

## Lesson 3: **What Are IRBs?**



**OASH**

Office for  
Human Research  
Protections

## Lesson 3: What Are IRBs?

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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

You will answer quiz questions throughout each part to test your knowledge.

#### 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.

# 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.**

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### Quiz 1: Purpose of IRBs

Answer the following quiz questions to test your knowledge.

#### *Question 1 of 2*

What are some important reasons for having IRBs?

- A. The law requires it for all research
- B. They provide independent review of research to help ensure that research is ethical and research participants are protected
- C. They monitor research data collection
- D. All of the above

#### *Question 2 of 2*

What are some reasonable objectives for IRB review? (Select all that apply)

- A. Minimize risks to human subjects
- B. Ensure financial benefits to participants
- C. Support public trust in research
- D. Propose improvements to the Common Rule

#### Quiz 1 Answers

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### IRB Members

**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:**

1. Someone who provides the perspective of a scientist;
2. Someone who provides the perspective of a “non-scientist”; and
3. Someone who is not affiliated with the research institution.

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, sex, cultural background, and sensitivity to community attitudes. Institutions may wish to put effort into having a roster of IRB members that is diverse and representative of the communities with whom they conduct research or rely on a similarly constituted IRB.

**Watch the video "[Membership Requirements for Institutional Review Boards](#)" to learn about the specific membership requirements for IRBs (13:01).**

**For more information, you can also, watch the OHRP webinar "[The Who, What, Why, and Where of IRB Meetings and Membership](#)" (1:02:55) (Optional).**

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### Quiz 2: IRB Members

Answer the following quiz questions to test your knowledge.

#### *Question 1 of 3*

Under the Common Rule, what is the minimum number of members required for an IRB??

- A. 3
- B. 5
- C. 6
- D. 7
- E. It depends

#### *Question 2 of 3*

The Common Rule requires that an IRB must have which of the following types of members?  
(Select all that apply)

- A. IRB administrator
- B. Scientist
- C. Institutional official
- D. “Non-scientist”
- E. Representative of a minority group

#### *Question 3 of 3*

Only people with a graduate degree can serve as an IRB member. True or False?

- A. True
- B. False

#### Quiz 2 Answers

# 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 the HRPP's job is to coordinate the administrative work needed to support their research studies, including IRB review.

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.



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It is **important that researchers familiarize themselves with the Common Rule and their institution's policies** and seek assistance from their institution's 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 on [OHRP's website](#) or through your institution's learning platform

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### Quiz 3: Human Research Protection Programs

Answer the following quiz questions to test your knowledge.

#### *Question 1 of 2*

What are some of the characteristics of an effective HRPP or IRB office?

- A. Has experienced IRB administrative staff
- B. Has written institutional policies for research oversight
- C. Provides relevant education and advice on human research protections to investigators
- D. Communicates effectively with investigators
- E. All of the above

#### *Question 2 of 2*

When would an investigator want to reach out to their institution's HRPP office?

- A. When they have questions about applicable regulations, laws, and institutional policies
- B. When preparing a protocol for submission to the IRB for review
- C. When determining whether a research project is non-exempt human subjects research
- D. All of the above
- E. None of the above

#### Quiz 3 Answers

### PART 3: SINGLE IRBS

#### Single IRBs

To streamline the review of cooperative research, or non-exempt human subjects research involving more than one institution, there has been a move toward relying on a single IRB 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](#)
- Lesson 5: Institutional Oversight of Human Research, which covers the related concept of institutional engagement (access on [OHRP's website](#) or through your institution's learning platform)
- [2020 OHRP Exploratory Workshop on single IRB review](#)

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### Quiz 4: Single IRBs

Answer the following quiz question to test your knowledge.

#### *Question 1 of 1*

Reliance on a single IRB for a multi-institutional project is becoming less common in the field of research. True or false?

- A. True
- B. False

#### Quiz 4 Answer

### CONCLUSION

#### Congratulations!

You've completed this module of OHRP's Human Research Protection Foundational Training, Lesson 3: What Are IRBs?



### APPENDIX: QUIZ ANSWERS

#### Quiz 1 Answers: Purpose of IRBs

[Return to Quiz 1](#)

##### *Question 1 of 2*

**What are some important reasons for having IRBs?**

**Answer:** B. They provide independent review of research to help ensure that research is ethical and research participants are protected

##### *Question 2 of 2*

**What are some reasonable objectives for IRB review? (Select all that apply)**

**Answers:** A. Minimize risks to human subjects and C. Support public trust in research

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### Quiz 2 Answers: IRB Members

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#### *Question 1 of 3*

**Under the Common Rule, what is the minimum number of members required for an IRB??**

**Answer:** B. 5

#### *Question 2 of 3*

**The Common Rule requires that an IRB must have which of the following types of members? (Select all that apply)**

**Answers:** B. Scientist and D. “Non-scientist”

#### *Question 3 of 3*

**Only people with a graduate degree can serve as an IRB member. True or False?**

**Answer:** B. False

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### Quiz 3 Answers: Human Research Protection Programs

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#### *Question 1 of 2*

**What are some of the characteristics of an effective HRPP or IRB office?**

**Answer:** E. All of the above

#### *Question 2 of 2*

**When would an investigator want to reach out to their institution's HRPP office?**

**Answer:** D. All of the above



### Quiz 4 Answer: Single IRBs

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*Question 1 of 1*

**Reliance on a single IRB for a multi-institutional project is becoming less common in the field of research. True or false?**

**Answer:** B. False