NIH Policy Manual

3014-103 - Education Program

Issuing Office: OD/OIR/OHSRP **Phone:** (301) 402-3713

Release Date: 5/07/2019 ? **Partial Revision Date:** 11/07/2022 ?

Transmittal Notice

1. **Explanation of Material Transmitted:** NIH Human Research Protection Program (HRPP) policies have been revised to comport with the revised DHHS Common Rule (45 CFR 46) and to reflect the newly consolidated IRB structure within the NIH Intramural Research Program (IRP). This policy describes the human subjects protection educational requirements for NIH investigators, NIH IRB members, and the Office of Human Subjects Research Protections (OHSRP). Upon implementation, this policy fully supersedes the *SOP 25 – Training Requirements for the NIH Human Research Protection Program (HRPP)*. **Partial Revision 11/07/2022:** Addition of new training requirements for Associate Investigator post-doctoral Intramural Research Training Awardees (IRTAs)/Cancer Research Training Awardees (CRTAs) and post-doctoral Visiting Fellows (VFs) who obtain informed consent of subjects.

2. **Filing Instructions:**

- **Insert:** NIH Manual Chapter 3014-103, dated 05/07/2019, **Partial Revision Date:** 11/07/2022
- **Implementation Date:** 06/01/2019

3. **PLEASE NOTE:** For information on:

- The current policies can also be found at: https://irbo.nih.gov/confluence/display/ohsrp/Policy.
- Content of this chapter, contact the issuing office listed above.
- NIH Policy Manual, contact the Division of Compliance Management, OMA, on (301) 496-4606, or enter this URL: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx

A. Purpose

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).

B. Scope

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.

C. Policy

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.
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.

D. Definitions

OHSRP has developed a comprehensive glossary of definitions that describe the terms listed below. The glossary can be found at the following link: NIH IRP HRPP Policy Glossary

Note: There *may be more than one definition per term*, so please review terms carefully to make sure they match the terms listed below. Qualified terms are indicated with a parenthetical qualification. When reviewing a definition, be sure that you are reviewing the appropriate definition that links to this policy. To further assist the reader, each term in the glossary cites the relevant policy number(s) indicating where the term is utilized.

The 2018 Common Rule changed the definition of some of the terms below. In those cases, we have provided the definitions for both the 2018 Common Rule and the Pre-2018 Common Rule. Definitions demarcated with (**Pre-2018 Common Rule definition**) apply to research approved by an IRB (or deemed to be exempt or for which no IRB review was required under the regulations) prior to the effective date of the 2018 Common Rule (on or after January 21, 2019).

Definitions demarcated with (**2018 Common Rule definition**) apply to all research approved by an IRB (or deemed to be exempt or for which no IRB review was required under the regulations) on or after January 21, 2019 and to research transitioned to the 2018 requirements in accordance with HRPP policy.

1. Biomedical Research
2. Collaborative Institutional Training Initiative (CITI)
3. Federal Employee
4. (The) Ethical and Regulatory Aspects of Clinical Research
5. Good Clinical Practice (GCP)
6. Human Subject (2018 Common Rule definition)
7. Human Subject (Pre-2018 Common Rule definition)
8. NIH Investigator
9. Non-NIH Investigators
10. Social Behavioral Research

E. Responsibilities and Requirements

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:

a. 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.
b. 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).

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

    a. Completing the required initial human subjects training and refresher training, as well as maintaining documentation of such certification, as specified in this policy.
    b. Complying with any additional training requirements set forth within the NIH IRP (e.g., IC training requirements),

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.

a. 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 3014-300 Investigator Responsibilities.

b. NIH Investigators must complete the following training:

I. 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 course and/or CITI Social-Behavioral-Educational Basic course based on the type of research that the investigator conducts.)

4. **NIH investigators conducting non-exempt human subjects research:**

   a. All investigators conducting non-exempt human subjects research must complete CITI Good Clinical Practice (US FDA Focus) and the requirements of E.3. b. above.
   b. Post-doctoral IRTAs/CRTAs and post-doctoral VFs who are Associate Investigators and obtain informed consent of a prospective subject without the presence of a qualified NIH federal employee investigator must also complete, in advance of obtaining any informed consent, *Elements of a Successful Informed Consent* course and the validated *Objective Structured Clinical Examination (OSCE) for the Informed Consent Process* offered by the NIMH Human Subjects Protection Unit (HSPU).

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

   a. 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.
   b. 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).

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

   a. Training as required in section E.5.a. above.
   b. Attend an OHSRP IRB member in-person training.
   c. Attend and observe one IRB meeting in person.

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.

8. **Refresher Training for Investigators, OHSRP, ORSC staff (as defined in this policy) and IRB members:**

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

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

    a. 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, or the NIH IRB as requested;
    b. 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.

        I. 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.

    c. 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.

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

    a. 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 E.9. above.

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

F. References

1. **Federal Regulation and Resources: N/A**
2. **NIH Policies**

Policy 3014-105 IRB Reliance
Policy 3014-201 NIH IRB Membership and Composition
Policy 3014-300 Investigator Responsibilities