

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

OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

Policy Number: 200

SOP Title: IRB Scope & Authority

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

Revision Approval:



**Deputy Director for Intramural
Research**

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Implementation date: 09/21/2020

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POLICY

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

Definitions demarcated with (Pre-2018 Common Rule definition) apply to research approved (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* – an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain a certain outcome.
2. *Human Subjects Research* – any activity that either:
 - I. 4.2.1. Meets the Health and Human Services (HHS) definition of research and involves human subjects as defined in the HHS regulations (see below); OR

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- II. Meets the Food and Drug Administration (FDA) definition of research and involves human subjects as defined in FDA regulations (see below).
- 3. *Human Subject (HHS Regulations) (2018 Common Rule definition)* – A living individual about whom an investigator (whether professional or student) conducting research:
 - I. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; **OR**
 - II. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- 4. *Human Subject (HHS Regulations (Pre-2018 Common Rule definition))* – A living individual about whom an investigator (whether professional or student) conducting research:
 - (1) Data through intervention or interaction with the individual, or
 - (2) Identifiable private information.
- 5. *(Human) Subject (FDA Regulations)* – For research involving drugs, “subject” means a human who participates in an investigation, either as a recipient of the investigational new drug or as a control. A subject may be a healthy human or a patient with a disease.
 - a. For research involving medical devices, “subject” means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.
- 6. *Identifiable Biospecimen (2018 Common Rule definition)* – A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
- 7. *Identifiable Private Information (2018 Common Rule definition)* – Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- 8. *Intervention (2018 Common Rule definition)* – Includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
- 9. *Intervention (pre-2018 Common Rule definition)* – Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
- 10. *Interaction* – Includes communication or interpersonal contact between the investigator and subject.

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11. *Private Information* – Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g. a medical record).
12. *Research (HHS Regulations)* – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
13. *Research (FDA Regulations)(Clinical investigation)* – Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act or need not meet the requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. For research involving drugs, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.
14. *Test Article* – Any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug and Cosmetics Act, as amended, or under sections 351 or 354-360F of the Public Health Service Act.
15. *Institutional Review Board (IRB)* – The FDA defines IRB as “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 HRPP policy, IRB review includes additional types of human subjects research (e.g. socio-behavioral) and is not limited to biomedical research.
16. *Undue influence* – An offer of an excessive or inappropriate reward or other overture in order to obtain a certain outcome.

E. RESPONSIBILITIES

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.

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- II. Research for which NIH has accepted responsibility for review under the terms of a Reliance Agreement (see *Policy 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 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.

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- 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 100 NIH Intramural Research Program Human Research Protection Program* and *Policy 101 Organizational Structure of the HRPP*).
- 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](#)

2. NIH Policy:

[Policy 100 NIH Intramural Research Program Human Research Protection Program](#)

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[Policy 101 Organizational Structure of the HRPP](#)

[Policy 105 IRB Reliance and Collaborative Research](#)

3. Guidance:

[OHRP Guidance: Engagement of Institutions in Human Subjects Research](#)

G. APPENDICES: NA

H. REVISION HISTORY: NA

I. SUPERSEDES DATE: 09/21/2020

Introduction to the NIH Human Research Protection Program (HRPP)

SOP 1 – Human Subjects Research and the NIH IRB System

SOP 2 – IRB Membership and Structure