NIH Policy Manual

3014-203 - Support of IRB Operations

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

Release Date: 12/10/2019 ? **Technical Revision Date:** 4/16/2021 ?

Transmittal Notice

1. **Explanation of Material Transmitted:** NIH Human Research Protection Program (HRPP) policies have been revised to comport with the revised DHHS Common Rule (45 CFR 46) and to reflect the newly consolidated IRB structure within the NIH Intramural Research Program (IRP). This policy describes the requirements for support of the NIH Institutional Review Board (IRB) based on federal regulation and policy, including NIH policy. Upon implementation, this policy partially supersedes SOP 2 IRB Membership and Structure, and fully supersedes SOP 3 Management and Administrative Operations of the IRB.
2. **Filing Instructions:**
    - **Insert:** NIH Manual Chapter 3014-203, dated 12/10/2019
    - **Implementation Date**: 10/12/2020
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 Compliance Management, DCM, on 301-496-4606 or enter this URL: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx

A. Purpose

1. Describe the National Institutes of Health (NIH) Office of Human Subjects Research Protections (OHSRP) support of the NIH Institutional Review Board (IRB).

B. Scope

1. This policy applies to OHSRP, which includes the OHSRP Office of IRB Operations (IRBO) and OHSRP staff.

C. Policy

1. OHSRP will promote the protection of the rights and welfare of research subjects through effective management and operations of the NIH IRB in compliance with federal regulations and policy, including NIH policy.

1. OHSRP will provide administrative support to the NIH IRB and serve as the liaison between the IRB and investigators.

1. OHSRP will ensure that the NIH IRB is constituted consistent with federal regulations and policy. (See Policy 3014-201 IRB Membership and Composition.)

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. NIH Investigator

E. Responsibilities and Requirements

1. **Requirements for support of IRB operations by OHSRP**

    a. All review of exempt and non-exempt human subjects research by OHSRP must be conducted in accordance with federal regulations and policies. (See Policy 3014-205 Requirements for IRB Submissions.) Accordingly, OHSRP will:

        I. Promote the protection of the rights, safety and welfare of subjects participating in research activities at the NIH by advising and providing guidance to NIH investigators and the NIH IRB based on federal regulations and policies.
        II. Provide administrative support to the NIH IRB and serve as the primary liaison between the IRB and NIH investigators (e.g., send reminders to investigators and notify investigators about IRB determinations.) (See, e.g., Policy 3014-204 Levels of IRB Review and Criteria for IRB Approval of Research.)
        III. Promote the efficiency of the NIH IRB and its effective review of research by conducting pre-review of submissions to the IRB to verify that submissions meet regulatory and policy requirements and are complete prior to assigning them to the IRB agenda. (See Policy 3014-205

Requirements of IRB Submissions and Policy 3014-106 Ancillary Reviews)

IV. Comply with HRPP training requirements as specified in Policy 3014-103 Education Program.
V. Manage IRB meetings (e.g. establish meeting schedules, set submission deadlines, provide meeting space and communications, and take minutes.).
VI. Support IRB members by, including but not limited to, creating and sending meeting agendas; scheduling IRB members and consultants as applicable; and tracking attendance and quorum at IRB meetings.
VII. Manage Informed Consent Documents for use by investigators.
VIII. Manage IRB records, including but not limited to IRB meeting minutes and agendas, IRB submissions, and agreements, consistent with the requirements in Policy 3014-206 Maintenance of Records.
IX. Maintain the IRB roster and composition, consistent with the requirements in Policy 3014-201 IRB Membership and Composition.
X. Provide information and reports, upon request and as appropriate, to:

    i. Other NIH offices (e.g. to the NIH Office of Protocol Services and NIH or IC leadership); and
    ii. Relying institutions, as consistent with the terms of the reliance agreement.

XI. Track IRB membership conflict of interests consistent with the requirements in Policy 3014-202 Board Member Financial Conflict of Interest.
XII. Support and participate in accreditation activities as directed.

F. References

NIH Policy

Policy 3014-103 Education Program

Policy 3014-106 Ancillary Reviews

Policy 3014-201 IRB Membership and Composition

Policy 3014-202 Board Member Financial Conflict of Interest

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