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

Policy and Procedure

TITLE: Scientific or Scholarly Validity of Proposed Research

PURPOSE:

To describe the policy and procedure for review of scientific or scholarly validity of proposed human subjects research activities.

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:

Research involving human subjects must be reviewed for scientific or scholarly validity prior to submission for Institutional Review Board (IRB) review. This review process provides information to the IRB which enables it to determine that all of the following requirements are satisfied:

1. risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and
2. risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

PROCEDURE:

1. The scientific review must be performed by independent reviewers who are not members of the research team or IRB members. Types of review include:

- Department of Population Medicine (DPM) scientific review committee; or
- external review by federal funding agency or external peer-review committee.

2. The actual protocol being submitted to the IRB must be reviewed in its current form. Peer review of a grant that describes research in general terms does not meet these requirements. Industry-sponsored clinical trials designed by the sponsor with or without external consultants do not satisfy the criterion for independent peer-review.

3. The principal investigator (PI) is responsible for certifying and the Grants Manager is responsible for confirming that the scientific review had been conducted.

4. During the screening of the initial study review, IRB staff will confirm that the PI has indicated the type of scientific review in the Initial Application submitted through IRBNet.

5. The Office of Sponsored Programs Director or IRB staff may require the PI to submit copies of scientific validity review documentation prior to approving project submissions.

6. The IRB shall not begin review of any proposed human subjects research activity unless there is documentation that the scientific review had been completed.

REVISION HISTORY:

Department: Office of Sponsored Programs	**Title**: Scientific or Scholarly Validity of Proposed Research
Effective Date: 12/8/22	**Owner:** Director, Office of Sponsored Programs, Research Integrity and Compliance Officer
Replaces P/P Dated: IRB SOP (02/17); P/P (01/21/19, 11/26/19)	
Related Documents: Forms: Initial Application, Initial Application – Data/Health Information; Grant Manager Project Checklist; Reviewer Sheets: Initial Review, Continuing Review	
References: 45 CFR 46.111(a)(1)(i); 45 CFR 46.111(a)(2); 21 CFR 56.111(a)(1)(i); 21 CFR 56.111(a)(2); ICH-GCP: 2.4, 2.5, 2.13; AAHRPP Element I.1.F.	