Renewal. The details of the circumstances will dictate whether the IRB is capable of completing this action.

IRB approval of a modification typically does not alter the original approval or expiration date of the protocol. However, if the Modification request substantially alters the risk-to-benefit ratio of study participation, it may also alter the expiration date previously assigned to the protocol.

The type of IRB review (i.e. Expedited or Full Board) a proposed Modification will undergo is dependent upon whether the proposed changes potentially alter the risk/benefit ratio of the study. The IRB chairperson or his/her designee has final responsibility for this designation.

Examples of common modifications include:

- changes to study personnel
- the addition or alteration of research activities
- the addition or alteration of recruitment materials
- the addition or alteration of data collection forms
- an increase or decrease in proposed human research subject enrollment supported by a statistical justification
- revising the inclusion or exclusion criteria
- alterations in the dosage or route of administration of an administered drug
- changing the type, volume or frequency of biological sample collections
- changing the length or number of study visits
- alterations in human research subject compensation
- the addition or deletion of study sites
- changes specifically requested by the IRB; Human Use Subcommittee, Radiation Safety Committee; Radioactive Drug Research Committee; or Clinical and Translational Research Center
- the addition of serious unexpected adverse events or other significant risks

OSIRIS Submissions:

I. Exempt Protocols

a. Modifications to change the Principal Investigator (PI) of an exempt protocol **are not** permitted. If a change in PI is required, the following must be done:
   - Submit a new exempt protocol with the new PI listed
   - Close the original protocol in OSIRIS once the new protocol is approved

b. Modifications to add a new source of funding on an exempt protocol **are not** permitted. If a new source of funding needs to be added, the following must be done:
   - Submit a new exempt protocol with the new source of funding listed
   - Close the original protocol in OSIRIS once the new protocol is approved

c. Modifications to add/remove Co-Investigators, Coordinators and other Key personnel **are** permitted.

   To change study personnel:

1. Go to the title page of the currently approved exempt protocol
2. Press the “Send Comments to IRB Staff” button located on the left-hand side under the “My Activities” header
3. In the text-box provided, write a note indicating that a change to Co-Investigators, Coordinators or other Key personnel needs to be made.
4. The IRB staff member who originally approved the protocol will receive the note and provide limited editorial access to make study team revisions only. An email notification from the OSIRIS system will be sent to the PI when the protocol has been opened to edit study team members.
5. Edit the study team members in the OSIRIS application. After changes are made the application will be locked to edits once again.
6. The IRB staff person who originally approved the protocol will receive the note and will review the requested changes. IRB staff will either send a note approving the personnel changes or request additional information.

Note, only the Principal Investigator is able to complete the steps to revise study team members

d. All other Modifications (for instance: changes in research sites, data collection tools, recruitment materials, compensation amount, etc.)

   To change anything other than study personnel:

   1. Go to the title page of the currently approved exempt protocol
   2. Press the “Send Comments to IRB Staff” button located on the left-hand side under the “My Activities” header
   3. In the text-box provided, write a note indicating what changes are being requesting AND provide an explanation of why each change is necessary/desired. If the changes include the revision or creation of attachments, the new or revised attachments should be uploaded using the “Add” button found beneath the text box.
   4. The IRB staff person who originally approved the protocol will receive the note and will review the requested changes to determine if the changes would alter the current risk level or category under which the protocol was originally approved.
   5. If the IRB determines the changes do not alter the risk level or category of approval, the IRB Reviewer will send a note to the study team via OSIRIS indicating the changes have been approved and may be implemented.
   6. If the IRB determines the changes do alter the risk level or category of approval, the IRB Reviewer will send a note to the study team via OSIRIS explaining why the changes cannot be approved and providing further instruction for how to proceed.

II. Expedited and Full Board Protocols

There is a formal modification submission pathway in OSIRIS to create and submit modifications to approved Expedited and Full Board protocols.

To create and submit changes to Expedited and Full Board protocols:

1. Follow the instructions beginning on page 17 of the document below: OSIRIS Information Sheet for Investigators

2. After the Principal Investigator submits the Modification, IRB review will be conducted. Requested changes cannot be implemented until you receive a formal Modification approval letter from the IRB.

Paper Submissions:

A small number of old research projects were not required to be converted to the electronic OSIRIS system when it launched in 2007. If is necessary to submit a Modification for a study that is still in paper format, please email one copy of the following documents to askirb@pitt.edu:

- Modification Request form– found at http://www.irb.pitt.edu/paper-submission-forms
- The currently approved protocol with any modifications highlighted
- The currently approved informed consent document(s) with any modifications highlighted
- If applicable, a copy of the sponsor's research protocol amendment addressing the respective modification(s)
- Notification of modification approval from UPMC Fiscal (i.e., for modifications involving changes to research-related procedures conducted at UPMC facilities)