Northeastern University
IRB Charter & Board Member Manual

Section I: Overview
I.1 Authority of the IRB
I.2 Jurisdiction of the IRB

Section II: Roles & Responsibilities
II.1 Institutional Official
II.2 Office of Human Subject Research Protection
II.3 Institutional Review Board
II.4 Chairperson of the IRB
II.5 IRB Members
II.6 IRB Alternate Members
II.7 Use of Consultants, i.e., External Reviewers
II.8 RB Subcommittees

Section III: Review Types & Review Actions
III.1 Full Board Review
III.2 Expedited Reviews
III.3 RB criteria for approval
III.4 Review Actions
III.5 Rebuttal or Appeal of IRB Decisions
III.6 Exempt Determinations

Section IV: IRB Meetings
IV.1 Composition of the IRB
IV.2 IRB Meeting Schedule
IV.3 Quorum
IV.4 IRB Member Conflicts of Interest
IV.5 Attendance Expectations

Section V: Documentation of IRB Determinations

Section VI: IRB Member Training & Continuing Education
VI.1 Initial Education
VI.2 Continuing Education

Section VII: Resources

Section I: Overview

Northeastern University (NU) fosters a research environment that promotes and respects the rights and welfare of individuals recruited for and/or participating in research conducted by or under the auspices of the University. In the review and conduct of research, actions by NU will be guided by the principles (i.e., respect for persons, beneficence, and justice) set forth in the *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (often referred to as the Belmont Report), and will be performed in accordance with the Department of Health and Human Services (DHHS) policy, and regulations at 45 CFR 46 (also known as the "Common Rule"), and the Food and Drug Administration regulations at 21 CFR 50 and 21 CFR 56. The actions of NU will conform to all other applicable federal, state, and local laws and regulations as well as policies of NU's network of domestic campuses.

Northeastern University holds a Federalwide Assurance (FWA), approved by the DHHS. This is as an assurance of compliance with the federal regulations for the protection of human subjects in federally funded research. The FWA is also approved by Office for Human Research Protection (OHRP) for federal-wide use, which means that other departments and agencies that have adopted the Common Rule may rely upon the FWA for the research that they conduct or support.

Northeastern University's:
FWA registration: FWA00004630
OHRP registration: IRB00000356
Institution organization: IORG0000211

I.1 Authority of the IRB

The IRB ensures that appropriate safeguards exist to protect the rights and welfare of research subjects [45 CFR 46.111]. In fulfilling these responsibilities, the IRB reviews all relevant documents that detail the research activities, including but not limited to: the application or protocol, the consent/assent document(s), survey instruments, focus group guides, questionnaires and similar measurement tools, and recruitment materials.

Before any human subject is involved in research anywhere in the Northeastern network, the IRB will give proper consideration to:

i. The risks to the subjects;
ii. The anticipated benefits to the subjects and others;
iii. The importance of the knowledge that may reasonably be expected to result; and
iv. The informed consent process to be employed.

The IRB has the authority to:

- Approve, require modifications to secure approval, and disapprove all research activities overseen and conducted by the Northeastern research community.
- Suspend, place restrictions, or terminate approval of research activities that fall within its jurisdiction that are not being conducted in accordance with IRB requirements or that have been associated with serious harm to subjects.
- Observe or have a third party observe the consent process and/or the research.

I.2 Jurisdiction of the IRB

The IRB jurisdiction extends to ALL research (funded and not funded) involving human subjects conducted by NU faculty members, students, and staff affiliated with any domestic Northeastern University campus.

If an IRB chair, IRB member, or member of the Office of Human Subject Research Protection (OHSRP) feels that the IRB has been unduly influenced by any party, they shall make a confidential report to the Institutional Official. Upon receiving the report, the Institutional Official will conduct a thorough investigation and corrective action will be taken to prevent additional occurrences.

Section II: Roles & Responsibilities

II.1 Institutional Official (IO)

The President of the University has designated the Senior Vice Provost for Research as the Institutional Official (IO). The IO has:

- The responsibility to ensure that the NU OHSRP has the resources and support necessary to comply with all institutional policies and with federal regulations and guidelines that govern human subjects' research;
- the signatory of the FWA and assumes the obligations of the FWA;
- the authority to review and sign the Department of Defense (DoD) Addendum for DoD sponsored research;
- the role of point of contact for correspondence addressing human research with the DHHS, OHRP, and the FDA.
- The authority to delegate the performance of these duties, as necessary.

II.2 Office of Human Subject Research Protection (OHSRP)

The Office of Human Subject Research Protection (OHSRP) serves as the official oversight office for human subject research conducted by faculty members, student or staff affiliated with any domestic Northeastern University campuses.

The OHSRP staff function independently of, but in coordination with, other institutional regulatory committees. The OHSRP is a unit within NU-RES and has three primary responsibilities:

(i) Protect the rights and welfare of potential and engaged research participants.
(ii) Provide administrative support, services and resources to the all IRBs across the Northeastern network.
(iii) Promote ethical research through partnerships with the research community.

II.3 Institutional Review Board (IRB)

It is the responsibility of the IRB to:

- Review research protocols involving human subjects.
- Evaluate both risk and the procedures protecting subjects against risk.
- Assist the investigator(s) in complying with federal, state and local regulations.

II.4 Chairperson of the IRB

The NU Institutional Official, in consultation and approval with the IRB members and the Executive Director of the OHSRP, appoints a Chair and Vice Chair (as needed) of the IRB to serve for renewable three-year terms.

The IRB Chair should be a highly respected individual from within the University, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The IRB must be perceived to be fair, impartial and immune to pressure by the institution's administration, the investigators whose protocols are brought before it, and other professional and nonprofessional sources.

An IRB Chair has the following roles and responsibilities:

- Providing leadership to the IRB to help ensure the rights and welfare of human subjects participating in research reviewed by the IRB.
- Conducting convened meetings.
- Leading discussions with investigators and/or administrators to resolve controversial and/or procedural matters relating to research approval and conduct.
- Managing conflicts of interest, including by ensuring that IRB members with conflicts are not present for review of research for which a conflict may exist.
- Administering IRB decisions.
- Participating in the development of meeting agendas, policies, procedures, and educational efforts to support the OHSRP.
- Maintaining a current knowledge of and assuring compliance with relevant regulations, laws, and policies related to the protection of human subjects.
- Regularly consulting with the OHSRP staff regarding IRB issues.

- Assisting with investigations and review of alleged noncompliance with human subjects' protections requirements.
- Ensure a determination is made and voting takes place for each action item on the agenda.
- Reviews minutes resulting from each meeting and leads a vote to approve the minutes.

II.5 IRB members

The OHSRP 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 OHSRP 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 OHSRP staff cannot identify a primary reviewer with appropriate expertise, the IRB Chair, or the Executive Director of the OHSRP will solicit consultants from the university or the community with competence in special areas. This process is discussed in further detail in the "Use of Consultants and External Reviewers" section.

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 [46.111] 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.

II.6 IRB alternate members

The appointment and function of alternate members is the same as that for primary IRB members, and the alternate's expertise and perspective are comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting or recuses themselves from voting.

The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member.

II.7 Use of Consultants, i.e., External Reviewers

When necessary, the IRB Chair or the Executive Director of the OHSRP solicit individuals from the university or the community with competence in special areas to assist in the review of issues or protocols which require appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB. The need for an outside reviewer is determined by the Executive Director or the Chair during the protocol review. The OHSRP will ensure that all relevant materials are provided to the outside reviewer. Only the IRB Chair, or one or more designated reviewers among members of the IRB, may carry out the review.

Written statements of consultants will be kept in IRB records. Key information provided by consultants at meetings will be documented in the minutes. Written reviews provided by the outside reviewer will be filed with the protocol.

The Executive Director of the OHSRP reviews the conflicting interest policy for IRB members with consultants and consultants must verbally confirm to the Executive Director that they do not have a conflict of interest prior to review. Individuals who have a conflict of interest or whose spouse or family members have a conflict of interest will not be invited to provide consultation.

The consultant's findings will be presented to the full board for consideration either in person or in writing. If in attendance, these individuals will provide consultation but may not participate in or observe the vote.

II.8 IRB subcommittees

The Chair, in consultation with the Executive Director, may designate one or more other IRB members, i.e., a subcommittee, to perform duties, as appropriate, for review, signature authority, and other IRB functions.

Duties of a subcommittee may include the following:

1. Serve as designees by the IRB Chair for the **expedited review** of new or continuing protocols, and/or modifications of continuing protocols. The subcommittee must be experienced in terms of seniority on the IRB and must be matched as closely as possible with their field of expertise to the study.
2. **Review and approve the revisions requiring only simple concurrence** submitted by investigators for a protocol given provisional approval, i.e., "Pending Conditional" by the convened IRB.
3. **Conduct an inquiry** into allegations of non-compliance. The OHSRP and/or IRB should notify the NU-RES compliance team about any inquiry deemed necessary.

Section III: Review Types and Review Actions

III.1 Full board reviews

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:

Review process
Items are placed on an IRB agenda when it is determined to be complete and all protocol documents are provided. Submission types include: (i) initial protocol applications; (ii) modifictions; (iii) renewals; and, (iv) unanticipated incidences, including protocol violations (noncompliance), participant complaints, and adverse events.

As submissions are ready to be placed on a meeting agenda, the OHSRP staff assigns a primary and secondary presenter. The expectation is that the reviewers provide comments to the OHSRP several days prior to the meeting. The isues are consolidated and shared at the time of the meeting. This allows for a more efficient discussion of the protocol and needed revisisons. The OHSRP will make every effort to get the submissions to the reviewers in hopes that identified issues may be resolved prior to the meeting.

When making reviewer assignments, the OHSRP 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 a reviewer with appropriate expertise cannot be identified, the IRB Chair, or the Executive Director will solicit consultants from the university or the community with competence in special areas.

III.2 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. The submission and non-exempt reviewer guide will be sent as email attachments. The expectation is the minimal risk protocols are reviewed between 3-5 business days. Following their review, members are to return the completed reviewer guide. At this point, the staff reviewer will communicate stipulations with the research team. A board member may request to see the revised material or indicate that the staff can approve when all issues are addressed.

We understand there may be conflicts with schedules making it difficult to review in the 3-5 day time frame. It is requested that board members inform the OHRSP staff if they are unable to complete the review expeditiously so an alternate reviewer may be identified. Furthermore, if members already know about times when they will be unable to review, e.g., sabbatical, grant

applications deadlines, we ask that this be communicated to the OHRSP staff as soon as possible.

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.

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.

II.3 IRB criteria for approval

All IRB protocols are required to meet criteria for approval before the research may begin. The criteria are based on federal regulations and the ethical principles discussed in the Belmont Report.

The IRB forms are designed to address these criteria and thereby assist the IRB in collecting enough information to make a determination of approval. For minimal risk protocols, where expedited review is appropriate, the assigned reviewer will complete a reviewer guide which include the seven criteria. For more than minimal risk protocols, that are reviewed by the convened IRB, discussion will take place regarding the seven criteria and the meeting minutes will reflect the Board's determination.

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.

III.4 Review actions

The convened IRB can make any of the following determinations:

- **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 – for expedited reviews: The designated expedited reviewer 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.

III.5 Rebuttal or appeal of IRB decisions

If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision, and give the investigator an opportunity to respond in person and/or in writing.

Investigators may appeal an IRB decision. A principal investigator may appeal the decision by writing a letter to the IRB requesting reconsideration. At the discretion of the chair, the investigator may make such an appeal in person and/or in writing to the IRB.

An appeal of a disapproved research project must be reviewed at a full board meeting.

In the case of a decision by the IRB to disapprove, suspend, or terminate a project, the decision may not be reversed by the Vice President for Research or any other officer or agency of the University of Virginia, state government or federal government.

The IRB retains the final authority for approval of proposed research with human subjects.

III.6 Exempt determinations

All research engaging human subjects must be approved by NU. However, there are certain types of required review based on the nature of the research, study sponsor, eligible subjects and risks to subjects. 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 OHSRP or IRB..

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

Section IV: IRB Meetings

IV.1 Composition of the IRB

The requirements for IRB membership are addressed in the HHS regulations at 45 CFR 46.107 [Note: 45 CFR 46.304 requires a specialized IRB composition when research involving prisoners is being reviewed, including the presence of a prisoner representative]. IRB members are appointed by the Institutional Official in consultation with members of the NU-RES team and academic department leaders.

An IRB must:

1. have at least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution;
2. make every nondiscriminatory effort to ensure that the membership is not composed of entirely men or entirely women;
3. include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
4. include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; and

5. not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

A list of our current membership can be found on the OHSRP website.

IV.2 IRB meeting schedule

The IRB meets monthly via a virtual platform; e.g., Microsoft Teams, Zoom, etc. Members may also attend by phone and meetings may occur in person. The IRB will schedule ad hoc meetings, when the need arises. A current list of IRB meeting dates can be found on the OHSRP website.

IV.3 Quorum

A quorum consists of a simple majority of the voting membership (or their designated alternates), including at least one member whose primary concern is in a non-scientific area. When the meeting agenda includes research protocols involving prisoners, a prisoner representative must also be present**.** A quorum must be maintained before calling the meeting to order and throughout the duration of the meeting.

All registered, full-time members preset at a convened meeting have full voting rights, unless they recuse themselves during the review due to a conflict of interest. Alternate members may vote when substituting for a primary member. For the research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

The non-affiliated member represents the perspective of research participants. These members serve an essential and unique role to the IRB. While the presence of a non-affiliated member at the meeting is not mandated by DHHS or FDA to meet quorum, NU strives to ensure their attendance at every meeting.

IV.4 IRB Member Conflicts of Interest

An IRB member is said to have a Conflict of Interest (COI) whenever that IRB member, or their spouse, domestic partner, or first degree relative:

- Is an investigator or key personnel on the protocol under consideration;
- Acts as an officer or a director of the sponsor or an agent of the sponsor;
- Is involved in the research as a coordinator, protocol consultant, co-investigator, and/or primary advisor;
- Per the NU Policy on Conflict of Interest & Commitment: Has a financial interest, including a compensation arrangement or receipt of income, equity interests, or intellectual property rights, from, with, or in an investigator or sponsor of the protocol under consideration;11

- Has identified themself for any other reason as having a conflicting interest (e.g., having a close personal or professional association with the submitting investigator, serving as co-investigator and/or the primary mentor for a student or postdoc investigator).

It is the responsibility of each IRB member to disclose any COI in a study submitted to the IRB and recuse themself from the review of that protocol. No member may participate in the discussion of any research project in which the member has a conflict of interest, except to provide information or answer questions from the IRB as requested. Members with a COI for a protocol may not be present during IRB voting on that protocol.

IV.5 Attendance expectations

Members are expected to attend all all scheduled IRB meetings. If a member is unable to attend a scheduled meeting, they should inform the IRB Chair, Vice Chair, or an OHRSP staff member. If an IRB member is to be absent for an extended period, such as for a sabbatical, they are instructed to notify the OHRDP as soon as possible so an appropriate replacement can be obtained.

Section V: Documentation of IRB Determination

The OHSRP retains documentation of all approved IRB protocols and related attachments.

Proceedings of each IRB meeting are written and available for review by members before voted on. Once approved by the members at an IRB meeting, the minutes may not be altered by anyone including a higher authority.

IRB members are to be informed of all actions taken by the IRB, regardless of review types. A report is generated and distributed monthly to committee members which details submissions approved using an expedited review process.

Section VI: IRB Member Training & Continuing Education

A vital component of a comprehensive human research protection program is an education program for the IRB members. Northeastern University is committed to providing training and continuing education for IRB members and the OHSRP staff.

VI.1 Initial Education

All IRB members will receive an orientation to include a review of: federal regulations and university policies; the human research protection review process at NU; and, the role and responsibilities of IRB members.

Northeastern University has a contract with the Collaboration of Institutional Training initiative (CITI) who offers an interactive set of modules designed to improve knowledge of the Common Rule and the Belmont Report principles. In addition to completing the CITI Core Training modules, IRB members are to complete the "What Every IRB Member Needs to Know" module.

VI.2 Continuing Education

To ensure that oversight of human research is ethically grounded, and the decisions made by the IRB are consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service. Educational activities include, but are not limited to:

- In-service training at IRB meetings;
- Training workshops;
- Copies of appropriate publications;
- Identification and dissemination by the OHSRP of new information that might impact the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues to IRB members via email, mail, or during IRB meetings;
- Access to webinars and other on-line education programs; and
- Regional or national conferences, virtual or in-person.

Section VII: Resources

Belmont Report

Common Rule

Exemption Categories

Expedited Categories

FDA: Protection of Human Subjects

FDA: Institutional Review Boards

Federal Regulations: Criteria for Approval

NU's Office for Human Subject Research Protection (OHSRP)