

HRPP POLICY APPROVAL & IMPLEMENTATION
OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

Policy Number: 203

SOP Title: Support of IRB Operations

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

Revision Approval:

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**Deputy Director for Intramural
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Implementation date: 10/12/2020

NIH Intramural Research Program		
Office of Human Subjects Research Protections	Effective Date: 10/12/2020	
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POLICY

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.
2. OHSRP will provide administrative support to the NIH IRB and serve as the liaison between the IRB and investigators.
3. OHSRP will ensure that the NIH IRB is constituted consistent with federal regulations and policy. (See Policy 201 IRB Membership and Composition.)

D. DEFINITIONS

1. *NIH Investigator* – An NIH federal employee (intramural or extramural) who is conducting human subjects research on behalf of the NIH. Additionally, this designation includes an investigator who is not an NIH federal employee but who is conducting human subjects research while working at an NIH site with an NIH employee. These researchers may include Guest Researchers, Special Volunteers, contractors (subject to the terms of the contract), Intramural Research and Cancer Research Training Awardees and colleagues from academia and industry who are not Special Government Employees (SGEs) or Intergovernmental Personnel Act appointees.

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 205 Requirements for IRB Submissions*.) Accordingly, OHSRP will:

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- 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 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 205 Requirements of IRB Submissions* and *Policy 106 Ancillary Reviews*)
- IV. Comply with HRPP training requirements as specified in *Policy 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 206 Maintenance of Records.*
- IX. Maintain the IRB roster and composition, consistent with the requirements in *Policy 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 202 Board Member Financial Conflict of Interest.*

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XII. Support and participate in accreditation activities as directed.

F. REFERENCES

1. **Federal Regulations:** NA

2. **NIH Policy**

Policy 103 Education Program

Policy 106 Ancillary Reviews

Policy 201 IRB Membership and Composition

Policy 202 Board Member Financial Conflict of Interest

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

Policy 205 Requirements for IRB Submissions

Policy 206 Maintenance of Records

3. **Guidance:** NA

G. REVISION HISTORY: NA

H. SUPERSEDES DATE: 10/12/2020

SOP 2 – IRB Membership and Structure

SOP 3 – Management and Administrative Operations of the IRB