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: Deputy Director for Intramural Research

Implementation date: 10/12/2020
A. PURPOSE


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:
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.
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