NIH Policy Manual

3014-201 - IRB Membership and Composition

Issuing Office: OD/OIR/OHSRP **Phone:** (301) 402-3713

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Transmittal Notice

1. **Explanation of Material Transmitted:** 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. 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. **Partial Revision 04/21/2026**: This policy has been revised to specify that no NIH IRB shall be comprised solely of one sex consistent with the requirements of 45 CFR 46.107 and 21 CFR 56.107.
2. **Filing Instructions:**

- **Insert:** NIH Manual Chapter 3014-201, dated 11/19/2020 **Partial Revision Date:** 04/21/2026
- **Implementation Date:** 12/07/2020

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://nih.sharepoint.com/sites/OD-OMA-DCM/PolicyManual/NIH

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:
    a. NIH IRB (e.g., the Intramural IRB and the Research Compliance Review Committee (RCRC)), its members, including Chairs, primary members, alternates and nominees, and will be referred to as "members" throughout the remainder of this policy, and
    b. The Office of Human Subjects Research Protections (OHSRP) including its staff. 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 will 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 will 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 will 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.
    c. Unaffiliated members must 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 will 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 employee).
    d. No NIH IRB will have a membership consisting solely of a single sex.
    e. The NIH IRB will 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. When the research involves prisoners, the regulatory requirements at 45 CFR 46.304 apply to the composition of the IRB when reviewing research that includes this subject population. (See *Policy 3014-401 Research Involving Prisoners*.)

f. The NIH IRB will 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. When needed, the NIH IRB Chair may invite consultants to assist in the review of issues that require additional expertise.
   a. Consultants are not considered voting members of the IRB.
3. The IRBO Director will recommend individuals to serve as Board Chairs to the OHSRP Director and Executive IRB Chair.
4. The IRBO Director will identify and recommend board member appointments and re-appointments to the Executive IRB Chair.
5. At the time of initial appointment, the IRBO will provide information about liability coverage to prospective IRB members . (*See Information Sheet: Federal Torts Claims Act (FTCA) Coverage for NIH IRB Members*.)
6. The IRBO will maintain a roster of IRB members and Chairs.
   a. The roster will document the names, 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, affiliation status, scientist/non-scientist status, employment status at NIH, primary/alternate membership, specialty (e.g., indications of experience, representative capacity including member expertise with vulnerable populations and representation by community members), and sex.
7. 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 be requested to complete an annual self-evaluation and evaluation of the IRB review process.
   c. The results of this evaluation will be shared with IRB members.
8. 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 when they:

I. Are a study team member;

II. Are a family member of a study team member; or

III. 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. An IRB member who is conflicted will recuse themselves from review of, and voting upon, a matter before the IRB.
    c. 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.
9. The IRBO Director (or designee) will maintain the NIH Federalwide Assurance (FWA) and IRB registration with the Office of Human Research Protections (OHRP) as required by 45 CFR Part 46 and NIH policy.
10. The NIH generally does not prospectively disclose its IRB membership to outside entities.
11. The Executive IRB 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.
12. Terminated members, or those who are about to be terminated, may ask the Institutional Official (IO) for reconsideration.
    a. The IO will consider this request in consultation with the OHSRP Director and Executive IRB Chair.
13. 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 Volunteer (SV) (for the purposes of Policy 3014-201)
8. Unaffiliated member

E. Responsibilities and Requirements

1. **NIH IRB Chair Responsibilities**
    a. 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:
        I. If requested, identifying the expertise needed to comprise the IRB and recommend potential members.
        II. 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.)
        III. 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.
        IV. Conduct or delegate the authority to review projects that qualify for review by expedited procedures. (45 CFR 46.110(b)(2))
        V. Provide consultation to PIs as needed.
        VI. Provide additional consultation to the members and to IRBO staff as requested.
2. **NIH IRB Member Responsibilities**
    a. 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:
        I. Attend IRB meetings at least once per month, as feasible.
        II. Prepare for IRB meetings by reviewing all relevant materials.
        III. Review 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*.)
        IV. Vote at full board meetings when not recused due to a conflicting interest as described above in section C.8.
3. **Alternate NIH IRB Member Responsibilities**
    a. Alternate NIH IRB members may be designated as a replacement for a specific member with particular expertise or may be appointed for their general area of competency 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.

b. Alternate NIH IRB members must apply all the responsibilities of regular members described at E.2. above when serving at a convened committee meeting.
c. The alternate member must receive and review the same material that the primary member would have received.
d. 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.
e. When an alternate member is attending a meeting, the Minutes will document who the alternate member is replacing.

4. **IRB Consultant Responsibilities**
   a. When requested by the NIH IRB Chair, the IRB consultant is responsible for reviewing a specific study based on his/her area of expertise. Consultant expertise may be based for example, on individual qualifications, scientific knowledge, and ability to evaluate potential ethical concerns inherent to the study.
   b. 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.
   c. Consultants may not vote with the IRB.
   d. Consultant selected to advise the IRB may not consult on any action in which they are conflicted. (See Policy 3014-202 Board Member Financial Conflicts of Interests.)
5. **IRBO Responsibilities**
   a. The IRBO Director (or designee) is responsible for maintaining the NIH FWA and IRB registration consistent with C.9. above, and as follows:
      I. Changes in NIH IRB membership will be updated at least annually with OHRP.
      II. NIH IRB registration will be completed every 3 years.
      III. Change of an IRB Chairperson, or change in institutional contact person, will be reported within 90 days.
      IV. OHRP will be notified of disbanding of an NIH IRB within 30 days after permanent cessation of IRB review activities.
   b. The IRBO Director is responsible for recommending individuals to serve as Board Chairs to the OHSRP Director and IRB Executive Chair. The IRBO Director may consult with the IC SD and/or CD regarding the appointment.
      I. Board Chairs will be appointed for an initial 1-year term.
      II. If continued service is deemed mutually agreeable, the Chair may be reappointed to serve for two (2) renewable 3-year terms.

c. The IRBO Director is responsible for identifying and recommending board member appointments and re-appointments to the IRB Executive Chair. The IRBO Director may consult with the IC SD and/or CD regarding the appointment.
    I. Members will be appointed for an initial 1-year term.
    II. If continued service is deemed mutually agreeable, the member may be reappointed to serve for up to two (2) renewable 3-year terms.
    III. Additionally, in certain circumstances, e.g., when specific expertise is required, the member may be appointed to serve for a longer term.
d. When the IRB will review research involving vulnerable populations, IRBO is responsible to ensure that members with appropriate background and experience relevant to the research will be assigned to the Board.
e. When the IRB will review research involving prisoners, IRBO is responsible for ensuring that 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*)

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.)

2. 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

3. Guidance:

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