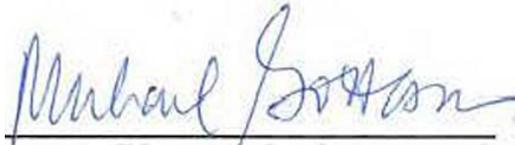


**HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL & IMPLEMENTATION OFFICE OF
HUMAN SUBJECTS RESEARCH PROTECTIONS**

Policy Number: 101

SOP Title: **Organizational Structure of the OHSRP**

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

 7/9/19

Revision Approval:

**Deputy Director for Intramural
Research**

Date

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POLICY

A. PURPOSE

1. Describe the organizational structure and responsibilities of the Office of Human Subjects Protections (OHSRP) within the NIH Intramural Research Program's (IRP) Human Research Protection Program (HRPP).

B. SCOPE

1. This policy applies to the staff of the OHSRP and its offices including the Office of IRB Operations, the office of Compliance and Training, the office of Policy and Accreditation, and the IRB Executive Chair.

C. POLICY

1. OHSRP promotes the rights, safety and welfare of human subjects and promotes the NIH's research mandate by supporting the IRP. The functions of OHSRP include:
 - a. Review exempt and non-exempt human subjects research activities;
 - b. Develop NIH policies and procedures consistent with federal regulations and policy;
 - c. Organize and conduct educational activities for NIH investigators and the NIH Institutional Review Board (IRB); and
 - d. Conduct quality assurance and quality improvement activities to ensure NIH IRB compliance with federal regulations and policies.

D. DEFINITIONS

1. *Institutional Official (IO)* – The individual who is legally authorized to act for the institution and can obligate the institution to the terms of the Federalwide Assurance (FWA). The Institutional Official (IO) is the signatory on the FWA which is on file with the US Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP).
2. *NIH Human Research Protection Program (HRPP)* – The NIH HRPP is made up of certain NIH Institutes' and Centers' (ICs) intramural programs, NIH officials, the NIH Institutional Review Board (IRB), NIH Investigators who conduct exempt and non-exempt human subjects research, and those who provide support for research protocols involving human subjects.

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3. *NIH Intramural Research Program (IRP)* – The IRP consists of separately funded programs within the Institutes and Centers (ICs) of the NIH. The IRP is the internal research program of the NIH whose investigators conduct exempt and non-exempt human subjects research.
4. *NIH Institutional Review Board (IRB)* – Any board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, to approve the initiation of and conduct periodic review of such research. However, for the purposes of NIH Human Research Protection Policy (HRPP) policy, IRB review includes additional types of human subjects research (e.g. socio-behavioral) and is not limited to biomedical research.
5. *NIH Institutional Review Board (IRB) Executive Chair* – The individual in Office of Human Subjects Research Protections (OHSRP) who oversees the IRB Chairs. This individual assists the Office of IRB Operations (IRBO) Director and the OHSRP Director in supporting the mission of the NIH Human Research Protection Program (HRPP).
6. *Office of Compliance and Training* – The Office of Human Subjects Research Protections (OHSRP) office responsible for review and management of reportable events that occur during the conduct of Intramural Research Program (IRP) human subjects research (HSR) activities. This office conducts: (a) noncompliance investigations, and (b) Quality Assurance (QA)/Quality Improvement (QI) reviews of NIH Institutional Review Board (IRB) activities. This office also provides education and training related to human subjects protections policies and procedures.
7. *Office of Human Subjects Research Protections (OHSRP)* – An Office within the NIH Office of the Director (OD) that reports to the NIH Institutional Official (IO) who is the Deputy Director for Intramural Research (DDIR). The OHSRP carries out the day-to-day operations and regulatory oversight of human research activities within the Human Research Protection Program (HRPP) via a delegation from the DDIR to the Director of OHSRP. (The organizational structure of the OHSRP is depicted in Policy 101, Appendix 1, *Organizational Structure of the NIH OHSRP*)
8. *Office of IRB Operations (IRBO)* – The Office of Human Subjects Research Protections (OHSRP) office that manages the NIH Institutional Review Board (IRB) for the NIH Intramural Research Program (IRP).
9. *Office of Policy and Accreditation* – The Office of Human Subjects Research Protections (OHSRP) office that writes Human Research Protection Program (HRPP) policies and manages accreditation activities for the NIH HRPP.

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10. *Office of Research Support and Compliance (ORSC)* – The office, located within the NIH Clinical Center (CC) and which reports to the Chief Executive Officer (CEO) of the NIH CC, that ensures the quality and integrity of clinical research and product manufacturing/compounding conducted at the NIH by providing regulatory and compliance support and guidance for all NIH researchers in the areas of protocol navigation and coordination, quality assurance auditing and monitoring, support for FDA regulated studies and centralized facility oversight.
11. *Quality Assurance/Quality Improvement Review (QA/QI Review) of the NIH IRB* – A comprehensive, systematic, and independent assessment of the NIH IRB and IRB office (IRBO) actions.

E. RESPONSIBILITIES AND REQUIREMENTS

1. The Institutional Official (IO) is responsible for:

- a. Ensuring the HRPP, under the auspices of OHSRP, functions effectively and that the NIH IRP provides the resources and support necessary to comply with all requirements to safely and effectively conduct research involving human subjects. To accomplish this oversight, the IO has the following responsibilities including, but not limited to, those listed below:
 - I. Serves as the signatory for the NIH IRP’s Federalwide Assurance ([45 CFR 46.103](#)).
 - II. Serves as the signatory (unless otherwise delegated in writing) for other institutional documents related to the NIH HRPP such as program-wide reliance agreements, and HRPP policy, and communications with non-NIH HRPPs regarding concerns related to human subjects research occurring in the setting of collaborative research.
 - III. Sets the tone for an institutional culture of respect for human research subjects by ensuring the standing of the IRB within the institution.
 - IV. Ensures effective institution-wide communication and guidance on human subjects research.
 - V. Receives reports of alleged undue influence on the IRB process that have undergone initial assessment by the IRBO Director and/or OHSRP Director and takes necessary action.

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- VI. Receives and responds to concerns from investigators that could not be resolved by the usual processes within the HRPP.
- 2. The Director of OHSRP will work closely with the IO to ensure that resources are adequate to maintain the proper functioning of the NIH HRPP and the functional offices of OHSRP.
- 3. OHSRP’s office of Compliance and Training is responsible for:**
 - a. The ongoing evaluation of the effectiveness of the NIH IRB and the IRBO. It promotes and ensures IRB compliance with human subjects protection regulations and policy. This office helps NIH Investigators and the NIH IRB understand and comply with the ethical guidelines, regulatory requirements, and NIH policies and procedures for research involving human subjects.
 - b. Conducting QA/QI reviews of the NIH IRB:
 - I. QA/QI of the activities of NIH IRB will be performed by the QA/QI reviewers in the office of Compliance and Training. It will conduct reviews to evaluate adherence to regulatory standards and NIH policies, and to recommend corrective and preventative actions.
 - II. QA/QI of the activities of the Research Compliance Review Committee (RCRC) will be performed by the NIH Clinical Center (CC) Office of Research Support and Compliance (ORSC). It will conduct reviews to evaluate adherence to regulatory standards and NIH policies, and to recommend corrective and preventative actions.
 - III. The Director of the OHSRP and the IO, as representatives for the Institution, are responsible for reviewing QA/QI summary reports. (See *Policy 108 Quality Assurance and Quality Improvement Program for NIH IRBs.*)
 - IV. Scope and responsibilities for QA/QI activities performed by other entities within the HRPP are discussed in *Policy 108 Quality Assurance and Quality Improvement Program for NIH IRBs*, Appendix 1, and OHSRP tracks some of these activities as well.
 - c. Conducting investigations of alleged noncompliance with federal regulations and NIH policy related to protection of human subjects that are/were under the jurisdiction of an NIH IRB or that may involve additional alleged noncompliance within the NIH HRPP.

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- d. Assessment, triage, and management of problem reports submitted to OHSRP as well as reporting unanticipated problems, serious and/or continuing noncompliance and IRB suspension or termination of research to federal agencies as required. (See *Policies [801 Reporting Research Events](#) and [802 Non-Compliance in Human Subjects Research](#)*, respectively.)
- e. Providing NIH investigators and the NIH IRB with programs and educational resources in research ethics and human subject safety, with an emphasis on the proper conduct of research (*[Policy 103 Education Program](#)*). The NIH CC ORSC may also assist with targeted training as needed.

4. The OHSRP office of Policy and Accreditation is responsible for:

- a. Writing and maintaining HRPP policy as needed. This office may make other policy decisions and/or hear requests for policy exceptions.
- b. Managing and ensuring the continued accreditation of the NIH HRPP, including all required reporting and preparation for site visits and site visit responses.

5. Unless otherwise determined by written agreement, the NIH IRB(s) are responsible for the review and approval of all non-exempt human subjects research conducted by NIH investigators. The NIH IRB ensures the rights, safety and welfare of human subjects are adequately protected and its review of research is conducted in accordance with applicable federal regulations and NIH policies. (See *Policy 200 IRB Scope and Authority*.)

6. The Office of IRB Operations (IRBO) is responsible for:

- a. Managing and supporting the efficient and effective regulatory oversight of the NIH IRB. (See *Policy 203 Support of the IRB Operations*, for specific responsibilities, roles and activities of the IRBO.)
- b. Interfacing, as necessary, with other divisions of the NIH IRP that are responsible for the review and approval of research (*Policy 100 Human Research Protection Program* and *Policy 106 Ancillary Reviews*).
- c. Maintaining documentation of IRB minutes and making these available upon request to the Director of OHSRP and the IO. (See *Policy 206 Maintenance of Records*.)
- d. Preparing the minutes of the NIH IRB. When clarifications of the minutes are requested by the IO or the Director of OHSRP, or their designees, these requests will be provided to the IRBO Director and then forwarded to the IRB for additional review and action, as required.

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- e. Executing cooperative research agreements such as reliance (authorization) agreements and Individual Investigator Agreements (IIA) between the NIH and non-NIH institutions or independent IRBs.

7. The NIH IRB Executive Chair is responsible for:

- a. Overseeing the NIH IRB Chairs.
- b. Educating NIH IRB Chairs and members.
- c. Identifying individuals to serve as IRB Chairs and members.
- d. Providing feedback (along with the IRBO Director), to the Director of OHSRP about the performance of IRB members and Chairs and periodically evaluating the IRB composition to confirm adherence to regulatory and organizational requirements.
- e. Removal of an IRB member, (after consultation with the IRBO Director and the IRB Chairs) from the IRB if s/he is not acting in accordance with the IRB’s mission or policies, or applicable NIH policies (e.g., IRB member conflict of interest or the anti-harassment policy).
- f. Designating IRB members to conduct expedited reviews.
- g. Assisting the NIH IRB or IRBO designated exempt or expedited reviewers with related determinations.
- h. Providing consultation when needed to IRBO staff or IRB reviewers to determine if a study involving an:
 - I. Investigational drug meets the exemption criteria as defined in [21 CFR 312.2\(b\)](#) or that the PI will be required to contact the FDA to either obtain an IND or written documentation that an IND is not necessary. (See *Policy 500 Research Involving Drugs, Biological, and Nutritional Products.*) This function can also be performed by the Executive Chair’s designee.
 - II. Investigational device meets the exemption criteria as defined in [21 CFR 812](#). (See *Policy 501 Research Involving FDA Regulated Devices.*) This function can also be performed by the Executive Chair’s designee.
- i. Providing consultation, as needed, to IRBO staff or IRB reviewers as to whether sufficient information has been provided to the IRB to determine the approvability of a protocol.

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- j. Reviewing requests for and providing IRB Chair concurrence for single patient emergency and non-emergency uses of investigational drugs or devices. This function may be delegated to another IRB Chair.
 - k. Communicating allegations of noncompliance to HRPP leadership and assisting the office of Compliance and Training with subsequent related investigations. (See [Policy 802 Non-compliance in Human Subjects Research](#).)
 - l. Providing consultation to the office of Compliance and Training, as needed, in the evaluation of problem reports.
 - m. Otherwise providing support to the OHSRP Director and IRBO Director to facilitate the operation of the NIH IRB.
- 8. The CC ORSC, overseen by the Clinical Center CEO, assists the NIH IRP by providing:**
- a. Regulatory and compliance support including post-approval monitoring to ensure investigator compliance with the protocol and federal regulations as well as NIH policies.
 - b. Guidance to NIH researchers in the areas of protocol navigation and coordination, quality assurance, auditing and monitoring, support for FDA regulated studies, and centralized facility oversight.
 - c. QA/QI of the NIH RCRC (see [C.1.d.](#) above).
9. For additional information regarding the responsibilities or requirements, and procedures of OHSRP offices see the following policies: *103 Education Program; 105 IRB Reliance and Collaborative Research; 108 Quality Assurance and Quality Improvement Program for the NIH IRB; 200 IRB Scope and Authority; 201 IRB Membership and Composition; 202 Board Member Conflict of Interest; 203 Support of the IRB Operations; 206 Maintenance of Records; 204 Levels of IRB Review and Criteria for IRB Approval of Research; 205 Requirements for IRB Submissions; [801 Reporting Research Events](#); and [802 Non-Compliance in Human Subjects Research](#).*

F. REFERENCES

1. Federal Regulations

HHS: [45 CFR 46](#)

FDA: 21 CFR parts [312](#) and [812](#)

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2. NIH Policies

Policy 100 NIH Human Research Program

[Policy 103 Education Program](#)

Policy 105 IRB Reliance and Collaborative Research

Policy 106 Ancillary Committee Reviews

Policy 108 Quality Assurance and Quality Improvement Program for the NIH IRB

Policy 200 IRB Scope and Authority

Policy 201 IRB Membership and Composition

Policy 202 Board Member Conflict of Interest

Policy 203 Support of the IRB Operations

Policy 204 Levels of IRB Review and Criteria for IRB Approval of Research

Policy 205 Requirements for IRB Submissions

Policy 206 Maintenance of Records

Policy 500 Research Involving Drugs, Biological, and Nutritional Products

Policy 501 Research Involving FDA Regulated Devices

[Policy 801 Reporting Research Events](#)

[Policy 802 Non-compliance in Human Subjects Research](#)

3. Guidance: NA

G. APPENDICES

[Appendix 1: Organizational Structure of the NIH OHSRP](#)

H. REVISION HISTORY: NA

I. SUPERSEDES DATE: 09/21/2020

Introduction to the NIH HRPP

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J. APPENDIX 1: ORGANIZATIONAL STRUCTURE OF THE NIH OHSRP

