The Who, What, Why, and Where of IRB Meetings and Membership

HHS Office for Human Research Protections (OHRP)
Division of Education and Development (DED)

OASH | Office for Human Research Protections

Disclaimer

The opinions expressed are those of the presenter and do not necessarily reflect the policy of the U.S. Department of Health and Human Services.

For a complete and accurate description of the regulatory requirements, please refer to the text of the revised Common Rule available on OHRP's website.

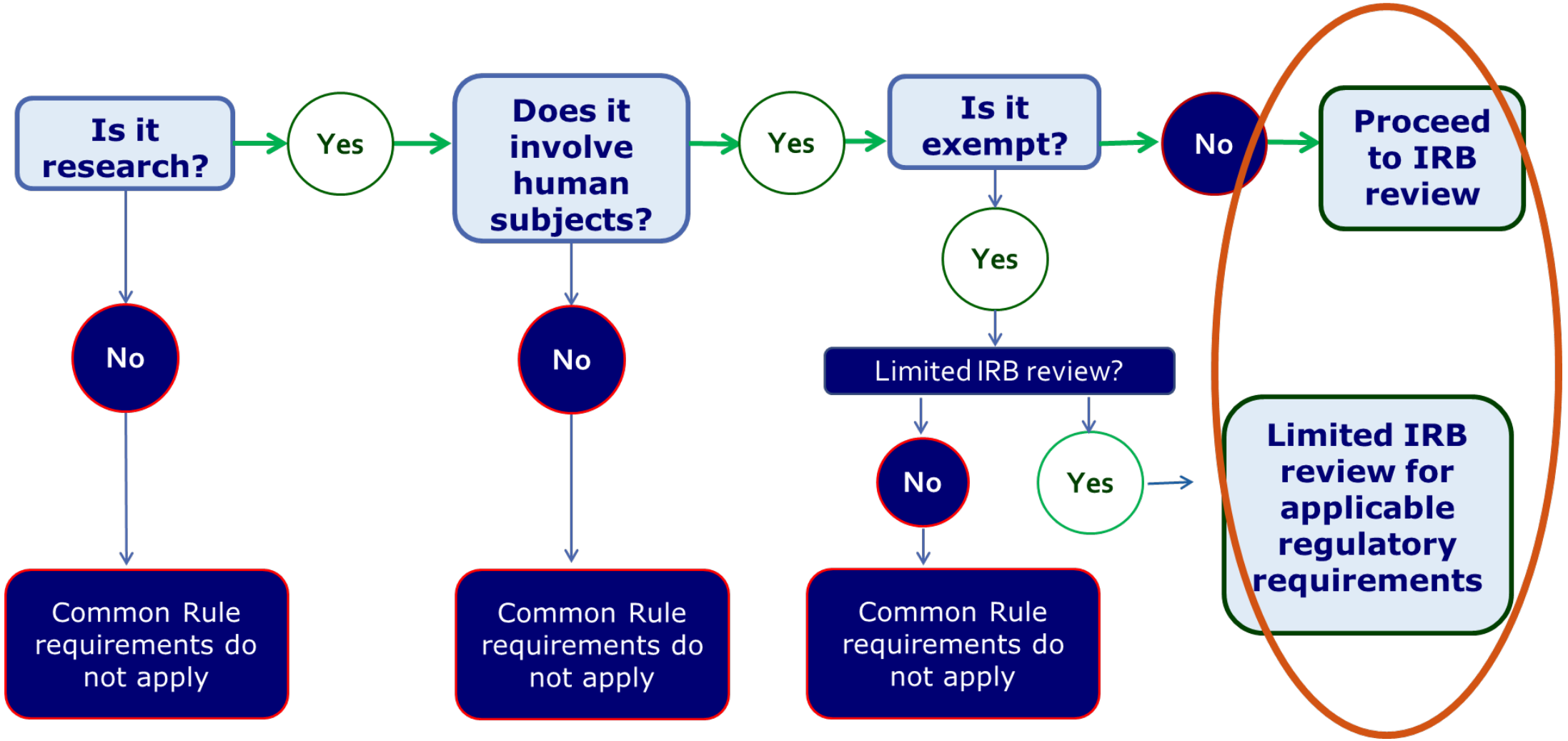
Learning Objectives

- Discuss Institutional Review Board (IRB) basic operations and functions.
- Explain the required membership composition of an IRB.
- Detail quorum and voting requirements.

What Is an IRB?

- An IRB is a committee that reviews and approves research in accordance with federal regulations and institutional policies.
- The Common Rule at 45 CFR 46, subpart A requires that an IRB reviews and approves certain human subjects research.
- While many institutions have their own IRB, it is not a requirement. Institutions may rely on other IRBs for review of some, or even all, of their researchers' studies.

Determining If IRB Review Is Required



What Does the IRB Review?

- Not all human research requires an IRB review: Studies that are “nonexempt” require review, and some “exempt” categories require what’s known as a limited IRB review (discussed next week).
  - Projects that qualify as “not research,” “not human subjects research,” and most “exempt” research do not require IRB review.
- IRB oversight is continuous, it extends beyond initial approval to cover all lifecycle actions to ensure that the researcher is adhering to the proposed (and approved) research plan.

What Does an IRB Need? Guiding Procedures and SOPs

- Written procedures for initial and continuing review
  - For the IRB to report its determinations and actions to the investigator and institution
- Policies for ensuring investigators follow the approved research proposal (including when changes have been proposed)
- Written procedures for prompt reporting to the IRB (and others) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance
  - As well as any suspension or termination of IRB approval

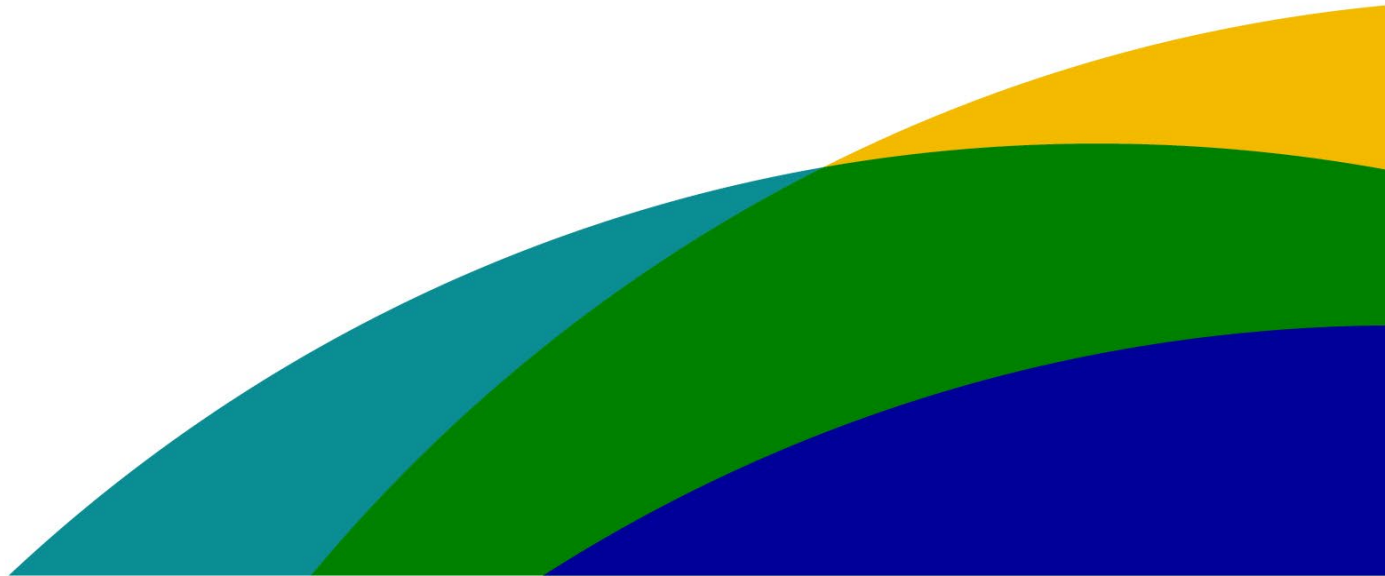
45 CFR 46.108

What Else Does An IRB Need?

- The regulations require that the IRB has a space to meet and sufficient staff to support the IRB's review of research and record keeping duties.
- An IRB needs members! A list of members (roster) must be maintained that contains:
  - Names, experience, and earned degrees.
  - Representative capacity (what kind of member).
  - Any employment or other relationship between each member and the institution.

45 CFR 46.108

IRB Membership



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Who Is on an IRB?

- The IRB must be sufficiently qualified through the experience, expertise, and diversity of its members to review the institution's research activities and to safeguard the rights and welfare of human subjects.
  - Relevant considerations include training and education, race, gender, cultural background, and sensitivity to community attitudes.
  - This is a **GREAT** opportunity to incorporate community viewpoints through the diversity of the board.
- IRBs that review research with vulnerable populations should have member(s) who are knowledgeable and experienced in working with these groups

Who's ready to review research??

45 CFR 46.107

Membership Requirement for Prisoner Research

- If an IRB reviews a study with prisoners, as defined in subpart C, at least one member of the IRB must be a prisoner or a prisoner representative.
  - Prisoner representatives should have a close working knowledge, understanding, and appreciation of prison conditions from the prisoner's perspective.
- Additionally, a majority of the members must not be affiliated with the prison involved (this is excluding any prisoners who serve as members).

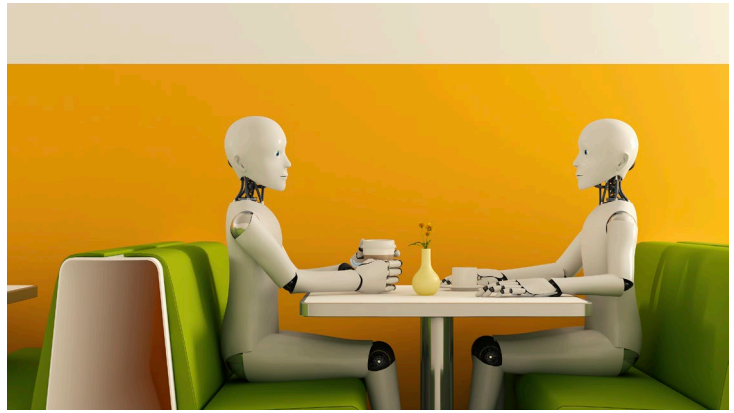
IRB Member Roles

- Minimum of 5 members
- At least one member whose primary concerns are in nonscientific areas (nonscientist) and one whose primary concerns are in scientific areas
- At least one member unaffiliated with the institution (unaffiliated/community member)
- An IRB Chairperson
- IRB may allow experts and others to assist in reviews – but these people are **NOT** members and may **NOT** vote

45 CFR 46.107

Who Can Be a Scientist and Who Can Be a Nonscientist?

- Ask if an individual's training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline?
  - If "yes" – scientist
  - If "no" – nonscientist
- Remember: An IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.



Case #1 - Is Dolph a Scientist? (1 of 3)

- Dolph Lundgren, made famous as an actor through his role as Ivan Drago in *Rocky IV*, has been asked to join an IRB at Local University.
- Education:
  - Royal Institute of Technology, BSc, Chemical Engineering, 1980
  - University of Sydney, MSc, Chemical Engineering, 1982
  - Fulbright Scholarship to MIT, 1983
- Experience:
  - Actor, Producer, Director in over 100 films

Case #1 (2 of 3)

The Local University IRB reviews mostly social-behavioral research relying on surveys and interviews. Could Dolph qualify as a scientist?

- ❑ Yes, probably
- ✓ No, probably

Case #1 (3 of 3)

Could Dolph be a nonscientist on the Local University IRB?

- ✓ Yes, possibly
- ❑ No, possibly

Case #2 - Is Sally a Scientist?

- Sally is a professor and researcher in the epidemiology department at State University. She has been asked to serve on the IRB, which primarily reviews longitudinal observation studies.
- Sally's Education:
  - State University, BA, Theater, 1990
  - The Juilliard School, MFA, 1996
  - State University, PhD, Statistics, 2004
- Experience
  - Associate Professor, 2008-Present
  - Recipient of NIH Grants totaling $2 million

Case #2 - Cont.

Could Sally qualify as a scientist for the State University IRB?

✓ Yes, probably

❑ No, probably

How to Know If a Member Is Unaffiliated

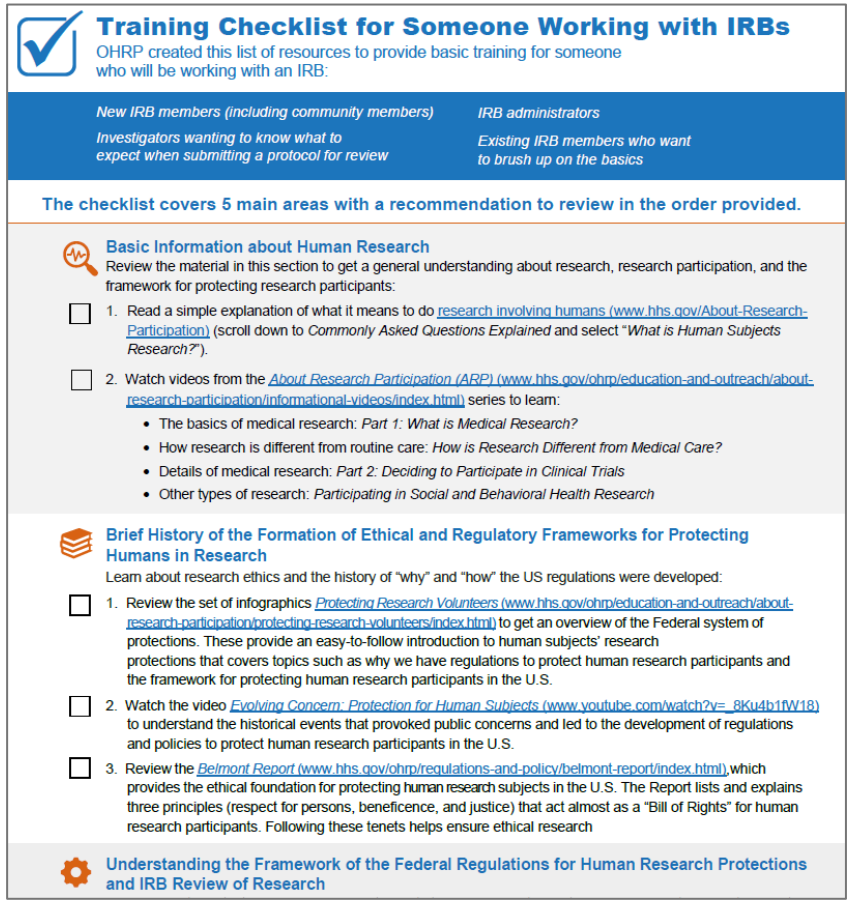
- Look at the relationship between the person and the institution.
- An employee or agent of the institution registering the IRB, or an immediate family member of that person, is considered affiliated:
  - Part-time employees
  - Students
  - Members of a governing board
  - Paid or unpaid consultants
- If the only association is being a member, that person is considered unaffiliated. Paying this member does not make them affiliated:
  - Patient
  - Participant
  - Former student

What Is an "Alternate" Member?

- An alternate member is someone who fills in for a primary IRB member who is not available to vote at an IRB meeting.
- OHRP has permitted alternates with the assumption that an alternate member is comparable to the "primary" member they are filling in for:
  - Background, expertise, knowledge.
  - Scientist, nonscientist, unaffiliated.
- Alternates can be used for either a full meeting or part of a meeting (the primary member is unable to attend the whole meeting or needs to excuse him/herself due to conflict of interest).
- The alternate may only vote when filling in for the primary member.
  - The reason an alternate substitutes a primary member should be noted in the meeting minutes.

Resource for IRB Members

- OHRP checklists provide comprehensive information on protection of human subjects and are suitable for someone brand new to the IRB or a veteran looking to brush-up on a topic.



Training Checklist for Someone Working with IRBs

OHRP created this list of resources to provide basic training for someone who will be working with an IRB:

New IRB members (including community members)
Investigators wanting to know what to expect when submitting a protocol for review
IRB administrators
Existing IRB members who want to brush up on the basics

The checklist covers 5 main areas with a recommendation to review in the order provided.

Basic Information about Human Research

Review the material in this section to get a general understanding about research, research participation, and the framework for protecting research participants:

1. Read a simple explanation of what it means to do research involving humans (www.hhs.gov/About-Research-Participation) (scroll down to *Commonly Asked Questions Explained* and select "*What is Human Subjects Research?*").
2. Watch videos from the *About Research Participation (ARP)* (www.hhs.gov/ohrp/education-and-outreach/about-research-participation/informational-videos/index.html) series to learn:
   - The basics of medical research: *Part 1: What is Medical Research?*
   - How research is different from routine care: *How is Research Different from Medical Care?*
   - Details of medical research: *Part 2: Deciding to Participate in Clinical Trials*
   - Other types of research: *Participating in Social and Behavioral Health Research*

Brief History of the Formation of Ethical and Regulatory Frameworks for Protecting Humans in Research

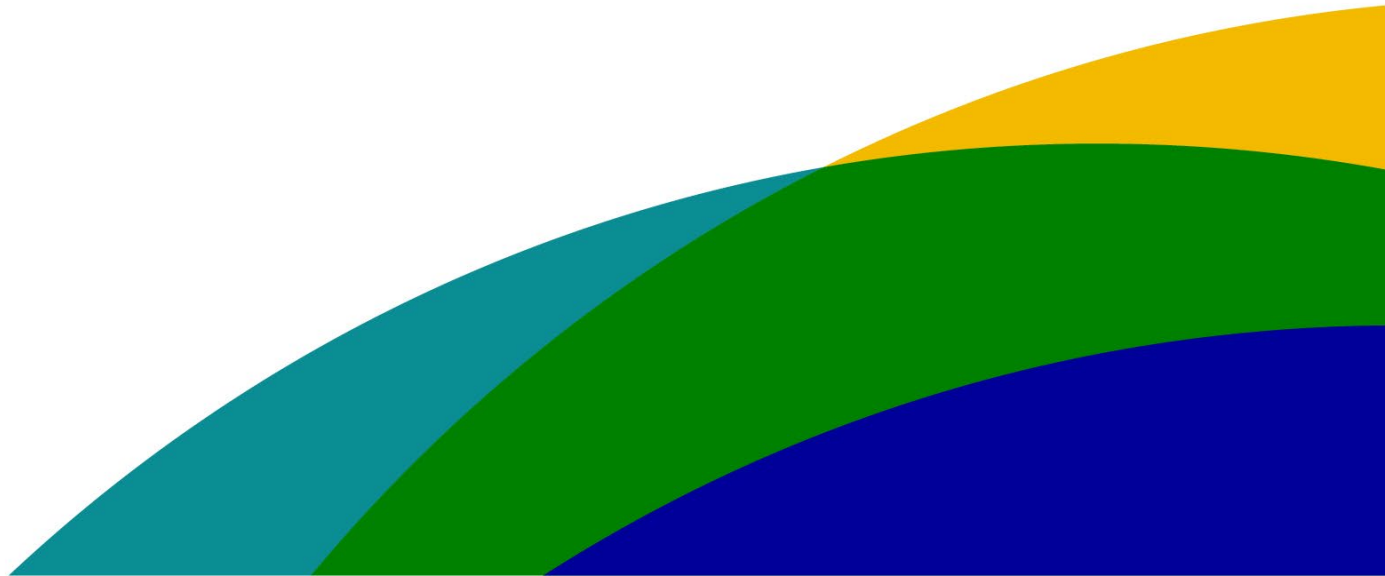
Learn about research ethics and the history of "why" and "how" the US regulations were developed:

1. Review the set of infographics *Protecting Research Volunteers* (www.hhs.gov/ohrp/education-and-outreach/about-research-participation/protecting-research-volunteers/index.html) to get an overview of the Federal system of protections. These provide an easy-to-follow introduction to human subjects' research protections that covers topics such as why we have regulations to protect human research participants and the framework for protecting human research participants in the U.S.
2. Watch the video *Evolving Concern: Protection for Human Subjects* (www.youtube.com/watch?v=_8Ku4b1fW18) to understand the historical events that provoked public concerns and led to the development of regulations and policies to protect human research participants in the U.S.
3. Review the *Belmont Report* (www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html), which provides the ethical foundation for protecting human research subjects in the U.S. The Report lists and explains three principles (respect for persons, beneficence, and justice) that act almost as a "Bill of Rights" for human research participants. Following these tenets helps ensure ethical research

Understanding the Framework of the Federal Regulations for Human Research Protections and IRB Review of Research

https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/index.html

Convened IRB Meeting



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What's the Convened Meeting About?

- IRBs review proposed research items at a convened meeting, which consists of a majority of the members, including the nonscientist.
  - The minutes must provide sufficient information to identify the research activities being reviewed and voted on by the IRB at that meeting (e.g., initial review, protocol title/number). The minutes should serve as a central repository for IRB actions on proposed research activities.
- The IRB may vote to:
  - Approve
  - Require modifications (in order to approve)
  - Disapprove
  - Table the research to discuss at another time

More Meeting Basics

- Meetings can take place in person or virtually.
  - Members can attend via teleconference or videoconference, provided they have received the materials ahead of time.
- The minutes need to reflect who is in attendance.
  - This can be done by having a current IRB roster attached to the minutes with proper notations. The minutes should reflect the manner in which members attended if not in person.

How Many Members Need to Be in Attendance?

- **Quorum** is the minimal number and type of IRB members that must be present at a convened meeting.
  - This is the majority of the designated primary members (or appropriate alternates) **AND** the nonscientist.
- To calculate the majority of an IRB with:
  - An even number of members, take the total of the primary members, divide by 2 and add 1 (# of members ÷ 2, then + 1)
    - Example: 10 members:
      - ✓ 10 ÷ 2 = 5.
      - ✓ 5+1= 6. For a majority to be present there must be at least 6 members.
  - An odd number of members, take the total, divide by 2 and round up to a whole number: 11 ÷ 2 = 5.5. Rounding up, 6 members are needed.

More on Quorum

- Quorum must be maintained throughout the meeting, if quorum is lost, then the IRB may not vote on proposed research.
- IRB members may leave during the meeting, either arriving late, departing early, or needing to step out. The minutes should provide sufficient information that quorum is maintained.
  - With today's virtual meetings, it is recommended that IRB members leave their cameras on, so their presence can easily be documented, ensuring quorum!

Case #3 - Is Quorum Met?

Tech University's IRB has a roster of 10 Primary members and 4 alternates. At the start of the meeting, 7 primary members, including Father Ignatius (the nonscientist) are present. The unaffiliated member, Ms. Bluth, is absent. The IRB plans to conduct 3 initial reviews. Is quorum met?

✓ Yes

❑ No

Voting

- To vote on an action, there must be **quorum**.
- The minutes must be detailed enough to show the voting on each action reviewed, including the number of members voting for, against, and abstaining
  - Example: 7 primary voting members present total: 5 for; 1 against; 1 abstain.
- When a member recuses themselves due to a conflict of interest, the minutes should state which action item, the reason for the recusal, and the vote count.
  - Recused member do **NOT** count towards quorum. This is different from abstention.
  - Example: 8 primary total [minus 1 for excused to COI]: 6 for, 1 against, 1 recused;
    - 7 members present for quorum purposes.
- In order to approve an action, the **majority** of the voting members present at the meeting must vote to approve.

Case #4 - How Many Votes Are Needed for Approval?

At the Tech IRB meeting (remember, there are 10 primary members) with 7 primary members (the nonscientist) and 4 alternates present, the last study to be reviewed is a study by Dr. Dulany—a primary member. Dr. Dulany presents his research and recuses himself before voting. He does not have a designated alternate. How many votes are needed for approval?

- ❑ 6
- ❑ 5
- ✓ 4
- ❑ 3
- ❑ The IRB has lost quorum and cannot vote

Resources

Questions?

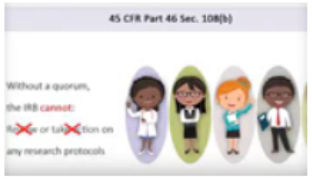
- Minutes of Institutional Review Board (IRB) Meetings Guidance for Institutions and IRBs
- Mini-tutorial on IRB Membership
- Mini-tutorial on Quorum & Voting

Email us at OHRP@hhs.gov

Membership Requirements for Institutional Review Boards (IRB) (13:01)

This webinar from the Office for Human Research Protections (OHRP) discusses the HHS regulations and policies related to IRB membership requirements. It explains the requirements and provides examples to help viewers think through applying the regulations. (April 28, 2017)

Quorum and Voting in IRB Meetings (22:16)



This webinar from the Office for Human Research Protections (OHRP) discusses the regulatory requirements for quorum and voting in convened IRB meetings. It explains the requirements and provides examples to help viewers think through applying the regulations. (October 18, 2019)

Watch: Quorum and Voting in IRB Meetings

Upcoming OHRP Educational Events

www.hhs.gov/ohrp/education-and-outreach/index.html

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2023 OHRP Exploratory Workshop

2023 OHRP Exploratory Workshop

Livestream on Thursday, September 14, 2023
9:45 AM – 4:20 PM EDT
No registration required

Psychedelics are powerful psychoactive substances that alter perception and mood and affect numerous cognitive processes. Their origins predate written history, and early cultures used them in many sociocultural and ritual contexts. The name 'psychedelics' was coined by Humphrey Osmond in 1957, suggesting that they have a mind-manifesting capability that may reveal useful or beneficial properties of the mind. For decades, psychedelics have been classified as illegal drugs. Recent research suggests that these substances may provide a potential breakthrough in the treatment of a myriad of mental health conditions. This exploratory workshop will examine the ethical and practical considerations for psychedelics research with the goal of promoting an open and grounded discourse on how to conduct research that is inclusive and protective of participants.

Access workshop website from OHRP homepage or directly at:

https://www.hhs.gov/ohrp/education-and-outreach/exploratory-workshop/index.html

Save the date! OHRP's next Research Community Forum (RCF) will be held in beautiful Ann Arbor, Michigan on Sept. 26-27

Making a difference in human subjects research: empowering participants, engaging communities, and protecting data

September 26 - 27, 2023
Ann Arbor, Michigan

https://research-compliance.umich.edu/human-subjects/ohrp-research-community-forum

Thank you!

Questions?

Email:

ohrp@hhs.gov