Guidance: Review types & processes

Overview

Northeastern University human research protection office (HRPO) has three primary roles: (i) protect human participants by ensuring applicable studies comply with the federal regulations; (ii) promote ethical and compliant research by providing education and training tools; and (iii) enhance research efforts in the development of resources, e.g., forms, templates, checklists, and guidance. This guidance details components on how the HRPO protect human participants by ensuring applicable studies comply with the federal regulations.

Protect human participants by ensuring applicable studies comply with the federal regulations.

Northeastern University has a Federalwide Assurance with the Department of Health and Human Services which sets forth a program that adhere to regulations, aka The Common Rule, for all research that falls under the definition of human subject research. At Northeastern, it is the practice that the HRPO makes exempt determinations, and the Institutional Review Board (IRB) is responsible for reviewing and approving minimal high risk research efforts for new applications, modifications, renewals and unanticipated incidences.

The HRPO staff initially screens submissions to determine the completeness and the appropriate type of review. It is during this process that the review type, comprehensive, exempt or not regulated is determined. Submissions may be returned to the study team for changes before the review type is assigned. The review type may be reassessed at any time during the review process.

The following determine the type of review required:

- Level of risk to participants
- Type of research being conducted (e.g., an educational intervention, a survey, an ethnographic observation, etc.)
- Sensitivity of the research questions or complexity of the research design
- Involvement of vulnerable populations as research participants
- Use of identifiable information or identifiable biospecimens
- Applicability of one or more of the criteria for exempt or expedited review.

Research requiring comprehensive IRB review

The IRB may conduct either an expedited (defined as minimal risk research) or full board review (more than minimal risk study) and determine the following criteria for approval are met before approval is granted:

Criteria #1	Risks to subjects are minimized.
Criteria #2	Risks the subjects are reasonable in relation to benefits.
Criteria #3	Selection is subjects is equitable.
Criteria #4	Informed consent will be sought from each prospective subject are the subjects legally authorized representative unless this requirement is waived by the IRB.
Criteria #5	Informed consent will be appropriately documented as regulated by local, state and federal regulations unless the requirement is waived by the IRB.
Criteria #6	For greater than minimal risk research or NIH funded/FDA regulated clinical investigations, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. the proposed plan should be commensurate with the nature, size, and complexity of the research as well as the degree of risk involved.
Criteria #7	When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Full board review

Regulations and institutional policy require a review by the convened IRB when the research involves **more than minimal risk** to human subjects or does not meet the criteria for one of the expedited categories or has been referred to the committee by an expedited reviewer or IRB Chair. Regardless of risk level, the HRPO may require review by the convened IRB when:

- Vulnerable populations, particularly prisoners
- Sensitive topics, including illegal behaviors which may require an NIH Certificate of Confidentiality to protect subject data from compelled disclosure.
- Research involving genetic/genomic analyses.
- A complex research design requiring the expertise of multiple board members.

Rather than being deadline driven, items are placed on an IRB agenda when it is determined to be complete, and all required attachments are provided. The HRPO staff assigns a primary and secondary presenter from the members of the IRB for all protocols requiring initial full review, continuing full review and for all protocols requiring full review of modifications to previously approved research.

When making reviewer assignments, the HRPO staff takes into consideration: subject population targeted, especially when they include a vulnerable group; procedures the subjects will undergo; and the appropriate scientific or scholarly expertise. If HRPO staff cannot identify a primary reviewer with appropriate expertise, the IRB Chair, or the Executive Director of the HRPO will solicit consultants from the university or the community with competence in special areas.

At the meeting, the primary reviewer presents an overview of the goals, design, study procedures, safety procedures, and qualifications of the investigators and leads the IRB through the completion of the regulatory criteria for approval. The secondary presenter will follow with additional comments. Following both presenters' review, members of the IRB may respond to items raised and add additional comments and/or concerns. Regardless of the assignment of presenters, there is an expectation that all IRB members will review the protocols on the month's agenda.

Expedited review

If a study is deemed to have minimal risk the expedited review process may be applied. These submissions require review by only one IRB member and do not require board discussion. An HRPO staff member will identify an appropriate board member and inquire if they are able to complete a review. It is requested that board members inform the HRPO staff if they are unable to complete the review expeditiously so an alternate reviewer may be identified. When a protocol is reviewed by the expedited procedure, reviewers are provided and are expected to review all information that the convened IRB would have received. For expedited review protocols, any IRB member can also request a full board review by contacting the HRPO.

The following two criteria must be met before a protocol may be considered for an expedited review process:

1. The activity must present no more than minimal risk to subjects. The regulatory definition of "minimal risk" is the probability and magnitude of 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; and
2. The protocol procedures must be listed as one of the categories in the regulations' list of procedures that qualify for an expedited review process.

Comprehensive review actions

The IRB can make any of the following determinations for both expedited and full-board reviews.

- **Approved** – The submission is approved with no revisions requested by the IRB.
- **Pending Stipulations** – The submission and/or supporting documents require minor revisions, with suggestions or direct actions recommended by the board member or convened board. The HRPO staff, listed on the OHRP roster, may approve the study upon receipt and approval of the revisions without further action or review required. Approval of the submission will not be granted until all required changes are addressed, and documents revised accordingly.
- **Deferred** – The protocol and/or supporting documents require major revisions and the IRB was unable to vote on all 7 criteria for approval due to the need for additional information, revisions, or clarification. Revised material and responses to the IRBs questions will return to the next appropriate IRB when determined.
- **Disapproved** – Questions are significant that one or more 7 criteria for approval cannot be met, and the IRB is unsure how the protocol could be approved or determines the risk level far outweighs the research benefits. Disapprovals are communicated to the PI and provide the reason(s) for the disapproved action. If an expedited reviewer believes a protocol should be disapproved, it will be placed on the next appropriate IRB agenda.

Note: A designated member may approve, request modifications, or request review of a protocol by the full board. A designated reviewer does not have the authority to disapprove an application.

Exempt determinations

The Code of Federal Regulations identifies several different categories of minimal risk research as being exempt from the Common Rule, 45 CFR, Part 46. Exempt research is the lowest level of review, available for research that falls in one of 6 categories. At Northeastern, the exempt determination must be made by an authorized or appointed member of the HRPO or IRB.

Note: Northeastern University is not utilizing the broad consent option currently under categories 7 and 8.

Modifications do not need to be submitted for exempt studies so long as the research remains minimal risk and stays within the boundaries of the exemption categories that the IRB found were applicable to the research.

There are also instances where modifications will not impact risks to participants or impact exempt determination, however, must still be reported to the office. Examples of these include:

- change of Principal Investigator
- new data collection sites where a letter of support is required.
- addition of external funding source

Notification of exempt determination & IRB approval

Human subject research cannot begin until the PI is in receipt of an exempt determination letter or notification of IRB approval sent by the OHRSP. The following material be provided with the approval packet.

1. Exempt determination letter or notification of IRB approval letter.
2. IRB application form containing a list of all research related documents and associated version dates.
3. Copies of written consent/assent documents to be signed by the participant.

Modifications to exempt or IRB approved protocols

All required modifications are to be submitted with a modification form. When the protocol form is revised, the document should identify the version dte. In addition, all research related documents are to either have an updated version date (if revised) and/or inclusion of any new documents added to the study. The same approval material will be provided as noted above.

Not regulated research

Not all research-related activities that involve people, their data, or their biospecimens are covered by the regulations governing human research. Submission to the IRB is not required for the following activities:

- Case studies
- Class activities
- Journalism/documentary activities
- Oral history
- Quality assurance and quality improvement activities
- Research on organizations
- Research using deidentified data or biospecimens
- Research using publicly available data sets.
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Some categories require IRB review for the purpose of assessing compliance with HIPAA or other regulations. These include:

- Research involving existing information or biospecimens that have been coded before the researcher receives them, but identifiers exist.
- Research involving deceased individuals only.
- Pre-review of clinical data sets preparatory to research.

- Standard public health surveillance or prevention activities.

Multi-site research

To help reduce the administrative burden with duplicative reviews and manage the complexity of multi-site research, reliance agreements may be established. Guidance has been developed for Northeastern University (NU) researchers who are collaborating with coinvestigators/research team members who are affiliated with other institutions or are independent investigators.

Northeastern applies the same principles detailed in the federal regulations, CFR Title 45, Part 46 regardless of funding source. Therefore, the reliance agreement processes extend to research studies with no external funding.

There are two different types of reliance agreements:
Institutional Authorization Agreement (IAA): a formal, written agreement in which the reviewing IRB agrees to serve as the IRB of record for a relying institution. Agreements are generally used to cover a single research study, categories of research studies, or all human subjects research under an organizations FWA.

Individual Investigator Agreement (IIA): an agreement is when one institution agrees to serve as the IRB of record for a non-NU investigator who's collaborating on the research study and is not affiliated with an institution with its own IRB.

Note: Northeastern will not engage in reliance agreements with institutions that do not hold a FWA. External researcher agreements or separate IRB oversight (i.e., a commercial IRB) be sought in those cases.

Resources & References

Applying the 7 criteria for approval
Code of Federal Regulations, 45 Part 46
Components of informed consent
Definitions & terms used in human subject research
Designing human subject research
Establishing reliance agreements
Exemption categories and considerations
Expedited Categories
Overview of human subject research
Secondary analysis of existing data sets
Undergraduate research & classroom activities