NIH Policy Manual

3014-103 - Education Program

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

Approving Official(s): DDIR

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Transmittal Notice

1. **Explanation of Material Transmitted:** 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. **Partial Revision 07/21/2024:** Revisions including grammatical corrections, formatting to bring this very old policy into our more current structure, and removing inline external links so that external links reside only in References which should make the policy links easier to manage.
2. **Filing Instructions:**
    - **Insert:** NIH Manual Chapter 3014-103, dated 05/07/2019, **Partial Revision Date:** 07/21/2024
    - **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 human subjects research (HSR) training requirements of the NIH Intramural Research Program's (IRP) Human Research Protection Program (HRPP).

B. Scope

1. This policy applies to the following individuals:

    a. All NIH investigators conducting human subjects research (HSR). Since NIH policy requires that all study team members conducting HSR under a protocol be listed as study investigators, the term "investigators" used within this policy includes these study team members.
    b. Office of Human Subjects Research Protections (OHSRP) leadership and staff.
    c. Clinical Center (CC) Office of Research Support and Compliance (ORSC) staff as described in E.6. below.
    d. All NIH IRB members including IRB Chairs, Vice Chairs, primary and alternate members.
    e. Non-NIH investigators when the NIH IRB is the reviewing IRB, as described in E.10. below.

C. Policy

1. Human subjects research (HSR) training is required, as specified in this policy, for the following staff:

    a. NIH investigators who are conducting HSR, regardless of reviewing IRB.
    b. OHSRP leadership and staff.
    c. ORSC staff as described in E.6. below.
    d. IRB members.

2. Non-NIH investigators when the NIH IRB is the reviewing IRB, must meet applicable requirements described in E.10. below.
3. NIH investigators conducting non-exempt HSR are required to complete Good Clinical Practice (GCP) training and, as applicable, additional training commensurate with their roles and responsibilities.
4. The NIH IRB 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.
5. NIH HRPP or Institute/Center (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**:

    a. OHSRP office of Compliance and Training is responsible for assisting investigators in protecting the rights, welfare and safety of human subjects by providing programs and educational resources in research ethics and human subject protections, with an emphasis on proper conduct of research. To accomplish this, the OHSRP office of Compliance and Training will:

I. In conjunction with the Directors of OHSRP, the IRB Office (IRBO) and the ORSC, set requirements for, and ensure access to, initial human subjects training and refresher training.
II. Provide additional training opportunities designed to supplement the human subjects training requirements (e.g., training seminars and classes intended for investigators conducting human subjects research).
III. Maintain the course selection in Collaborative Institutional Training Initiative (CITI), the entity that NIH has contracted with for online human subjects training, and assist with questions related to access to CITI for NIH staff and IRB members.

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

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

3. **NIH investigators conducting human subjects research:**

    a. The Principal Investigator (PI) must designate all investigators who are conducting HSR on the protocol as a sub-investigator on the protocol, (e.g., Associate Investigators (AIs)) consistent with *Policy 3014-300 Investigator Responsibilities*.
    b. 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.
    c. All NIH Investigators must complete the initial human subjects protections 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 NIH investigators conducting non-exempt human subjects research must complete CITI Good Clinical Practice (US FDA Focus) and the requirements of E.3. above.
    b. Post-doctoral IRTAs/CRTAs and post-doctoral VFs who are Associate Investigators and will 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, and all IRB members must complete the following required training:**

    a. CITI Biomedical Basic course.

6. **ORSC staff (as described below) must complete the following required training:**

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

7. **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 training.
    c. Attend and observe one IRB meeting.

8. **Optional or Just-In-Time Training:**

    a. The NIH IRB, Clinical Directors, or PIs may require NIH investigators to complete additional Just-In-Time training.
    b. When NIH IRB requires investigators to complete protocol-specific training, it must document the specific training requirement.
    c. The OHSRP Director, the IRBO Director, or IRB Chairs may require IRB members or OHSRP staff to take additional training courses.
    d. NIH investigators, OHSRP staff and other members of the larger HRPP, and IRB members may also take these courses even if not required.

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

    a. Upon expiration of current training, NIH investigators, staff of OHSRP, staff of ORSC (as described in E.6. above) and IRB members, will be required to take applicable refresher training(s):

        I. CITI Biomedical Basic
        II. CITI Social-Behavioral-Educational Basic
        III. CITI GCP Course (US FDA focus).

    b. The OHSRP Director or the IRBO Director may require completion of additional refresher training.

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

a. Non-NIH investigators must comply with training as required by their home institution.
b. Unless otherwise specified in an agreement, (e.g., reliance agreement), the Lead Site Investigator/PI must confirm that the site study team has fulfilled the HSR training requirements of their home institution in the Participating Site Addendum that is submitted in the electronic IRB system to the NIH IRB.

    I. In addition, written notification from the home institution HRPP office confirming that the site study team has fulfilled institutional requirements, (e.g., HSR training) consistent with Policy 3014-105 IRB Reliance and Collaborative Research.

c. Non-NIH investigators must provide certification that they have fulfilled the HSR training requirements of their home institution to the NIH PI as requested.
d. 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.

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

11. **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 the applicable training requirements of this policy have been satisfied.
b. Non-NIH investigators may not conduct research on a protocol approved by the NIH IRB until they have satisfied the requirements specified in section E.10. above.
c. IRB members may not serve or continue to serve on an NIH IRB, unless they have satisfied the training requirements, including section E.7. above.
d. OHSRP staff may not support or continue to support the activities of the NIH OHSRP, unless they have satisfied training requirements of this policy.
e. ORSC staff may not support or continue to support the activities of CC ORSC, unless they have satisfied the applicable requirements specified in section E.6. above.

F. References

1. **Federal Regulation and Resources: NA**
2. **NIH Policies**
    - Policy 3014-105 IRB Reliance and Collaborative Research
    - Policy 3014-201 IRB Membership and Composition
    - Policy 3014-300 Investigator Responsibilities
3. **NIH Resources**
    - NIH IRP HRPP Policy Glossary
    - NIMH Human Subjects Protection Unit (HSPU)