NIH Policy Manual

3014-101 - Organizational Structure of the OHSRP

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

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Transmittal Notice

1. **Explanation of Material Transmitted:** This policy describes the organizational structure of the NIH Office of Human Subjects Research Protections (OHSRP) and the functions of the established offices located within OHSRP. **Partial Revision 06/07/2021:** Sections E.1.b and E.2.b. are revised to describe the assessment of resources by the OHSRP Director. **Partial Revision 11/21/2022**: This revision specifies that the OHSRP office of Policy and Accreditation establish and maintain a Continuity of Operations Plan (COOP) and HRPP Mission Essential Function (MEF) in case of an emergency that impacts the NIH IRP HRPP and the rights, safety or welfare of its research subjects. **Partial Revision 12/06/2024:** This revision specifies responsibilities of the NIH Intramural Research Program (IRP) Institutional Officials (IOs) consistent with the updated Delegation of Authority, General No. 44.
2. **Filing Instructions:**

- **Insert:** NIH Manual Chapter 3014-101, dated 07/09/2019, Partial Revision Date: 06/07/2021; Partial Revision Date: 11/21/2022; **Partial Revision Date: 12/06/2024**
- **Implementation Date:** 09/21/2020

3. **PLEASE NOTE:** For information on:

- The current policies can also be found at: https://irbo.nih.gov/confluence/display/ohsrp/Policy.
- Content of this chapter, contact the issuing office listed above.
- NIH Policy Manual, contact the Division of Management Support, OMA, on (301) 496-4606, or enter this URL: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx

A. Purpose

Describe the organizational structure and responsibilities of the NIH Intramural Research Program (IRP) Institutional Officials (IOs) and the Office of Human Subjects Protections

(OHSRP) within the NIH IRP's Human Research Protection Program (HRPP).

B. Scope

1. This policy applies to the:

    a. NIH Institutional Officials;
    b. Staff of the OHSRP, including the internal activities of IRB Operations, Compliance and Training, Policy and Accreditation; and
    c. IRB Executive Chair.

2. This policy applies to the Clinical Center (CC) Office of Research Support and Compliance (ORSC) within the NIH IRP HRPP.

C. Policy

1. The NIH IRP has Institutional Officials (IO) delegated by the NIH Director with sufficient standing to establish and maintain the NIH IRP HRPP, needed to promote the rights safety and welfare of human subjects.

    a. The NIH Director has delegated DDIR and Director, OHSRP as co-Institutional Officials responsible for the NIH IRP HRPP.

2. 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

OHSRP has developed a comprehensive glossary of definitions that describe the terms listed below. The glossary can be found at the following link: NIH IRP HRPP Policy Glossary

Note: There may be more than one definition per term, so please review terms carefully to make sure they match the terms listed below. Qualified terms are indicated with a parenthetical qualification. When reviewing a definition, be sure that you are reviewing the appropriate definition that links to this policy. To further assist the reader, each term in the glossary cites the relevant policy number(s) indicating where the term is utilized.

1. Institutional Official (IO)
2. NIH Human Research Protection Program (HRPP)
3. NIH Intramural Research Program (IRP)
4. NIH Institutional Review Board (IRB)
5. NIH Institutional Review Board (IRB) Executive Chair
6. Office of Compliance and Training
7. Office of Human Subjects Research Protections (OHSRP)
8. Office of IRB Operations (IRBO)
9. Office of Policy and Accreditation
10. Office of Research Support and Compliance (ORSC)
11. Quality Assurance/Quality Improvement Review (QA/QI Review) of the NIH IRB

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.
        VI. Receives and responds to concerns from investigators that could not be resolved by the usual processes within the HRPP.

    b. As co-Institutional Officials, the Director of OHSRP and the DDIR will work closely together to evaluate the resources necessary to maintain the proper functioning of the HRPP annually, (e.g., the IRB, personnel, and space), and ensure that resources are adequate to maintain the proper functioning of the NIH HRPP and the functional offices of OHSRP.

2. **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 periodic QA/QI reviews of the NIH IRB:

I. The office of Compliance and Training will submit the QAQI plan to the Director of OHSRP and IRBO Director for review and approval, and to ensure sufficient resources are available to conduct the review, consistent with *Policy 3014-108 OHSRP Quality Assurance and Quality Improvement Program*.
II. 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.
III. 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.
IV. The Director of the OHSRP and the IO, as representatives for the Institution, are responsible for reviewing QA/QI summary reports. (See *Policy 3014-108 Quality Assurance and Quality Improvement Program for NIH IRBs*.)
V. Scope and responsibilities for QA/QI activities performed by other entities within the HRPP are discussed in *Policy 3014-108 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.
d. Assessment, triage, and management of reportable events submitted to OHSRP and serve as the primary liaison between the oCT and NIH investigators regarding reportable events.
e. Providing administrative support to the Research Compliance Review Committee (RCRC) and serve as the primary liaison between the RCRC and NIH investigators.
f. Reporting unanticipated problems, serious and/or continuing noncompliance and IRB suspension or termination of research to federal agencies as required. The IO will be copied on these letters to the federal agencies. (See *Policy 3014-801 Reporting Research Events* and *Policy 3014-802 Non-Compliance in Human*

Subjects Research, respectively.)

g. 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 3014-103 Education Program*). The NIH CC ORSC may also assist with targeted training as needed.

3. **The OHSRP office of Policy 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.
c. Establishing and maintaining the HRPP Continuity of Operations Plan (COOP) and the HRPP Mission Essential Functions (MEF) consistent with the established COOPs and MEFs of the NIH Office of Intramural Research (IRP) and HHS. OHSRP office of Policy and Accreditation will:

I. Work with the NIH Division of Emergency Management (DEM) to ensure: 1) that the HRPP COOP and MEF are consistent with law, regulation and policy and 2) describe the continuity of operations of the NIH IRB and the mission essential functions of the OHSRP to protect the rights, safety and welfare of human subjects participating in NIH IRP research during and following an emergency. (For more information see Manual Chapters (MC) 3014-100, 1428, 1429 and 1430, the NIH IRP HRPP COOP, and the Human Research Protections MEF.)
II. In coordination with NIH DEM, review the HRPP MEF and HRPP COOP on a periodic basis consistent with the HHS review cycle and revise according to need.
III. Coordinate with the OD Emergency Coordinator or designee, to participate in annual testing, training and exercise in compliance with HHS policy and work with OHSRP leadership to ensure OHSRP staff maintain skills necessary to maintain and restore OHSRP and IRB operations in response to an emergency affecting the NIH IRP HRPP and its subjects.
IV. Educate and inform NIH IRB staff, members, relying institutions and investigators for whom the NIH IRB is the reviewing IRB, about IRB expectations during and after an emergency.

4. **The NIH IRB:**

a. 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 3014-200 IRB Scope and Authority*.)
b. Unless otherwise determined by written agreement, the NIH IRB is responsible for the review and approval of all non-exempt human subjects research conducted by NIH investigators.

5. **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 3014-203 Support of 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 3014-100 NIH Intramural Research Program's Human Research Protection Program* and Policy 3014-106 Ancillary Reviews).
c. Maintaining documentation of IRB minutes and making these available upon request to the Director of OHSRP and the IO (e.g., via the electronic IRB system). (See *Policy 3014-206 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.
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.

6. **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 3014-500 Research Involving Drugs, Biologics, 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 3014-501 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.
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 3014-802 Non-compliance in Human Subjects Research*.)
l. Providing consultation to the office of Compliance and Training, as needed, in the evaluation of reportable events.
m. Otherwise providing support to the OHSRP Director and IRBO Director to facilitate the operation of the NIH IRB.

7. **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 E.2.b.III. above).

8. For additional information regarding the responsibilities or requirements, and procedures of OHSRP offices see the following policies: *Policy 3014-103 Education Program; Policy 3014-105 IRB Reliance and Collaborative Research; Policy 3014-108 Quality Assurance and Quality Improvement Program for the NIH IRB; Policy 3014-200 IRB Scope and Authority; Policy 3014-201 IRB Membership and Composition; Policy 3014-202 Board Member Conflict of Interest; Policy 3014-203 Support of the IRB Operations; Policy 3014-204 Levels of IRB Review and Criteria for IRB Approval of Research; Policy 3014-205 Requirements for IRB Submissions; Policy 3014-206 Maintenance of Records; Policy 3014-801 Reporting Research Events; and Policy 3014-802 Non-Compliance in Human Subjects Research*.

F. References

1. Federal Regulation and Resources

HHS: 45 CFR 46

FDA: 21 CFR parts 50, 312and 812

2. NIH Policies

Policy 3014-100 NIH Intramural Research Program's Human Research Protection Program

Policy 3014-103 Education Program

Policy 3014-105 IRB Reliance and Collaborative Research

Policy 3014-106 Ancillary Reviews

Policy 3014-108 Quality Assurance and Quality Improvement Program for NIH IRBs

Policy 3014-200 IRB Scope and Authority

Policy 3014-201 IRB Membership and Composition

Policy 3014-202 Board Member Conflict of Interest

Policy 3014-203 Support of IRB Operations

Policy 3014-204 Levels of IRB Review and Criteria for IRB Approval of Research

Policy 3014-205 Types of IRB Submissions

Policy 3014-206 Maintenance of Records

Policy 3014-500 Research Involving Drugs, Biologics, and Nutritional Products

Policy 3014-501 Research Involving FDA Regulated Devices

Policy 3014-801 Reporting Research Events

Policy 3014-802 Non-compliance in Human Subjects Research

Policy 1428 - NIH Emergency Management Program

Policy 1429 - NIH Institute and Center Emergency Management Programs

Policy 1430 - NIH Occupant Emergency Management Program

3. Guidance: N/A

APPENDIX I: Organizational Structure of the NIH OHSRP