

- Where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy.

A formal relationship must be established between the University and the other institution(s) through either a Cooperative Agreement, a Memorandum of Understanding, or an IRB Authorization Agreement (IAA). This relationship must be formalized before the University will accept any human research proposals from the other institution or rely on the review of the other institution.

### Collaborative Research general requirements

For all collaborative research in which NYU serves as an engaged institution, the PI must identify all institutions engaged in the research and the responsible IRB(s). The procedures for dissemination of protocol information (IRB initial and continuing approvals, relevant reports of unanticipated problems, protocol modifications, and interim reports) between all participating institutions will be determined in the following ways:

- When New York University relies on another IRB, the HRPP staff will ensure that the other organization has an active IRB registration and appropriate policies in place.
- When New York University reviews research on behalf of another institution, the particular characteristics of each institution's local research context must be considered, either (i) through knowledge of its local research context or (ii) through subsequent review and documentation by the appropriate designee of the relying institution.

The investigator is responsible for serving as the single liaison with outside regulatory agencies, with other participating facilities, and for all aspects of internal review and oversight procedures. The investigator is responsible for ensuring that all participating facilities obtain review and approval from their IRB of record and adopt all protocol modifications in a timely fashion. The investigator is responsible for ensuring that the research study is reviewed and approved by any other appropriate committees at the collaborating facility and the participating facilities before the enrollment of participants.

## 2. THE INSTITUTIONAL REVIEW BOARD

The following describes the authority, role, and procedures of the New York University Institutional Review Board (IRB).

### 2.1 PURPOSE

The IRB is established to ensure the protection of human participants in research under the auspices of New York University.

## 2.2 IRB AUTHORITY

The IRB is authorized to:

1. approve, require modifications to secure approval, or disapprove all research activities overseen and conducted under the auspices of New York University;
2. suspend or terminate approval of research not being conducted under the IRB's requirements or that has been associated with unexpected serious harm to participants;
3. observe, or have a third party observe the consent process; and
4. observe, or have a third party observe, the conduct of the research.

Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. However, those officials may NOT approve of research if the IRB has disapproved of it. University officials may strengthen requirements and conditions, or add other modifications to secure University approval or approval by another University committee.

## 2.3 NUMBER OF IRBS

There is currently one Institutional Review Board. The IO, the HRC Director, and the Chair of the IRB shall review the activities of the IRB at least annually to determine the appropriate number of IRBs needed for the institution.

## 2.4 ROLES AND RESPONSIBILITIES

### **Chairperson of the IRB**

The New York University IO (Vice Provost for Research), in consultation with the HRC Director, appoints a Chair and Vice-Chair of the IRB. Any change in appointment, including reappointment or removal, requires written notification. Appointments have a specified term of three years with the first year probationary. At the end of the probationary period, the new member is invited to continue on for two additional years, upon agreement of the new member and the IO, in consultation with the Chair and HRCO.

The IRB Chair shall be a highly respected individual with an active appointment at the University, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the Chair. The IRB must

be perceived to be fair, impartial, and immune to pressure by the institution's administration, the investigators who bring protocols before it, and other professional and nonprofessional sources.

The IRB Chair is responsible for conducting the meetings and is a signatory for full-board correspondence generated by the IRB, as is the Vice Provost for Research, the Vice-Chair, or HRC Director.

The IRB Chair may designate other IRB members to perform duties, as appropriate, for review, signature authority, and other IRB functions (e.g., the Vice-Chair and HRC Director.)

The IRB Chair may advise the IO and HRC Director about IRB member performance and competence.

IRB Chair performance review is on an annual basis by the HRC Director in consultation with the IO. If the Chair is not acting in accordance with the IRB's mission, is not following these policies and procedures, has a disproportionate number of absences, or is not fulfilling the responsibilities of the Chair, the Chair will be removed.

### **Vice-Chair of the IRB**

The Vice-Chair has comparable qualifications to the IRB Chair. In the Chair's absence, the Vice-Chair may exercise the authority and duties of the Chair.

### **Subcommittees of the IRB and Delegation of Expedited Review**

The Chair, in consultation with the HRC 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:

- Serve as designees by the IRB Chair for the expedited review of new or continuing protocols, and modifications. The subcommittee must be experienced in terms of seniority on the IRB.
- Review and approve the revisions requiring only simple concurrence submitted by investigators for a protocol given conditional approval by the convened IRB.
- Conduct an inquiry into allegations of non-compliance
- Conduct on-site review. The IRB determines on a protocol-by-protocol basis of the review interval and the need for additional supervision and participation. (For example, for an investigator who is performing particularly risky research,

or for an investigator who has recently had a protocol suspended by the IRB due to regulatory concerns, an on-site review by an IRB subcommittee might occur, or approval might be subject to an audit of study performance after a few months of enrollment or after enrollment of the first several participants).

## 2.5 IRB MEMBERSHIP

IRB members are selected based on appropriate diversity, including consideration of race, gender, cultural backgrounds, and specific community concerns, in addition to representation by multiple, diverse professions, knowledge, and experience with vulnerable participants and inclusion of both scientific and non-scientific members. The structure and composition of the IRB must be appropriate to the volume and nature of the research that is reviewed. Every effort is made to have member representation that understands the areas of specialty that encompass most of the research performed at New York University.

In addition, the IRB will include members who are knowledgeable about and experienced working with vulnerable populations that typically participate in New York University research or have ready access to consultants with appropriate knowledge and experience.

The IRB must promote respect for its advice and counsel in safeguarding the rights and welfare of research participants and possess the professional competence necessary to review specific research activities. A member of the IRB may fill multiple membership position requirements for the IRB.

## 2.6 COMPOSITION OF THE IRB

If the IRB regularly reviews research that involves a vulnerable category of participants, consideration will be given to the inclusion of one or more individuals on the IRB who are knowledgeable about and experienced in working with these participants. When protocols involve vulnerable populations, the review process will include one or more individuals who are knowledgeable about or experienced in working with these participants, either as members of the IRB or as consultants.

Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB shall not consist entirely of members of one profession.

The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.

The IRB includes 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.

One member may satisfy more than one membership category.

Senior staff of the Human Research Compliance Office may serve as voting members of the IRB.

## 2.7 APPOINTMENT OF MEMBERS TO THE IRB

### Member appointment process and terms

The IO, IRB Chair, Vice-Chair, or the HRC Director may identify a need for a new or replacement member or alternate member. Individual IRB members may nominate candidates and send the names of the nominees to the HRC Director. Department Chairs and others may forward nominations to the IO, to the HRC Director, or to the IRB Chair or Vice-Chair. The IO, the IRB Chair, and the HRC Director have the final decision in selecting a new member. Appointments are made in writing by the IO or the HRC Director.

Faculty appointments to the IRB are usually for three-year renewable terms, with the first year probationary. Unaffiliated member and student member appointments are for terms of one year or less. Any change in appointment, including reappointment or removal, will be provided through written notification.

Members may resign by written notification to the Chair, HRC Director, or the IO.

All appointments are subject to annual review by the HRC Director and IRB Chair; recommendations for changes in membership shall be submitted to the IO for review. The IRB Chair and the HRC Director will review the membership and composition of the IRB to determine if it continues to meet both regulatory and institutional requirements. Recommendations for changes to Board composition will be submitted to the IO.

### Alternate members

The appointment and function of alternate members are 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. When an alternate member substitutes for a primary member, the alternate

member will receive and review the same materials before the IRB meeting that the primary member received or would have received.

The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The IRB minutes will document when an alternate member replaces a primary member. If both primary and alternate members are present at the meeting, it will be made clear at the outset which member is there in a voting capacity.

### Use of Nonvoting Consultants

When necessary, the IRB Chair or HRC Director may solicit individuals from the University or the community with competence in select areas to assist in the review of issues or protocols which require appropriate expertise beyond or in addition to that available on the IRB. Requests for review by a non-voting consultant are made in advance of the meeting by IRB staff at the request of the Chair or HRCO. The Human Research Compliance Office (HRCO) staff shall provide all relevant materials to a non-voting consultant before the convened meeting.

Meeting minutes will document key information provided by consultants at meetings. The HRCO staff will ensure that consultants abide by the IRB Member and Consultant Conflict of Interest requirements and sign a COI statement.

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.

## 2.8 DUTIES OF IRB MEMBERS

All IRB members have access to the agenda, minutes from the previous meeting, and the protocols to be reviewed at the meeting. Members are provided these materials in a timely fashion, usually one to two weeks before the convened meeting.

All members will review their assigned work and add their review comments in the IRB's Electronic Research Administration system at least two days before the meeting. Members must come prepared to answer questions about their assigned reviews and provide the board with possible resolutions to issues and concerns. Members should discuss minor issues with consent documents and missing information with the HRC Office staff before the convened meeting.

IRB members will treat the application materials as confidential. Members must hand-in to the HRC Office any physical copies of applications and supporting materials made for review purposes immediately following the meeting.

IRB members will not disclose IRB decisions and business outside of the convened meeting. All IRB determinations must be conveyed to investigators in writing.

## 2.9 ATTENDANCE REQUIREMENTS

Primary members are required to attend the majority of convened IRB meetings on an annual basis. To ensure continuity in the knowledge of IRB decisions, alternate members should attend meetings as much as possible, either in person or remotely. All IRB members are expected to attend convened meetings for which they have indicated a positive response to the meeting invitation. Occasional attendance via teleconference (e.g., Zoom conferencing) or telephone is permissible; however, the expectation is that members will attend in-person whenever possible.

If members are unable to attend a scheduled meeting, they must inform the HRC Office via email AND cc the IRB Chair. Members assigned to complete a review for a convened meeting must attend; if an emergency arises, an assigned reviewer is expected to inform the HRC Office immediately.

If an IRB member is to be absent for an extended period, such as for a sabbatical, the member will notify the HRC Office at least 30 days in advance so that an appropriate replacement can be secured, if necessary. The replacement can be temporary, for the period of absence, or permanent if the member is not returning to the University. If the member has a designated alternate, the alternate is expected to serve during the primary member's absence.

## 2.10 INITIAL AND ONGOING EDUCATION OF CHAIR AND IRB MEMBERS

A vital component of a comprehensive human research protection program is an education program for the IRB Chair and the IRB members. New York University is committed to providing training and ongoing education for all IRB members related to ethical concerns and regulatory and institutional requirements for the protection of research participants.

New IRB members are required to attend an orientation session. At a minimum, the session will cover:

- The Belmont Report;
- New York University policies and procedures; and
- Federal regulations governing human subjects research (AKA Federal Common Rule)
- How to review a protocol in the Cayuse Human Ethics (IRB) System
- New members must complete the orientation requirement before they may serve as a Primary Reviewer.

## CITI training requirements

Upon appointment, IRB members will promptly complete the following training:

- NYU CITI training for Human subjects for researchers; and
- The IRB Member training in CITI

## 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, the HRC Office will provide continuous training for IRB members throughout their service on the IRB. Educational activities may include, but are not limited to;

- in-service training at IRB meetings;
- training workshops and special issues meetings;
- copies of appropriate publications;
- new information that might affect the IRB, including laws, regulations, policies, procedures, and emerging ethical and scientific issues.
- links in the meeting agenda to relevant articles, videos, and podcasts as well as scheduled webinars sponsored by national organizations such as PRIM&R

## 2.11 REVIEW OF IRB MEMBER PERFORMANCE

The IRB members' performance will be reviewed annually by the HRC Director, who will report performance issues to the IRB Chair and IO. Members will be removed from service who are not acting in accordance with the IRB's mission or policies and procedures or complying with attendance requirements.

## 2.12 MEMBER COMPENSATION

IRB Participation by NYU faculty, staff, or students is considered a component of their University responsibilities as established by their respective departments and schools. Full voting members may be modestly compensated for the time spent on IRB activities. Full voting Members who are not affiliated with NYU may receive appropriate reimbursement as consultants and miscellaneous expenses (e.g., commuting expenses).

## 2.13 REPORTING AND INVESTIGATION OF ALLEGATIONS OF UNDUE INFLUENCE

If an IRB Chair, member, or HRC Office staff person feels that any party has unduly influenced the IRB, they shall make a confidential report to the HRC Director, or the

Institutional Official, depending on the circumstances. The official receiving the report, or his/her designee, will conduct a thorough investigation, and corrective action will be taken to prevent additional occurrences as warranted.

### 3. THE IRB REVIEW PROCESS

#### 3.1 PURPOSE

The following describes the procedures required for the review of research by the IRB.

#### 3.2 DEFINITIONS: IRB REVIEW

**IRB Approval:** *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

**Minimal Risk.** Minimal Risk means that 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.

**Minimal Risk with Prisoners:** *Minimal Risk* is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. [\(45 CFR 46. 303\(d\)\).](#)

**Minor change.** A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in:

- the level of risks to participants
- the research design or methodology (adding procedures that are not eligible for expedited review would not be considered a minor change)
- the qualifications of the research team
- the facilities available to support safe conduct of the research
- any other factor which would warrant a review of the proposed changes by the convened IRB.

**Quorum.** A quorum of the IRB consists of a majority of the voting members, including at least one member whose primary concern is in a non-scientific area. Research involving prisoners requires that the quorum count contain a prisoner representative.