NIH Policy Manual

3014-200 - IRB Scope and Authority

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

Release Date: 12/09/2019 ? **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. This policy describes the scope and authority of the NIH intramural Institutional Review Boards. Upon implementation, this policy, partially supersedes the *Introduction to the NIH Human Research Protection Program (HRPP)* and fully supersedes SOPs *1 Human Subjects Research and the NIH IRB System* and *2 IRB Membership and Structure.*
2. **Filing Instructions:**

    - **Insert:** NIH Manual Chapter 3014-200, dated 12/09/2019
    - **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 Compliance Management, OMA, on (301) 496-4606, or enter this URL: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx

A. Purpose

1. Define the role and responsibilities of the NIH Intramural Research Program's (IRP's) Institutional Review Boards (IRBs), established under the Human Research Protection Program, to ensure oversight of human subjects research conducted at NIH.

B. Scope

1. This policy applies to all human subjects research conducted under NIH Federalwide Assurance (FWA) or for which an NIH IRB provides review and oversight.

C. Policy

1. NIH IRB's and the IRBO have sole authority to review and approve human subjects research activities conducted by NIH IRP, unless such authority is deferred to another IRB in writing by the Deputy Director for Intramural Research (DDIR) or OHSRP. The IRB Operations Office (IRBO) has the sole authority to determine whether an activity constitutes human subjects research (HSR), to determine whether human subjects research activities are exempt from IRB review, to perform limited IRB review, and to determine whether NIH, through its staff, is engaged in HSR. NIH investigators may not commence research activities until all required approvals have been obtained (e.g. institutional approvals, as applicable, and approvals from IRB, and ancillary committees).

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.

Definitions demarcated with (Pre-2018 Common Rule definition) apply to research approved by an IRB (or deemed to be exempt, or for which no IRB review was required under the regulations) prior to the effective date of the 2018 Common Rule (January 21, 2019).

Definitions demarcated with (2018 Common Rule definition) apply to all research approved by an IRB (or deemed to be exempt, or for which no IRB review was required under the regulations) on or after January 21, 2019, and to research transitioned to the 2018 requirements in accordance with HRPP policy.

1. Coercion
2. Human Subjects Research
3. Human Subject (HHS Regulations) (2018 Common Rule definition)
4. Human Subject (HHS Regulations (Pre-2018 Common Rule definition)
5. (Human) Subject (FDA Regulations)
6. Identifiable Biospecimen2018 Common Rule definition)
7. Identifiable Private Information2018 Common Rule definition)
8. Intervention (2018 Common Rule definition)
9. Intervention (pre-2018 Common Rule definition)
10. Interaction
11. Private Information
12. Research (HHS Regulations)

13. Research (FDA Regulations)(Clinical investigation)
14. Test Article
15. Institutional Review Board (IRB)
16. Undue influence

E. Responsibilities and Requirements

1. **Responsibilities of the NIH Institutional Review Board(s)**

    a. When NIH Institutional Review Board(s) (IRB(s)) are the reviewing IRB, NIH IRB(s) are responsible for the review and approval of all human subjects research to protect the rights and welfare of human subjects, including:

        I. Research conducted by NIH investigators in connection with his/her institutional responsibilities.
        II. Research for which NIH has accepted responsibility for review under the terms of a Reliance Agreement (see *Policy 3014-105 IRB Reliance and Collaborative Research*).

    b. When NIH IRB(s) are the reviewing IRB, they are responsible for oversight of the human subjects research, as outlined in *Policy 3015-105 IRB Reliance and Collaborative Research*.
    c. Only NIH IRB(s) or the IRBO has the authority to determine whether a project meets the criteria for human subjects research based on whether the activity represents "research" and involves "humans" as subjects, and whether a project causes NIH to become engaged in human subjects research.

        I. If an IRB or the IRBO determines that a project does not engage NIH in human subjects research, it shall notify the investigator.

    d. As authorized by NIH policy and the federal regulations for the protection of human subjects (HHS 45 CFR 46 and FDA 21 CFR 56), NIH IRBs have the authority and responsibility to:

        I. Review, approve, require modifications to secure approval, or disapprove any research activities required to have NIH IRB(s) oversight/review. Further, to take these actions based upon whether human subjects are adequately protected, including, based on the 2018 Common Rule, those exempt research activities for which limited IRB review is a condition of exemption.

            i. Certain NIH officials with supervisory authority (i.e. NIH Director, NIH DDIR, Institute and Center (IC) Directors, Scientific Directors (SD), and Clinical Directors (CDs)), may subsequently disapprove research that was approved by NIH IRB(s). However, these officials may not override NIH IRB(s)'s decision to disapprove a project (see HHS 45 CFR 46.112 and FDA 21 CFR 56.112).

II. Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements, NIH policy, or federal regulations.
III. Suspend or terminate approval of research that has been associated with serious events, serious problems, or unexpected serious harm. This includes the authority of the Chair to take immediate action to suspend a research project to protect research subjects from serious risk of harm.
IV. Observe, or have a third party observe, the consent process.
V. Observe, or have a third party observe, the conduct of the research.

e. IRB Chairs, members, or staff who experience, or believe they have experienced, coercion or undue influence on the actions of the IRB, or who have knowledge of an attempt at undue influence or coercion on the actions of the IRB, are responsible for reporting such allegations promptly to the IRBO Director or Director OHSRP who will convey these reports to the IO.

I. In instances where an investigator is the alleged source of undue influence or coercion, the IRBO Director and/or OHSRP Director will conduct an initial assessment of the allegation and report their findings to the Institutional Official (IO).
II. Depending on the level and/or topic of concern, the IO may conduct the investigation him/herself or may form an *ad hoc* panel to perform the investigation. If evidence substantiates that undue influence or coercion occurred or was attempted, the individual identified as the alleged source of undue influence or coercion will be provided with the evidence and may provide a response to the findings. The IO, in consultation with the Directors of IRBO and OHSRP, and others as appropriate, will determine the subsequent course of action. This may include, but is not limited to: no action, dismissal, letter of caution, administrative suspension or termination of studies, and requirement for remedial action.

f. The IRB will interface as necessary with other offices and ICs within NIH IRP that are involved in research (see *Policy 3014-100 NIH Intramural Research Program Human Research Protection Program* and *Policy 3014-101 Organizational Structure of the OHSRP*).
g. For additional procedures related to NIH IRBs, please see the policies listed in section F.2., References.

F. References

1. **Federal Regulations:**

HHS: 45 CFR 46
FDA: 21 CFR parts 56 and 812

1.NIH Policy:

Policy 3014-100 NIH Intramural Research Program Human Research Protection Program
Policy 3014-101 Organizational Structure of the OHSRP
Policy 3014-105 IRB Reliance and Collaborative Research

2.Guidance:

OHRP Guidance: Engagement of Institutions in Human Subjects Research