Lesson 5

INSTITUTIONAL OVERSIGHT OF HUMAN RESEARCH

OASH Office for Human Research Protections

INSTITUTIONAL OVERSIGHT OF HUMAN RESEARCH

Overview

Purpose of this Lesson

This lesson will introduce you to the regulatory requirements for research conducted or supported by the Department of Health and Human Services (HHS). **This lesson focuses on the Revised Common Rule (or 2018 Requirements) that became effective in 2018.**

Lesson Overview

This lesson contains three parts:

- **Part 1:** Institutional Assurance of Regulatory Compliance
- **Part 2:** Institutional Policies and Procedures and IRB Written Procedures
- **Part 3:** Beyond Regulatory Compliance

Learning Objectives

After completing this lesson, you will be able to:

1. Identify the requirements for institutions that are engaged in non-exempt human subjects research.
2. Define the concept of institutional engagement in research.
3. Describe the institutional requirements for internal and external IRB review and approval of research.
4. Understand the requirement for IRBs to establish and follow written procedures to conduct their functions and operations.

Part 1: Institutional Assurance of Regulatory Compliance

Institutional Assurance of Regulatory Compliance

The **Department of Health and Human Services (HHS)** is a major sponsor of health-related research, including research sponsored by the National Institutes of Health (NIH). In order to receive HHS funding, institutions that are **engaged in non-exempt human subjects research** must first:

1. Hold an active Federalwide Assurance, or FWA, with the HHS Office for Human Research Protections (OHRP), ***and***
2. Certify to the federal funding agency, when appropriate, that the research has been reviewed and approved by an Institutional Review Board (IRB) registered with OHRP.

These institutions file an FWA to affirm their commitment to HHS that they will adhere to the regulatory requirements at 45 CFR part 46, **including all its subparts**.

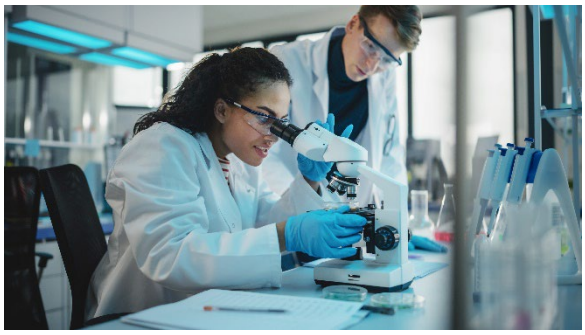
Other Common Rule departments and agencies may require their own assurance or may also rely on the FWA filed with OHRP for the non-exempt human subjects research they fund. For a list of Common Rule departments and agencies, click here. This lesson will focus on the regulatory requirements for HHS-conducted or HHS-supported research.

Institutions can review videos on how to file FWAs at www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/resources-on-how-to-file-an-fwa-and-related-resources/index.html and file their FWAs at www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/index.html.

For a detailed explanation of what constitutes non-exempt human subjects research under the Common Rule, review Lesson 2: What Is Human Subjects Research.

Institutional Engagement in Research

When institutions conduct HHS-funded non-exempt human subjects research, the requirements of the regulations at 45 CFR part 46 apply. An institution that is the primary awardee of federal funds for conducting non-exempt human subjects research is generally considered to be "engaged."



Also, with some exceptions, an institution is considered to be "engaged" when, for the purpose of HHS-funded or HHS-conducted research, its employees or agents undertake any activities that OHRP considers to constitute human subjects research that comes under the Common Rule, including when they:

1. Obtain information or biospecimens through intervention or interaction with individuals and use, study, or analyze the information or biospecimens for the purpose of the research;
2. Obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens for the purpose of the research; ***or***
3. Obtain the informed consent of research subjects.

Institutions that meet any one of these criteria generally are considered engaged, regardless of whether they are the primary awardee, a sub-awardee, or a collaborating institution in a cooperative research project.

Of course, not all institutions collaborating on a non-exempt cooperative human research project will be conducting human subjects activities. Those that are not, are referred to as "not engaged." These institutions do not need to be covered by an active FWA and do not need to have their portion of the research activities reviewed by any IRB.

Click here to watch a webinar discussing the intricate relationships between FWAs, IRBs, and institutional engagement.

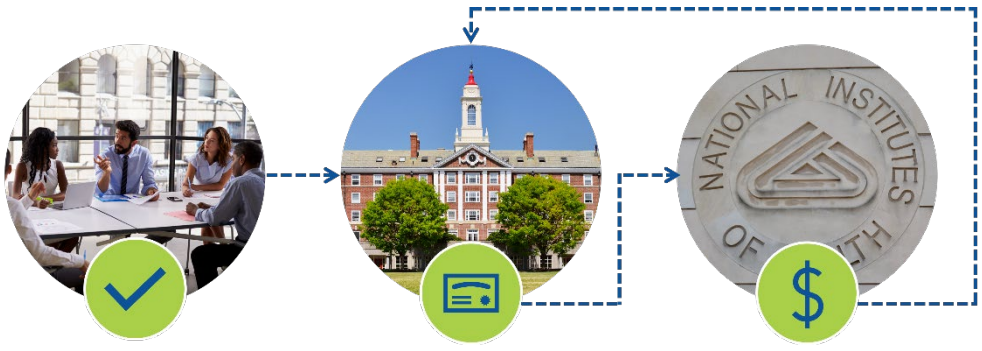
Institutional Engagement Resources

For a detailed discussion of the concept of institutional engagement in research, check out OHRP's mini-tutorial *Institutional Engagement in Human Subjects Research* at https://www.hhs.gov/ohrp/education-and-outreach/online-education/mini-tutorials/index.html.

Read the OHRP guidance documents *Engagement of Institutions in Human Subjects Research (2008), Determining When Institutions are Engaged in Research (January 13, 2009), Correspondence on When Institutions are Engaged (2009),* and *Correspondence on "Non-Engaged" Scenarios (2011)* at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html.

Institutional Certification of IRB Review and Approval of Research

Institutional certification of IRB review and approval of non-exempt human subjects research is usually made to the federal funding agency, such as the NIH, before funds can be released and the research with human subjects can begin.



Many research institutions establish their own IRBs to review and approve the research studies they conduct. For these institutions, the Common Rule requires that IRBs have meeting space and sufficient staff to support IRB functions. However, institutions are not required to establish their own IRBs. Some institutions may not have the resources to support an internal IRB. Others may not have the volume of research to make having their own IRB worthwhile. Institutions may rely on an external IRB, such as the IRB of another institution, or an independent IRB, for review and approval of some or all of their non-exempt human subjects research.

Since January 20, 2020, the Common Rule has mandated the use of a single IRB for certain cooperative research projects. Consequently, even institutions that have their own IRBs may be required to rely on an external IRB in these situations.

External IRBs and Institutional Reliance

An institution relying on an external IRB and the organization operating the IRB must establish and document the reliance and responsibilities that each of them will undertake to ensure compliance with the regulatory requirements. The relying institution must ensure that the external IRB reviews research in compliance with the terms of assurance outlined in its FWA. It is also responsible for complying with the determinations made by the external IRB.

IRBs, regardless of whether they are internal or external to the institution conducting the research, must comply with the relevant regulatory requirements, including the requirements related to the IRB's composition, and the determinations that the IRB is required to make before the research can be approved.

The Common Rule is flexible regarding how institutions might choose to document the reliance agreement. The relying institution and the external IRB should establish clear and adequate channels of communications to ensure appropriate protections for human research subjects.

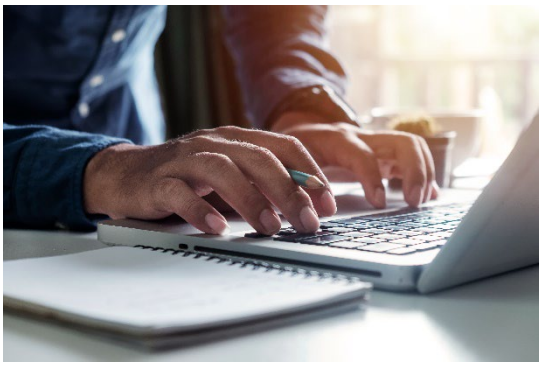
Part 2: Institutional Policies and Procedures and IRB Written Procedures

IRB Written Procedures

The Common Rule requires IRBs to establish and follow certain written procedures to conduct their functions and operations. These include, for example, written procedures for:

- Conducting initial and continuing review of research and reporting findings and actions to the investigator and the institution;
- Determining which projects require review more often than annually, and determining which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;
- Ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval;
- Ensuring that investigators promptly submit proposed changes to a research activity for IRB review and approval prior to implementing them, except those necessary to eliminate apparent immediate hazards to the human subjects;
- Ensuring prompt reporting to the IRB, appropriate institutional officials, any relevant federal department or agency head, and OHRP of any:
    - Unanticipated problems involving risks to subjects or others;
    - Serious or continuing noncompliance with the applicable HHS regulations or the requirements or determinations of the IRB;
    - Suspension or termination of IRB approval.

Developing Effective Written Procedures



Institutions and IRBs can develop written procedures that focus solely on the regulatory responsibilities of the IRB, or they can incorporate institutional policies for the institution's human research protection program (HRPP).

The scope and content of written procedures can vary depending on organizational structure, the types of research conducted at the institution, and institutional policies and administrative practices, as well as local and state laws and regulations.

The Common Rule allows for flexibility in both format and content to accommodate such variabilities. For example, detailed administrative procedures for the IRB support staff (e.g., how to track study approvals for scheduling continuing review) may be included, or may be managed through other locally written policies and procedures (e.g., work instructions, standard operating procedures (SOPs), electronic document systems, or a staff operations manual). Institutions and IRBs should use the flexibility afforded by the regulations to develop written procedures that are suitable for their organizations.

Developing effective written procedures involves a comprehensive and critical assessment of the IRB's responsibilities, functions, and operations, and the institution's organizational structure. Written procedures should be sufficiently detailed to help IRB members and administrative staff understand how to carry out their duties in a consistent and effective way that ensures the protection of subjects' rights and welfare and the IRB's compliance with the regulations. **OHRP recommends against developing written procedures that simply restate the regulations because this approach does not provide sufficient detail about the IRB's operations.**

Please review OHRP's *Institutional Review Board Written Procedures: Guidance for Institutions and IRBs (2018)*.

Part 3: Beyond Regulatory Compliance

Beyond Regulatory Compliance

The ethical conduct of human subjects research is a shared responsibility. **Institutions are ultimately in charge of the research they conduct, whether they use their own IRBs or rely on external IRBs.**

The Common Rule provides a necessary framework for protecting the rights and welfare of research participants. This framework is based on ethical principles that acknowledge the value of human research to society.

It is important to recognize that while compliance with the regulations means that the ethical standards established by the Common Rule have been met, it does not necessarily mean that all possible ethical concerns that could be raised about a research study have been addressed. Investigators, IRBs, research institutions, and sponsors should always keep an open mind as to how a research project might negatively impact participants, and what they can do to try to avoid this.