

**Western Carolina University
Office of Research Administration
Institutional Review Board Standard Operating Procedures**

SOP# 101.2	TITLE: IRB Member Responsibilities and Appointment	Date Effective: 05/06/2021 Last Revision Date: 10/31/2023
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I. Purpose

Each Institutional Review Board (IRB) member's primary charge is the protection of the rights and welfare of the individual human beings who are serving as the subjects of that research. In order to fulfill their duties, IRB members are expected to be versed in federal regulations governing human subject protection, research ethics, and the WCU IRB policies and procedures germane to human subject protection. This document provides an overview of IRB member responsibilities and appointment.

II. Scope

This procedure is applicable to all members of the WCU IRB.

III. Definitions

Quorum: the minimum number of voting members that must be present at a convened meeting in order to conduct business.

Conflict of Interest: a situation in which a person is involved in multiple interests and serving one interest could involve working against another.

Institutional Review Board: declarative body established to protect the rights and welfare of human subject research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

Institutional Official: The individual who is legally authorized to act for, and on behalf of, the institution.

IV. Member Responsibilities

i. Duty to Western Carolina University

The IRB is an Institutional Committee. The IRB members serve Western Carolina University as a whole, rather than a particular department. IRB members must not allow their own interest or that of their department to supersede their duty to protect the rights and welfare of research subjects.

ii. Conflict of Interest

No IRB member may 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.

iii. Regular Attendance

Voting members of the IRB establish quorum. A simple majority of six (6) voting members is required to be present at a scheduled meeting in order to satisfy quorum. Therefore, each member is expected to attend, either in-person or virtually, all scheduled meetings. IRB member meeting availability is requested in advance; members are expected to notify the research compliance office of any schedule conflicts. If a member is unable to attend a scheduled meeting, they must notify the research compliance office with as much notice as possible. Failure to attend 5 or more scheduled meetings in one academic year will result in member removal.

iv. Meeting preparation, review of materials

IRB Members are expected to prepare for full board meetings by reviewing all materials provided by the administrator. The research compliance office will assign research protocols to the member with the most appropriate expertise for reviewing a specific protocol. The reviewer shall complete an initial review of the assigned protocol within two weeks of assignment.

v. Conduct and confidentiality

IRB members are expected to behave according to professional standards of courtesy and respect in discussions with each other and about researchers. IRB members review documents that may contain personal, confidential, and/or propriety information. Members are responsible for maintaining all IRB proceedings and documents in strict confidence within the limits of applicable state and federal laws. Such information may not be used for any purpose other than the IRB review and may not be disclosed to anyone outside of the IRB and Office of Research Administration (ORA), except as required by law.

vi. Knowledge and adherence to federal regulations and WCU policies and procedures

IRB Members are expected to have an adequate working knowledge of, and adherence to applicable regulations, ethical principles, and WCU policies and procedures. Members are expected to:

- Complete initial training through CITI titled, IRB Member;
- Understand the three basic principles of the Belmont Report;
- Have a working knowledge of the Common Rule (45 CFR 46) including the criteria for IRB approval;
- Review guidance and training materials provided by the ORA.

vii. The IRB Chair

In addition to the duties of a voting member, the IRB Chair has supplemental responsibilities which include:

- Communicating stipulations of full board approval to the research team;
- Meeting with the research compliance office at scheduled times;
- Reviewing policy and procedure produced by the Office of Research Administration;
- Reviewing and/or approving all reliance requests for collaborative research throughout the year;

- Using expedited review procedures, when appropriate, to review and/or approve research submitted during the summer.

viii. Vice Chair

In addition to the duties of a voting member, the IRB Vice Chair has supplemental responsibilities which include:

- Meeting with the research compliance office at scheduled times;
- Reviewing policy and procedure produced by the Office of Research Administration;
- Communicating stipulations of full board approval to the research team, in the Chair's absence.

ix. Primary Reviewer

The primary reviewer is the reviewer assigned to complete the initial review of a research project. When that project needs Full Board review, the primary reviewer is responsible for leading the meeting.

x. Member Resignation

A member that needs to resign from the Board prior to the end of their term must notify the ORA as soon as the decision is made. Resignation may impact the committee's ability to conduct regular business or maintain quorum, therefore timely notice is required.

xi. Member Removal

The ORA reserves the right to remove members for lack of attendance at scheduled meetings.

V. IRB Structure and Member Appointment

i. Basic Structure of the IRB

1. The IRB shall have at least five members with diversified backgrounds, including consideration of race, gender, and cultural backgrounds of members, as well as sensitivity to such issues as community attitudes;
2. The Board shall consist of at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas;
3. The Board shall consist of at least one member who is unaffiliated with Western Carolina University, nor shall that person be of the immediate family of a person who is affiliated;
4. The Board shall consist of at least one member whose primary area of study is children.

In addition, the IRB includes members who can determine the acceptability of proposed research in terms of regulations, applicable law, and standards of professional conduct and practice.

Furthermore, the IRB invites individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available to the IRB, such as legal counsel or Tribal representation. Invitees shall not be allotted a vote.

ii. Member Appointment

The Institutional Official is the Chief Research Officer. The CRO appoints the Chair, Vice Chair, and voting members to the IRB. The ORA is responsible for soliciting recommendations from a variety of sources including Deans, Department Heads, and current voting members of the IRB.

IRB members serve 3 year renewable terms. There are no term limits. Members may resign at any time by submitting a letter of resignation to the IRB Chair and IRB Director. The IRB Chair may remove members from the committee if the member is not able to complete his/her responsibilities as an IRB member. A member may be removed at the end of their term at the discretion of the IRB Chair. No voting member, except the Chair, is required to serve during the summers.

VI. Responsibilities

Office of Research Administration, IRB Chair, IRB Vice Chair, IRB Members, research compliance office

VII. References

45 C.F.R. § 46.107 (a)-(e), (2018)