

## **THE INTRAMURAL NIH HUMAN RESEARCH PROTECTION PROGRAM (HRPP)**

The NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability (for more information see <http://www.nih.gov/about/mission.htm>). The NIH's Intramural Research Program (IRP) has a Human Research Protection Program (HRPP) to protect the rights and safeguard the welfare of human subjects who participate in its research studies. The HRPP is made up of NIH Institutes and Centers, NIH officials, NIH Institutional Review Boards, and researchers and staff who conduct and support research involving human subjects.

The intramural NIH HRPP is governed, in part, by a variety of standard operating procedures (SOPs), which can be accessed via the links below. These SOPs generally apply to NIH intramural staff and NIH intramural program activities. They generally do not apply to human subjects research carried out by NIH grantees. For more information on requirements for NIH grantees, see the [NIH Office of Extramural Research \(OER\)](#).

The SOPs are primarily based on the [Belmont Report](#) and U.S. Federal Regulations that protect human subjects ([45 CFR 46](#) and applicable FDA regulations under [21 CFR](#) parts 50, 56, 312 and 812). For questions regarding the intramural NIH policies or procedures, contact the Office of Human Subjects Research Protections (OHSRP) at 301-402-3444.

### **Instructions**

To access an NIH HRPP SOP, click a title below.

#### **A. Administration of the NIH HRPP**

1. [Introduction to the NIH Human Research Protection Program](#)
2. [SOP 1 - Human Subjects Research and the NIH IRB System](#)
3. [SOP 2 - IRB Membership and Structure](#)
4. [SOP 3 - Management and Administrative Operations of the IRB](#)
5. [SOP 4 - Human Research Protection Program \(HRPP\) Documentation and Records](#)
6. [SOP 26 - Evaluation of NIH IRB Chairs, Vice Chairs and Members, IRB Administrative Staff and IRB Committee Activities](#)

## **B. Responsibilities and Training in the HRPP**

1. [SOP 19 - Investigator Responsibilities](#)
2. [SOP 25 - Training Requirements for the NIH Human Research Protection Program \(HRPP\)](#)

## **C. Types of Research Activities and Requirements for Review**

1. [SOP 5 - NIH Research Activities with Human Data/Specimens](#)
2. [SOP 6 - Determinations, Including Exemptions, Made by the Office of Human Subjects Research Protections \(OHSRP\) Under 45 CFR 46](#)
3. [SOP 20 - NIH HRPP Requirements for Collaborative Research](#)
4. [SOP 20A - Obtaining a Reliance \(Authorization\) Agreement at the NIH](#)
5. [SOP 20B - NIH IRB Responsibilities When Reviewing Local Context Considerations for Offsite Research](#)
6. [SOP 20C - Responsibilities When the NIH Intramural Research Program Serves as a Coordinating Center for a Multi-site Trial](#)
7. [SOP 20D - NIH FWA Coverage for Non-NIH Employees Working on NIH Protocols](#)
8. [SOP 27 - Transfer of Protocols Between Institutional Review Boards \(IRBS\)](#)
9. [SOP 28 - NIH Public Health Emergency Research Review Board \(PHERRB\)](#)

## **D. NIH Institutional Review Board Activities**

1. [SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards \(IRBs\)](#)
2. [SOP 7A - Requirements for Expedited Review of Research by NIH Institutional Review Boards](#)
3. [SOP 8 - Procedures and Required Documentation for Submission and Initial Review of Protocols](#)
4. [SOP 9 - Continuing Review by the Convened IRB](#)

5. [SOP 10 - Amendments to IRB-approved Research](#)
6. [SOP 11 - Suspensions and Terminations of IRB Approval and Administrative Holds](#)
7. [SOP 11A - Closure of an IRB-approved Protocol](#)

#### **E. Additional Human Subject Protections Requirements**

1. [SOP 12 - Requirements for Informed Consent](#)
2. [SOP 13 - Recruitment, Selection and Compensation of Research Subjects](#)
3. [SOP 14A - Research Involving Vulnerable Subjects \(General Considerations\)](#)
4. [SOP 14B - Research Involving Pregnant Women, Human Fetuses and Neonates](#)
5. [SOP 14C - Research Involving Prisoners](#)
6. [SOP 14D - Research Involving Children](#)
7. [SOP 14E - Research Involving Adults Who Are or May Be Unable to Consent](#)
8. [SOP 14F - Research Involving NIH Staff as Subjects](#)
9. [SOP 18 - Privacy and Confidentiality](#)

#### **F. Research Regulated by the FDA**

1. [SOP 15 - Research Regulated by the Food and Drug Administration \(FDA\): General Procedures for Both IND and IDE Applications](#)
2. [SOP 15A - Research Regulated by the Food and Drug Administration \(FDA\): Information and Policies Specific to Research Involving Investigational New Drugs \(Including Biological Products\)](#)

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3. [SOP 15B - Research Regulated by the Food and Drug Administration \(FDA\): Information and Policies for Investigational Device Exemption \(IDE\) Applications](#)

**G. Reporting, Evaluation and Prevention of Adverse Events, Protocol Deviations, Non-compliance and Research-related Complaints**

1. [SOP 16 - Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations](#)
2. [SOP 16A - Allegations of Non-compliance with Requirements of the NIH Human Research Protection Program \(HRPP\)](#)
3. [SOP 17 - Data and Safety Monitoring](#)
4. [SOP 21 - Conflict of Interest Requirements for Researchers and Research Staff](#)
5. [SOP 22 - Research Subject Information and Services and Research-related Complaints from Research Subjects](#)
6. [SOP 23 - Quality Management System for the NIH HRPP](#)
7. [SOP 24 - OHSRP Reporting to the Office for Human Research Protections \(OHRP\) and Food and Drug Administration \(FDA\) Regarding Unanticipated Problems, Serious or Continuing Non-compliance or Terminations or Suspensions](#)