



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

Policy and Procedure

TITLE: IRB Meeting Minutes

PURPOSE:

To describe the policies and procedures for:

- how the Institutional Review Board (IRB) documents discussions, decisions, and findings on research studies and activities; and
- the creation and publication of the IRB meeting minutes and expedited procedure reviews in IRBNet.

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:

The IRB shall document its discussions, decisions and findings in meeting minutes and, when the expedited procedure for review is used, through documentation in IRBNet.

Minutes of IRB meetings shall be clear about the actions the IRB takes and document exactly what the IRB approved during the meeting. Minutes shall specify the modifications required to secure approval and the reason the IRB is requesting the modifications. Minutes shall indicate proposals or motions voted upon by the IRB and the results of each vote. When conducting initial or continuing review, minutes shall document the IRB's determinations of the approval period.

PROCEDURE:

1. During the convened IRB meeting, staff shall record the minutes using the *IRB Minutes Template* and will transpose the minutes into IRBNet after the fully convened IRB meeting takes place. Staff may also use a tape recorder if desired to aid in preparation of draft minutes.

2. IRB meeting minutes should document:
 - a. actions taken by the IRB;
 - b. separate deliberations for each action;
 - c. votes for each protocol as numbers for, against, or abstaining;
 - d. names of individuals in attendance at the meeting;
 - e. the presence of a quorum;
 - f. when an alternate member replaces a primary member, document the name of the alternate member and the name of the primary member replaced;
 - g. the basis for requiring changes in research;
 - h. the basis for disapproving initial and continuing research;
 - i. a written summary of the discussion of controverted issues and their resolution;
 - j. the names of IRB members who leave the meeting because of a conflict of interest along with the fact that a conflict of interest is the reason for the absence;
 - k. for initial and continuing review, the approval period;
 - l. exit and re-entry of IRB members;
 - m. a written summary of the discussion of controverted issues and their resolution.

3. The meeting minutes shall also include the required determinations and protocol-specific findings justifying those determinations for:
 - a. waiver or alteration of the consent process;
 - b. research involving pregnant women, fetuses, or neonates (documentation of findings required under 45 CFR 46 Subpart B);
 - c. research involving prisoners (presence of appropriate prisoner representative or reliance on an IRB with a prisoner representative and documentation of findings required under 45 CFR 46 Subpart C);
 - d. research involving children (documentation of findings in accordance with 45 CFR 46 Subpart D);
 - e. research involving subjects with diminished capacity to consent;
 - f. consideration of additional safeguards for vulnerable subjects;
 - g. consideration of additional requirements/documentation if the project involves international research; and
 - h. for FDA studies, the rationale for significant risk/non-significant risk device determinations, when applicable.

4. To transcribe minutes in IRBNet, staff will click on the appropriate agenda *Minutes Builder* link and update the following fields using the *Next* tab to advance to applicable screens (alternatively, staff can also use the 'Jump To' field to navigate to a specific agenda item more quickly):
 - a. date and time the meeting was called to order;

- b. date and time the meeting was adjourned;
- c. whether a quorum was present when the meeting was called to order;
- d. names of those who attended the meeting as voting members, non-voting members, staff, guests, and the recorder.

5. Remarks shall be recorded as applicable to the specific agenda items. Click the paper/pencil icon to update.

6. The expedited/exempt submissions paper/pencil icon shall be updated to include a statement that the list of expedited/exempt submissions reviewed by a single reviewer, was also reviewed by the IRB. Each individual expedited/exempt submission will already have comments entered at the time the single reviewer review is completed.

7. After all agenda fields are updated as applicable, staff will click the link *Preview minutes*. Minutes shall be reviewed for completeness and edited as necessary.

8. IRB staff attach a copy of the draft minutes to the agenda *Meeting Documents* for review at the next convened Board meeting.

9. If the draft minutes are approved during the convened meeting, IRB staff will click the *Minutes Builder* link for the appropriate agenda and then click *Publish Minutes*. If the IRB requests/edits are made to the previous month's minutes, staff will edit as applicable and will then publish minutes when edits are complete.

REVISION HISTORY:

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| Department: OSP - Research Integrity & Compliance | Title: IRB Meeting Minutes |
| Effective Date: 01/21/19 | Owner: Senior Compliance Manager, IRB |
| Replaces P/P Dated: IRB SOP (02/17) | |
| Related Documents: IRB Minutes Template | |
| References: 45 CFR 46.115(a)(2); 45 CFR 46.204; 45 CFR 46.205; 45 CFR 46.206; 45 CFR 46.207; 45 CFR 46.305; 45 CFR 46.306; 21 CFR 56.115(a)(2); AAHRPP Element II.5.B; AAHRPP Tip Sheet 3 | |