IRB Standard Operating Procedures		
SOP#: 001 **Revision#:**	**Title: Amendments to Previously Approved Research**	**Effective Date: December 10, 2019**
Approved By:	**Institutional Review Board**	**Approval Date: December 10, 2019**

PURPOSE

To define policies and procedures for review of amendment requests for previously approved research on human subjects research.

DEFINITIONS

Amendment - Any planned modification in the research protocol and/or the procedures used to recruit or enroll research participants.

Convened review - Review of proposed human subjects research by an IRB that meets the membership requirements specified in federal regulations regarding the number, qualifications, diversity, and affiliation of its members, at which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas. Review by the convened IRB may be referred to as either "full review" or "full board review".

Exempt review – research may qualify for Exempt status if it involves very minimal or no risk and meet the criteria for exemption specified by federal regulations.

Expedited review refers to the review of minimal risk research outside of a convened IRB meeting by one or more experienced IRB members. Initial review, continuing review, amendments to previously approved research, post-approval reporting, and final reports may be reviewed by this process when they meet the criteria specified by federal regulations.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

IRB means an institutional review board established in accord with and for the purposes expressed in this policy.

Minimal risk means that the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

POLICY

1. All proposed amendments to previously approved research, regardless of the level of review and the type of funding, must be reviewed by the IRB. A PI may not implement an amendment prior to IRB approval, except when necessary to avoid an immediate danger to the subject.
2. The IRB reviews amendments to determine whether they affect the risk/benefit analysis or exempt status of the research study.
3. Amendments to full review studies will be reviewed by the convened IRB, unless the proposed change(s) are minor.
    a. Minor changes represent: 1) changes not materially affecting the assessment of risk and benefit; 2) changes not substantially changing the specific aims or design of the study. Refer to Appendix Minor Changes in Research Studies for details.
    b. Minor changes in research previously approved by the convened IRB are eligible for expedited review. Amendments that include both minor and more than minor changes cannot be separated if combined into the same submission, and must be reviewed by the convened IRB in their entirety.
    c. Approval expiration dates of full review studies do not change with the approval of amendments.

    4. Amendments to expedited studies will be reviewed by the expedited procedures to determine that 1) the research continues to pose no more than minimal risk and 2) new or revised procedures are consistent with the expedited categories 1-7. Studies previously meeting the criteria for expedited review will subsequently require review by the convened IRB when the changes proposed in the amendment increase the risk level to more than minimal or involve procedures

which do not fall within one or more of the seven categories eligible for expedited review.

4. Amendments to exempt studies will be reviewed by the exempt procedures to determine whether the proposed change affects exempt status of the research study. Exempt research may be moved to expedited or convened review dependent upon the nature of the amendment.

5. Administrative amendments that only include changes in research personnel, performance sites and funding may be reviewed and approved by the IRB staff.

PROCEDURES

Pre-review Procedures

1. Incomplete applications will not be reviewed. The entire application packet will be sent back to PI to complete prior to submission.
2. Once application materials have been submitted and determined to be complete in accordance with IRB requirements [Applying to the IRB], IRB staff will screen the application for errors or omissions in the application and possible regulatory issues as part of "Administrative Pre-review".
3. All application material and pre-review notes from the administrative pre-reviewer will be shared with the IRB chair.
4. The IRB Staff will consult with the IRB Chair as to whether the requested amendment constitutes a minor or more than minor change, with the IRB Chair or designee making the ultimate determination.
5. Amendments that include more than minor changes will be submitted for review by the convened IRB.
6. Amendments that include minor changes will be submitted for review the IRB Chair or designee.
7. Amendments to claims for exemption will be reviewed by the IRB Chair or designee reviewer to determine if the study still qualifies for exemption.

Review

1. The reviewer is responsible for notifying the IRB staff if they have a conflict of interest as outlined in SOP IRB Member Conflict of Interest or if they do not feel qualified to review the proposal.
2. The reviewer will document their review and assessment of the research by completing an IRB Reviewer Sheet.
3. The reviewer must determine when the changes to research activities affect one or more of the approval criteria and whether the criteria for approval are still met.

4. The reviewer must consider whether the changes to research activities require changes to the informed consent forms and whether currently enrolled subjects and/or previously enrolled subjects must be re-consented no matter what the level of review.
5. The reviewer must also determine as part of their review whether any significant new findings that arise from the review process and that might affect subjects' willingness to continue participation should be communicated to the participants. This determination should be based on whether new information affects the risk/benefit analysis in a way that could affect a subject's decision as to their willingness to participate or continue participation in the research study.
6. When informed consent forms or recruitment documents are modified by the amendment, the start date for approval on the revised documents is updated to reflect the date of IRB approval of the revised documents.

IRB Determinations

1. Amendment is approved.
2. Additional information or clarifications are needed to secure approval.

Post-review Procedures

1. IRB actions and findings will be reported to the principal investigator in writing.
2. The investigator's department head and, if applicable, faculty sponsor are copied on all communications.
3. The communication contains, as applicable:
    a. Any issues requiring resolution;
    b. Recommendations for changes in the level of review;
    c. Requests for further information.
4. For approved amendments:
    a. Summary of changes
    b. Reminder of the investigator's responsibility to submit any amendment to the research for review;
    c. Reminder of the investigator's responsibility to respond to an annual survey-reminder of researcher responsibilities & project termination.

Review of Investigator's Responses to the IRB

1. The IRB Staff reviews responses from investigators for modifications required to secure approval. The response is then forwarded to the convened IRB or the IRB Chair (or designee) for review.

Regulations

45 CFR 46.109, 45 CFR 46.111, 45 CFR 46.116
21 CFR 56.109, 21 CFR 56.111, 21 CFR 50.25
Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs. OHRP, HHS, FDA, May 2018
OHRP Guidance on Expedited Review Procedures, OHRP, DHHS August 11, 2003

Author Reference

NEIU IRB
UIC Amendments to Previously Approved Research

Related Policies

SOP IRB Member Conflict of Interest
SOP Exempt Research
SOP Expedited Review of Research
SOP Convened Review of Research

Contact Information

Please direct questions or concerns about this policy to:

Contact	Phone	E-Mail
IRB Office	773-442-4675	irb@neiu.edu
Dean of the College of Graduate Studies and Research	773-442-6012	gradstudies@neiu.edu

Disclaimer

The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as the Responsible Officer calls for review. Requests for exception to any portion of this policy, but not to the policy statement, must be presented in writing to the Responsible Officer.

Minor changes in research

Minor changes in research previously approved by the convened IRB are eligible for expedited review.

Minor changes in research represent:

1. Changes not materially affecting the assessment of risk and benefit;
2. Changes not substantially changing the specific aims or design of the study;
3. For protocols initially approved by expedited review process, the research continues to pose no more than minimal risk; and new or revised procedures are consistent with the expedited categories 1-7.

Examples of minor changes include, but not limited to:

1. Administrative changes (addition of personnel, performance sites, and funding)
2. Minor consent form revisions (e.g., grammar corrections, change in contact information, editorial changes that clarify but do not change the material),
3. Addition of procedures that do not increase risks, such as expanding collection of information or samples already being obtained for non-research purposes,
4. Changes to recruitment procedures, recruitment materials or submission of new recruitment materials to be used in accordance with approved recruitment methods,
5. Non-substantive changes to study documents such as surveys, questionnaires or brochures,
6. New study documents to be distributed to or seen by subjects that are similar in substance to those previously approved,
7. Changes in the amount or process for compensating subjects that do not significantly impact the risks or benefits,
8. Decrease in the number and volume of sample collections as long as they do not negatively alter the risks or benefits,
9. Addition or removal of co-investigators, key personnel or performance sites (when do not adversely affect study resources),
10. Increasing subject enrollment,
11. Addition of template short form consents, and
12. Foreign language translations of materials already approved.

Examples of changes that are not minor include, but not limited to:

1. New or expanded procedures (e.g., tissue biopsy, more frequent blood drawings) or changes in design (e.g., add or remove treatment arm, new study population) that increase risks or adversely impact the risk-benefit ratio,
2. Changes in eligibility criteria that impact the risk-benefit ratio (e.g., lowering or raising the age limit),
3. Information concerning previously unknown risks or lack of benefit that is substantial or adversely affects the risk-benefit ratio, significant changes to materials to be given to

subjects (e.g., new information about frequency or severity of adverse effects, negative outcomes from related studies), and

4. Replacement of the Principal Investigator.