

Policy Number:	201	Version Number:	2.0
Approval Date:	February 14, 2020		
Title:	Charge to the Institutional Review Board		

Purpose

The purpose of this policy is to support the Princeton University Institutional Review Board’s charge to assure the protection of human subjects participating in research conducted by Princeton faculty, staff, and students.

Scope

These procedures apply to all voting members of the Princeton University Institutional Review Board.

Regulatory Background

Proposed research may be reviewed by full committee or by an expedited review procedure. Except when an expedited review procedure is used, an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary activity is in a nonscientific area and at least member who is unaffiliated with the institution. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

An initial review using expedited review procedure may be carried out by the IRB Chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewer(s) may exercise all of the authorities of the IRB, except that expedited reviewers may not disapprove the research. A research activity may be disapproved only after review at a convened meeting.

Definitions

IRB Member(s): an individual appointed by the Institutional Official. The IRB member reviews research at convened IRB meetings or by expedited procedures. Each IRB member receives one vote at convened meetings.

Policy

An IRB must have at least five members with varying backgrounds for the complete and adequate review of research activities commonly conducted by the institution. An IRB must be sufficiently qualified through the experience and expertise of its members, i.e., professional competence. An IRB must also be diverse in its members, including race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes. This diversity will promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB must be able to ascertain the

acceptability of proposed research in terms of institutional commitments including policies and resources. The IRB must include persons knowledgeable in the regulations, applicable law, and standards of professional conduct and practice.

An IRB must include at least one member whose primary concern is in a scientific area and at least one member whose primary concern is in nonscientific areas.

An IRB must 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.

An IRB cannot allow a member to participate in the IRB's initial or continuing review of any protocol in which the member has a conflicting interest, except to provide information requested by the IRB.

An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals cannot vote with the IRB.

Approval of research is by a majority vote of the quorum of voting IRB members. "Quorum" means that greater than half of the IRB members are present at an IRB meeting and the following criteria are met: at least one member whose primary concerns are in a scientific area is present at the meeting; at least one member whose primary concerns is in a non-scientific area is present at the meeting; and at least one unaffiliated member is present at the meeting. A Board member may fulfill more than one criterion.

The Institution is responsible for providing appropriate initial and continuing education and training about human subject protections to the IRB members. Specifically, prospective members receive one-on-one training by an IRB staff member before appointment to the Board. Members participate in continuing education at IRB meetings. This training program helps ensure that the requirements of Princeton's Federalwide Assurance (FWA) are satisfied.

Expectations of Board Members:

A prospective member must complete new member orientation conducted by an IRB staff member.

New members receive a 1 year appointment on the Board. In general, appointments are made on an academic calendar schedule. However, the cycle of rotating members on and off the Board may be staggered to maintain consistency of review. Re-appointments are for 3 year terms.

Members may have a maximum of two re-appointments, for a potential term limit of seven years. The member should have a 75% attendance rate at IRB meetings. Members are encouraged to attend meetings in person, rather than via teleconference.

The member should promptly respond to inquiries from IRB staff.

Members should use the electronic management system.

If a member agrees to serve as a designated reviewer to review an IRB submission outside of a fully convened meeting, the member should review the expedited item within 5 business days.

Members must review all meeting materials such that they can meaningfully participate in the Board discussion.

Members must disclose any potential conflict of interest (COI) concerning an agenda item. Members must also disclose any perceived COI concerning an agenda item. Recusals due to a COI will be noted in the meeting minutes. Examples of COIs include, but are not limited to, serving as research personnel in a study under review, helping to design a study under review, or serving in an advisory role in a study under review.

The presenter(s) of an agenda items are also responsible for:

1. Performing an in-depth review of the proposed research.
2. Having a thorough knowledge of the details of the proposed research.
3. Leading the discussion of the proposed research at the convened meeting.
4. Recommending one of the motions noted in IRB policy #202.

References

45 CFR §46.107

45 CFR §46.108

Federalwide Assurance

Version History

Version Number	Revision Date	Revision Description
1.0	N/A	N/A
2.0	2/14/2020	Revised to reflect RIA policy template