

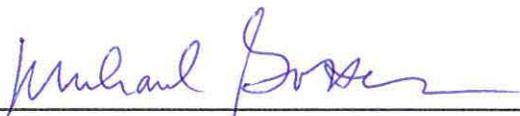
**HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL &
IMPLEMENTATION**

OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

SOP Number: 26

**SOP Title: EVALUATION OF NIH IRB CHAIRS, VICE CHAIRS AND MEMBERS, IRB
ADMINISTRATIVE STAFF AND IRB COMMITTEE ACTIVITIES**

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

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IRB ADMINISTRATIVE STAFF AND IRB COMMITTEE ACTIVITIES**

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SOP 26 EVALUATION OF NIH IRB CHAIRS, VICE CHAIRS AND MEMBERS, IRB ADMINISTRATIVE STAFF AND IRB COMMITTEE ACTIVITIES

26.1 PURPOSE

This Standard Operating Procedure (SOP) describes standards for evaluation of the performance of NIH IRB Chairs, Vice Chairs, IRB members, NIH IRB activities and NIH IRB administrative staff.

26.2 POLICY

NIH officials conduct periodic evaluations of IRB Chairs and Vice Chairs, IRB members, IRB activities and IRB administrative staff to assure that the NIH IRBs comply with regulatory requirements and the NIH HRPP SOPs, and to identify areas that need improvement, and to justify changes, when needed.

26.3 PROCEDURES AND OFFICIALS RESPONSIBLE FOR EVALUATION ACTIVITIES

26.3.1 EVALUATION OF NIH IRB CHAIRS

- A. An NIH IRB Chair will receive a written copy of performance standards for his/her activities as Chair, through the HHS Employee Performance Plan (Form HHS-704B) or through a contract, as applicable. The performance standards addressing his/her performance as IRB Chair consist of one or more critical elements, depending on whether the Chair's IRB activities are full- or part-time. This evaluation will take place consistent with the HHS performance plan or contract requirements.
Appendix A contains sample language for these performance standards.
- B. The Director, OHSRP or designee will evaluate the performance of all NIH IRB Chairs by attending each IRB meeting at least annually or more frequently, if necessary. S/he may seek information from IRB members and others as appropriate.

- C. Standards for IRB Chair evaluation are contained in **Appendix B**.
- D. If at any time, issues related to a Chair's leadership, knowledge or performance are identified, the OHSRP Director will discuss them with the Institutional Official (IO, the Deputy Director for Intramural Research (DDIR)) and with the Chair. If appropriate, a plan for improvement may be implemented, including but not limited to additional educational and/or mentoring activities. Failure to perform acceptably despite an improvement plan may result in being removed as IRB Chair as determined by the Institutional Official.

26.3.2 EVALUATION OF NIH IRB VICE CHAIRS

- A. The Vice Chair will be evaluated annually by the IRB Chair according to the elements that are applicable to the Vice Chair's responsibilities listed in **Appendix B** for IRB Chairs.
- B. Any issues related to the Vice-Chair's performance will be discussed and a plan for improvement may be implemented. Failure to perform acceptably despite an improvement plan may result in being removed as Vice Chair as determined by the Institutional Official.

26.4 EVALUATION OF NIH IRB MEMBERS

- A. **Primary** 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. **Alternate IRB members, who have attended a minimum of 3 meetings, will be evaluated at least annually to assess their knowledge of ethical principles and basic regulatory requirements, preparedness for and participation in meetings.** See **Appendix C** for IRB member **performance elements and see Appendix F: IRB Member Evaluation Instrument.**
- B. These evaluations **are delegated by OHSRP to the IRB Chair. The IRB Chair will perform these evaluations about the members' function on the IRB based on his/her observations at convened meetings or through other appropriate means.** Information about performance also may be obtained from self-evaluation activities and/or from other IRB members and the Chair.

- C. Any issues related to members' performance will be discussed and a plan for improvement may be implemented. Failure to perform acceptably despite an improvement plan may result in being removed from membership on the IRB as determined by the IO.

26.5 EVALUATION OF NIH IRB ADMINISTRATIVE STAFF

- A. IRB administrative staff members are employees of the individual Institutes or are contractors. Each IC will designate a mechanism for supervision and at least an annual evaluation of the NIH IRB staff. For NIH employees, this would be the employee's HHS Employee Performance Plan (Form HHS-704B).
- B. Standards and responsibilities may include, but are not limited, to those listed in **Appendix D**.

26.6 EVALUATION OF IRB ACTIVITIES

26.6.1 CONVENED MEETINGS

- A. OHSRP staff members regularly attend convened NIH IRB meetings to provide regulatory or other advice and to provide information to the OHSRP Director and IO about the meeting and the quality of reviews. They also evaluate the conduct of the meetings (see **26.6.1.B** below).
 - 1. When OHSRP staff identifies issues of concern resulting from their regular attendance at convened meetings, they shall bring them to the attention of the Director, OHSRP and, when appropriate, the IRB and/or the IRB Chair. Concerns may be addressed and resolved in several ways including, but not limited to, discussions with the IRB Chair and members and/or additional education on particular topics.
- B. Evaluation of meetings will include the elements provided in **Appendix E**. The evaluation also will address how the IRB handles new protocols (initial review), continuing reviews, amendments and the review and discussion of unanticipated problems and serious adverse events. It will also take into consideration the accuracy of the IRB minutes, and

confirm that members are requested to recuse themselves in the event of conflict of interest.

- C. OHSRP staff will discuss their observations directly with the Chair and, when appropriate, with the convened IRB or IRB members, and will report their observations to the OHSRP Director.
- D. The Director OHSRP, the IRB Chair or members may ask that additional evaluations of the convened IRB take place. These can be conducted by the Director, OHSRP, the IRB Chair and members (self-evaluation), OHSRP staff, other NIH experts (such as Chairs or members from other NIH IRBs) or non-NIH experts.

26.6.2 RESEARCHERS' ASSESSMENT OF IRB PERFORMANCE

- A. Principal Investigators (PIs) will evaluate IRB performance annually using a subset of the Researchers' Assessment Tool or other questionnaire.
- B. Following IRB review of new or continuing protocols, a subset of PIs who are NIH employees will complete a short survey regarding their experience with the IRB review process.
- C. OHSRP will consider concerns presented by investigators outside of these surveys.
- D. OHSRP will provide collated results to the IRB Chair. Substantive issues will be discussed with the IO and the Deputy Director for Clinical Research, and a plan for improvement may be implemented.

26.6.3 OTHER IRB ACTIVITIES

OHSRP encourages and supports educational activities for the IRBs, such as attendance at PRIM&R and other human research subjects protection programs. OHSRP will organize an annual IRB Professional Administrators Committee (IPAC) retreat/workshop as an educational activity for the benefit of IPAC members. OHSRP staff will also attend any educational activities and retreats organized by the IRBs and will arrange for presentations from OHSRP staff on topics requested by the IRBs.

LIST OF APPENDICES

Appendix A: Performance Element Description for IRB Chairs

Appendix B: IRB Chair and Vice Chair Performance

Appendix C: NIH IRB Member Performance

Appendix D: IRB Administrative Staff Performance

Appendix E: Performance of Convened NIH IRBs

Appendix F: IRB Member Evaluation Instrument

APPENDIX A: PERFORMANCE ELEMENT DESCRIPTION FOR IRB CHAIRS

Performance Outcomes/Measures:

- A. Display current knowledge of DHHS, FDA and NIH policies and procedures in human subjects research as reflected by familiarity with NIH HRPP policy, Clinical Center policy, DHHS and FDA regulations and guidance, etc.
- B. Meet with principal investigators and others in research teams to assist with protocol development, especially as relates to human subjects protection and informed consent process.
- C. Maintain current knowledge of ethical conduct requirements, conflict of interest policy, computer security and other administrative requirements. (May be evidenced by attendance at meetings such as PRIM&R)
- D. Organize agenda and chair scheduled and called meetings of IRB.
- E. Lead discussion of selected topics of interest relevant to human subjects research at beginning of meetings prior to active business of the IRB.
- F. Conduct meetings that encourage input from IRB members to protect human subjects and ensure highest quality clinical research, and foster civility and respect among IRB members, principal investigators and guests during deliberations.
- G. Maintain written notes of proceedings and edit minutes of IRB meetings to ensure accurate documentation of IRB deliberations and fulfill IRB requirements.
- H. Organize annual “retreats” to discuss IRB policies and practice; invite speakers for special topics of interest.
- I. Attend scheduled meetings of Human Subjects Research Advisory Committee (HSRAC) as the representative of the IRB, and report summary of proceedings to the Clinical Director and IRB administrative staff at scheduled staff meetings and to IRB, as appropriate.

- J. Work with the Clinical Director in addressing issues raised in the “*Barriers to Clinical Research*” report with regard to IRB process and implement recommendations as appropriate.
- K. Serve as Institute(s) IRB liaison with Intramural Clinical Research Steering Committee (ICRSC) and Office of Human Subjects Research Protection (OHSRP), especially in preparation for national accreditation of NIH’s Human Research Protection Program.
- L. Evaluate educational needs regarding human subjects protection within the institute(s) and organize educational programs as needed.

APPENDIX B: IRB CHAIR AND VICE CHAIR PERFORMANCE

The responsibilities and duties of NIH IRB Chairs and Vice Chairs are described in SOP 2 – IRB Membership and Structure and are stated below. IRB Chair and Vice Chair performance evaluations will take into account the following:

A. Leadership skills:

1. 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 biomedical research.
2. 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)**).
3. The ability to set a tone of openness that encourages dialogue in IRB meetings.
4. 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.
5. The confidence and ability to uphold IRB judgments that may not always be popular with Principal Investigators, and
6. Investment of adequate time, interest and commitment to provide guidance and expertise to IRB members.

B. Duties of the Chair:

1. The Chair either votes or abstains from voting on all actions for which votes are taken, unless recused. Chairs will recuse themselves, as appropriate, when conflicts of interest exist.

2. Provides guidance and expertise about human subjects research to IRB members, investigators and others.
3. Upholds the independent decisions of the IRB with investigators and Institute officials.
4. 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.
5. Stays informed of established and emerging DHHS and FDA policies and guidance pertaining to the protection of human subjects involved in research.
6. Promotes continuing education of IRB members and IRB staff, including providing IRB members and staff with information about relevant educational opportunities.
7. Serves as a member of the Human Subjects Research Advisory Committee, attends at least 75% these meetings in person if based on the Bethesda campus, and shares issues discussed at them with the IRB members and investigators as appropriate.
8. 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 (or engage OHSRP for assistance).
9. Conducts expedited reviews or delegates them to the Vice Chair or other qualified IRB member and assures that determinations are documented as required by SOP 7A - Requirements for Expedited Review of Research by NIH Institutional Review Boards.
10. When 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.
11. Prepares for and handles any audits by OHRP or the FDA.

12. Coordinates education of investigators with the appropriate Clinical Director.

C. Conduct of convened meetings:

1. Ensures the presence of a quorum
2. 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 require the voice or show-of-hands vote of the members present following discussion and the making and seconding of a motion
3. Leads IRB discussions by identifying regulatory requirements of 45 CFR Part 46, 21 CFR Parts 50 and 56, the ethical principles of The Belmont Report, and the NIH HRPP sops as the criteria for the review of all research studies
4. 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 both the deliberations and vote on that action and the member must leave the meeting room during that portion of the meeting. (See SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs))
5. Ensures that all IRB members who are not recused have the opportunity to contribute to the IRB's deliberations
6. In IRBs where a primary and/or 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 reviews.
7. Ensures that the NIH IRB Protocol Review Standards (SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs)) are addressed by the PI at the convened meeting for all initial protocol reviews

8. Ensures that the IRB addresses and documents in the minutes all the regulatory standards embodied in the NIH IRB Protocol Review Standards (SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs)) for every initial review
9. Ensures thorough evaluation of initial and continuing reviews, amendments and unanticipated problems including adverse events

APPENDIX C: NIH IRB MEMBER PERFORMANCE

The responsibilities of NIH IRB members are described in SOP 2 – IRB Membership and Structure and stated below. IRB member performance evaluations will take into account the following:

Members of the IRB shall:

- A. In convened meetings, apply the NIH IRB Protocol Review Standards when reviewing protocols
- 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. 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))
- E. Participate in required training and continuing education opportunities, or IRB retreats (see SOP 25 - Training Requirements for the NIH Human Research Protection Program (HRPP))
- F. 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)
- G. Recuse themselves in the case of a conflict of interest, such as being an investigator on a protocol under review or having a financial interest in the conduct or outcome of a protocol (see SOP 21 - Conflict of Interest Requirements for NIH Researchers and Research Staff)

APPENDIX D: IRB ADMINISTRATIVE STAFF PERFORMANCE

Performance evaluation may include, but is not limited to, the following:

A. Pre-review of protocols and other IRB submissions:

1. Timeliness of processing protocols and other IRB submissions
2. Completion of any required checklists/review tools

B. IRB meeting activities:

1. Timely preparation and distribution of agendas and materials
2. Timely preparation and maintenance of minutes, as appropriate
3. Attendance at convened meetings, as assigned, for vote counting and other purposes
4. Informs investigators of the dates of IRB meetings and deadlines for submission of materials

C. IRB membership activities:

1. Maintenance of up-to-date IRB rosters
2. Preparation and processing of IRB member appointment correspondences
3. Organization of educational activities, such as IRB retreats, as appropriate

D. IRB files and records:

1. Completes and maintains IRB records correctly (including paper, and/or electronic files)

E. Educational activities:

1. Completion of any educational requirements, see SOP 25 - Training Requirements for the NIH Human Research Protection Program (HRPP)
2. Attendance at other appropriate educational sessions
3. Attainment and maintenance of certification as appropriate (e.g., Certified IRB Professional (CIP))
4. Regularly attends the IRB Professional Administrators Committee (IPAC) meetings

F. Other subjective criteria:

1. Preparedness for meetings
2. Quality of pre-reviews
3. Knowledge of regulations and ethical principles
4. Knowledge of NIH Standard Operating Procedures
5. Effective communication with IRB Chair and Vice Chair
6. Effective communication/interaction with OPS and OHSRP
7. Effective communication with investigators
8. Ability to help investigators

APPENDIX E: PERFORMANCE OF CONVENED NIH IRBS

- A. Evaluation of IRB implementation of federal requirements and ethical principles: In evaluating convened meetings, the evaluator will use, as applicable, the NIH IRB Protocol Review Standards (see SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs)).
- B. OHSRP will conduct annual audits of the IRBs as described in SOP 23 - Quality Management System for the NIH HRPP.
- C. Subjective evaluation of IRB meeting processes and dynamics will include at least the following:
1. The IRB focused on enhancing human subject protections
 2. Free and open communication was encouraged by the Chair and other members
 3. Interactions between the IRB and investigators were respectful
 4. The review was well organized with systematic review procedures
 5. A majority of the members participated
 6. IRB members demonstrated mutual respect for each other's varying opinions
 7. Disagreements between members were resolved effectively

Appendix F: IRB Member Evaluation Instrument

This tool was approved for use in 2016:

NIH IRB Member Self-Evaluation and Feedback for IRB Improvement

IRB name:

Date:

IRB member name:

Role/Expertise:

Member status: Primary Member OR Alternate* (*only those who have attended 3 or more meetings in the past year)
 Affiliated OR Non Affiliated

Please answer the following questions based on your experience as an IRB member during the last year. Note that the comment boxes will expand as you type.

1. **Do you feel you have adequate knowledge of ethical principles, human subjects protection regulations, NIH policy and procedures to fulfill your role on the IRB?**
 Yes No/Need additional training

Identify what additional knowledge or training would be helpful to you:

2. **Review of IRB Actions:**

- A. **In the past year have you been able to adequately prepare for review of:**

- i. **The agenda items for each meeting?**

Always Usually Sometimes Rarely

- ii. **The minutes from the previous meetings?**

Always Usually Sometimes Rarely

If “sometimes” or “rarely” for either question, please identify the reasons that you were not able to adequately prepare, and what can be done to assure adequate preparation.

B. Are you easily able to apply the NIH IRB Protocol Review Standards when reviewing protocols?

- Always Usually Sometimes Rarely

If so, please describe any challenges or issues in applying the Review Standards and suggestions for remediation:

C. IRB discussions should focus on human subjects protections and regulatory compliance.

i. Are you able to stay focused on those issues and contribute substantively to the discussion?

- Always Usually Sometimes Rarely

If sometimes or rarely, what would help you stay focused on the issues and contribute more substantively?

ii. Are you comfortable expressing your own opinions or assessments, even if those appear to differ from the majority of the group?

- Always Usually Sometimes Rarely

If sometimes or rarely, what can be done to make you feel more comfortable expressing your opinions or assessments?

3. Training and Resources:

A. List any human subject protections education you received this year, other than that at IRB meetings. Include IRB retreat attendance, PRIM&R attendance, on line training, OHSRP presentations, classes, workshops, etc.

B. Do you have any recommendations for IRB member continuing education topics, for example at IRB meetings or retreats?

4. SOP 26 requires the following of IRB members: (Please confirm your concurrence by initialing each item.)

A. ____ I confirm that I maintain the confidentiality of IRB discussions, the votes of individual members, and the protocols and related materials, including any proprietary information.

- B. ____ I confirm that I inform or will inform the IRB immediately if any status changes in a way that might impact my membership (such as a new affiliation with the NIH for a member who was previously considered unaffiliated).**
- C. ____ I confirm that I recuse myself in the case of a conflict of interest, such as being an investigator on a protocol under review or having a financial interest in the conduct or outcome of a protocol.**

5. Do you have any concerns or comments?

Thank you for completing the IRB member self-assessment. The form will be returned to you with chair comments. If you wish to meet with the IRB chair, please call the IRB office to schedule an appointment.

IRB Chair Review

1. Has the member attended at least 75% of meetings? Yes No
2. Comments for the IRB member:
3. Information, documents or other guidance for the IRB member:
4. Meeting with IRB member requested: Yes No