Lesson 3

WHAT ARE IRBs?

OASH Office for Human Research Protections

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Overview

Purpose of this Lesson

This lesson will explain the purpose and membership requirements of Institutional Review Boards, or IRBs. **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 Review Boards
- **Part 2:** Human Research Protection Programs
- **Part 3:** Single IRBs

Learning Objectives

After completing this lesson, you will be able to:

1. Identify the purpose of IRBs.
2. Describe the membership requirements of IRBs.
3. Identify the role of human research protection program (HRPP) offices.
4. Describe the importance of relying on single IRBs to approve research.

WHAT ARE IRBs?

Part 1: Institutional Review Boards

Purpose of IRBs

Institutional Review Boards, or IRBs, review research studies to ensure that they comply with applicable regulations, meet commonly accepted ethical standards, follow institutional policies, and adequately protect research participants.

Some people may also call IRBs Independent Review Boards or refer to them as Ethics Review Committees.

IRB reviews help to ensure that research participants are protected from research-related risks and treated ethically, a necessary prerequisite for maintaining the public's trust in the research enterprise and allowing science to advance for the common good.

IRB Membership

IRBs are made up of a diverse group of members.

The Common Rule requires at least five members with varying backgrounds on the IRB, so that research is reviewed from a collection of different perspectives.

At a minimum, members must include someone who provides the perspective of a scientist, someone who provides the perspective of a nonscientist, and someone who is not affiliated with the research institution.

WHAT ARE IRBs?

The IRB, as a group, must be sufficiently qualified through the experience, expertise, and diversity of its members to be able to review the research activities commonly conducted by the institution. Relevant considerations may include training and education, race, gender, cultural background, and sensitivity to community attitudes. Institutions may wish to put effort into having a roster of IRB members that is diverse, inclusive, and representative of the communities with whom they conduct research.

Video: Membership Requirements for Institutional Review Boards

Watch this video to learn about the specific membership requirements for IRBs.

Part 2: Human Research Protection Programs

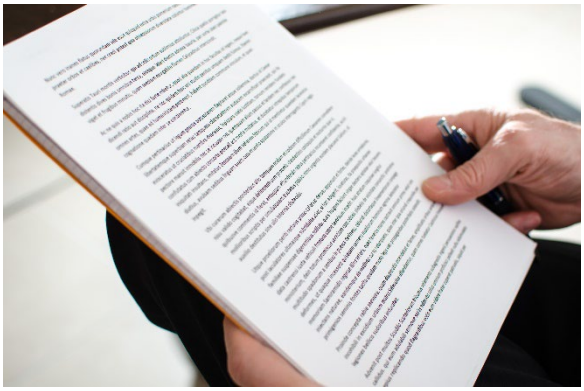
What are HRPPs?

Research institutions with sizeable human research portfolios often have a human research protection program (HRPP) office, part of whose job is to coordinate the administrative work needed to support their research studies, including IRB review.

WHAT ARE IRBs?

IRB administrators working in HRPPs support the work of the IRBs. They may also serve as IRB members if they meet the requirements for membership. In addition, administrators provide a valuable resource for researchers involved in human subjects research because of their familiarity with relevant regulations and knowledge of institutional policies. Experienced IRB administrators often provide researchers with meaningful advice on how to better protect research participants in their studies.

Institutional Policies



Many institutions conducting human subjects research adopt the Common Rule's provisions to protect research participants regardless of whether the research comes under the jurisdiction of the Common Rule. Institutions may do this by developing policies that are consistent with the Common Rule provisions. Some institutions may even choose to go beyond the Common Rule requirements by including institutional policies that provide more protections for research participants.

It is **important that researchers familiarize themselves with the Common Rule and their institution's policies** and seek assistance from their institutions' HRPP or IRB office.

Effective HRPPs or IRB offices establish efficient communication mechanisms with their investigators to promote a strong sense of collaboration toward the common goals of promoting ethical research and protecting research participants.

For additional information, please review the following resources:

- OHRP's Infographics on Protecting Research Volunteers
- Lesson 1: When HHS Regulations Apply

Part 3: Single IRBs

Single IRBs

In order to further facilitate nonexempt research and increase the efficiency of IRB review of cooperative research, or research involving more than one institution, there has been a move toward relying on single IRBs to review and approve research. Since January 20, 2020, certain cooperative research that comes under the Common Rule must rely on a single IRB for approval of the portion of the research conducted in the U.S.

U.S. researchers collaborating on a non-exempt human subjects research project should understand how the Common Rule single IRB requirement works. They should know which collaborating institutions need to rely on the single IRB, which IRB will be the single IRB of record, and how to ensure seamless communications amongst all the parties involved.

You can review the following resources to learn more:

- 2022 Draft Guidance on the Use of a Single IRB for Cooperative Research
- Review the related concept of *Institutional Engagement* in Lesson 5
- 2020 OHRP Exploratory Workshop on single IRB review