Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-009.4
Policy Title: Institutional Review Board – Convened Meeting Operations

Purpose

The purpose of this policy is to describe the particulars of a convened board meeting. This policy is not inclusive of the policy/procedure used to conduct individual reviews at a convened board meeting.

Definitions

See policy 2011-007.0 for definition of the following terms:

Member, Non-scientific | Quorum

Policy

It is the policy of the HSPP to post on the web the meeting schedule and submission deadlines for IRB panels that meet on a regular basis. Adjustments to the meeting schedule may be made because of holidays or other issues. Material requiring review by the convened board must be submitted by the published submission deadlines to provide sufficient time for screening and review prior to the meeting date. If a study is deferred at a convened meeting, the investigator is granted a one-week extension on the submission deadline for the meeting to be held in the following month.

The panel conducting the review is determined by the submission date of the application with the following exception:

- all studies that require full board review that propose to involve prisoners are reviewed by a panel that has a prisoner representative as a member

A Chair may refer initial review of a study to another panel due to conflict of interest issues; due to more appropriate expertise lying on the other panel; or other reason deemed appropriate by the Chair (e.g. volume of submissions).

A majority of the members, including one non-scientific member, must be present to establish quorum to convene a meeting. If a required member (e.g., non-scientific) leaves the room, and no other persons with that role are present; quorum is lost even if over half of the membership is present. The IRB cannot take any action until quorum is restored.

While federal regulations do not require it, the practice of the IRBs that meet monthly is that a non-affiliated member and a member who represents the interest of participants be present for at least 9 out 12 meetings. One member may fulfill all three roles (i.e., non-scientific, non-affiliated, and participant representative). Members may be considered present via video or teleconferencing that allow for two way communication. The IRB Regulatory Specialist (RS) documents attendance in the minutes which can then be used for tracking.

The convened meetings will be conducted in a location that allows access to current and historical IRB records (electronic files via internet connections). When reviewing electronic submissions, the agenda item (inclusive of supporting documents) being discussed will be projected to a screen in the meeting room or shared on the screen in the videoconference. Members may also choose to follow along on

individual laptops, but this is not required. In all cases, the reviewer form provided to the primary reviewers addresses the regulatory criteria for approval. This form is available to all members at any time from the web and also for projection at the meeting.

After initial review a study remains under the oversight of the panel to which it was initially presented. Another panel may take action on a study under a different panel's oversight only in rare circumstances, e.g., to prevent a lapse in approval that is not due to the investigators failure to request continuation. One panel cannot approve a study that the other panel has denied or deferred.

Under unusual circumstances the Chair of any panel may call an emergency meeting of their own panel, e.g., due to audit findings that indicate subjects are at risk. However, such a meeting cannot be called due to the negligence of the investigator to submit material on time.

IRB meetings are not public meetings. Guests, including principal investigators, may attend an IRB meeting only at the invitation of the Chair. Principal investigators who are present will be excused prior to deliberation and voting. Principal investigators may elect to be available by phone during the meeting to be called upon to provide clarifications should that need arise.

Voting by Members
Each full board agenda item will be individually reviewed and voted on by the members present, inclusive of Chair and Vice Chair. If a member abstains from voting that abstention will be noted and counted as a vote of no. The abstaining member's presence will count towards quorum.

A member cannot review or vote on a study, (whether it is for initial review, continuing review, a request for modification, or any other action such as a vote regarding unanticipated problems or non-compliance) if: 1) the member or immediate family member is involved with the conduct of the study, 2) the member or immediate family member has any financial conflict of interest with the study. Members who cannot vote on a specific study may provide information to and/or answer questions from the committee but cannot be present for the deliberations and voting and cannot count towards quorum for that particular vote.

At the conclusion of discussion for an agenda item, the Chair will call for a motion. A majority vote of the members present will be required to carry a motion. In general, the vote will be taken by a show of hands and the RS will record the motion and the number for, against and abstaining in the minutes. The Chair reserves the right to use an alternate method of voting, such as by ballot, or voice if it is deemed necessary.

Procedure

Meeting Schedule: On an annual basis, designated IRB staff will prepare and post the meeting schedule and submission deadlines to the web. An IRB staff person will send an e-mail message to announce any adjustments to the published meeting schedule.

Emergency Meetings: A designated IRB staff person will be responsible for coordinating an emergency meeting. If material is not already distributed to members from the previous meeting, or if it is not available through electronic means, the IRB RS will distribute material as soon as possible to allow for sufficient time for the review. The material to be distributed will depend on the nature of the issue being

discussed. For example, if the PI disagrees with the contingencies previously imposed by the convened board and risks to subjects is involved, the board may review the original approved contingent letter, the response of the principal investigator and the applicable associated documents such as the consent form, the protocol or survey tools. The investigator may be asked to attend the meeting to address questions or provide additional information or clarification.

General Meeting Procedures: The Chair will call the meeting to order when a quorum is reached. The Chair will perform the following functions, as indicated on the agenda: 1) remind members that they cannot partake in the review/vote of any study with which they have a conflict, 2) call for comments regarding exempt and expedited activity that is presented for informational purposes, and 3) ensure appropriate expertise is available for the review (written comments may be acceptable).

The IRB RS will ensure that a quorum is maintained throughout the convened meeting. The IRB RS will use the IRB roster to track attendance at the meeting to ensure that a quorum has been met and is maintained. If quorum is lost, the IRB cannot continue deliberations or voting until quorum is restored.

The IRB RS will obtain a signed confidentiality statement from guests (e.g., consultants), other than principal investigators who are present to provide information for a specific study.

Minutes: The IRB RS will take minutes at each meeting and finalize them using a template that reflects:

- that a quorum was met and maintained throughout the meeting,
- the start and stop time of the meeting,
- members, staff and any guests present at the meeting,
- identification of members fulfilling the non-scientific role, non-affiliated role, and prisoner advocate role,
- notation of when a member leaves or joins a meeting,
- summary and findings of each project discussed (new studies, continuing review, requests for modifications),
- IRB number, principal investigator, project title,
- the risk/benefit assessment,
- findings of the Board (basis for contingencies for approval or reasons for denial of approval),
- details of the vote reflecting number voting in favor, number opposed and number abstaining along with the name of who abstained,
- by study, the name of any IRB member with a conflict of interest who left the room for deliberations and voting, including notation that reason was due to conflict,
- the review interval required,
- rationale for conducting continuing review on research that otherwise would not require continuing review.

When applicable the IRB RS will also ensure that the minutes reflect:

- attendance of any member who is serving as an alternate and the identity of the member for whom they are the alternate
- the approval category for the inclusion of population requiring additional protections (e.g. children, prisoners),
- protocol specific information for how criteria for vulnerable populations or fetal transplantation are satisfied,

- information justifying an alteration to or waiver of informed consent,
- information justifying a waiver of consent for planned emergency research
- the requirements that were met to grant a waiver of the requirement to document consent,
- the rationale for a determination of significant risk or non-significant risk for device studies,
- review and approval of data safety monitoring plans/boards,
- discussion and determination regarding unanticipated problems involving risk to subject or others
- discussion and determination regarding serious or continuing non-compliance
- discussion and determination of any suspension or termination of IRB approval
- a summary of controverted issues and the resolution of those issues,
- other discussion items and the motion and vote of those discussions
- a justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample informed consent document.

At each meeting the Chair will ensure that appropriate expertise is available for the reviews. The Chair will also ask for a motion to approve the minutes of the previous meeting. The IRB RS will send the approved IRB minutes by e-mail to the Institutional Official designated on the FWA and Director of the Human Subjects Protection Program and other parties with legitimate interest as needed / requested (e.g. Research Compliance).

Related Policies

2011-006.0 – Vulnerable Populations: General Policy
2011-007.0 – Definitions Applied to Policies
2011-009.5 – IRB Convened Review

Basis

45 CFR 46
21 CFR 56

Document Attributes:

Date Effective: 11/20/23

Replaced Version: 6/9/23

Reviewed and Approved By:

Richard H. Simon, MD *11/01/23*

Richard H. Simon, MD **Date**
Director Human Subjects Protection Program