Section 8: Amendment of Human Subjects Research Activities*

8.1 Requirement for Amendments
Modifications to consent forms or process, protocols, or procedures/study-related activity must be reviewed and approved by the IRB prior to making any changes in study procedures except when necessary to eliminate apparent immediate hazards to subjects. If modifications are made prior to IRB review to remove immediate hazards to subjects, the modification must be promptly reported to the IRB and the modification(s) will be reviewed to verify that it was appropriate to implement prior to IRB review and approval.

8.2 Submission Requirements
All amendments must be submitted through IRBNet. The requirements for amendments are:
1. Completed amendment application.
2. Revised consent process described in protocol or document with changes highlighted if modified.
3. Protocol, recruitment, enrollment, or other study activity or procedure if modified.
4. Requests must describe what modifications are desired, why the changes are required, and if the changes pose any additional risks to the subjects.

Amendments may only be submitted after any prior amendment for the same protocol has been approved. If a protocol amendment is submitted while a prior amendment request is still under review for the same protocol, the new amendment request will be held until the previous amendment has been reviewed and approved.

8.3 Assignment of Expedited Reviewer
Upon receipt, the IRB Compliance Administrator will verify the amendment is appropriate for expedited review. They will work with the PI to assure that all required documentation has been uploaded and the application is complete. The amendment is then reviewed by the IRB Chair, Vice Chair, ORIE Director, or IRB designated reviewer.

8.4 Review of Amendment Requests
Minor changes (those which involve minimal risk procedures and/or do not increase the risk or decrease the potential benefit to subjects, do not involve one or more of the regulatory criteria,
and may include Categories 1-7 on the Expedited list) may be approved through an expedited review process. Typical changes considered to be minor include changes in personnel, non-significant changes in sample size, an addition of a questionnaire that does not include sensitive or controversial questions, a change in the compensation schedule, an addition of a site, etc. Reviewers using the expedited review process must consider the following:

1. The amendment is a minor modification to previously approved research,
2. The regulatory criteria for approval are met.

At the reviewer’s discretion the amendment may be referred to the convened IRB. All amendments reviewed through an expedited process are reported, as a list included with the minutes of the previous convened meeting, to the IRB at a convened meeting.

Changes considered as more than minor or those that involve one or more of the regulatory criteria must be reviewed at a convened meeting of the IRB. When amendments are reviewed by the convened IRB, all IRB members will be provided with a copy of all documents submitted by the PI. Each amendment to be considered will be assigned and presented by the assigned Primary Reviewer. IRB Compliance Administrators will assure that appropriate scientific expertise, local knowledge, and other expertise specific to the protocol(s) is present at the IRB meeting and at least one member who is knowledgeable about or experienced in working with such subjects, when research involving subjects who are vulnerable to coercion are reviewed, will be present at the IRB meeting. If a member with the appropriate expertise, knowledge, or experience in working with the specific vulnerable population cannot be present, the IRB staff will notify the IRB Chair to obtain a consultant, if needed. To be properly presented and discussed, a quorum of the members must be present for the entire presentation, discussion, and deliberation of the amendment request. Members not present for a substantial part of the discussion and deliberations should abstain from voting.

8.5 Possible IRB Protocol Determinations
Either the IRB Chair or a designated reviewer will render one of the following determinations for each protocol:

1. **Approved**: It is approved as written with no explicit conditions.
2. **Approved with Explicit Conditions**: The protocol was approved with explicit conditions requiring minor changes or simple concurrence of the PI. These will be identified to the PI and must be completed and documented prior to continuing the research.
3. **Deferred**: The information in the submitted documents has deficiencies that prevent accurate determination of risks and benefits. The deficiencies will be identified to the PI, who must address all concerns in a written response.

A designated reviewer for an expedited amendment may not render a decision of disapproval. Protocol disapprovals may only be rendered by the IRB at a convened meeting.

8.6 Criteria for Approval of Amendments
In order to approve an amendment to research activities, the IRB will provide ethical and scientific scholarly review of all human subjects research to determine that all requirements are satisfied according to 45 CFR 46.111 Criteria for IRB approval of research.

8.7 Length of Approval Period
Amendment approvals do not change the approval period of the protocol. Therefore, the expiration date will remain the same as was determined for the protocol at the time of initial or continuing review.
8.8 Notification of Investigators of IRB Determination
Within five (5) working days after each IRB meeting a letter is prepared and sent to the PI of all protocols notifying them of the IRB determinations for their protocols. An approval letter requires no further action and the PI can begin research. Letters giving approval with explicit conditions will contain a list of required conditions and PIs will not receive final approval until all required conditions have been met. Along with the determination the IRB will determine whether the PI's responses to the explicit conditions will need to be reviewed for appropriateness and completeness by another IRB convened meeting, the IRB Chair or designated reviewer. Responses to clarifications that are directly relevant to regulatory criteria must be reviewed by the convened IRB. When the PI has responded appropriately and completely to all conditions, via IRBNet, then final approval is granted. The PI will be notified by an approval letter that research can begin and when the protocol will require continuing review.

For deferred protocols the PI will be notified by letter, via IRBNet, the reasons the protocol was deferred. The entire submission, with all required documents, will need to be revised as needed and resubmitted.

For disapproved amendments, the PI will be notified by letter the amendment was disapproved and the reason(s) for the disapproval.