IRB Standard Operating Procedures		
SOP#: 008 **Revision#:**	**Title: Expedited Review of Research**	**Effective Date:** **May 3, 2019**
Approved By:	**Institutional Review Board**	**Effective Date:** **May 3, 2019**

PURPOSE

To define policies and procedures for conducting expedited review of human subjects research.

DEFINITIONS

Common Rule - also known as the Federal Policy for the Protection of Human Subjects - subpart A of the HHS Code of Federal Regulations [CFR] 45 Part 46. The Common Rule was updated on January 18, 2017 and went into effect on January 21, 2019.

Expedited review - 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 - 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.

Classified research - research conducted under the specific designation as Classified by the Federal funding sponsor or other governmental agency.

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

- For IRB purposes, the term "expedited" refers to the type of review, not the expediency of the review protocol. The IRB may review a research study using expedited review procedures if the study poses no more than minimal risk to subjects, as assessed by the reviewer; and meets specified criteria within the federal regulations, as listed in 45 CFR 46.110(b)(1).
- Expedited review procedures may not be used where identification of the subjects and/or their responses would place them at risk of criminal or civil liability or be damaging to the subjects' reputation, financial standing, employability, etc., unless reasonable and sufficient protections will be implemented so that risks related to invasion of privacy and/or breach of confidentiality are no greater than minimal.
- The expedited review procedure may not be used for classified research involving human subjects.
- The expedited review procedure should not be used for research involving prisoners. However, if an IRB chooses to use expedited review for research involving prisoners, OHRP recommends that the prisoner representative of the IRB be one of the designated reviewers.
- An expedited review may be performed by the IRB chair and/or experienced IRB member designated by the chair. In conducting expedited review, the IRB reviewers may exercise all of the authorities of the IRB except that they may not disapprove the research. A research activity may be disapproved only after review by the convened IRB. The reviewer may seek consultation and ask for an additional reviewer, or refer the application to the full committee if necessary. If it is determined that the study requires a full IRB review, the PI will be notified and the study will be treated as a greater than minimal risk study and reviewed by the full IRB.

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.

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. 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 the "Administrative Pre-review".
- All application material and pre-review notes from the administrative pre-reviewer will be shared with the IRB chair.

- The IRB chair will review the submitted material. The IRB chair will either conduct the review, or in consultation with IRB staff, assign an IRB member for formal review of the submission.
- If the IRB staff and IRB chair determine the submission is not eligible for expedited review, the study will be referred for full-IRB review and discussed at a convened IRB.

Initial Review

- The following individuals may review exempt applications: IRB chair, IRB members designated by the IRB chair.
- 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. The reviewer is expected to perform an in-depth review of the complete set of documents submitted by the investigator. Their review includes all materials submitted in conjunction with the IRB application and any additional materials obtained from the investigator by IRB staff during the pre-review process.
- By completing the review guide, the reviewer confirms that they have no conflicting interests and have the appropriate experience to review the research.
- The reviewer evaluates whether the criteria for approval at 45 CFR 46.111 (and subparts B, C, and D, when applicable) or 21 CFR 56.111 and other protocol-specific determinations are met for initial review. Evaluation of the requirements for the informed consent process and documentation or waiver or alteration (45 CFR 46.116 or 21 CFR 50.25) is also provided in writing. The reviewer documents these determinations on the designated review guide.
- The reviewer may also document on the appropriate review guide that the study meets the criteria for one of the following:
    a. Exempt: Refer to SOP Exempt Research.
    b. Non-Human Subjects Research: Refer to Non-Human Subjects Research checklist.
    c. Not Engaged in Human Subjects Research. Refer to SOP External Research.
- The completed review guides serve as documentation of the expedited review process and are maintained with the protocol record.
- The reviewer will share the final determination, along with any additional feedback, with IRB staff, who will then notify the PI."

Continuing Review

- As of January 21, 2019 – the effective date of the revised Common Rule – annual continuing reviews will no longer be required for most expedited studies. The NEIU IRB has the authority to decide which expedited studies will require continuing review.
- Expedited studies not subject to annual reviews will receive annual survey reminders with information regarding researcher responsibilities and project termination. Failure to respond to the survey will result in a hold on the PI's future IRB submissions.

Review of Amendments

- Amendments to research previously approved by the convened board are eligible for the expedited review process when the proposed changes are minor. Criteria defining a minor change and examples of minor changes are provided in Appendix Minor Changes in Research.
- In addition, a proposed change to an expedited approved protocol is eligible for expedited review if the proposed change in the research involves no greater than minimal risk and the research continues to meet the expedited review criteria.
- The reviewer evaluates whether the criteria for approval at 45 CFR 46.111 (and subparts B, C, and D, when applicable) or 21 CFR 56.111 and other protocol-specific determinations are met for amendments when the changes affect a criterion for approval.

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.
- **Modifications required to secure approval:** The IRB requires that the investigator (a) make specified changes to the research protocol or informed consent document(s), (b) confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted, or (c) submit 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).
- **Refer for convened IRB review:** Either the proposal does not meet the requirements for minimal risk, the expedited review categories, or minor change to previously approved research; the IRB reviewer(s) has concerns regarding the protocol and would like a convened review (e.g., complex design, involves a vulnerable population, approval criteria not met); or the IRB reviewer feels the research is not approvable.

Post-review Procedures

- IRB actions and findings will be reported to the PI in writing.
- Documentation for initial reviews conducted under an expedited review procedure include: (a) the specific permissible categories justifying the expedited review; and (b) documentation of the review and action taken by the IRB Chair or designated reviewer and any findings required under the HHS regulations.
- When the study is referred to the convened IRB for review, the letter describes the reason for referral, the date of the convened IRB meeting if known, and any recommendations for revisions, clarifications or additional information prior to convened IRB review.
- A monthly progress report regarding expedited IRB reviews will be developed and distributed to IRB members.
- 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 (i.e., and authorize it to proceed) that has not been approved by the IRB.

Review of Investigator's Responses to the IRB

1. Once the PI is notified of IRB stipulations, they must respond to all items listed on the notification letter. The PI must highlight their responses on the document and all supporting documentation and submit their response to the IRB.
2. The IRB staff reviews responses from investigators for modifications required to secure approval and notes their pre-review comments. The response is then assigned to the chair (or designee) for review and final determination.
3. 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).

Regulations

45 CFR 46.110, 45 CFR 46.111, 45 CFR 46.116
21 CFR 56.110, 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
Ohio State University Expedited Review Procedures
UIC Expedited Review Process
University of Missouri-Kansas City Expedited Review

Related Policies

SOP IRB Membership
SOP IRB Member Conflict of Interest
SOP Continuing Review
SOP Exempt Research
SOP Amendment to Previously Approved 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.