3.14 Amendment of an Approved Protocol

PIs who wish to modify or amend their approved applications must seek IRB approval before making any changes in approved Research. This requirement exists even though the changes are planned for the period for which IRB approval has already been given. One noteworthy exception is for changes necessary to eliminate an immediate hazard to the subject, in which case the IRB must then be notified at once).

Amendments may be approved if they are within the scope of what the IRB originally authorized. For example, if a Researcher wishes to add a population to an existing study, but not alter the study procedures or purpose, an amendment request is usually appropriate. Likewise, amending a procedure without changing the study's purpose or study population may also be appropriate. If, however, the Researcher wishes to add a population and revise study procedures, he or she will need to submit a new application for Human Subjects approval.

Investigators must submit documentation to inform the IRB about the changes in the status of the study. To this end, Investigators are required to submit the changes through the modification/Amendment package in IRBNet:

- Completed Amendment Form (TU Form 601);
- Revised Sponsor’s Protocol (if applicable);
- Revised approved Consent (TU Forms 402, 403)/Assent (TU Form 401) documents (if applicable) or other documentation that would be provided to subjects when such information might relate to their willingness to continue to participate in the study;
- Revised or additional recruitment materials; or
- Any other relevant documents provided by the Investigator

HRPO staff or HRPO/HRPP Director will determine whether the proposed changes may be approved through an Expedited Review process, if the changes are minor, or whether the amendment warrants Convened IRB Review. The reviewer(s) using the Expedited procedure has the ultimate responsibility to determine that the proposed changes may be approved through the Expedited Review procedure and, if not, must refer the Protocol for Convened IRB Review for review of whether each change was consistent with ensuring the participant’s continued welfare.

Regulations & Guidance: OHRP Guidance on Written IRB Procedures.

3.14.1 Expedited Review of Protocol Amendments/Modifications

An IRB may use Expedited Review procedures to review Minor Changes in ongoing previously-approved Research during the period for which approval is authorized. An Expedited Review may be carried out by the IRB Chair and/or designee(s) among the IRB members.

The reviewer(s) complete the Amendment Reviewer Sheet (TU Form 503) to determine whether the modifications meet the criteria allowing review using the Expedited procedure, and if so, whether the Research with the proposed modifications continues to meets the regulatory criteria for approval.

The reviewer will also consider whether information about those modifications might relate to Participants’ willingness to continue to take part in the Research and if so, whether to provide that information to Participants.

When a proposed change in a Research study is not minor (e.g., procedures involving increased risk or discomfort are to be added), then the IRB must review and approve the proposed change at a convened meeting before the change can be implemented. The only exception is a change necessary to eliminate apparent immediate hazards to the Research subjects. In such a case, the IRB should be promptly informed of the change following its implementation and should review the change to determine that it is consistent with ensuring the subjects' continued welfare.

All documents provided by the PI are accessible to all IRB members for review via IRBNet.

At the meeting, the Primary Reviewer presents an overview of the modifications and leads the IRB through the completion of the regulatory criteria required for approval. The IRB will determine whether the Research with the proposed modifications continues to meet the regulatory criteria for approval.

When the IRB reviews modifications to previously approved Research, the IRB consider whether information about those modifications might relate to Participants’ willingness to continue to take part in the Research and if so, whether to provide that information to Participants.

3.14.3 Changes in the Informed Consent Document

When a modification makes it necessary to change the informed consent document, regardless of whether any Participants are enrolled, two copies of the revised consent document are to be submitted to the IRB. One “marked up” copy should show all changes from the previous version (i.e., highlighting all additions and striking through all deletions). The one clean copy will contain the IRB – approval stamp that is to be used to enroll subjects.