Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute, LLC
Office of Sponsored Programs

Policy and Procedure

TITLE: Conduct of IRB Meetings

PURPOSE:

To describe the conduct of meetings of the convened Institutional Review Board (IRB) to allow the IRB to carry out its functions effectively and consistently according to applicable laws, regulations, codes, and guidance and organizational policies and procedures.

PERSONS AFFECTED:

This policy & procedure (P/P) applies to all Harvard Pilgrim Health Care, Inc. (HPHC) and Harvard Pilgrim Health Care Institute, LLC (HPHCI) (collectively, HPHC/I) personnel engaged in research, teaching or research administration activities in support of the charitable and educational mission of HPHC.

POLICY:

Except when an expedited review procedure is used, the IRB shall:

- meet regularly;
- in person or via electronic means;
- with a quorum of IRB members;
- to review proposed research; and
- approve research by majority vote of the members present at the research review and discussion.

Despite the presence of a quorum, no action shall be taken where the assembled members do not have the expertise to review the proposed research.

DEFINITIONS:
For purposes of this policy:

Quorum
In accordance with HHS regulations, a quorum exists at a meeting convened to review proposed research when the following two conditions are met:

- the majority of the IRB members (or the alternate for a specific member) are present (in person or via telephone or other electronic means); and
- the members present include at least one of each of the following:
  - an individual with non-scientific area of expertise;
  - a scientist;
  - an individual who represents the perspective of subjects (aligned to the research that involves categories of subjects vulnerable to coercion or undue influence); and
  - an individual who is a non-affiliated member.

When a quorum is lost during a meeting (e.g., through excuse of members with conflicting interests, early departures, member temporarily leaves the room, failure of the connecting electronic equipment or any other absence of non-scientist, scientist, subject representative and unaffiliated members) the IRB may not take further actions or vote until the quorum is restored.

PROCEDURE:

Responsibilities of IRB staff
1. Unless a submission to the IRB is determined to be exempt, qualifies for expedited review, or otherwise does not require full board review, it is scheduled for, presented at, and voted on at a convened IRB meeting.

2. IRB meetings shall be scheduled to occur once a month except that the IRB shall not be scheduled to meet in August and December.

3. If circumstances require, additional meetings between the regularly scheduled monthly meeting shall be scheduled as needed in adherence to this policy and procedure.

4. Meeting dates/time are posted by IRB staff on the HPHC website and in IRBNet. The meeting dates/times shall reflect a meeting schedule and place that is convenient for the IRB.

5. Staff will determine that all IRB members have access to technology that will allow them to access IRBNet.

6. One week prior to the next scheduled IRB meeting, IRB staff will finalize the IRB agenda in IRBNet. The agenda will include educational items (as applicable), submissions that require full

IRB review, draft minutes from the previous meeting, a list of expedited and exempt reviews that have occurred since the previous convened meeting (as applicable), a list of reportable events since the previous convened meeting (as applicable), and any other business as needed.

7. IRB staff shall also make meeting arrangements including, but not limited to:
   a. ordering a meal, taking into consideration any preferences and allergies of the IRB, if the meeting will occur in person; or
   b. arranging for and notifying the IRB of any telephone or other electronic means to conduct the meeting, if not in person.

8. All IRB members and staff shall have access to IRBNet prior to and during the convened meetings. If attending meetings in person, IRB staff will provide IRB members with the appropriate credentials for Internet access.

9. IRB staff will assign the full agenda items to the appropriate IRB members for review by clicking on the *Share* link in the IRBNet submission package.

10. IRB staff will grant all expected attendees shared access while designating appropriate primary and secondary (if applicable) reviewers. Staff will consult with the IRB Chair on special assignments, as necessary.

11. The HPHC Institutional Official (IO) shall be provided access to the full agenda, meeting minutes and any other meeting documents as applicable.

12. IRB staff shall notify the IRB that the submission has been shared by notifying users that access to the submission has been granted. A note regarding the assignment is sent to the reviewers which includes the date of the IRB meeting and identification of the primary reviewer (and secondary reviewer, if applicable).

13. After all full agenda items have been shared, staff will proceed to the *Agenda Builder* via the IRBNet *Agendas and Minutes* tabs for the appropriate IRB meeting.

14. To add *Meeting Documents*, such as educational material and draft IRB minutes from the previous meeting, IRB staff will assemble all appropriate meeting documents here by clicking the “paper” icon to upload and attach the materials to the agenda. The meeting materials supplement the documents already in the specific submission packages.

15. IRB staff shall design the meeting agenda to allow for adequate discussion, not to exceed two hours, of each item on the agenda, resolution of controverted issues, and IRB determinations.

16. To organize the agenda, which includes the specific submission packages, IRB staff will click on the *Agenda Builder* link for the appropriate IRB meeting.

17. The Agenda shall be prepared in the following format:
   a. Welcome and Opening Remarks;
   b. Next Meeting Date and General Announcements;
   c. Review of Previous Minutes;
   d. Continuing Education;
   e. New Studies;
   f. Amendments;
   g. Renewals;
   h. Expedited/Exempt Submissions;
   i. Safety Reports;
   j. Other Business; and
   k. Adjourn.

18. IRB staff will review the agenda details and click the link to *Add /Update/Delete Sections* as appropriate for the planned meeting.

19. All unassigned items shall be moved under the appropriate header. Staff will click the link *Move* to assign the item under the appropriate header. After all items are assigned, the items shall be ordered under each section as appropriate.

20. If the Chair is participating by telephone, the IRB staff designated as the meeting administrator will administer the meeting.

21. IRB staff will click on the tab *Publish Agenda* which posts the agenda in the meeting documents and makes it available for the IRB members to access.

22. The minutes of all IRB meetings will be published in IRBNet no later than one week after the IRB reviews the minutes at the next convened IRB meeting, confirms accuracy, and gives the final approval.

<u>Responsibilities of IRB members</u>

1. IRB members are expected to attend the scheduled IRB meetings and prepare for these meetings by reviewing project submissions in IRBNet prior to the meeting (including those protocols for which the IRB member is not the primary reviewer) in enough depth to be familiar with the protocol, to be prepared to discuss the protocol at the meeting, and to be prepared to determine whether the research meets the regulatory criteria for approval.

2. IRB members shall provide advance notification to IRB staff of an expected absence as member absences may affect the quorum and therefore the ability to conduct an IRB meeting.

3. IRB members shall be prepared to serve as designated reviewers when assigned, participate in research study discussions, express concerns with the study under review, vote on protocols and recuse themselves from a review in the event they have a conflict of interest.

4. At the beginning of each convened IRB meeting, in accordance with the *Policy and Procedure on IRB Members and Consultant Conflict of Interest***,** the Chair or the Chair's designee, shall ask IRB members to disclose any COI with agenda items scheduled for review.

5. Any IRB member with a COI shall identify and disclose the nature of the conflict.

6. The IRB member with a COI shall be allowed to remain in the meeting room to provide information requested by the IRB.

7. The IRB member, including the IRB Chair, with the COI will be asked to leave the meeting room before any discussion and voting on the research with which the IRB member has a COI.

8. While they are out of the room, they are not counted towards the quorum.

9. Primary reviewer(s) will present the research submission to the IRB members at the convened meeting, after which the IRB will discuss the research project and vote.

10. When research involves vulnerable subjects, one or more individuals who are knowledgeable about or experienced in working with such subjects will be present at the meeting.

11. IRB members who are serving as designated reviewers are required to record their comments, concerns and recommendations for an assigned submission on the Reviewer's Sheet in IRBNet.

12. IRB members are expected to perform full committee, expedited and exempt reviews, as assigned.

13. IRB members are encouraged to ask IRB staff to contact investigators prior to the IRB meeting to get questions answered and allow time for submission revisions.

14. IRB members, including the Chair, who are in attendance and who are not excused are entitled to one vote on each research submission presented to the IRB for vote.

15. Approval of a proposed protocol requires a majority of the voting members at a convened meeting at which a quorum has been established.

16. Alternate members are provided with and review the same material as the primary members.

17. Alternates may vote in place of an absent or excused regularly appointed member. If alternates are appointed, they may attend all meetings; however, their votes are counted only in the absence of the regularly appointed member.

18. Meeting minutes must indicate when an alternate member replaces the appointed member.

19. All subject matter of board meetings that is related to protocols, including discussion involving investigators or subjects, or of an otherwise sensitive nature, shall be treated as confidential information by IRB members.

Responsibilities of IRB Chair

1. The Chair presides over the IRB convened meetings. If participating by electronic means, the IRB Chair shall delegate a member of the IRB staff to administer the meeting.

2. Prior to initiating any research review at an IRB meeting, the Chair shall determine and the meeting minutes shall reflect that a quorum is present and the voting members, alternates, and consultants collectively constitute sufficient and appropriate expertise to review the full range of protocols under review at the meeting.

3. The Chair presents the meeting agenda and conducts the meeting, allowing sufficient time and opportunity for discussion and vote on the research studies under review.

4. The Chair provides clarification and leadership for IRB members and also performs expedited and exempt reviews.

5. Whenever the Chair is not available to conduct IRB business, the Chair may designate an experienced IRB member as acting Chair during the period of his/her absence.

6. When the convened IRB reviews research involving prisoners, the prisoner representative must be present unless the IRB is relying on an external IRB with a prisoner representative.

7. The IRB Chair may specifically request the research investigator be present during discussion at a meeting to address the IRB and/or provide answers to IRB inquiries. However, the investigator will not be present during the final discussion and vote. Investigator attendance at a convened meeting is solely at the discretion of the IRB Chair.

IRB Meeting Process

1. IRB Chair shall call the meeting to order at the appointed time.

2. IRB staff shall record the names of the IRB members attending in person or via teleconference.

3. IRB staff shall note the time the meeting begins.

4. The IRB Chair shall determine the presence of a quorum by establishing that the IRB members in attendance include:
   a. at least one member whose primary concerns are in a non-scientific area;
   b. one member who is a scientist;
   c. at least one member who represents the perspective of subjects (especially when the research involves categories of subjects vulnerable to coercion or undue influence); and
   d. one non-affiliated member.

5. IRB staff shall record the determination of the presence of a quorum.

6. The IRB Chair shall determine that all IRB members have received a copy of all of the documents that will be reviewed at the meeting,

7. To allow for appropriate discussion, temporary disconnections of the telephone or other electronic connection that are quickly re-established shall not affect the member's attendance status. The electronic equipment utilized must adequately allow the members to hear the discussions and be heard by all others in attendance.

8. The IRB Chair shall conduct the meeting to exceed no more than two hours.

9. The meeting shall be conducted in the order presented in the agenda.

10. IRB staff will use the *IRB Minutes Language Template* to then be transferred into IRBNet using the *Minutes Builder*.

11. Using the *Minutes Builder*, IRB staff shall record the results of the approval process:
   a. All approvals shall be by majority reflected by a voice vote. For example, following a thorough discussion during and after which the IRB Chair will ask if everyone has had an opportunity to ask questions and raise issues, the IRB Chair shall then ask, "Does everyone agree with the recommendation (of the IRB member who reviewed and presented the particular research study)"?
   b. The count is then voted and recorded by IRB staff.
   c. A vote of <u>approval</u> indicates that the IRB has concluded that the research and consent/assent forms meet the criteria for approval or that the research meets the criteria for a waiver or alteration of consent/assent.
   d. A vote to <u>approve with conditions</u> indicates that the IRB has approved the research pending the following actions from the investigator:
      (1) make specified changes to the research protocol or informed consent document(s);
      (2) confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted; or
      (3) submit additional documents, such that, based on the assumption that the conditions are satisfied, the IRB will be able to make all of the determinations required for approval under the federal regulations or other applicable law.
   e. The IRB Chair and/or other IRB member(s) with appropriate expertise or qualifications have the authority to approve minor modifications. If substantive clarifications or

modifications regarding the protocol or informed consent documents are required as a condition of approval, approval must be deferred pending subsequent review of responsive material by the convened IRB.

f. A vote of deferred indicates that the IRB withholds approval pending submission of major revisions/additional information. Generally, this means that extensive and/or substantive changes are necessary before the research study can be effectively reviewed.
g. Disapproval of a research protocol usually occurs when the IRB determines that the risk of the procedures outweighs any benefit to be gained or if the proposed research does not meet the criteria for IRB approval. An investigator may appeal a disapproval to the IRB.
h. IRB staff publishes a determination letter in IRBNet informing the investigator of the IRB's decision, describing modifications or listing the reasons for deferral or disapproval.
i. When a protocol receives final approval, the IRB assigns the start of the approval period as the date of the convened IRB meeting. If a protocol has received a conditional approval and the investigator completes the revisions, the date conditions are met will be the start of the approval date and the expiration date will be based on the approval period starting from the meeting date of the convened IRB on which the IRB initially reviewed the protocol.

REVISION HISTORY:

Department: OSP - Research Integrity & Compliance	**Title**: Conduct of IRB Meetings
Effective Date: 04/04/19	**Owner:** Senior Compliance Manager, IRB
Replaces P/P Dated: P/P 01/21/19; IRB SOP (2/2017); IRB Procedure 007.01 (10/13)	
Related Documents: Policy and Procedure: *IRB Members and Consultant Conflict of Interest*; IRB Roster Composition and Membership Appointments; IRB Minutes Template	
References: 45 CFR 46.108(b); OHRP Guidance on Written Institutional Review Board Procedures; 21 CFR 56.108; ICH-GCP: 3.3.2; AAHRPP Tip Sheets 16 and 18; AAHRPP Element II 2 C	