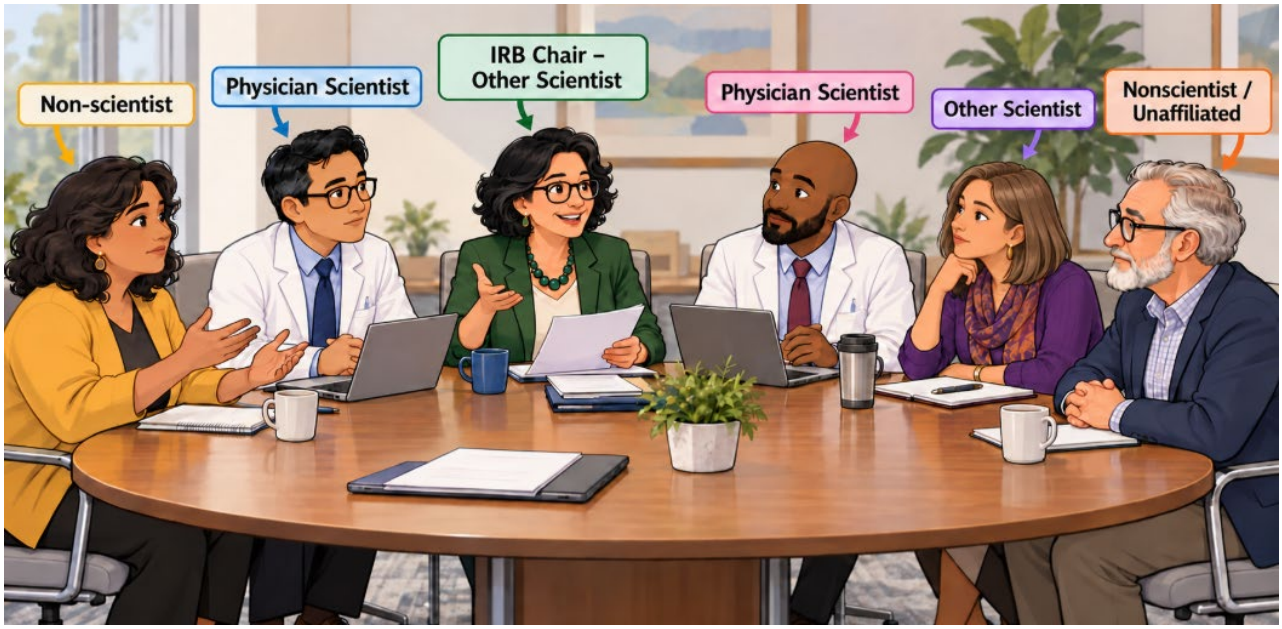
IRB Membership and Meeting Requirements

IRB Membership Requirements (45 CFR 46.107 (July 19, 2018))

- There must be **at least five primary members**. The NIH IRB has nine primary members and many alternates for the primary members.
- Be **sufficiently qualified** through experience, expertise and diversity of its members to review the institution's research activities. Members should have a mix of backgrounds — different training, genders, races, and cultural experiences.
- The IRB membership roster must include **scientists, non-scientists, and at least one unaffiliated member** (someone not connected to NIH except for serving on the IRB).
  - The NIH IRB further distinguishes between scientist members who are physician scientists vs. other scientists.
  - Immediate family members (spouses, parents and children) of an individual affiliated with NIH may not serve as an unaffiliated member.
- If the IRB reviews studies involving vulnerable groups (e.g., children), it must include members who have experience with those groups.



What's Needed to Hold a Meeting?

For an IRB meeting to be official (called a "quorum"), these rules apply:

- **More than half** of the primary members or their alternates must be present. For the NIH IRB, that means at least five members are needed to hold a meeting.
- **At least one non-scientist** must be there.
- Members who have the **expertise** to review the protocols assigned to the meeting must be present.
- If research involving prisoners is being reviewed, **an IRB member who is a prisoner representative** must be present. (Additional requirements apply.)

Who Else is Permitted to Attend?

- **Consultants:** Are not IRB members and are invited to give advice based on their expertise, but they cannot vote and do not count toward the quorum . Their attendance must documented in the minutes.
- **Guests:** Need advance approval from the IRB Director and must sign a Confidentiality Agreement before the meeting, as our IRB meetings are closed to the public. An example of an acceptable guest(s) is a student(s) at the NIH who is required to attend an IRB meeting to meet the requirements in their course curriculum.
- **Investigators:** May be invited if the IRB is discussing their specific study — For example, the NIH RCRC IRB invites the PI to attend when they are considering whether an event on their protocol is possible serious and/or continuing noncompliance. The NIH IRB rarely invites investigators, since the analyst/IRB member tries to get their questions answered prior to the meeting.

What Determinations (Decisions) Can the IRB Make?

The IRB Chair makes a motion to do one of the following, and IRB members vote on the motion unless they abstain or are recused (see below).

- **Approve** as submitted
- **Minor changes** required for approval: Approval of a study by the convened IRB which requires specific changes be made in order for the action to be approved.
- **Defer**: The research study requires resolution of one or more criteria for approval, or there are other substantive issues (e.g., risks are significant and have not been adequately minimized, or the safety monitoring plan is not adequate). Deferred actions must be reviewed by the convened IRB after the requested changes have been made in order to be approved.
- **Disapprove**: The research study cannot be approved in its present form (e.g., for reasons such as subject safety or scientific validity).

How Does Voting Work?

Members may:

- Vote to **agree or disagree** with the motion. A **majority** of members present who count towards quorum must agree for any motion to pass.
- **Abstain:** A member can choose not to vote if they feel uninformed. They still count towards quorum (as being "present").
- **Recuse:** If a member has a conflict of interest with a study, they must leave the meeting and cannot vote on it. Recusal has the same effect as if the member was not at the meeting. If the recusal results in break of quorum, the meeting cannot continue unless quorum is reestablished.

