Conduct of Full Board Meetings

Table of Contents: Conduct of Full Board Meetings

Policy Statement

The ORSPO (Office of Research and Sponsored Projects Operations) ensures that IRB (Institutional Review Board) meetings are prepared for and conducted in a consistent manner in order to meet federal and institutional requirements. The IRB will review research protocols at full board meetings except when exempt and expedited review procedures are used.

Description and Procedures

A. Review Submissions and Determination of Type of Review

All review submissions (including initial review applications, continuing reviews, amendments, reports of unanticipated problems, or closures) are screened by IRB staff in the ORSPO. The screening process is completed prior to assignment to a board meeting or expedited reviewer.

At initial review, one of three types of protocols (Exempt, Expedited, and Full Board) can be requested by the PI. Regardless of the review type requested by the PI, the IRB will determine the review type based on the criteria outlined in 45 CFR 46 or 21 CFR 56.

B. Meeting Scheduling

The IRB is scheduled to meet at least once per month during the Spring and Fall Semesters, except during the winter break. Summer meetings are scheduled as needed and determination will be made on a case by case basis. Individual meetings may be cancelled by the Human Protections Administrator or designee, following consultation with the Chairperson(s), due to: 1) insufficient applications requiring full board review, 2) University holiday, 3) inability to secure a quorum for attendance, or 4) other reasons (such as inclement weather) that make a scheduled meeting unnecessary or otherwise inappropriate.

For a current listing of meeting dates, see the IRB website.

C. Meeting Agendas and Document Distribution

Each convened meeting of the IRB will have an agenda clearly showing the topics and items the Board will consider at the meeting. The agenda will also be used to inform IRB members of research protocols determined to be exempt or approved using the expedited procedure. Agendas are posted to the Meeting section of the IRB reviewer website and will remain as part of the official record to assist location of a specific item or action in the minutes of the meeting. Corrected agendas will be provided to IRB members if changes are made subsequent to the agenda being distributed.

For protocols determined to be more than minimal risk and subject to full IRB Review, IRB staff in conjunction with the IRB Chair(s) will assign primary reviewer(s) knowledgeable about or experienced in working with the specific types of studies and populations involved. IRB staff will ensure that either the Primary or Secondary Reviewer is present at the convened meeting or available by teleconference.

All materials necessary to review convened submissions and verify that the approval criteria are met are distributed to reviewers and attending IRB members in sufficient time prior to the meeting to allow for adequate review (minimum of two weeks), including the pre-review forms and all submitted materials, including but not limited to the full protocol, consent document(s), recruitment materials, and other supporting materials.

D. Calling to Order, Quorum, Teleconferencing and Voting Requirements

a. Requirements for Calling the Meeting to Order:

The IRB meeting is called to order by the presiding chairperson only when a quorum of members is in attendance, present either in situ or via teleconference. The meeting ends or is suspended if a quorum is no longer present for deliberations. A quorum is also required to review research and vote.

b. Requirements for Quorum

A quorum requires a majority of the voting members of the Board to be present. The IRB staff and/or IRB Chair(s) determine if a quorum is met, and document quorum status in the meeting minutes. The following special conditions apply to achieving and retaining quorum:

1. At least one scientific and one non-scientific member must be present.
2. At least one unaffiliated member must be present.
3. When the convened IRB reviews research involving prisoners or another category of vulnerable subjects, a member with expertise in research involving prisoners or the relevant category of vulnerable subjects must be present.

c. Voting Requirements:

1. Only members may vote.
2. No one may vote who has a conflict of interest with respect to the research under consideration.
3. Votes by proxy are not allowed.
4. A favorable vote of the majority of the members present is required to approve research activities.

5. Votes may be taken by a show of hands, voice vote, or electronic polling if teleconferencing is used.

d. Requirements for Teleconferencing:

If necessary, individual IRB members may participate in the meeting via telephone or computer conference call, or meetings may be conducted exclusively via telephone or computer conference call only if the following conditions are met:

1. Each member must have received all pertinent material prior to the meeting.
2. Each participating member must be able to actively and equally participate in the discussion of all protocols reviewed during the teleconference.

E. Motions

During a convened meeting of an IRB panel, any voting member may motion for an action of the panel using one of the following motions:

1. **Approved**: defined as approved as is, with no further action requested or required.

2. **Approved with conditions**: defined as approved on condition that the investigator does one or more of the following –
    a. makes precise language changes to the research protocol or supporting documents;
    b. confirms specific assumption or understandings on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the research excludes children);
    c. submits additional document(s) (e.g., documentation of site access or certificates of training completion); and/or
    d. makes substantive changes to the protocol or supporting documents along with clearly stated parameters that the changes must satisfy.

    The approval assumes that if all of the conditions are satisfied, the study meets all of the conditions for approval documented in 45 CFR 46.111 and applicable subparts B, C, and D.

    The IRB motion must include
    a. the conditions that must be met in order to approve the study; and
    b. names of the individual(s) designated to review the response on behalf of the IRB. The designated individual(s) must have the appropriate expertise and qualifications to determine that the conditions have been met and the study adheres to the criteria for approval outlined in 45 CFR 46.111 and applicable subparts.

    The designated individual(s) will take one of the following actions:
    a. approve the study if the response is satisfactory, or
    b. refer to the study to the convened panel for additional review if the response is not satisfactory.

3. **Tabled**: defined as the requirement that modifications and/or additional information must be provided before the IRB is able to determine that the study meets the criteria for approval specified in 45 CFR 46.111 and applicable subparts. Responses must be returned to the panel for further review.

4. **Disapproved**: defined as not approved by the panel for reasons specified in a Letter of Disapproval.

5. **Suspended**: the suspension of previously approved research is defined as temporarily discontinuing any interventions with human participants for research purposes.

6. **Termination**: the termination of previously approved research is defined as indefinitely (possibly permanently) discontinuing any interventions with human participants for research purposes.

7. **Other Motions**: The IRB may make additional motions as outlined below:

    I. **Unanticipated Problem**: The IRB may determine that an event meets the criteria of an unanticipated problem involving risk to subjects or others.
    II. **Noncompliance**: The IRB may determine that an event meets the definition of general noncompliance or serious and/or continuing noncompliance
    III. **Acknowledgement**: The IRB may vote to acknowledge reports of deviations, adverse events, unanticipated problems or noncompliance. An acknowledgement motion may be made in addition to another motion when the IRB has determined further information or modifications are required. Additionally, an acknowledgement motion may be accompanied by a separate determination.

Effective Date

August 24, 2020

Revision History

References

45 CFR 46
21 CFR 50
OHRP Guidance on IRB Approval of Research with Conditions