Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute, LLC

Office of Sponsored Programs

Policy and Procedure

TITLE: Human Research Protection Program Oversight

PURPOSE:

To describe the policy and procedure for determining whether proposed activities are subject to human research protection program (HRPP) oversight.

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:

HPHC/I follows written policies and procedures for determining when activities are overseen by the HRPP. It is the responsibility of all HPHC/I personnel, including employees, faculty, staff, students, contractors and volunteers to seek Institutional Review Board (IRB) review before engaging in any activity involving humans or human data. Research that has been approved by the IRB may be subject to further appropriate review by HPHC/I administrators. However, those administrators may not approve research if it has not been approved by the HPHC IRB.

DEFINITIONS (see GLOSSARY for meaning of listed terms):

Clinical Investigation under FDA regulations
Engaged
Generalizable Knowledge
Human Subject
Interaction
Intervention
Principal Investigator (PI)
Private Information
Research
Sponsor
Systematic Approach

PROCEDURE:

1. The IRB shall review and approve all proposed research activities before any HPHC/I personnel can engage in human subjects research. HPHC/I personnel are considered engaged in human subjects research and come under the purview of HPHC's HRPP when they obtain for the purposes of the research project:

- information or biospecimens about the subjects of the research through intervention or interaction with them;
- identifiable private information or identifiable biospecimens about the subjects of the research; or
- the informed consent of human subjects for the research.

2. For all research involving human subjects, the PI shall submit an IRB application via IRBNet. For all activities not involving human subjects or education and training, HPHC/I personnel shall submit a *Not-Human Subjects Research Determination* form in IRBNet detailing the proposed undertaking.

3. The IRB Chair (or Senior Compliance Manager designee) is responsible to review the *Not-Human Subjects Research Determination* form and make the decision as to whether the activities meet either:

a. the United States Department of Health and Human Services (DHHS) definitions of "engaged", "research", and "human subjects"; and/or
b. the Food and Drug Administration (FDA) definitions of "clinical investigations" and "human subjects."

If the activities meet the respective definitions, the IRB will determine that the proposed project constitutes human subjects research and falls under the purview of HPHC's HRPP.

4. The IRB Chair (or designee) shall be familiar with regulations, organizational policies, and the nature of the research.

5. The determination by the IRB Chair (or designee) of whether an activity constitutes human subjects research or not, shall be based on all applicable international, federal and state regulations, statutes, codes, guidance and HPHC/I policies, and such review shall be noted in the IRBNet reviewer comments.

6. In some cases, IRB staff may ask the PI to complete and submit an initial application to the IRB in addition to the *Not-Human Subject Determination* form (see the *Policy and Procedure on Initial Full Review and the Policy* and *Procedure on Initial Expedited Review* for requirements for submission). Instructions on the *Not-Human Subjects Determination* form indicate that if HPHC is the prime recipient of a federal award through a grant, contract or cooperative agreement but another institution or entity is charged with carrying out the not-exempt human subjects research activities, the Office for Human Research Protections (OHRP) considers HPHC engaged in human subjects research and HPHC IRB approval is required.

7. When the *Not-Human Subjects Research Determination* form is submitted, IRB staff is alerted to a *New Project* submission in IRBNet via email and by the appearance of the *New Project* submission flagged in the *Submissions Manager* page in IRBNet.

8. A *New Project* submission that seeks an IRB determination of not-human subjects research must include the following:

a. a completed HPHC *Not-Human Subjects Research Determination* form and applicable attachments;
b. the study protocol or statement of work;
c. the PI's electronic signature; and
d. the grant manager's signature (for HPHC studies) or Atrius Health Director of Research signature (for Harvard Vanguard Medical Associates/Atrius Health studies).

9. This *New Project* submission may also include:

a. IRB approvals from other institutions (when appropriate); and
b. other materials as requested.

10. If the submission is missing information or requires clarification, the submission package is "unlocked" by IRB staff and the required follow-up is listed in the message to the PI detailing the reasons for this action. Once the required information is present and all updates are made, the PI (or PI's designee) will mark the revisions complete in IRBNet which queues the submission back to IRB staff.

11. When the submission is complete, the IRB Chair or Senior Compliance Manager (SCM) shall determine whether a research proposal meets or does not meet the definition of human subjects research by reviewing the proposed activities as set forth in the *Not-Human Subject Research Determination* form.

12. Specifically, for non-FDA funded research, the IRB Chair or SCM shall determine the existence of two key elements:

a. the activity involves a systematic investigation; and
b. the goal/purpose/intent of the activity is to develop or contribute to generalizable knowledge.

13. Having none or only one of these key elements means that the non-FDA funded activity is not research and should not be handled by the IRB.

14. If it is determined that the activity includes both elements, then the next step is to determine whether the activity involves "human subjects."

15. Specifically, for non-FDA funded research, the IRB Chair or SCM shall determine if the activity involves a living individual about whom the person planning to conduct research will obtain data through intervention or interaction with the human subject or identifiable private information.

16. If the key elements indicate there is no involvement of human subjects, under both the DHHS and the FDA regulations, the SCM will proceed with Step 17. If human subjects are involved in the research, the PI will be notified to submit an Initial Application in IRBNet for IRB review.

17. The SCM will:

a. update the *Review Details* of the submission in IRBNet and assign it for administrative review. The IRBNet "administrative agenda date" for review on Not-Human Subjects submissions is "12/30/1990". IRB staff will record any notes in the comments section of the package in IRBNet; and
b. *Share* the submission assigning her/himself as the primary reviewer and assigning the IRB Chair as a secondary reviewer, if necessary. The SCM will click on the alarm bell in IRBNet if assigning the submission to the IRB Chair to ensure automatic notification of a completed review.
c. When assigning the submission to the IRB Chair, the SCM will also notify the IRB Chair that the submission is ready by clicking to notify users that access to the submission has been granted and including a note regarding the submission.

18. The SCM and IRB Chair (as applicable) will:

a. record any comments regarding their review in the IRBNet *Reviewer Comments* section;
b. upload the *Not-Human Subjects Research Reviewer Sheet*;
c. record the determination of the review; and
d. mark the review complete.

19. If the IRB Chair (or SCM delegate) requests additional information prior to completing the review, the SCM will follow-up with the PI and/or Project Manager, and will notify the IRB Chair when a reply has been received.

20. After the not-human subject determination has been made, the SCM will update IRBNet with the appropriate determination within 5 days following the review. The following fields will be updated:

a. Review Type, Action, Effective Date, Project Status; and
b. The *Discussion and Remarks* field in IRBNet will be updated noting the project was determined to be not-human subjects research.

21. If applicable, a not-human subjects research determination letter will be generated using the *Not-Human Subjects Research Determination Letter Template*.

22. The letter will be published in IRBNet and the notification of the published letter will automatically be sent to the PI or delegate in IRBNet.

23. The SCM will apply submission tag(s) as applicable to the study.

24. If applicable, the IRB staff will use the *Project Notes* section in IRBNet to document any special requirements or notes that apply to the entire study that are unavailable by tag. *Project Notes* can only be viewed and edited by users with administrative access.

25. If the submission is determined to be human subjects research, and no study application has been submitted, the determination letter will include a requirement that the PI submit an initial application in response.

26. Investigators and research staff may contact the SCM with questions regarding what qualifies as human subjects research or what activities need a not-human subjects research determination.

REVISION HISTORY:

Department: OSP – Research Integrity & Compliance	**Title**: Human Research Protection Program Oversight
Effective Date: 01/22/20	**Owner:** Senior Compliance Manager, IRB
Replaces P/P Dated: IRB SOP (02/08/17); P/P (01/21/19, 07/27/18)	
Related Documents: Policy and Procedures: Initial Full Review, Initial Expedited Review; Not-Human Subjects Research Determination Letter template; Reviewer Sheet: Not-Human Subjects Research Determination; Form: Not-Human Subjects Research Determination	
References: 45 CFR 46.101 and 112; 21 CFR 50.1; 21 CFR 50.3(a); 21 CFR 50.3(c); 21 CFR 50.3(g); 21 CFR 50.3(j); 21 CFR 56.101; 21 CFR 56.102(c); 21 CFR 56.102(l); AAHRPP Elements I.1.A. and III.1.A.	