

NIH HRPP SOP 3 v.1

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

OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

SOP Number: 3

SOP Title: MANAGEMENT AND ADMINISTRATIVE OPERATIONS OF THE IRB

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

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SOP 3. MANAGEMENT AND ADMINISTRATIVE OPERATIONS OF THE IRB

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SOP 3. MANAGEMENT AND ADMINISTRATIVE OPERATIONS OF THE IRB

3.1. PURPOSE

This SOP provides basic requirements for the management and administrative operations of NIH Institutional Review Boards (IRBs).

3.2. POLICY

NIH IRBs are expected to adhere to the basic requirements of this SOP but are allowed some flexibility in their operations and management in order to handle the wide range of clinical research activities conducted in the NIH's Intramural Research Program (IRP).

3.3. IRB ADMINISTRATIVE STAFF RESPONSIBILITIES

3.3.1 IRB Administrative Office

Each NIH IRB has an Administrative Office. The title, number, grade level and responsibilities of the administrative support staff vary depending on the IRB's workload and research portfolio and are decided by appropriate Institute/Center leadership.

3.3.2 IRB Administrative Staff

IRB administrative staff who are employees of the individual Institutes or are contractors, are selected and appointed by the Institute Scientific Director or Clinical Director.

- A. Each IC will designate a mechanism for supervision of the NIH IRB administrative staff.
- B. IRB administrative staff members may not serve as a voting IRB member on the IRB that they administer.

3.4 IRB ADMINISTRATIVE STAFF INITIAL AND CONTINUING TRAINING AND EDUCATIONAL REQUIREMENTS

- A. Initial and continuing educational requirements for IRB administrative staff are described in SOP 25 “Training Requirements for the NIH HRPP.”
- B. All IRB administrative staff members are encouraged to become professionally certified as IRB professionals (e.g. Certified IRB Professional - CIP) and to attend professional meetings.

3.5 THE IRB PROFESSIONAL ADMINISTRATORS’ COMMITTEE (IPAC)

As part of their continuing training requirements, IRB administrative staff members are expected to attend meetings of IPAC regularly in order to keep up to date on the latest developments in human subject research protections. The IPAC, founded in 2004, consists of IRB support staff and representatives from OHSRP and the Office of Protocol Services, and is dedicated to ensuring compliance with regulatory standards governing human subjects research by developing and promoting effective and consistent procedures and practices across the IRB offices. (See List of Links for the link to the OHSRP website and the IPAC mission statement and accomplishments.) The IPAC Chair is a voting member of the Human Research Subjects Advisory Committee (HSRAC).

- A. Monthly meetings: A representative from the administrative staff of each NIH IRB is expected to attend the monthly meetings of the IPAC. Agendas for these meetings include exchange of information about the latest regulatory rulings, changes in NIH policies and procedures, sharing best practices, and other matters as appropriate.
- B. Annual Retreat: IPAC holds an annual retreat, which all IRB administrative staff members are expected to attend.

3.6 IRB RESOURCES AND FACILITIES

Each IRB receives resources from the IC(s) it serves. Each IRB shall maintain a record of its resources, including the following information, which will be provided to OHSRP upon request:

DHHS/NIH/OD/OIR/OHSRP

- A. Financial resources.
- B. Names, titles, and contact information for IRB administrative staff.
- C. Size and location of office.
- D. Computer equipment.
- E. Information technology support.
- F. Website, if applicable.
- G. Protocol management databases, and
- H. Physical and electronic security to protect files and records.

3.7 PROTOCOL SUBMISSION DEADLINES

Each IRB office establishes its own deadline for the submission of protocols, continuing reviews and amendments by PIs to the IRB for review. The IRBs will have a written statement with this information on file with OHSRP. This statement can be updated as needed.

3.8 ADMINISTRATIVE REVIEW OF SUBMISSIONS

3.8.1 Complete Submissions

IRB administrative staff verifies that all submissions to the IRB are complete. Incomplete submissions will not be reviewed by the IRB.

3.8.2 Required Elements For Each Type Of IRB Submission

Required elements for each type of IRB submission are described in SOP 8 “Procedures and Required Documentation for Initial Review of Protocols by a Convened NIH IRB” and SOP 9 “Continuing Review by the Convened IRB”, SOP 10 “Amendments to IRB-approved Research”.

3.9. THE IRB MEETING AGENDA

The agenda is prepared by the IRB administrative staff in conjunction with the IRB Chair and must include the following, when applicable:

- A. Announcements.
- B. Minutes of the Previous IRB Meeting (see SOP 4 NIH IRB Minutes).
- C. Reports of Expedited Actions.
- D. New Protocols for Review.
- E. Continuing Reviews.
- F. Amendments.
- G. Reports of Unanticipated Problems Requiring Full Board Review.
- H. Relevant Additional Items.

3.9.1 PROVISION OF AGENDAS TO IRB MEMBERS

Agendas with accompanying attachments are provided to IRB members electronically or in hard copy at least 5 days before the IRB meeting. Copies of the agendas should be sent to OHSRP at the same time as they are distributed to members.

3.9.2 ATTACHMENTS TO AGENDAS

Attachments for the most common types of review are detailed below.

- A. Initial Reviews: (See also SOP 8 “Procedures and Required Documentation for Submission and Initial Review of Protocols”).
At a minimum, all IRB members receive:
 - 1. The NIH Intramural Initial Clinical Protocol Application (Appendix 1).
 - 2. The full protocol.

3. The proposed informed consent/assent document(s).
4. Documentation of completed scientific review.
5. Recruitment materials (e.g. advertisements), if any.

B. Continuing Reviews: (See also SOP 9 “Continuing Review by the Convened IRB”). At a minimum, all IRB members receive:

1. The NIH Intramural Clinical Protocol Continuing Review Application (Appendix 2)
2. Current consent/assent document(s).
3. DSMB reports (if applicable).
4. Annual reports to the FDA (when applicable, if requested by the IRB).

Note: A copy of the complete protocol, incorporating all amendments previously approved by the IRB is available for members' review at each IRB meeting. Upon request, all records, including relevant IRB meeting minutes, are available for any member for review prior to the meeting.

C. Amendments: (See also SOP 10 “Amendments to IRB-approved Research”). At a minimum, all IRB members receive:

1. The NIH Intramural Clinical Protocol Amendment Application (Appendix 3)
2. Revised protocol and consent documents (as applicable).
3. Any other relevant materials.

D. Study Closure: (See also SOP 9 “Continuing Review by the Convened IRB”). At a minimum, all IRB members receive:

1. The NIH Intramural Clinical Protocol Study Closure Application (Appendix 4)

2. Any other relevant materials.

3.10 ROUTING OF IRB DOCUMENTS AFTER IRB APPROVAL

IRB-approved documents are forwarded for approval/review and signature(s) as appropriate to the: IRB Chair or designee(s), IC Clinical Director, Office of Protocol Services (OPS), CC Director or the Deputy Director for Clinical Research.

LIST OF APPENDICES*

Appendix 1: NIH Intramural Initial Clinical Protocol Application

Appendix 2: NIH Intramural Clinical Protocol Continuing Review Application

Appendix 3: NIH Intramural Clinical Protocol Amendment Application

Appendix 4: NIH Intramural Clinical Protocol Study Closure Application

LIST OF LINKS

OHSRP website: <https://federation.nih.gov/ohsr/nih/ipac.php>

*To be posted at a later date