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

Policy and Procedure

TITLE: Performance Evaluation of IRB Chair, IRB Members and IRB Staff

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PURPOSE:

To describe the process for conducting the periodic evaluation of the performance of the Institutional Review Board (IRB) Chair, IRB members and IRB staff.

PERSONS AFFECTED:

This policy and 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, including the IRB.

POLICY:

The periodic evaluation of the IRB Chair, IRB members and IRB staff is essential to a well-functioning IRB. Evaluations serve to validate performance and identify areas which need improvement (both in function and knowledge). Evaluations shall be conducted annually. Outcomes of evaluation shall be used to make determinations regarding training, overall improvement of the human research protections program, and the composition of the IRB.

DEFINITIONS (for purposes of this policy):

Administrative Evaluation
Evaluation is conducted by supervisor or other administrator such as the IRB Chair, the Director, Research Integrity & Compliance Officer (DRICO), or the Institutional Official (IO).

Peer Evaluation
Evaluation is conducted by all IRB members and staff.

Self-Evaluation
Self-assessment by each individual involved in IRB activities.

PROCEDURE:

1. Evaluation Period

Evaluations shall be coordinated annually by the Research Compliance Specialist – Quality Assurance/Quality Improvement (QA/QI Specialist).

2. Evaluation Types

There shall be three types of evaluations: self, peer and administrative. During this review process, the composition of the IRB shall be evaluated, with input from the IRB Chair, IRB members, IRB staff, Institutional Official (IO) and Director, Research Integrity & Compliance Officer (DRICO), and when necessary, adjusted so that IRB composition meets legal and organizational requirements.

3. Process

a. The QA/QI Specialist shall provide the IRB members and staff with the evaluation survey on an annual basis.
b. Respondents shall complete the evaluation survey within the requested time frame.
c. The QA/QI Specialist shall compile and analyze the data, including, but not limited to:
    (1) Communication;
    (2) Training needs;
    (3) Year to year comparison of data, gap analysis; and
    (4) Suggestions for improvement.
d. A summary of the results shall be provided to the full IRB as well as to the Research Compliance Committee and the Board of Managers.

Note: the evaluation criteria shall appear in the evaluation survey as set forth below.

4. Administrative Evaluation of IRB Members

a. Each year, the DRICO shall provide the IRB Chair with administrative feedback on IRB member activities for the prior 12 months, including, but not limited to:
    (1) the number of meetings each IRB member attended during the year;
    (2) whether reviewer worksheets were completed fully;
    (3) timeliness to complete assignments, when this data is available; and
    (4) attendance.

b. The IRB Chair will review member performance and provide the results to each individual being evaluated by sending an email to each IRB member as part of their performance assessment. Depending on the nature of the feedback, a phone call may be a preferred method of follow-up.

c. The IRB Chair will document in the evaluation survey that the IRB member performance assessment has been completed and that notification of the assessment has been sent to each IRB member.
d. When appropriate, the results will also be provided to the Research Compliance Committee, the HPHC Board of Managers, and a summary of the results will be provided to the full IRB.
e. Upon completion, the evaluations shall be used in support of an action, such as direct feedback, changes, or individual and group education for identified areas of need.

5. Peer and Self-Evaluation of IRB Members

The IRB Member annual evaluation may include, but not be limited to, the following:

a. Objective Evaluation Criteria:
   (1) meetings attended;
   (2) timeliness of reviews;
   (3) completion of required checklists;
   (4) completion of educational requirements;
   (5) attendance at educational sessions; and
   (6) identification of future training topics.
b. Subjective Evaluation Criteria:
   (1) preparedness for meetings;
   (2) contribution to IRB meetings;
   (3) quality of reviews;
   (4) knowledge of regulations and identification of areas for improvement;
   (5) knowledge of HPHCI policies and procedures and identification of areas for improvement;
   (6) communication with investigators;
   (7) communication with IRB Chair and other IRB members and staff; and
   (8) ability to work with IRB staff.

6. IRB Chair Evaluation

Administrative evaluation of the IRB Chair shall be conducted by the IO, as deemed appropriate. The IRB Chair annual evaluation survey shall include peer and self-evaluation, and may include, but not be limited to the following:

a. Objective evaluation criteria:
   (1) meetings attended and chaired;
   (2) completion of educational requirements;
   (3) attendance at educational sessions; and
   (4) number of educational sessions conducted.
b. Subjective Evaluation Criteria:
   (1) leadership of the IRB;

(2) ability to lead meetings;
(3) preparedness for meetings;
(4) knowledge of regulations and identification of areas for improvement;
(5) knowledge of HPHCI policies and procedures and identification of areas for improvement;
(6) communication with investigators;
(7) communication with HPHCI personnel;
(8) communication with IRB members and staff;
(9) ability to help investigators; and
(10) any issues related to the human research protection program.

7. IRB Staff Evaluation

The IRB Staff Evaluation is in addition to any performance evaluations directed by Human Resources. This evaluation will assess compliance with the unique requirements and knowledge necessary for IRB staff. Any IRB staff who also serves as an IRB member shall be evaluated by the IRB member evaluation process as well.

The IRB Staff annual evaluation may include, but not be limited to the following:

a. Objective Evaluation Criteria
   (1) workload – handles workload efficiently;
   (2) number of exempt determinations made;
   (3) number of protocols processed that were reviewed by the expedited procedure;
   (4) number of protocols processed that went to the convened IRB;
   (5) timeliness of processing materials;
   (6) completion of required checklists;
   (7) completion of checklists and documentation;
   (8) maintaining paper files efficiently and correctly;
   (9) maintaining IRBNet files efficiently and correctly;
   (10) preparing IRB meeting agendas in a timely manner;
   (11) preparing convened IRB minutes in a timely manner;
   (12) maintaining IRB rosters efficiently and correctly;
   (13) preparing IRB records efficiently and correctly;
   (14) completion of educational requirements;
   (15) attendance at educational sessions;
   (16) number of educational sessions conducted;
   (17) attainment and maintenance of certification (e.g., CIM or CIP).
b. Subjective Evaluation Criteria
   (1) preparedness for meetings;
   (2) quality of pre-reviews;
   (3) completing and maintaining convened IRB records efficiently and correctly;

(4) knowledge of regulations and identification of areas for improvement;
(5) knowledge of HPHCI policies and procedures and identification of areas for improvement;
(6) communication with IRB Chair;
(7) communication with supervisor;
(8) communication with investigators;
(9) ability to help investigators.

8. The IRB Chair and IRB members may at any time during the year provide feedback to the DRICO or the QA/QI Specialist if performance issues or training needs are identified outside of an annual evaluation process.

9. The DRICO shall report any unexcused absences or member workload issues to the IRB Chair and DRICO.

REVISION HISTORY:

Department: OSP - Research Integrity & Compliance	**Title**: Performance Evaluation of IRB Chair, IRB Members and IRB Staff
Effective Date: 1/28/25	**Owner:** Research Compliance Specialist - QA/QI
Replaces P/P Dated: P/P (3/8/22); P/P (1/15/19); 7/18/18; IRB Membership Evaluation Procedure, Version 015.01 (7/4/17)	
Related Documents: IRB Annual Evaluation Survey	
References: 45 CFR 46.107; 45 CFR46.304; OHRP Institutional Review Board Written Procedures: Guidance for Institutions and IRBs (2018); 21 CFR 56.107; FDA Information Sheets: Non-Local IRB Review, IRB Membership; ICH-GCP: 3.2.1, 3.3.1; AAHRPP Element II.1.B; AAHRPP Tip Sheet 7	