

# NIH Policy Manual

## 3014-201 - IRB Membership and Composition

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**Release Date:** 11/19/2020 ? **Partial Revision Date:** 5/04/2022 ?

Transmittal Notice

1. **Explanation of Material Transmitted:** NIH Human Research Protection Program (HRPP) policies have been revised to comport with the revised DHHS Common Rule (45 CFR 46) and to reflect the newly consolidated IRB structure within the NIH Intramural Research Program (IRP). This policy describes the requirements for the membership and composition of the NIH Institutional Review Board (IRB) for the NIH Intramural Research Program (IRP) based on federal regulation and policy, including NIH policy. Upon implementation, this policy fully supersedes the *SOP 2 IRB Membership and Structure* and partially supersedes *SOP 26 Evaluation of NIH IRB Chairs, Vice Chairs and Members, IRB Administrative Staff and IRB Committee Activities*. **Partial Revision 05/04/2022:** This policy has been revised to add the requirement to share the results of the annual IRB member evaluations with IRB members.

2. **Filing Instructions:**

- **Insert:** NIH Manual Chapter 3014-201, dated 11/19/2020 **Partial Revision Date:** 05/04/2022
- **Implementation Date:** 12/07/2020

1. **PLEASE NOTE:** For information on:

- The current policies can also be found at: <https://irbo.nih.gov/confluence/display/ohsrp/Policy>.
- Content of this chapter, contact the issuing office listed above.
- NIH Policy Manual, contact the Division of Compliance Management, OMA, on (301) 496-4606, or enter this URL: <https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx>

### A. Purpose

1. Describe the composition of the NIH Institutional Review Board (IRB), as well as the roles and responsibilities of IRB members.

## B. Scope

1. This policy applies to the NIH IRB (e.g., the Intramural IRB and Research Compliance Review Committee (RCRC)) , including its members (members include Chairs, primary members, alternates and nominees, and will be referred to as “members” throughout the remainder of this policy), and the OHSRP Office of IRB Operations (IRBO), including its administrative staff.
2. Note: The role of the NIH IRB Executive Chair is described in *Policy 3014-101 Organizational Structure of the OHSRP*.

## C. Policy

1. The composition of the NIH IRB shall comply with federal regulations regarding membership composition and NIH policy ([45 CFR 46.107](#), [45 CFR 46.303\(c\)](#), [45 CFR 46.304](#) and [21 CFR 56.107](#)):
  - a. The NIH IRB shall be composed of no less than five members who are qualified through their experience and expertise, to review research projects in terms of compliance with regulations, ethical principles, applicable laws, and NIH policies. (See *Policy 3014-100 NIH Intramural Research Program’s Human Research Protection Program*)
  - b. The NIH IRB shall consist of members of various professions, including at least one scientist, one non-scientist, and one member who is not otherwise affiliated with the NIH (e.g., a community member).
  - c. Unaffiliated members will complete the *Statement of Status as An Unaffiliated IRB Member* as part of the member survey at the time of appointment and annually.
    - I. Research participants or their immediate family members may be unaffiliated IRB members.
    - II. A member may not be considered “unaffiliated” if they are part of the immediate family of a person who is affiliated with the NIH (e.g. the spouse of a current NIH Principal Investigator (PI)).
  - d. The NIH IRB shall reflect diversity in its membership in terms of experience and expertise and consider race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes as factors in membership selection.
  - e. The NIH IRB shall include representatives who are knowledgeable about the perspective of research subjects and are experienced in working with a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals lacking decision-making capacity, or economically or educationally disadvantaged persons.
    - I. In addition, when the research involves prisoners, the regulatory composition requirements at [45 CFR 46.304](#) also apply. (See *Policy*

*3014-401 Research Involving Prisoners.)*

- f. The NIH IRB may invite consultants to assist in the review of issues that require additional expertise. Consultants are not members and therefore may not vote with the IRB.
  - g. The NIH IRB shall not include in its membership, whether primary or alternate:
    - I. NIH employees whose primary responsibility is establishing scientific priorities of the NIH.
    - II. Institute/Center (IC) Directors, Scientific Directors (SDs), or Clinical Directors (CDs).
2. The IRBO Director is responsible for recommending to the OHSRP Director and Executive IRB Chair, individuals to serve as Board Chairs. The IRBO Director may consult with the IC SD and/or CD regarding the appointment.
    - a. Board Chairs will be appointed for an initial 1-year term.
    - b. If continued service is deemed mutually agreeable, the Chair may be reappointed to serve a renewable 1-year term.
  3. The IRBO Director is responsible for identifying and recommending board member appointments and re-appointments to the Executive Chair. The IRBO Director may consult with the IC SD and/or CD regarding the appointment.
    - a. Members will be appointed for a 1-year term. If continued service is deemed mutually agreeable, the member may be reappointed to serve a renewable 3-year term.
  4. Upon request, the IRBO will provide an information sheet about liability coverage to prospective IRB members at the time of initial appointment. (See “Information Sheet: Federal Torts Claims Act (FTCA) Coverage for NIH IRB Members”.)
  5. The IRBO will maintain a roster of IRB members and Chairs.
    - a. The roster shall document the names, as well as qualifications and indications of experience sufficient to describe each member’s anticipated contribution to the Board.
    - b. The roster will indicate the following information: name, earned degrees, indications of experience, affiliation status, scientist/non-scientist status, employment or other appointment status at NIH (e.g., Federal Employee, SV, IRTA, Visiting Fellow), primary/alternate membership (and, for alternates, the class of member for whom the alternate can substitute, such as, scientific status, affiliation or specialty), representative capacity including member expertise with vulnerable populations and representation by community members, and gender.
  6. NIH IRB members will undergo periodic evaluation as follows:
    - a. The NIH IRB Executive Chair will evaluate IRB Chairs annually.

- b. NIH IRB members, including Chairs, will complete an annual self-evaluation and evaluation of the IRB review process, the results of which will be shared with IRB members.
- 7. No NIH IRB member may participate in a review of, or vote upon, an action in which the member has a conflicting interest, except to provide information requested by the IRB. ([45 CFR 46.107](#) and as applicable [21 CFR 56.107](#))
  - a. An IRB member is conflicted, and will recuse themselves from review of, and voting upon, a matter before the IRB when:
    - I. They are a study team member;
    - II. They are a family member of study team member; or
    - III. They have a financial conflict of interest with the research under review by the IRB. (See *Policy 3014-202 Board Member Financial Conflicts of Interest.*)
  - b. Under circumstances other than those specifically described in this section, an IRB member may recuse themselves from review of, or voting upon, any matter in which they feel that they cannot perform an unbiased review.
- 8. The IRBO Director (or designee) will maintain the NIH Federalwide Assurance and IRB registration with the Office of Human Research Protections (OHRP) as required by [45 CFR Part 46](#) and NIH policy.
  - a. Changes in NIH IRB membership will be updated at least annually with OHRP.
  - b. NIH IRB registration will be completed every 3 years.
  - c. Change of an IRB Chairperson, or change in institutional contact person, will be reported within 90 days.
  - d. OHRP will be notified of disbanding of an NIH IRB within 30 days after permanent cessation of IRB review activities.
- 9. The NIH generally does not prospectively disclose its IRB membership to outside entities.
- 10. The OHSRP Director, in consultation with the Executive Chair and IRBO Director, may act to remove a member of the IRB, including a Board Chair, before the end of his/her term. This may occur, for example, if his/her participation in IRB activities is deemed to be inadequate, inappropriate, or not meeting the necessary institutional standards.
- 11. Terminated members, or those who are about to be terminated, may ask the Institutional Official (IO) for reconsideration.
- 12. The IRBO will:
  - a. Appoint members and Chairs.
  - b. Communicate responsibilities to members.
  - c. Remove members and Chairs for cause.

## D. Definitions

OHSRP has developed a comprehensive glossary of definitions that describe the terms listed below. The glossary can be found at the following link: [NIH IRP HRPP Policy Glossary](#)

Note: There may be more than one definition per term, so please review terms carefully to make sure they match the terms listed below. Qualified terms are indicated with a parenthetical qualification. When reviewing a definition, be sure that you are reviewing the appropriate definition that links to this policy. To further assist the reader, each term in the glossary cites the relevant policy number(s) indicating where the term is utilized.

1. [Affiliated IRB member](#)
2. [Alternate IRB Member](#)
3. [Board Chair or Chair](#)
4. [Experienced Board Member](#)
5. [Prisoner Representative](#)
6. [Scientist/Non-scientist members](#)
7. [Special Government Employee \(SGE\)](#)
8. [Special Volunteer \(SV\) \(for the purposes of Policy 3014-201\)](#)
9. [Unaffiliated member](#)

## E. Responsibilities and Requirements

1. The IRB Chair is responsible for leading convened IRB meetings as a voting member when the NIH IRB is the Reviewing IRB. In addition to the responsibilities for all IRB members noted in section *E.2.* below, the Chair's responsibilities include, but are not limited to the following:
  - a. If requested by OHSRP, identifying the expertise needed to comprise the IRB and recommend potential members.
  - b. Determine if a consultant is needed to supplement the expertise of the IRB. (This task may be delegated to another board member or to IRBO staff.)
  - c. Direct the discussion and proceedings of the convened IRB, with the assistance of the IRBO Staff, to keep discussion focused on the criteria for approval and on the established agenda, and to ensure that meeting procedures are followed.
  - d. Conduct or delegate the authority to review projects that qualify for review by expedited procedures. ([45 CFR 46.110\(b\)\(2\)](#))
  - e. Provide consultation to PIs as needed.
  - f. Provide additional consultation to the IRBO staff as requested.
2. All NIH IRB members, including the IRB Chair, are responsible for determining that the rights and welfare of human subjects in research are adequately protected. This includes but is not limited to the following actions:
  - a. Attending IRB meetings at least once per month, as feasible.

- b. Preparing for IRB meetings by reviewing all relevant materials.
  - c. Reviewing the research protocol to determine if the applicable regulatory criteria specified by [45 CFR Part 46](#) (including applicable subparts) are met, and if applicable, [21 CFR Parts 50, 56, 312](#), and [812](#), as well as determining if NIH HRPP policies that relate to the protection of human subjects are satisfied. (See [Policy 3014-204 Levels of IRB Review and Criteria for IRB Approval of Research.](#))
  - d. Voting at full board meetings when not recused due to a conflicting interest as described above in section [C.7](#).
3. Alternate IRB members will apply all the responsibilities of regular members when serving at a convened committee meeting.
- a. The alternate member receives and reviews the same material that the primary member would have received.
  - b. Alternates may be designated as a replacement for a specific member with particular expertise or may be appointed for their general area of competency.
  - c. Alternate members may attend any or all IRB meetings, but may only vote and exercise the privileges of a primary member at such meetings when they are expressly substituting for a primary member.
  - d. Alternate members may serve as alternates as follows:
    - I. Those appointed as Physician Scientists (PS) may serve as alternates for primary members that are appointed as either Physician Scientists or Other (non-physician scientist) Scientists (OS) members
    - II. Those appointed as OS may only serve as alternates for primary members that are appointed as OS members.
    - III. Non-scientists (NS) may only serve as alternates for primary members that are appointed as NS members.
  - e. If both the primary member and the designated alternate attend the same meeting, only one may vote on that action.
  - f. When an alternate member is used, the minutes will reflect who the alternate member is replacing.
4. Consultants are responsible for providing additional expertise that may be needed for reviewing a specific study.
- a. Expertise may be based for example, on individual qualifications, scientific knowledge, and ability to evaluate potential ethical concerns inherent to the study.
  - b. Based on their expertise, consultants may be asked to evaluate potential risks or benefits of the study procedures or concerns relative to the study population particularly when vulnerable subjects are involved.
5. When research involves prisoners, a prisoner representative with appropriate background and experience will be assigned to the IRB to participate in the review of

- research involving prisoners. In these cases, a majority of the Board (exclusive of prisoner member(s)) shall have no association with the prison(s) involved, apart from their membership on the Board. (See *Policy 3014-401 Research Involving Prisoners*)
6. Research involving vulnerable populations will be reviewed by a board that contains members with appropriate background and experience relevant to the research.

## **F. References**

1. Federal Regulations

HHS: [45 CFR Part 46](#)

FDA: [21 CFR Part 56](#)

Federal Tort Claims Act (FTCA) ([28 U.S.C. § 2671 et seq.](#))

SGE: [18 U.S.C. § 202](#)

1. NIH Policy

[Policy 3014-100 NIHs Human Research Protections Program](#)

[Policy 3014-101 Organizational Structure of the OHSRP](#)

[Policy 3014-202 Board Member Financial Conflicts of Interest](#)

[Policy 3014-204 Levels of IRB Review and Criteria for IRB Approval of Research](#)

[Policy 3014-401 Research Involving Prisoners](#)

[Manual Chapter 2300-308- 1 - Guest Researcher/Special Volunteer Programs](#)

1. Guidance:

Information Sheet: Federal Torts Claims Act (FTCA) Coverage for NIH IRB Members