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HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL & IMPLEMENTATION

OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

SOP Number: 2

SOP Title: IRB MEMBERSHIP AND STRUCTURE

Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB Chairs, IRB Administrators, Protocol Navigators

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SOP 2 - IRB MEMBERSHIP AND STRUCTURE

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SOP 2 - IRB MEMBERSHIP AND STRUCTURE

2.1 PURPOSE

This Standard Operating Procedure (SOP) describes NIH Institutional Review Boards (IRBs) structure and membership requirements.

2.2 POLICY

The NIH Human Research Protection Program (HRPP) ensures that its IRBs are constituted consistent with federal regulatory requirements. It has procedures in place for (1) appointing and reappointing members; (2) maintaining current IRB rosters; (3) communicating members' responsibilities to them; (4) removing members for cause, and (5) clarifying their legal liability.

2.3 REQUIREMENTS FOR IRB MEMBERSHIP

2.3.1 Regulatory Requirements

Consistent with the requirements of 45 CFR 46.107 and 21 CFR 56.107, the IRB must:

A. Be composed of at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution;

B. Be sufficiently qualified through the experience and expertise of its members and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects;

C. Have a membership not consisting entirely of men or entirely of women, so long as no member is chosen on the basis of gender;

D. Have at least one member whose primary concerns are in scientific areas;

E. Have at least one member whose primary concerns are in non-scientific areas;

F. Have at least one member who is not otherwise affiliated with the NIH and who is not part of the immediate family of a person who is affiliated with the NIH; and

G. If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more members who have knowledge about and experience with these subjects.

One person may fulfill both the requirements of item E and those of item F.

2.3.2 IRB Member Area of Expertise and Affiliation

A. In determining member expertise, affiliation and status as primary or alternate member, the following criteria apply:

1. Affiliated member: An NIH employee (or a member of that person's immediate family) is considered affiliated. Affiliated members also include, but are not limited to, individuals who are at or involved with NIH as: part-time employees; current students; trainees; members of any panel or board; paid or unpaid consultants; healthcare providers holding credentials to practice at the NIH; guest researchers; and volunteers.

2. Unaffiliated member: If an individual has no affiliation with the NIH, other than as an IRB member, then s/he is considered unaffiliated. Unaffiliated members may include people whose only association with the NIH is that of a research participant, or former student, trainee, contractor or employee. Paying unaffiliated members for their services would not make the member "otherwise affiliated", or cause the member to have a conflicting interest.

a. **Note:** An IRB member will only be considered "unaffiliated" when he/she has properly completed and submitted to the designated IRB a "Statement of Status as Unaffiliated Member of an NIH IRB" (see **Appendix A**). The designated IRB will make the statement available to the Office of Human Subjects Research Protections (OHSRP).

Concerns about affiliation will be submitted to OHSRP, which will make the final determination regarding the member's affiliation status.

3. Members whose primary interests are in scientific areas: A member whose highest level of education/training and/or occupation is from a scientific discipline or profession, e.g. the physical sciences, biomedical sciences, social/behavioral sciences, or mathematical sciences and who would be inclined to view scientific activities from these standpoints. The IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

4. Member whose primary concerns are in non-scientific areas: A member whose education, training, background, and occupation would incline him/her to view research activities from a standpoint other than any biomedical or behavioral scientific discipline should be considered a non-scientist.

5. Alternate members: (see **2.3.4** below) are members who may substitute for a primary IRB member or a category of member (e.g., physician or nurse). Each alternate IRB member has experience, expertise, background, professional competence and knowledge comparable to that of the primary IRB member(s) whom the alternate would replace.

B. The determination of whether the nominated IRB member's primary concerns are in scientific or non-scientific areas, will be made by the designated IRB at the time when members are nominated for appointment. The IRB will base this designation on a review of the nominee's *curriculum vitae* and IRB member survey (see **2.4.2** and **2.5** below). When there are concerns about this designation, OHSRP will make the final determination of whether a nominated IRB members' primary concerns fall into scientific or non-scientific areas consistent with criteria provided in **2.3.1** above.

C. Consistent with Office for Human Research Protections (OHRP) guidance, IRB members can only be appointed as either regular (primary) or alternate members. There is no category of non-voting member of the IRB.

D. It is the responsibility of the Clinical Director (CD), in conjunction with the IRB Chair, to ensure that the IRB's overall composition meets regulatory and NIH requirements. OHSRP will review IRB composition annually to ensure compliance (see **2.4.2** and **2.5** below).

E. The IRB Chair shall at least annually notify OHSRP in writing whether the IRB regularly reviews research that includes any of the categories of vulnerable individuals mentioned in **2.3.1.G** above.

2.3.3 Additional NIH Membership Requirements

A. Consistent with NIH Manual Chapter 3014, NIH has the following additional IRB membership requirements:

1. A scientific or professional staff member not affiliated with the IRB's Institute.

2. A member with expertise in statistics or an epidemiologist.

3. A member who is either a pharmacist or pharmacologist, and

4. An ethicist or individual who has expertise in the ethics of human subjects protection.

   a. The inclusion of an ethicist is desirable, where practicable. Individual IRBs have the discretion to include one as a primary member or consultant, depending on the existing composition of the board, as well as the nature of the research being reviewed.

   b. **Note:** For several of the intramural IRBs, a member of the senior staff of the Clinical Center (CC) Department of Clinical Bioethics participates as a primary member. For other NIH IRBs, the CC Department of Clinical Bioethics has recommended, as possible members, individuals who have knowledge and experience with research ethics. An IRB may also independently nominate an ethicist for its committee.

5. Non–scientist members: The U.S. Department of Health and Human Services (DHHS) human subjects regulations require that each IRB shall include at least one member whose primary concerns are in non-scientific areas. However, NIH strives to maintain a 20% ratio of non-scientist members on each IRB.

6. At least one member of the IRB must represent the perspective of research participants.

7. NIH IRB administrative staff may not be members of the IRB.

8. Institute and Center (IC) Directors, Scientific Directors (SDs), CDs and Office of Tech Transfer staff may not be members of the IRB.

B. Based on a written request and justification by the appropriate Institute CD, OHSRP can determine that an NIH IRB need not comply with the additional NIH policy requirements set forth in **2.3.3.A.** for a biostatistician, pharmacist, or bioethicist member. This does not preclude the regulatory requirement for a non-scientist at each IRB meeting to establish a quorum.

2.3.4 Additional Requirements for Alternate Members

A. Appointment process: The appointment process is the same as for primary members of the IRB (see **2.5** below). Alternates' names are included in the IRB's official membership roster (see **Appendix H** below) with the designation that they are alternates, together with the name(s) of the IRB member or category of members for whom they are an alternate.

B. Assignment of alternates: An alternate member may be assigned as a substitute for one or more named primary members or for a category of members. Alternates must have qualifications similar to those of the member(s) for whom they are allowed to be a substitute. Alternate members receive agenda packages for all IRB meetings and are encouraged to attend as many meetings as possible, even when not required to be present to act as an IRB member.

C. Alternate members and the quorum: When an alternate member substitutes for a regular member, the alternate member's vote counts towards the quorum in the same way as the regular member's vote.

D. Voting by alternate members:

1. Alternate members vote on protocols or other matters at convened meetings only when one of the primary members for whom they are an alternate is not participating in the vote (e.g., because that member is absent or has a conflict of interest). They should only participate when they have, prior to the meeting, adequately reviewed the materials distributed with regard to the protocol or other matters on which they would be voting. The IRB minutes should document the alternate member's votes.

2. A designated alternate IRB member may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Substitution during a meeting commonly occurs when the primary member is (a) absent from the room for part of the meeting, or (b) recused from review of certain research protocols because the primary IRB member has a conflicting interest with respect to a specific research protocol. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB member has replaced the designated primary IRB member.

2.4 ROSTERS OF IRB MEMBERS

2.4.1 Maintenance of Roster

Each NIH IRB must maintain a current roster (see **Appendix H** below) of its membership, using the Excel template provided by OHSRP, which includes at least the following information:

A. First and Last Name

B. Earned Degrees

C. Scientific Status (scientist or non-scientist; see **2.3** above)

D. Representative Capacity (indicate which, if any, vulnerable populations are being represented by this member, e.g. children, pregnant women, or prisoners, etc.; or if the member represents the perspective of research participants)

E. Area of Specialty

F. Indications of Experience (e.g. brief description of all relevant experiences that describe each member's expected contributions to the IRB)

G. Relationship to the organization (for example, current employee, former employee, trainee, special volunteer)

H. Affiliation Status

I. IRB Role (e.g., Chair, Vice Chair, primary member or alternate member)

J. Alternates for whom (e.g. alternate for pharmacist member, etc.)

K. Phone number

L. Email address

M. Postal address

N. Term effective date

O. Appointment term

P. Gender

Q. Race/ethnicity

R. Title

S. Term End Date

T. OHSRP approval date

2.4.2 Reporting Membership Changes to OHSRP

IRB administrative staff will record changes in the IRB roster as they occur and will ensure that OHSRP has an up-to-date roster and contact information in electronic form, using the roster template provided by OHSRP. The information should include the Statement of Status as an Unaffiliated IRB Member (**Appendix A**).

Annually all members will be surveyed by their designated IRB using the IRB Member Survey template. Members will have the opportunity to update their representative capacity, affiliation, and be reminded of the need to report any undue influence[1] to OHSRP. IRBs will be notified of when to issue the survey by OHSRP.

[1] Undue influence means attempting to interfere with the normal functioning and decision-making of the IRB or to influence an IRB member or staff, a PI or any other member of the research team outside of established processes or normal and accepted methods, in order to obtain a particular result, decision or action by the IRB or one of its members or staff.

Surveys will be returned to the designated IRB and stored on SharePoint. IRBs must notify OHSRP as soon as possible whenever the affiliation or scientific designation of a member has changed.

2.4.3 Reporting Membership Changes to OHRP

OHSRP reviews IRB rosters, maintained by the IRBs, and provides membership updates to the OHRP (see the Introduction to the NIH Human Research Protection Program (HRPP)).

2.5 APPOINTMENT AND REAPPOINTMENT PROCEDURES AND TERMS OF SERVICE

2.5.1 Procedures for Initial Appointment to the IRB

A. Identifying members: The Institute CD or CDs (in the case of multi-Institute IRBs), the IRB Chair, and, at the discretion of each IC, the SD, recommend the appointment of the IRB Chair, the IRB Vice Chair and IRB members (including alternate members). In making such recommendations, consideration will be given to the requirements above for IRB membership and representation. The designated IRB will provide the prospective nominee with the IRB Member Survey to ensure that they satisfy the IRB's composition and representative capacity requirements.

1. Nominees and their supervisors should agree to the nomination.

2. The Director, SD and CD of any IC may not serve as a member, IRB Chair or Vice Chair of any NIH IRB.

B. Nomination memorandums:

1. The designated IRB office prepares a nomination memorandum (see **Appendix B** below) for the approval of the CD(s), and SD as applicable.

2. Once signed, the designated IRB should notify OHSRP by email requesting a review of the new nomination located in SharePoint.

3. OHSRP will review this information to confirm that the nominee fulfills the requirements for IRB membership and representation. OHSRP will provide

the approval date in the Roster spreadsheet or notify the IRB office via email if there is a concern.

4. The designated IRB should not instruct nominees to commence training until OHSRP confirms its position.

5. Once approved by OHSRP, the signed nomination memorandum is retained by the designated IRB and a copy should be included in the appointment packet when it is forwarded to the Deputy Director for Intramural Research (DDIR) for approval.

6. The memorandum describes how the qualifications of the nominee will serve the IRB (see **Appendix B**). It specifies an appointment term (see **2.5.1.E** below) and includes the following attachments:

a. *Curriculum Vitae* for the person being nominated.

b. A "Statement of Status as Unaffiliated Member of an NIH IRB" (see **Appendix A**), signed by the nominee, as applicable.

c. IRB Member Survey

C. Specific considerations for nomination of Chair and Vice Chairs: Nominees for IRB Chair and Vice Chair should have experience in human subjects research, which could include previous experience serving on an IRB; be knowledgeable about the scientific mission and clinical program of the particular Institute or Institutes for which the IRB serves as the primary IRB, and be familiar with the federal regulations for the protection of human subjects (45 CFR 46 and 21 CFR 50 and 56) and the ethical basis for the regulations (The Belmont Report).

D. Completion of required training: Before beginning service as a member of the IRB, all nominees, including those for Chair and Vice Chair, must complete the training requirements that are specified in SOP 25 - Training Requirements for the NIH HRPP. Designated IRBs should notify nominees of their training requirements and ensure that all training requirements are met. IRBs are reminded to monitor continued compliance with training requirements for all IRB members.

E. Appointment letters: After completion of required training, the designated IRB prepares an appointment letter for approval by the DDIR. Upon approval, the

designated IRB sends the approved letter to the nominee confirming their appointment to the Institute's IRB for an initial one-, two-, or three-year term (see **Appendix C**). Appointment letters are copied to the CD, SD, IRB Chair, and OHSRP. This letter should be in Share Point as well as the personnel file of NIH and other Federal employees whose IRB service is part of their official duty (see **2.10.2** below)

Note: Nominees do not become a member of the IRB until they have received an appointment letter from the DDIR, although, at the discretion of the Chair, they may participate in IRB meetings prior to that time as consultants, consistent with the rules relating to such participation as a consultant (see **2.11**).

F. Appointment Packet: The appointment packet to the DDIR includes:

1. Cover letter from the designated IRB (**Appendix D**);

2. Appointment letter for approval by the DDIR (**Appendix C**);

3. Nomination letter approved by the CD and SD, as applicable;

4. The nominee's *curriculum vitae;*

5. The signed "Statement of Status as Unaffiliated Member of an NIH IRB", as applicable (**Appendix A**);

6. The checklist of completed training (**Appendix E**);

2.5.2 Reappointment Procedures

A. IRB administrative staff are responsible for allowing enough time in advance of members' term end dates for the submission and processing of reappointment requests.

B. Reappointment letters: The Institute CD and SD make reappointment requests as applicable. The reappointment letter will be prepared and signed by the designated IRB and then submitted to OHSRP, which has delegated authority from the DDIR for approving such requests (see **Appendix F**.) OHSRP will sign the letter and return it to the designated IRB for distribution to the

member. Term lengths for reappointments (including of Chairs and Vice Chairs) can be for one, two or three years.

a. The signed letter will be sent to the member via the designated IRB confirming reappointment and will be copied to the CD, SD, and IRB Chair (see **Appendix F**).

C. Expiration of Terms: After the expiration of the term of an appointment, an individual is considered to be inactive as a member of the IRB and may not participate in IRB meetings (except as a consultant, according to the requirements at **2.11**, below) until the reappointment letter from OHSRP has been signed.

2.5.3 Terms of Service

A. Unless reappointed, Chairs, Vice Chairs and members rotate off the Board when their terms expire and have not been renewed, when members tender their resignations, or when members are removed for cause.

a. Members who complete their term of service and are not reappointed will receive a Thank You letter from the DDIR. The designated IRB office will prepare the letter and submit it to the DDIR for signature. The DDIR will return the signed letter to the designated IRB. The signed letter will be sent to the member via the designated IRB and will be copied to the CD, SD, IRB Chair and OHSRP, (see **Appendix G**).

B. IRB Chairs, Vice Chairs and members may be reappointed in conformity with the rules stated in **2.5.2** above. There is no limit on the total number of years members may serve as a result of being reappointed multiple times, unless Institute management wishes to impose a limit.

C. Chairs and Vice Chairs may serve as regular IRB members on the same IRB or another NIH IRB after their terms as Chair and Vice Chair are completed.

2.5.4 Removal for Cause of a Member

A. Justification for Removal: To remove a member of an IRB, including the Chair or Vice Chair, before the end of that person's appointed term, just cause must be shown of that person's inability to meet his/her responsibilities as an IRB member, such as failure to attend meetings regularly; failure to follow

applicable laws, regulations and policies; mismanagement; misconduct, or an unresolved conflict of interest for which recusal is insufficient.

B. Procedures for Removal: The Institute CD, after consultation with the Institute SD and the Chair (if the Chair is not the member in question) should prepare a written memorandum to the DDIR through the Director, OHSRP, with the reasons for recommending premature termination of membership. The DDIR makes the final decision on termination and sends a termination letter to the member if s/he concurs with the recommendation for removal from the IRB.

C. Termination letters are copied to the CD, IRB Chair, OHSRP, and the designated IRB administrative office.

D. Reconsideration for Terminated Members: Terminated members or those who are about to be terminated may ask the DDIR for reconsideration.

2.6 RESPONSIBILITIES OF THE IRB CHAIR

2.6.1 Leadership Requirements for IRB Chairs

The Chair shall embody the following leadership requirements:

A. The ability to conduct meetings of the IRB in an efficient, expeditious and fair manner; attentiveness to the details and requirements of the Federal regulations and NIH policies in the context of NIH IRP protocol review; application of the requirements to foster ethically and scientifically sound human subjects research.

B. The promotion of methodical and systematic IRB review by applying the NIH IRB Protocol Review Standards (see SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs) for a copy of the review standards).

C. The ability to set a tone of openness that encourages dialogue in IRB meetings.

D. Respect for the diverse backgrounds, perspectives and sources of expertise of all IRB members, especially for the contributions of the non-scientists, and the ability to foster such respect among the IRB members.

E. The confidence and ability to uphold IRB judgments that may not always be popular with Principal Investigators (PI), and

F. Investment of adequate time, interest and commitment to provide guidance and expertise to IRB members and investigators.

2.6.2 Duties of the Chair

The Chair or designee either votes or abstains from voting on all actions for which votes are taken, unless recused. The Chair's vote counts toward the quorum. Chairs will recuse themselves, as appropriate, when conflicts of interest exist.

A. Provides guidance and expertise about human subjects research to IRB members, investigators and others. Ensures that investigators and IRB members receive information on new or revised policies and regulations pertinent to human subjects research.

B. Upholds the independent decisions of the IRB with investigators and IC officials.

C. Works closely with the IRB administrative staff to carry out the functions of the IRB and IRB office. For example, the Chair sets agendas and scheduling of convened meetings as often as required to accomplish the business of the IRB.

D. Stays informed of established and emerging policies and guidance pertaining to the protection of human subjects involved in research.

E. Promotes continuing education of IRB members and IRB staff, including providing IRB members and staff with information about relevant educational opportunities. See **2.14** below.

F. Serves as a member of the Human Subjects Research Advisory Committee (HSRAC), regularly attends HSRAC meetings, and shares issues discussed at them with IRB members and investigators, as appropriate.

G. When a Chair and/or Vice Chair needs to recuse himself/herself from the meeting, he/she designates an IRB member to serve temporarily as Acting Chair or Acting Vice Chair of the meeting.

H. Conducts expedited reviews or delegates them to the Vice Chair or other qualified IRB members and assures that determinations are documented as required by SOP 7A - Requirements for Expedited Review of Research by NIH IRBs.

I. As directed by the IRB, reviews and approves stipulations in cases where no more than simple concurrence is required, i.e., the stipulations do not have to be reviewed and approved by the convened IRB.

J. Prepares for and handles any audits by the OHRP or the U.S. Food and Drug Administration (FDA).

K. Coordinates education of investigators with the appropriate CD

L. Ensures that reports to OHSRP are completed in a timely fashion.

M. Evaluates IRB members (see **2.13** below).

2.6.3 Conduct of Convened Meetings

A. Ensures the presence of a quorum.

B. Conducts IRB meetings based on Roberts Rules of Order. That is, at a minimum, the Chair is in charge of the meeting, there is a predetermined agenda, the minutes of the prior meeting are voted upon, and all actions and resolutions are voted on by the members present following the making and seconding of a motion and discussion.

C. Leads IRB discussions by identifying regulatory requirements of 45 CFR 46, 21 CFR 50 and 56, the ethical principles of The Belmont Report, and NIH policy as the criteria for the review of all research studies.

D. Determines if any IRB members have a conflict of interest with regard to any given protocol or action under consideration by the IRB. The Chair will exclude members with a conflict of interest from participating in the deliberations and voting on that action. That member must leave the meeting room during the deliberations and vote (see SOP 21 - Managing Conflict of Interest in Research). Examples of non-financial perceived and actual conflicts of interest include:

1. Voting on a protocol when the member of the IRB is the protocol's PI, Associate Investigator (AI) or study coordinator;

2. Voting on a protocol when the member of the IRB or DSMB is or has a spouse, child, household member or any other individual with whom the protocol's PI, AI or study coordinator has the appearance of a conflict of interest; or

3. Voting on a protocol when the protocol's PI is the IRB member's supervisor (up the chain of command to the CD). For more information please refer to A Guide to Avoiding Financial and Non-Financial Conflicts or Perceived Conflicts of Interest in Clinical Research at NIH (September 2015) in SOP 21 - Managing Conflict of Interest in Research.

E. Ensures that all IRB members who are not recused have the opportunity to contribute to the IRB's deliberations.

F. In IRBs where a primary and/or primary and secondary reviewer system is used, chooses the reviewers and ensures that they are qualified to conduct the review. In cases where additional expertise is required, selects consultants to assist in review.

G. Ensures that the NIH IRB Protocol Review Standards are addressed by the PI for all initial protocol reviews (see SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs)).

H. Ensures that the IRB addresses and documents in the minutes all the regulatory standards embodied in the NIH IRB Protocol Review Standards for every initial review or uses an appropriate review tool for this purpose (see SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs)).

I. Ensures thorough evaluation of initial and continuing reviews, amendments and unanticipated problems including adverse events.

2.7 RESPONSIBILITIES OF THE VICE CHAIR

Each IRB is required to have a Vice Chair. The Vice Chair vote counts towards the quorum, unless recused, and they either vote or abstain from voting on all actions for which votes are taken. Vice Chairs will recuse themselves, as appropriate, when

conflicts of interest exist. The Vice Chair, in the Chair's absence, exerts all authorities ordinarily vested in the Chair (see **2.6** above).

2.8 RESPONSIBILITIES OF IRB MEMBERS

Members of the IRB (including the Chair, Vice Chair, and alternate members) must:

A. In convened meetings, apply the NIH IRB Protocol Review Standards or an appropriate reviewer tool when reviewing initial protocols (see SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs)).

B. Attend IRB meetings regularly (at least 75% of meetings per year) and in those instances in which they are unable to attend a meeting, provide the longest possible notice of their inability to attend.

C. Be well prepared to discuss each meeting agenda item as a result of having spent sufficient time prior to the meeting reviewing the materials distributed for that meeting, and reviewing the minutes of previous meetings for accuracy.

D. Complete the IRB Member Survey when it is issued on an annual basis.

E. Maintain the confidentiality of IRB discussions, the votes of individual members, and the protocols and related materials, including any proprietary information (see SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs)).

F. Participate in required training and continuing education opportunities, or IRB retreats (see SOP 25 - Training Requirements for the NIH HRPP), and

G. Inform the IRB immediately if their status changes in a way that might impact their membership (such as a new affiliation with the NIH for a member who was previously considered unaffiliated).

2.9 COMPENSATION OF IRB MEMBERS

Annually, each IRB will provide information to OHSRP in writing about if, and how, IRB members, including the Chair and Vice Chair, are compensated for their IRB service.

2.10 LIABILITY COVERAGE FOR IRB MEMBERS AFFILIATED WITH NIH THROUGH ANY OF THE FOLLOWING FOUR CATEGORIES: SPECIAL GOVERNMENT EMPLOYEES (SGEs), SPECIAL VOLUNTEER, CONTRACTOR, OR EMPLOYEE

2.10.1 Background

Liability coverage for IRB members differs depending on whether they are federal employees (either full-time or as a special government employee), or non-Federal employees who serve on the IRB without compensation (i.e., a volunteer member) or who are compensated.

2.10.2 NIH and Other Federal Employees

The Federal Tort Claims Act (FTCA) (28 U.S.C. 2671 et seq.) generally covers Federal employees in litigation when there are allegations of negligence that occurred within the scope of their employment.

A. NIH and other federal employees, whose IRB service is considered part of their official duties, are covered by the FTCA. Employees should have documentation in their personnel files that their IRB service is an official duty.

B. An individual who is not presently an employee may be appointed as a special government employee (SGE) specifically for service as an IRB member. The individual must complete various personnel forms, including a financial disclosure form and agree to abide by applicable Federal ethics requirements.

2.10.3 Volunteer Members of the IRB

It is considered that volunteers may be eligible under the FTCA for coverage from personal liability for damages or injuries that arise from actions occurring within the scope of their federal assignment as NIH IRB members and while under the direct supervision of a federal employee. However, the ultimate decision on issues of liability and coverage depends on the circumstances of each situation as it does for federal employees and is made by the U.S. Department of Justice. These individuals must obtain a Special Volunteer appointment at the NIH.

2.10.4 Compensated IRB Members Who are Not Federal Employees

Non-Federal employees may receive compensation for services as contractors. They are not covered by FTCA but may purchase private liability coverage for IRB services. The cost of such coverage may be reimbursed under their contract with NIH.

2.11 SELECTION AND USE OF CONSULTANTS FOR REVIEW

2.11.1 Use of Consultants

Consistent with requirements set forth at 45 CFR 45.117(f), an NIH IRB may choose to 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. This may include experts in scientific aspects of the research or related to human subjects protections.

2.11.2 Choosing Consultants

The IRB Chair, in cooperation with the CD(s), will identify appropriate experts (based on their *curriculum vitae, c*urrent work in the relevant scientific discipline, etc.). Consultants may be drawn from scientific or other NIH staff, as well as from outside the NIH.

2.11.3 Consultants' Conflict of Interest

Consultants are subject to the same NIH conflict of interest rules as IRB members and are required to self-identify if they have a conflict of interest (see SOP 21 - Managing Conflict of Interest in Research).

2.11.4 Provision of Consultant Advice

A. The IRB administrative office ensures that the consultant understands his/her confidentiality obligations and receives a copy of the proposed protocol and any other supporting documentation in a timely manner.

B. Consultants may attend IRB meetings in person or submit a written report to the Board. Consultants may attend the convened IRB meeting; question the protocol's PI during the PI's presentation; provide an oral critique of the protocol after the PI has left the room, and participate in discussions of the protocol with other IRB members.

C. Consultants do not vote and are excused from the meeting prior to the vote. Their presence is noted in the IRB meeting minutes.

2.12 USE OF SUBCOMMITTEES FOR REVIEW

Subcommittees of the IRB may be created as needed at the discretion of the Chair. They may be constituted to consider a specific issue or issues, or to review and approve a protocol under an expedited review process (SOP 7A - Requirements for Expedited Review of Research by NIH IRBs) or to review an investigator's response to stipulations when this authority has been specifically delegated to them by the IRB Chair or convened IRB. If a HRPP SOP requires that an issue be reviewed at a convened meeting of an IRB, then review by a subcommittee can never serve as a substitute for that convened IRB review. Subcommittee actions are reported to the full Board at the next convened meeting.

2.13 EVALUATION OF IRB MEMBERS

IRB members will be evaluated at least annually to assess their knowledge of ethical principles and basic regulatory requirements, attendance at, preparedness for and participation in meetings. The evaluation of the IRB Chair will be performed by the DDIR or OHSRP designee. IRB Chairs will evaluate the members of their designated IRB. For further guidance see SOP 26 - Evaluation of NIH IRB Chairs, Vice Chairs and Members, IRB Activities and IRB Administrative Staff."

2.14 TRAINING, EDUCATION AND PROFESSIONAL DEVELOPMENT FOR IRB MEMBERS

Incoming IRB members must complete all required training before they can commence their appointment. Reappointed IRB members must be compliant with all HRPP training requirements before resuming their position on the board. IRB Chairs may require IRB members to take additional training based on the type of research reviewed by the IRB. Additionally, IRB members should attend retreats and educational opportunities as provided by the IRB to which they belong. For further guidance see SOP 25 - Training Requirements for the NIH HRPP.

LIST OF APPENDICES

Appendix A - Statement of Status as an Unaffiliated IRB Member

APPENDIX A - STATEMENT OF STATUS AS AN UNAFFILIATED IRB MEMBER

I, _____, am already serving on the

_____ NIH IRB, or am now being invited to serve on that IRB, in the role of a member who will be considered ***not*** "affiliated" with the NIH. I have read the guidance on the bottom half of this page, which provides an explanation of when someone is considered to be affiliated with the NIH. Based on that guidance, I have concluded that there are no circumstances that I am aware of which would suggest that either I, or a member of my immediate family, is affiliated with the NIH. If I ever become aware of such circumstances, I will contact the administrator of the IRB so that my status as an unaffiliated member can be changed.

_____ _____

Signature Date

The following paragraph describes what it means to be "affiliated" with the NIH. If you have any questions about how it applies to your circumstances, please be sure to ask the administrator of the IRB.

An employee or agent of the NIH (or a member of that person's immediate family) is considered affiliated. Affiliated members include, but are not limited to individuals who are: part-time employees; current students; members of any governing panel or board of the NIH; paid or unpaid consultants; healthcare providers holding credentials to practice at the NIH; and volunteers working at NIH on business unrelated to the IRB. An individual that has no affiliation with the NIH, other than as an IRB member, is considered unaffiliated with the NIH. Unaffiliated members may include people whose only association with the NIH is that of a patient, subject, or former student at the NIH.

APPENDIX B - SAMPLE NOMINATION MEMOS FOR AN INITIAL APPOINTMENT

Note the practice is to place these letters on the appropriate letterhead

Primary Member Nomination Memo

«PrintDate»

To: Clinical Director, «IC» _____
(Signature)

Scientific Director, «IC» _____
(Signature)

From: «Chair», Chair, «IRB» IRB

Subject: New IRB [Primary Member] Nomination

The «IRB» IRB would like to appoint «First_Name» «Last_Name» «Earned_Degrees» as a primary, «Affiliation_Status», «Scientific_Status» member of the «IRB» IRB for a «Appointment_Term» term.

Field of specialty is: «Specialty»
Scientific Status: «Scientific_Status»
Representative Capacity: «Representative_Capacity»

Describe experience in a few sentences:

Thank you for your consideration.

Attachment: Nominee CV
IRB Member Survey
Statement of Status as Unaffiliated Member of an NIH IRB (if applicable)

cc: [Ms./Mr.] «IRB_Administrator», IRB Administrator, «IRB»
OHSRP

Alternate Nomination Memo

«PrintDate»

To: Clinical Director, «IC» _____
(Signature)

Scientific Director, «IC» _____
(Signature)

From: «Chair», Chair, «IRB» IRB

Subject: New IRB Alternate Member Nomination

The «IRB» IRB would like to appoint «First_Name» «Last_Name» «Earned_Degrees» as an alternate, «Affiliation_Status», «Scientific_Status» member of the «IRB» IRB for a «Appointment_Term» term.

Field of specialty: «Specialty»
Scientific Status: «Scientific_Status»
Representative Capacity: «Representative_Capacity»
Alternate for: «Alternates_For»

Describe experience in a few sentences:

Thank you for your consideration.

Attachment: Nominee CV
IRB Member Survey
Statement of Status as Unaffiliated Member of an NIH IRB (if applicable)

cc: [Ms./Mr.] «IRB_Administrator», IRB Administrator, «IRB»
OHSRP

APPENDIX C - SAMPLE APPOINTMENT LETTERS

Note the practice is to place these letters on the appropriate letterhead

New Appointment Letter Primary Member

«PrintDate»

«First_Name» «Last_Name», «Earned_Degrees»
«Postal_Address»

«GreetingLine»

Drs. «Clinical_Director», Clinical Director, «IC», «Scientific_Director», Scientific Director, «IC», and «Chair», Chair, «IRB» IRB have recommended your appointment to serve as a primary member of the «IRB» IRB.

You will serve on the «IRB» IRB in the following capacity:

NIH Affiliation: «Affiliation_Status»
Scientific Status: «Scientific_Status»
Specialty in: «Specialty»
If applicable, represent the perspective of: «Representative_Capacity»

I am pleased to confirm a «Appointment_Term» appointment, effective «Effective_Date».

The IRBs play a vital part in ensuring that the clinical research done at NIH is of the highest scientific and ethical standards, and that the safety and welfare of the people who participate in the research are protected. I am grateful that you are willing to take part in this very important process.

Sincerely yours,

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research
cc: Dr. «Clinical_Director», Clinical Director, «IC»
Dr. «Scientific_Director», Scientific Director, «IC»
Dr. «Chair», Chair, «IRB» IRB
[Ms./Mr.] «IRB_Administrator», IRB Administrator, «IRB» IRB
OHSRP

New Appointment Letter Alternate Member

«PrintDate»

«First_Name» «Last_Name», «Earned_Degrees»
«Postal_Address»

«GreetingLine»

Drs. «Clinical_Director», Clinical Director, «IC», «Scientific_Director», Scientific Director, «IC», and «Chair», Chair, «IRB» IRB have recommended your appointment to serve as an alternate member of the «IRB» IRB.

You will serve on the «IRB» IRB in the following capacity:

NIH Affiliation: «Affiliation_Status»
Scientific Status: «Scientific_Status»
Specialty in: «Specialty»
Alternate for: «Alternates_For»
If applicable, represent the perspective of: «Representative_Capacity»

I am pleased to confirm a «Appointment_Term» appointment, effective «Effective_Date».

The IRBs play a vital part in ensuring that the clinical research done at NIH is of the highest scientific and ethical standards, and that the safety and welfare of the people who participate in the research are protected. I am grateful that you are willing to take part in this very important process.

Sincerely yours,

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research

cc: Dr. «Clinical_Director», Clinical Director, «IC»
Dr. «Scientific_Director», Scientific Director, «IC»
Dr. «Chair», Chair, «IRB» IRB
[Ms./Mr.] «IRB_Administrator», IRB Administrator, «IRB» IRB
OHSRP

APPENDIX D - COVER LETTER FROM THE DESIGNATED IRB

MEMORANDUM

«PrintDate»

To: Dr. Michael Gottesman, DDIR

From: «Chair», Chair, «IRB» IRB

Dear Dr. Gottesman:

The «IRB» IRB recommends the appointment of «First_Name» «Last_Name» «Earned_Degrees» to serve as a member of the «IRB» IRB and has completed all required training. Once approved, please send back to the «IRB» IRB office for distribution.

Thank you.

Sincerely,

«Chair», Chair, «IRB» IRB

Attachments: Appointment Letter
Member CV
Training Checklist
IRB Member Survey
Statement of Status as an Unaffiliated IRB Member (if applicable)

APPENDIX E - CHECKLIST OF COMPLETED TRAINING

IRB Nominee Training Checklist

IRB Nominee:_____

NIH IRB: _____

New IRB member requirements consist of:

- ☐ Attendance, as an observer, at one meeting of any IRB: Date_____
- ☐ Attendance at an OHSRP orientation session: Date_____
  The IRB Orientation sessions are usually scheduled on the fourth Tuesday of each month at 10am-12pm, in OHSRP office in building 10, room 2C146. Please contact OHSRP for training date/time confirmation.
- ☐ NIH IRB Member Training. Please note that the IRB Member training links can be accessed on the OHSRP website under the HRPP Staff training: https://federation.nih.gov/ohsr/nih/behai_hrpp.php
  - AND
- ☐ NIH Clinical Research Training (CRT) http://crt.nihtraining.com/login.php
  - OR
- ☐ CITI Biomedical OR CITI Social and Behavioral Modules (commensurate with the type of research reviewed by the IRB) https://www.citiprogram.org/
  - OR
- ☐ The Ethical and Regulatory Aspects of Clinical Research offered by CC Bioethics - Completion certificate
  - AND
- ☐ NIAID Good Clinical Practice (GCP) course https://gcplearningcenter.niaid.nih.gov/Pages/default.aspx
  - OR
- ☐ CITI Good Clinical Practice for PI's course https://www.citiprogram.org/

- ☐ Statement of Status as Unaffiliated Member of an NIH IRB - OR - ____N/A

Questions? OHSRP office can be reached via e-mail at ohsr_nih_ddir@mail.nih.gov or by phone at 301-402-3444.

APPENDIX F - SAMPLE REAPPOINTMENT LETTERS

Note the practice is to place these letters on the appropriate letterhead

Primary Member Reappointment Letter

«PrintDate»

To: Office of Human Subjects Research Protections
Through: «IRB» IRB Office

From: Clinical Director, «IC» _____
(Signature)

Scientific Director, «IC» _____
(Signature)

Subject: IRB Primary Member Reappointment

We wish to reappoint «First_Name» «Last_Name» «Earned_Degrees» as a primary, «Affiliation_Status», «Scientific_Status» member of the «IRB» IRB for a «Appointment_Term» term.

Field of specialty is: «Specialty»
Scientific Status: «Scientific_Status»
Representative Capacity: Representative_Capacity»

Thank you for your consideration.

Attachment: IRB Member CV

cc: Dr. «Chair», Chair, «IRB»
Ms. «IRB_Administrator», IRB Administrator, «IRB»
OHSRP

Alternate Member Reappointment Letter

«PrintDate»

To: Office of Human Subjects Research Protections
Through: «IRB» IRB Office

From: Clinical Director, «IC» _____
(Signature)

Scientific Director, «IC» _____
(Signature)

Subject: IRB Alternate Member Reappointment

We wish to reappoint «First_Name» «Last_Name» «Earned_Degrees» as an alternate, «Affiliation_Status», «Scientific_Status» member of the «IRB» IRB for a «Appointment_Term» term.

Field of specialty is: «Specialty»
Scientific Status: «Scientific_Status»
Representative Capacity: «Representative_Capacity»
Alternate for: «Alternates_For»

Thank you for your consideration.

Attachment: IRB Member CV

cc: Dr. «Chair», Chair, «IRB»
[Ms./Mr.] «IRB_Administrator», IRB Administrator, «IRB»

APPENDIX G - THANK YOU LETTER

Note the practice is to place these letters on the appropriate letterhead

«PrintDate»

«First_Name» «Last_Name», «Earned_Degrees»
«Postal_Address»

«GreetingLine»

On behalf of the Director, NIH and the NIH Intramural Research Program, I want to thank you for your service as a member of the «IRB» Institutional Review Board (IRB). As you know, IRBs not only help to foster and sustain the quality of NIH's clinical research, but also protect the safety and welfare of the people who are research subjects.

NIH is fortunate that busy people like you are willing to devote considerable time and effort to the work of the IRBs. I am grateful that you were able to take part in this very important process.

Sincerely yours,

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research

cc: Dr. «Clinical_Director», Clinical Director, «IC»
Dr. «Scientific_Director», Scientific Director, «IC»
Dr. «Chair», Chair, «IRB» IRB
Ms. «IRB_Administrator», IRB Administrator, «IRB» IRB
OHSRP

APPENDIX H - OHSRP IRB ROSTER HEADINGS

The following data (column headers) are in included on the IRB Roster Spreadsheet regarding the appointment of each member, as applicable:

IRB
Title
First Name
Last name
Earned Degrees
Scientific Status
Representative Capacity
Specialty
Indications of Experience
Relationship to the Organization
Affiliation Status
IRB Role
Alternates For
Effective Date
Appointment Term
Term End Date
Phone Number
Email Address
Postal Address
Gender
Race/Ethnicity
Clinical Director
IC
Scientific Director
Chair
IRB Administrator
PrintDate
OHSRP Approval

Additionally, the following data (column headers) are in included on the IRB Roster Spreadsheet confirming that the IRB composition meets the regulatory and NIH policy requirements, as applicable:

IRB
5+ Members

Professional expertise covering IRB research activity type (education and life experience)
Diverse Member representation (race, gender, cultural background)
Scientific Member
Scientific Member not affiliated with IRB's institution
Non-scientist Member
Non-scientist Member (20%)
Unaffiliated Member
Vulnerable population/subject population representative (regularly reviewed by IRB)
Statistician or Epidemiologist
Pharmacist
Ethicist in HSR
Research Participant Representative