HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL & IMPLEMENTATION

OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

Policy Number: 201

SOP Title: Education Program

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

Revision Approval: Deputy Director for Intramural Research

Implementation date: 6/1/2019
POLICY

1. PURPOSE

1.1. This policy describes the training requirements and educational opportunities for individuals involved in the NIH Intramural Research Program (IRP) Human Research Protection Program (HRPP).

2. SCOPE

2.1. This policy applies to individuals responsible for protecting the rights and welfare of human subjects under the HRPP. This includes all investigators conducting human subjects research, OHSRP (leadership and staff), ORSC staff (as determined below) and all IRB members (to include IRB Chairs, Vice Chairs, and primary and alternate members). Since NIH policy requires that all research team members conducting human subjects research (HSR) under a protocol are listed as study investigators, the term "investigators" used within this policy includes these research team members.

3. POLICY

3.1. NIH investigators who are conducting human subjects research (HSR), non-NIH investigators conducting HSR overseen by the NIH IRB(s), OHSRP leadership and staff, ORSC staff as determined below, and IRB members are required to have HSR training as specified in this policy. Those investigators conducting non-exempt HSR are also required to complete Good Clinical Practice (GCP) training and, as applicable, additional training commensurate with their roles and responsibilities.

3.2. IRBs may require additional training for investigators at the IRB’s discretion, such as when investigators do not demonstrate understanding of specific areas, when investigators undertake a new type of research, or as part of a corrective action plan. HRPP or IC leadership may also require investigators to complete additional training.

4. DEFINITIONS

4.1. *Biomedical Research* - Basic, clinical, and translational medical research conducted to investigate the causes, treatments, and cures for both common and rare diseases.

4.2. *Collaborative Institutional Training Initiative (CITI)* - CITI is a subscription service that provides research ethics education to the members of the research community.
4.3. **Federal Employee** - An individual who is engaged in the performance of a Federal function under authority of law or an Executive act and subject to the supervision of an individual named by paragraph (1) in 5 U.S.C. 2105 while engaged in the performance of the duties of his position. This includes Special Government Employees or Intergovernmental Personnel Act appointees for the purpose of this policy.

4.4. **(The) Ethical and Regulatory Aspects of Clinical Research** - A seven (7) week course offered by the Clinical Center (CC) Bioethics Department each fall that provides a comprehensive overview of the ethical issues in human subjects research in the United States. For more information, see References.

4.5. **Good Clinical Practice (GCP)** - A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

4.6. **Human Subject (2018 Common Rule definition)** - In the context of investigators conducting HSR:

4.6.1. Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

4.6.1.1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

4.6.1.2. *Intervention* 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.

4.6.1.3. *Interaction* includes communication or interpersonal contact between investigator and subject.

4.6.1.4. *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).

4.6.1.5. **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

4.6.1.6. **An identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

4.7. **Human Subject (Pre-2018 Common Rule definition)** - means a living individual about whom an investigator (whether professional or student) conducting research obtains:
1) Data through intervention or interaction with the individual, or
2) Identifiable private information.

4.8. **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 Interpersonal Act appointee.

4.9. **Non-NIH Investigators** - Includes individuals who are not NIH employees who are conducting HSR at a non-NIH site on a protocol under review by an NIH IRB (see Policy 504, IRB Reliance and Collaborative Research).

4.10. **Social Behavioral Research** - Research involving the study of the interactions of biological factors with behavioral or social variables and how they affect each other. This includes, but is not limited to, individual or group characteristics or behavior (e.g., research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior). Methodologies may include basic and applied research; research employing survey, interview, focus group, human factors evaluation.

5. **RESPONSIBILITIES AND REQUIREMENTS**

5.1. **The Office of Human Subjects Research Protections (OHSRP), office of Compliance and Training:**
is responsible for assisting researchers in protecting the rights, welfare and safety of human subjects by providing programs and educational resources in research ethics and human subject safety, with an emphasis on proper conduct of research. To accomplish this, the OHSRP office of Compliance and Training:

5.1.1. In conjunction with the Directors of OHSRP and the IRB Office (IRBO), and the Office of Research Support and Compliance (ORSC), sets requirements for and ensures access to initial human subjects training and refresher training and provides additional training opportunities.

5.1.2. Implements additional training opportunities designed to supplement the initial human subjects training requirements (e.g., training seminars and classes intended for study team members conducting human subjects research).

5.2. All NIH Investigators conducting HSR, NIH IRB members and the OHSRP are responsible for:

5.2.1. Completing the required initial human subjects training and refresher training, as well as maintaining documentation of such certification, as specified in this policy.

5.2.2. Complying with any additional training requirements set forth within the NIH IRP (e.g., IC training requirements),

5.3. NIH investigators conducting human subjects research:
All NIH investigators conducting human subjects research, whether the related research is subject to IRB review or exempt from IRB review, must complete required training prior to conducting such research.

5.3.1. The PI must designate all investigators who are conducting HSR on the protocol as a sub-type of investigator on the protocol, e.g., “Associate Investigators” (AIs). See Policy 901 Investigator Responsibilities.

5.3.2. NIH Investigators must complete the following training:

5.3.2.1. Initial human subjects protections course: The Collaborative Institutional Training Initiative (CITI), the entity that NIH has contracted with for online human subjects training, has updated its content related to the revised Common Rule, and all investigators must complete the revised basic training course (CITI Biomedical Basic
5.4. **NIH investigators conducting non-exempt human subjects research:**
All investigators conducting non-exempt human subjects research must complete CITI Good Clinical Practice (US FDA Focus) and the requirements of 5.3.2 above.

5.5. **All OHSRP leadership and staff, ORSC staff (as determined below) and all IRB members: must complete the following required training.**

5.5.1. CITI Biomedical Basic course. The Collaborative Institutional Training Initiative (CITI), the entity that NIH has contracted with for online human subjects training, has updated its content related to the revised Common Rule, and all OHSRP and IRB members must complete the revised CITI Biomedical Basic training course.

5.5.2. ORSC staff members who provide clinical research support need to take the revised CITI Biomedical Basic course. For ORSC staff members who work in the Aseptic Processing Facilities (cGMP facilities), this training will be optional. Certain members of ORSC, as determined by ORSC leadership, must also complete the CITI GCP Course (US FDA focus).

5.6. **Incoming NIH IRB Members must complete the following requirements prior to becoming an active member:**

5.6.1. Training as required in section 5.5.1 above.

5.6.2. Attend an OHSRP IRB member in-person training.

5.6.3. Attend and observe one IRB meeting in person.

5.7. **Optional or Just-In-Time Training:** IRBs, Clinical Directors, or PIs may require NIH investigators to complete additional Just-In-Time training, and the OHSRP Director, the IRBO Director, or IRB Chairs may require IRB members or OHSRP staff to take additional training courses. If protocol-specific training is required of investigators by the IRB, the IRB should document the specific requirement. Investigators, OHSRP and other members of the larger HRPP, and IRB members may also take these courses even if not required.

5.8. **Refresher Training for Investigators, OHSRP, ORSC staff (as defined in this policy) and IRB members:**
5.8.1. NIH investigators, OHSRP, ORSC (as defined in this policy) and IRB members will be required to take refresher training for CITI Biomedical Basic or CITI Social-Behavioral-Educational Basic, as applicable, and CITI GCP Course (US FDA focus), as applicable, at the time that their current training expires.

5.8.2. The OHSRP Director or the IRBO Director may stipulate that additional refresher training is completed.

5.9. **Training Requirements for Non-NIH Investigators conducting non-exempt HSR on protocols overseen by an NIH IRB**

5.9.1. These investigators must comply with training as required by their home institution. Unless otherwise specified in an agreement, such as a reliance agreement, the non-NIH investigators must provide certification that they have fulfilled the HSR training requirements of their home institution to the NIH PI, and the PI will upload the training certificates into the electronic IRB document section so that they are available for IRB review.

5.9.2. If the non-NIH Investigator is not affiliated with an institution that requires or provides access to human subjects protections training (e.g., such as a physician in private practice), the investigator must take and provide evidence of human subjects protections training to the NIH PI.

5.9.2.1. The NIH IRB has the authority, on a case by case basis, to direct that a GCP course also be completed by individuals whose home institution does not offer GCP training.

5.9.3. If deemed appropriate by the NIH IRB, the NIH IRB may allow external investigators to complete a modified or alternative basic human subjects protection training program.

5.10. **Activities That May Not Commence Until Training Requirements Are Met**

5.10.1. NIH investigators may not conduct research activities for an IRB-approved study or an IRB-exempt study until these investigators have satisfied the applicable NIH OHSRP training requirements. Non-NIH investigators must not conduct research on a protocol approved by the NIH IRB until they have satisfied the requirements in Section 5.9 above.

5.10.2. IRB members may not serve or continue to serve on an NIH IRB, unless they have satisfied the NIH OHSRP training requirements.
5.10.3. OHSRP staff may not support or continue to support the activities of the NIH OHSRP, unless they have satisfied the NIH OHSRP training requirements.

6. REFERENCES

6.1. Federal Regulations: N/A

6.2. NIH Policies
- Policy 102 NIH IRP Human Research Protection Program
- Policy 302 NIH IRB Membership and Composition
- Policy 504 IRB Reliance and Collaborative Research
- Policy 901 Investigator Responsibilities

6.3. Guidance
- Case Study Involving Human Subject Research for Basic Science Research Training: see link at https://ohsr.od.nih.gov/nih/basic.php
- NIH IRP Sourcebook: https://oir.nih.gov/sourcebook
- The Ethical and Regulatory Aspects of Clinical Research: https://www.bioethics.nih.gov/courses/ethical-regulatory-aspects.shtml
Collaborative Institutional Training Initiative (CITI): [www.citiprogram.org](http://www.citiprogram.org)

7. **APPENDICES:** N/A

8. **REVISION HISTORY:** N/A

9. **SUPERSEDES DATE: 6/1/2019**

   SOP 25 – Training Requirements for the NIH Human Research Protection Program (HRPP) versions:

   - v.4 dated 02-29-2016
   - v.3 dated 02-26-2014
   - v.2 dated 10-1-2013
   - v.1 dated 06-23-2013