HUMAN RESEARCH PROTECTION

Role of IRB Chair and Meeting/Review Structure

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Contents

1. Chair Responsibilities

Beyond the role of an IRB member, the IRB Chair facilitates meetings by:

- adhering to the agenda to ensure all relevant items are addressed
- focusing member discussion to ensure relevant regulatory and ethical considerations are addressed
- encouraging all member contributions
- clarifying substantive issues vs. minor stipulations
- mediating discussion of controverted issues

Adhering to the Agenda

The typical meeting agenda will include the following items:

- Announcements
- Minutes to Approve / Minutes to share
- Expedited Actions to Accept
- Confirmation of No Member Conflicts
- Submissions for Review

Focusing Member Discussion

The primary reviewer will provide a summary of the submission and communicate any suggested stipulations. The reviewer worksheets address all criteria for approval, but the summary provided during the meeting review should focus around the criteria for approval. Any items that require considerable revision before the specific criterion is met should be addressed during the meeting discussion. Whenever discussion focus shifts from these criteria, the IRB Chair can ask questions to redirect or offer reminders of areas yet to be addressed in the discussion.

Whenever helpful during discussion, the IRB may refer back to reviewer worksheets (attached in the submission) or 197 GUIDANCE – Criteria for IRB Approval.

Encouraging All Member Contributions

After the primary reviewer provides their summary and any suggested stipulations, the IRB chair should encourage other IRB members to express questions regarding the submission and any stipulations that have not already been addressed. The primary reviewer is responsible for completing all required reviewer worksheets; however, all IRB members review all items on the agenda. The primary reviewer may address all concerns or suggested stipulations, but it is important to provide opportunity for all IRB members to contribute before moving forward with a vote.

Whenever stipulations have been expressed and a motion for *approval with minor stipulations* has been made, the IRB analyst will provide a summary of all stipulations before proceeding onto other submissions.

Clarifying Substantive Issues vs Minor Stipulations

The IRB should defer a study when the IRB is unable to make determinations required for approval at 45 CFR 46.111 and/or 21 CFR 56.111 (197 GUIDANCE – Criteria for IRB Approval), and any relevant subparts (B, C, D).

If the IRB requires *clarification* in order to confirm criteria for approval are met, the study should be **deferred**.

When the IRB has confirmed that criteria for approval has been met, but has *concrete or prescriptive stipulations*, the study can be approved with **minor stipulations**. The stipulations should be specific and not require additional review by the convened IRB.

Whenever possible, the IRB analyst will work with the Primary Reviewer and IRB Chair in order to identify areas of concern prior to the meeting. Identifying areas of concern in advance will allow the IRB analyst to reach out to the PI to clarify information *prior to* the meeting or identify items that must be addressed by the PI *during* the meeting.

The chair must help determine whether requested stipulations are truly **minor stipulations** or cause for **deferral**. If IRB members suggest stipulations that are not concrete or prescriptive, the chair should assist with either revising the stipulation language or deciding whether the request is a substantive issue which warrants deferral (this work/decision happens during meeting discussions prior to the vote). The Chair will also help in the review of meeting minutes, where language for stipulations is finalized.

A study should be **deferred** if the IRB:

- requests that the PI provide a justification for something (such as justification for the inclusion of a certain vulnerable population)
- requests that the PI revise the study design
- requests that the PI provide additional information in order to understand study procedures or assess risks
- requests that the PI provide additional information regarding the consent process

Whenever a study is deferred, the minutes must describe specific substantive issues which caused deferral, how the criteria for approval was NOT met, and what the PI must do before the submission returns to the full board.

A study should be approved with **minor stipulations** if the IRB:

- can stipulate that the PI confirm the IRB's understanding of something by revising the submission or study materials
- can stipulate that the PI make precise changes to the study materials with clearly stated parameters

Whenever a study is approved with minor stipulations, the minutes must include all minor stipulations. The submission will not return to the full board for further review; however, the IRB analyst may ask the IRB chair to review specific responses to the stipulations, if necessary.

Mediating Discussion of Controverted Issues

"Controverted issues are those that cause controversy and dispute among the IRB membership." (Section E of DHHS Minutes of IRB Meetings guidance) When controverted issues arise, they may be resolved through discussion or IRB members may remain in disagreement. In either scenario, the IRB meeting minutes (taken by the IRB analyst) must reflect the issue raised and the outcome. The IRB chair may contribute to the discussion but should also mediate discussion of controverted issues among the IRB members. Summarizing the issues and the outcome during the discussion will assist the IRB analyst in accurate documentation of such issues.

2. Review structure for initial submission

For the review of an initial submission (new study), the Principal Investigator (PI) and Primary Contact (PC) are asked to attend the IRB meeting. When the IRB analyst invites the PI and PC to attend the meeting, their attendance is staggered based on the meeting agenda. While meetings are conducted remotely, study team members remain in the zoom waiting room until the IRB analyst admits them into the meeting. A typical workflow would be:

I. Covering all administrative agenda items
    a. Announcements, Minutes to Approve / Minutes to share, Expedited Actions to Accept, Confirmation of No Member Conflicts
II. Review of Initial Submission
    a. IRB analyst admits study team into zoom meeting
    b. IRB Chair welcomes study team and asks them to provide a brief overview of the study
    c. Questions raised for study team to address (starting with the Primary Reviewer and then other IRB members)
    d. Study Team is dismissed from the meeting
    e. Primary Reviewer provides a summary of their review and communicates any suggested stipulations
    f. Other IRB members ask questions and/or suggest stipulations
    g. Motion is made for vote
        i. IRB analyst summarizes stipulations when a motion is made for a study to be approved with minor stipulations
III. Repeat Step II with next submission

3. Review structure for follow-on submission

For the review of a follow-on submission (such as a modification, renewal, incident), the study team is not invited to attend the meeting unless circumstances warrant the request. The IRB chair can request that the IRB analyst invite the PI and PC to the meeting. When study team members are not attending a meeting, a typical workflow would be:

I. Covering all administrative agenda items
    a. Announcements, Minutes to Approve / Minutes to share, Expedited Actions to Accept, Confirmation of No Member Conflicts
II. Review of Follow-on Submission
    a. Primary Reviewer summarized the submission, their review, and any suggested stipulations
    b. Other IRB members ask questions and/or suggest stipulations
    c. Motion is made for vote
        i. IRB analyst summarizes stipulations when a motion is made for a study to be approved with minor stipulations
III. Repeat step II with next submission