

7.3 Convened IRB Meetings

Except when an expedited review procedure is used, the IRB will conduct initial and continuing reviews of all non-exempt research at convened meetings at which a quorum (see below) of the members is present.

7.3.1 IRB Meeting Schedule

The IRB meets on a regular basis throughout the year. The schedule for the IRB may vary due to holidays or lack of quorum. The schedule for IRB meetings is posted on the IRB websites. Special meetings may be called at any time by the Chair, IRB Director or the HRPP Directors.

7.3.2 Pre Review

IRB Staff will perform a pre review of all submissions for determination of completeness and accuracy. Only complete submissions will be placed on the IRB agenda for review. The investigator will be informed either by e-mail, phone or in person of missing materials and the necessary date of receipt for inclusion on the agenda. If an investigator is submitting for the first time or is not well-versed in the submission procedures, consultations can be arranged with IRB staff.

7.3.3 Primary and Secondary Reviewers

After it has been determined that the submission is complete, an IRB Staff member with the assistance of the IRB Chair as needed, will assign submissions for review paying close attention to the subject matter of the research, the potential reviewer's area/s of expertise and representation for any vulnerable populations involved in the research. Primary and secondary reviewers will be assigned to each submission and receive and review the full submission materials. Reviewers may be assigned several submissions or other items for review. When the IRB is presented with a research study which may be outside of the knowledge base or representative capacity of the IRB members, an outside consultant will be sought (See Section 4.5). Research studies for which appropriate expertise cannot be obtained for a given meeting will be deferred to another meeting when appropriate expertise is available.

Primary and secondary reviewers are responsible for:

1. Having a thorough knowledge of all of the details of the proposed research.
2. Performing an in-depth review of the proposed research.
3. Beginning the discussion of the proposed research at the convened meeting, by summarizing the proposed research, and leading the IRB through the regulatory criteria for approval. (See Section 7.4).
4. Making suggestions for changes to the proposed research, where applicable.
5. Completing all applicable IRB reviewer forms or certifications.

Secondary reviewers are paired with a primary reviewer for each submission. A secondary reviewer may be assigned to review the full submission materials or may be asked to review specified sections of the submission (e.g., the consent/assent/permission forms).

All IRB members receive and are expected to review all studies, not just those assigned as primary and secondary reviewers.

When it can be anticipated that the primary reviewer may be absent from the meeting, a new primary reviewer may be assigned, providing that they have sufficient time to review the materials in advance of the meeting. Additionally, an absent reviewer can submit their written comments for presentation at the convened meeting. A secondary reviewer may serve as primary reviewer in a given meeting. If an absent reviewer submits comments, those can indicate a recommendation regarding approval, but such recommendation will not be counted as a vote.

7.3.4 Materials received by the IRB

All required materials need to be submitted to the IRB office 9 business days prior to the convened meeting for inclusion on the IRB agenda. The meeting agenda will be prepared by the IRB Staff in consultation as needed with the IRB Director or IRB Chair. All IRB members receive the IRB agenda and research submission materials no later than 6 to 7 business days before the scheduled meeting to allow sufficient time for the review process.

Each IRB member receives and reviews the following documentation, as applicable, for all studies on the agenda:

- A research protocol
- The IRB Study Application (if applicable)
- Consent/parental or guardian permission/assent forms, letters or scripts (if applicable)
- Recruitment materials including advertisements intended to be seen or heard by potential subjects (if applicable)
- Supporting documents such as interview guides, surveys or other data collection tools (if applicable)
- Investigator brochure(s) (if applicable)

Additionally, for DHHS-supported multi-site clinical trials, the primary reviewer should receive and review a copy of the DHHS-approved sample informed consent document(s) (when one exists) and the complete DHHS-approved protocol/research plan (when one exists).

If an IRB member requires additional information to complete the review, they may contact the investigator directly or may contact the IRB Office to make the request of the investigator.

Reviewers will use an IRB reviewer checklist as a guide to completing their review.

7.3.5 Quorum

A quorum of the IRB consists of a majority (more than half) of the voting membership, including at least one member whose primary concern is in a non-scientific area. When research involving an investigational new drug is on the agenda for review, a physician should be included in the quorum. At meetings of the IRB, a quorum must be established and maintained for the deliberation and vote on all matters requiring a vote.

The IRB Chair, with the assistance of the IRB staff, will confirm that quorum is present before calling the meeting to order. The IRB Chair, with the assistance of the IRB staff, will be responsible to ensure that the IRB meeting remains appropriately convened. If a quorum is not maintained, either by losing a majority of the members, losing all non-scientific members or another required member, the IRB cannot take further actions or vote on regulatory determinations until quorum is restored, even if half of the members are still present.

The IRB Staff will document the arrival and departure for all IRB members and notify the IRB Chair if a quorum is not present. Attendance and vote count are documented or monitored by the IRB staff for each study. It is generally expected that at least one unaffiliated member and at least one member who represents the general perspective of participants (one individual can serve in both capacities) will be present at all IRB meetings. The IRB may, on occasion, meet without this representation; however, this should be the exception.

If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or persons with impaired decision-making capacity, one or more individuals (e.g., IRB members, alternate members, or consultants) who are knowledgeable about and experienced with those subjects should be present during the review of the research.

When the IRB is presented with a research study which may be outside of the knowledge base or representative capacity of the IRB members, an outside consultant will be sought. Research studies for which appropriate expertise cannot be obtained for a given meeting will be deferred to another meeting when appropriate expertise is available.

IRB members are considered present and participating at a duly convened IRB meeting when either physically present or participating through electronic means (e.g., teleconferencing or video conferencing) that permits them to listen to and speak during IRB deliberations and voting. Whether or not physically present, the IRB member must have received all pertinent materials prior to the meeting and must be able to participate actively and equally in all discussions.

Opinions of absent members that are transmitted by mail, telephone, facsimile or e-mail may be considered by the attending IRB members but may not be counted as votes or to satisfy the quorum for convened meetings.

7.3.6 Meeting Procedures

The IRB Chair will call the meeting to order, once it has been determined that a quorum is in place. The Chair will remind IRB members to recuse themselves from the discussion and votes by leaving the room when they have a conflict.

The IRB reviews all submissions for initial and continuing review, as well as requests for modifications. The Primary Reviewer presents an overview of the research and assist the Chair in leading the IRB through the completion of the regulatory criteria for approval in the reviewer checklist. In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

The IRB Staff take notes of the proceedings and are responsible for preparing the meeting minutes.

7.3.7 Guests

Investigators and research staff may be invited to the IRB meeting, at the discretion of the IRB, to make a brief presentation or to answer questions about proposed or ongoing research. The investigator/research staff may not be present for the deliberations or vote on the research.

(List regularly attending guests by title.)

The IRB Directors and staff regularly attend IRB meetings and may participate in the IRB discussion and deliberations, but may not vote unless they are serving as an IRB member for the meeting.

Other guests may be permitted to attend IRB meetings at the discretion of the IRB Chair or IRB Staff. Such guests may be asked to sign a confidentiality agreement and do not participate in discussion unless requested by the IRB, under no circumstances may they vote.