Policy 200 IRB Scope and Authority – Policy Overview

This document summarizes changes in *Policy 200 IRB Scope and Authority* (referred to as Policy 200 in this document) that NIH investigators should be aware of, from the SOPs mentioned below.

The policy describes 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.

NIH investigators responsible for reviewing Policy 200 and complying with the requirements of the policy.

Note: Text from the policy and other policy titles are italicized.

Policy 200 IRB Scope and Authority	SOPs Superseded by Policy 200
Policy 200 partially supersedes:	**Introduction to the NIH Human Research Protection Program (HRPP)** This SOP has been inactivated and is archived in the Policy Archive.
Policy 200 supersedes:	**SOP 1 Human Subjects Research and the NIH IRB System** When inactivated, this SOP will be archived in the Policy Archive.
Policy 200 supersedes:	**SOP 2 IRB Membership and Structure** When inactivated, this SOP will be archived in the Policy Archive.

Applicability of Policy 200 - This policy applies to all human subjects research:

- conducted under the NIH Federalwide Assurance (FWA) or
- for which an NIH IRB provides review and oversight.

POLICY Requirement	SOP Requirement
Section C.1. – *NIH IRBs 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.* Policy 200 describes the NIH HRPP as it currently functions.	**Intro to the HRPP, 4.C.3.**– Described the authorities of the separate NIH IRBs. At the time of publication, there were 12 NIH IRBs. Since that time, the IRBs have been consolidated and the OHSRP has been reorganized. For additional information, see Dr. Jonathan Green's presentation, OHSRP and the NIH Intramural IRB, which describes the reorganization. **Intro to the HRPP, section 4.C.1.f.** – deemed the IRB & OHSRP "*the sole authority in the IRP for determining which research activities are exempt or excluded from IRB review per the 45 CFR …*:" This same authority is recognized in Policy 200.
Section C.1. – *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*	This responsibility was previously delegated to OHSRP, but is now managed by IRBO.

IRB review, to perform limited IRB review, and to determine whether NIH, through its staff, is engaged in HSR.	
Section C.1. – *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).* Generally, the NIH IRB will not review research until all ancillary reviews are completed. Now all approvals must be complete before research may commence, including ancillary review approvals.	Previously, NIH investigators could commence research when IRB approval and institutional approval was complete, even if approval by an ancillary review committee was pending.
Section E.1.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 105 IRB Reliance and Collaborative Research).* There are no changes in obligations. Policy 200 reorganizes the SOPs for clarity.	**SOP 1, section 1.3** – "*NIH IRBs review and approve research involving human subjects conducted in the Intramural Research Program in accord with 45 CFR 46 and/or 21 CFR 50, 56, 312 and 812 to protect subjects' rights and safeguard their welfare…*" **Intro to the HRPP section 1.E**.— *NIH establishes and maintains IRBs. These IRBs are responsible for the prospective and continuing review and approval of research activities involving human subjects. Their primary mandate is to protect the rights and safeguard the welfare of human research subjects.* Policy 200 reorganizes the SOPs for clarity.
Section E.1.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.* Policy 200 describes the NIH HRPP as it currently functions. Policy 105 discusses reliance arrangements in depth.	**Intro to the HRPP, SOP 1, and SOP 2** predated the NIH Single IRB Policy and the cooperative research provisions of the 2018 Common Rule, and did not specifically address NIH IRBs as the reviewing IRB in collaborative research. SOPs 20 and 20A addressed reliance.
Section E.1.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.*	**SOP 1, section 1.6**. – "*…At NIH, OHSRP has sole authority to make determinations to exempt, or otherwise exclude, research from IRB review under 45 CFR 46.101(b)(1)-(6) and 45 CFR 46.102."* **Intro to the HRPP section 4.C.1.F**.— *"Is the sole authority in the IRP for determining which research activities are exempt or excluded from IRB review…"*

I. If an IRB or the IRBO determines that a project does not engage NIH in human subjects research, it shall notify the investigator. Policy 200 describes the NIH HRPP as it currently functions, including IRB Operations and management of the IRP IRBs.	Policy 200 adds specificity for clarity.
Section E.1.d. – *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 <u>disapprove</u> research that was approved by NIH IRB(s). However, these officials <u>may not override NIH IRB(s)'s decision to disapprove</u> a project (see HHS 45 CFR 46.112 and FDA 21 CFR 56.112).* (emphasis added) *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.* The authorities of the IRB have not changed. However, Policy 200 adds specificity for clarity, including that NIH IRB disapprovals	**SOP 1, section 1.10.A.** — *Each NIH IRB has the regulatory authority to: 1. Approve, modify or disapprove research (45 CFR 46.109(a))* *2. Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. (45 CFR 46.113) 3. Observe, or have a third party observe, the consent process (45 CFR 46.109(e)).* **SOP 1, section 1.12.A.5**. — Stated the Scientific Directors of the Institute hold administrative responsibility, including: "*Ensuring the independence of the IRB, and upholding its decisions*." SOP 7, section 7.21 - *Because the Institutional Official (the DDIR) is responsible for policies and procedures followed by the NIH HRPP, including its IRBs, he may review IRB decisions to ensure that the IRB's decision-making processes are appropriate (for example, it follows NIH HRPP SOPs, etc.). If he has concerns about these IRB processes and procedures, he may request IRB reconsideration of the issue/decision. However, if an IRB disapproves research, the DDIR cannot permit the research to move forward/implement the research* (*sic*) Policy 200 adds specificity for clarity.

cannot be overridden by NIH officials and describes additional action that may be taken by the institution under supervisory authority.	
Section E.1.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.* Policy 200 reorganizes the SOP and adds specificity for clarity, including when an investigation may be warranted, and who is responsible for determining any resulting course of action. Reference to staff concerns has been added, as well as potential remedies .	***SOP 1, section 1.14, B through E*** – *B. The SDs' and CDs' administrative responsibilities for providing resources for IRBs and nominating potential IRB members do not include authority to unduly influence IRB decisions. IC Directors, SDs and CDs must respect IRB decisions.* *C. An IRB member who is concerned about undue influence or inappropriate communications from any source should first report the occurrence to the Chair of that IRB, who will attempt to mediate or resolve the concern, in consultation with the applicable CD, OHSRP, or other NIH officials, as necessary or appropriate.* *D. An IRB Chair who is concerned about undue influence or inappropriate communications from any source should first report the occurrence to OHSRP, which will attempt to mediate or resolve the concern, in consultation with the DDIR or other NIH officials, as necessary or appropriate.* *E. Any individual who believes that inappropriate communications or undue influence have not been appropriately resolved in a timely manner, should report the matter to OHSRP or the DDIR.* Policy 200 removes the expectation that the IRB Chair first attempt to mediate or resolve concerns, and provides additional specificity for clarity.