IRB Standard Operating Procedures		
SOP#: 06 **Revision#: 1**	**Title: Convened IRB Review**	**Effective Date:** **March 8, 2019**
Approved By:	**Institutional Review Board**	**Approval Date:** **March 8, 2019**

PURPOSE

To define policies and procedures for conducting full-board review of human subjects research.

DEFINITIONS

Appeal - request for reconsideration of an Institutional Review Board (IRB) determination in research involving human subjects, including (but not limited to) decisions regarding approval status, conditions for approval, or noncompliance. Note: An appeal is reviewed by the convened IRB responsible for the determination being appealed; for a decision made by expedited review, the corresponding convened IRB may review the appeal. Also: request for reconsideration.

Human subject - 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 - an institutional review board established in accord with and for the purposes expressed in the federal regulations for the protection of human research subjects.

Convened review - the 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 non-scientist. Review by the convened IRB may be referred to as either "full review" or "full board review".

Minimal risk - 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 - a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

POLICY

All research involving human subjects reviewed by the convened IRB must be evaluated for issues in proposed study design and conduct that may affect the rights and welfare of human subjects, consistent with Federal Regulations, state and local laws, professional standards, and Northeastern Illinois University (University) policy. A study that involves greater than minimal risk (see definition, below) requires approval by an IRB composed of members qualified to review research in that field. Refer to SOP IRB Membership for details.

Research that requires full committee review may include one or more of the following:

- Prisoners
- Pregnant women, fetuses, and neonates
- Individuals with impaired decision-making capacity
- Children and other vulnerable populations
- Microwaves or X-Rays
- General anesthesia or sedation
- Human in vitro fertilization

This list is not exhaustive. The final decision as to whether an application is reviewed by the IRB at a convened meeting is that of the IRB chair and/or board.

To be approved, research that is reviewed by the convened IRBs must satisfy all of the following requirements as defined by 45 CFR 46.111:

- Risks to participants are minimized (but not necessarily eliminated) by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk. Whenever appropriate, risks to participants are minimized by using procedures already being performed for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits (if any) and the importance of the knowledge that may reasonably be expected to result from the research.
- Selection of participants is equitable, taking into account the purposes of the research and the setting in which the research will be conducted.
- Informed consent is sought, obtained, and appropriately documented for each prospective participant or the participant's legally authorized representative as required by the regulations.
- If the research involves greater than minimal risk, the data and safety monitoring plan and/or data and safety monitoring board (where appropriate) makes adequate provision for monitoring the data collected to ensure the safety of participants.
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data in accordance with IRB policy.
- When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, adults unable to consent for themselves, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

PROCEDURES

- The IRB typically meets once per month.
- IRB meetings are conducted according to SOP IRB Meeting Procedures.

Pre-review Procedures

- The principal investigator (PI) will complete the most current application and forms available on the IRB website and submit a complete packet, including all supporting documentation electronically. Instructions for preparing the application are available on the IRB's website.
- Incomplete applications will not be reviewed. Missing items will be identified and requested during the administrative pre-review. If the items are not submitted within 1 week following the IRB request, the entire application packet will be sent back to the PI without review.
- Once completed application materials have been submitted, IRB staff will conduct an "Administrative Pre-review", and make note of possible issues on a pre-review document.
- All application material and pre-review notes from the administrative pre-reviewer will be shared with the IRB chair.
- IRB staff in consultation with the chair will assign a primary and secondary reviewer to each new study based on the IRB member's educational background, experience, and expertise. For research requiring expertise in multiple areas of science or ethics, additional reviewers may be assigned as determined by the IRB staff and chair.
- Only IRB members designated as scientists may serve as primary reviewers. Non-scientists may serve as secondary reviewers.
- When the research involves a vulnerable category of participants (e.g., children), a reviewer knowledgeable about and experienced in working with these participants will be selected.
- IRB staff will upload application materials to Google Drive and make them available for review by IRB members 7-10 days before convened meetings. In extenuating circumstances, when sufficient space exists on a meeting agenda for a late submission, every effort will be made to forward materials to reviewer(s) and IRB members past this deadline.
- IRB staff will provide pre-review comments to IRB members in advance of the meeting
- All IRB members will receive and review the following materials:
    a. Initial Review Application.
    b. Consent form(s), assent form(s) and permission form(s), and verbal script(s), including translated documents, as applicable.
    c. Recruitment materials, as applicable, including advertisements intended to be seen or heard by potential participants.
    d. Study instruments such as questionnaires, surveys, etc.
    e. Other materials, as applicable.
- All IRB members are responsible for reviewing the submitted materials in enough depth to be familiar with and prepared to discuss the information at the convened meeting.
- Any IRB member can access the complete IRB file for review prior to or during the convened meeting.

Initial Review

- Both the primary and secondary reviewer(s) are expected to perform an in-depth review of the research. The primary reviewer leads the IRB's discussion of the protocol, providing a summary of the research and potential concerns, if any.
- The primary reviewer makes recommendations for action by the IRB (i.e., approval, modifications required to secure approval, deferral), whether the criteria for approval under 45 CFR 46.111 (and subparts B, C, and D, when applicable) or 21 CFR 56.111 and any other required determinations are met, and whether the required elements of informed consent are present (45 CFR 46.116 or 21 CFR 50.25) or waiver or alteration granted according to the regulations and the consent process is appropriate.
- The secondary reviewer(s) provides additional comments or information before full Board discussion.
- The primary reviewer will document their review and assessment of the research by completing an IRB Reviewer Sheet and submitting it to IRB staff at the conclusion of the convened IRB meeting.

Continuing Review

- The IRB must conduct substantive and meaningful review of research on a continuing basis, at the interval (at least once a year) established by the IRB at the prior review. IRB review must be performed by the convened IRB unless the research meets the criteria for expedited review, as described in IRB SOP Continuing Review policy.
- As with initial review, for continuing review the IRBs must determine that the regulatory criteria for approval continue to be met. Additionally, the IRBs must also find that significant new findings that may relate to a participant's willingness to continue taking part in the research are provided.

Review of Amendments

- Amendments that do not meet the criteria for expedited review must be reviewed by the convened IRB. All IRB members will be provided all modified documents (and any other information supplied by the investigator) and are responsible for reviewing the submitted materials in enough depth to be familiar with and prepared to discuss the information at the convened meeting.
- As with initial and continuing review, for a proposed amendment the IRBs must determine that the regulatory criteria for approval are met (when the modification affects one or more criterion for approval). Additionally, the IRBs must also find that significant new findings that may relate to a participant's willingness to continue taking part in the research are provided.
- Minor changes to previously approved research can be reviewed by expedited procedures as described in SOP Amendment to Previously Approved Research.
- If the amendment change is significantly different, then the PI will be asked to submit an initial IRB application.

IRB Determinations

- **Approval:** An approval is granted if the research activities meet the criteria for approval (45 CFR 46.111 and/or 21 CFR 56.111 and, if applicable Subparts B, C, and D) and no changes to the research are required by the IRB. Determination of the approval period for research approved by the convened IRB is made as described in SOP IRB Approval Period and Determination of Expiration.
- **Modifications Required to Secure Approval:** The IRB requires that the investigator (a) makes specified changes to the research protocol or informed consent document(s), (b) confirms specific assumptions or understandings on the part of the IRB regarding how the research will be conducted, or (c) submits additional documents, such that, based on the assumption that the conditions are satisfied, the IRB is able to make all of the determinations required for approval (under 45 CFR 46.111 and/or 21 CFR 56.111 and, if applicable, subparts B, C, and D). Under this scenario, further review of the research by the convened IRB is not necessary. The IRB may designate the chair (or other designee) to review the written response from the investigator, determine whether the conditions for approval have been met and, when they are met, approve the research. The date of approval is the date the chair (or designee) determines the conditions for approval have been met.
- **Deferral:** Substantial revisions, requests for more information for IRB consideration or other additional documentation are required, and preclude the IRB from making the determinations required for approval. The response to the IRB's concerns and any revisions to the protocol or consent documents must be reviewed at a convened meeting of the IRB.
- **Tabled:** Criteria for a convened IRB meeting or review of the protocol are not met (e.g., loss of quorum, appropriate expertise or representation for a vulnerable group is not present). Study is reviewed at a subsequent meeting when criteria for review are met.
- **Disapproval:** A study is disapproved if it is found to violate ethical standards with reference to the Belmont Report, without scientific or scholarly merit and/or does not meet the criteria for approval. Written notification from the IRB of a decision to disapprove a protocol is accompanied by the IRB's reasons for the decision and an invitation for reply by the Investigator. A protocol may not be disapproved under expedited review procedures.

Post-review Procedures

- IRB actions and findings will be reported to the principal investigator in writing.
- The investigator's department head and, if applicable, faculty sponsor are copied on all communications.
- The Institutional Official is informed of the IRB's review actions through periodic reports.
- Research that has been approved by the IRB may be subject to further review and approval (or disapproval) by officials of the institution (e.g., Institutional Official, Deans, etc.). However, no one may approve human subjects research that has not been approved by the IRB.

Review of Investigator's Responses to the IRB

- The IRB staff reviews responses from investigators for modifications required to secure approval and notes their pre-review comments with the response as time permits. The response is then assigned to the chair (or designee).
- Responses from PIs for deferrals are reviewed by the IRB staff and changes are verified. The deferral responses are then assigned to the next IRB meeting for re-review by the convened IRB. The IRB that originally reviewed the protocol must review the deferral response. The re-review is assigned to the original primary reviewers whenever possible.
- Responses and resubmissions from investigators for disapproved submissions are prepared for convened IRB review. The IRB that originally reviewed the submission reviews the response and resubmission, unless it was stipulated that a different IRB is able to review the response and resubmission.
- Investigators are provided 60 calendar days to respond to the IRB's findings. Failure to respond to the IRB's findings within 60 calendar days will result in administrative withdrawal of the submission from the review process. University closures are not exempted from the count of calendar days in this subsection, (e.g., Winter Break).

Investigator Appeals

- Investigators may appeal an IRB decision by submitting a request in writing, including a statement of the reason(s) for the appeal and any materials supporting the request. Supporting materials may include (but are not limited to) letters of support, current literature, and/or other information relating to the state of the art/science in the research discipline.
- Requests for reconsideration will be reviewed by the convened IRB responsible for the determination being appealed. Decisions made by expedited review can be reconsidered by expedited review, but rejection of an appeal can be made only by the corresponding convened IRB. Investigators will be notified of and may attend the IRB meeting at which this review will occur.
- Appeals must be made within 30 calendar days of investigator notification of the IRB decision in question. The IRB will review the request within 30 calendar days of receipt of the investigator's written materials. Investigators and institutional officials will be notified of the IRB's decision regarding the appeal within 14 days of convened review. University closures are exempted from the count of calendar days in this subsection, (e.g., Winter Break).
- Institutional officials may not overrule IRB disapproval decisions regarding appeals in research activities involving human subjects.

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

Author Reference
NEIU IRB

Ohio State University Review of Research by the Convened IRB
UIC Review of Research by the Convened IRB

Related Policies
SOP IRB Membership
SOP IRB Member Conflict of Interest
SOP Continuing Review
SOP Amendment to Previously Approved Research
SOP IRB Meeting Procedures
SOP IRB Approval Period and Determination of Expiration

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.