



| IRB Standard Operating Procedures | | |
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| SOP#: 007 Revision#: v.2 | Title: Exempt Research | Effective Date: May 3, 2019 |
| Approved By: | Institutional Review Board | Approval Date: May 3, 2019 |

PURPOSE

To define policies and procedures for making “exempt” determinations for human subjects research.

DEFINITIONS

Belmont Report - document that outlines the basic ethical principles in research involving human subjects.

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.

Exempt review – research may qualify for exempt status if it involves minimal or no risk and meets the criteria for exemption 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.

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

POLICY

- Minimal risk research in which activities involving human subjects are limited to one or more of the categories defined in [45 CFR 46.104](#) of the revised Common Rule may qualify for exemption from the federal regulations outlined in [45 CFR 46](#).
- Although exempt research is not subject to the federal regulations outlined in 45 CFR 46, the NEIU policy requires all research involving human subjects, including exempt research, to be performed responsibly and in accordance with the ethical guidelines of the Belmont Report.
- Principal investigators (PIs) of exempt research are expected to institute appropriate protections, including obtaining informed consent as appropriate and implementing measures to protect privacy and confidentiality of research subjects.
- PIs do not have the authority under federal guidance and this policy to independently determine that research involving human subjects is exempt. PIs must submit a claim of exemption to the IRB and receive written documentation of the decision from the IRB before initiating the research.
- Changes to an exempt study that significantly alter the approved research design, instruments, subject population, and/or recruitment and consent procedures as determined by the IRB must be submitted for review as a new IRB application.
- Exempt determinations are valid for five (5) years. Exempt studies that continue beyond five (5) years must be re-submitted for review as a new IRB application.

PROCEDURES

The 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

- 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 PI without review.
- Once complete application material 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.
- 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 exempt review, the study will be referred for expedited or full-IRB review.

Review

- The following individuals may review exempt applications: IRB chair, IRB members designated by the IRB chair, and IRB staff 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.
- Exempt applications are reviewed to ensure the research will be conducted in accordance with the principles of The Belmont Report.
- The reviewer will document their review and assessment of the research by completing an IRB Review Sheet.
- If limited review is required, the review process will follow the provisions outlined in SOP Expedited Review.
- The reviewer makes the final determination about the category of exemption or any other appropriate determination.
- The reviewer will share the final determination, along with any additional feedback, with IRB staff, who will then notify the PI.

Review of Amendments to Exempt Research

- Any proposed amendments to a project that has received a certification of exemption must be submitted to the IRB for review prior to implementation.
- The proposed amendment is submitted using the amendment submission form. Refer to SOP Amendment to Approved Research.
- Amendments to research protocols that were granted an exemption are reviewed to determine whether or not the change to the research would alter the exempt status, thus requiring either expedited or convened IRB review.
- Exempt research may be moved to expedited or convened review dependent upon the nature of the amendment.

IRB Determinations

- Exemption is granted.
- Additional information or clarifications are needed before the final determination can be made.
- Non-Human Subjects Research: Refer to Non-Human Subjects Research checklist.
- Not Engaged in Human Subjects Research. Refer to SOP External Research.
- Research proposal requires limited review and must be reviewed by the IRB under the limited review processes. Refer to SOP Limited Review.
- Research proposal does not meet the criteria for exemption and must be reviewed by the IRB under expedited or convened review processes.

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 communication contains, as applicable:
 - a. Any issues requiring resolution;
 - b. Recommendations for changes in the level of review;
 - c. Requests for further information.
- For research granted an exemption, the communication contains documentation of:
 - a. The exemption category (ies);
 - b. The investigator's responsibility to submit any amendment to the research for review and other responsibilities;
 - c. Other applicable investigator's responsibilities
- A monthly progress report regarding expedited IRB reviews will be developed and distributed to IRB members.
- The Institutional Official is informed of the IRB's review actions through periodic reports.

Review of Investigator's Responses to the IRB

The IRB staff reviews responses from investigators for additional information and clarifications required to make an exempt determination. The response is then forwarded to the IRB chair (or designee).

Regulations

45 CFR 46.104
21 CFR 56.104

Author Reference

NEIU IRB
[UIC Exempt Review of Research](#)

Related Policies

[SOP IRB Member Conflict of Interest](#)
[SOP Amendment to Previously Approved Research](#)
[SOP Limited Review](#)
[SOP External Research](#)

Contact Information

Please direct questions or concerns about this policy to:

Contact

IRB Office
Dean of the College of
Graduate Studies and Research

Phone

773-442-4675
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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.