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

Policy and Procedure

TITLE: IRB Authority and Undue Influence of IRB Members

PURPOSE:

To describe IRB authority to protect subjects of human research and to function independently from other organizational entities, free of coercion and undue influence.

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 HPHC Institutional Review Board (IRB) has authority over all research projects that are administered by HPHC or conducted by HPHC/I investigators. It is designated to serve as the IRB for projects with Atrius Health, Inc upon request and for projects that are funded by HPHC or where oversight has been ceded to the HPHC IRB. The principal mission of the HPHC IRB is to ensure that research is designed and conducted in such a manner that protects the rights, welfare and privacy of research subjects. All research involving human subjects, regardless of funding or support, must be reviewed and approved by the HPHC IRB. This includes collaborative and international research conducted by a HPHC/I investigator.

In order to perform this role, the IRB shall function independently of other organizational entities and shall report in a timely manner any potential undue influence on their decisions regarding the safety and welfare of research subjects. The IRB has authority to approve, require modification, disapprove, suspend or terminate approval of research activities, including proposed changes to previously approved research. Disapproval of a research project by the IRB cannot be overridden. The IRB has authority to require progress reports from investigators and to oversee the conduct of a research study. The IRB shall monitor and conduct continuing review of all non-exempt human research at intervals appropriate to the degree of risk. For federally funded

research, continuing review must be conducted not less than once per year, except as follows: Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

(i) Research eligible for expedited review in accordance with 45 CFR 46.110;

(ii) Research reviewed by the IRB in accordance with the limited IRB review (described in 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);

(iii) Research that has progressed to the point that it involves only one or

both of the following, which are part of the IRB-approved study:

(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

PROCEDURE:

1. The IRB's authority to review and provide oversight of all research activities involving human subject is set forth in the HPHC Institutional Review Board Authority Statement and includes:
   - research that is funded by or through HPHC;
   - research that is conducted by or under the direction of an employee or agent of HPHC/I;
   - research that involves the use of HPHC/I property or facilities;
   - research that involves the use of HPHC's non-public information to identify or contact prospective subjects;
   - research that involves the use or disclosure of protected health information (PHI);
   - research where the research population from which subjects will be drawn is exclusively or substantially composed of individuals who are members or employees of HPHC/I;
   - research that is conducted in accordance with the Federalwide Assurances filed with the Office for Human Research Protections in which the HPHC IRB is designated as the IRB of record and has a signed IRB Authorization Agreement (IAA).

2. The IRB has primary responsibility to ensure that:
   - risks to subjects are minimized;
   - risks to subjects are reasonable in relation to anticipated benefits (if any);
   - selection of subjects is equitable;
   - informed consent is obtained in accordance with state and federal regulations;
   - informed consent is appropriately documented, in accordance with state and federal regulations;
   - there are adequate provisions for monitoring data collected, when appropriate, to ensure safety of subjects;
   - there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data, when appropriate;
   - additional safeguards are in place to protect the rights and welfare of subjects who are members of a vulnerable group, when appropriate;
   - timely continuing review of approved research is conducted as appropriate for each study;

- use of PHI is the minimal amount necessary to conduct the research;
- all federal and state laws regarding human subjects research protection are enforced.

3. The IRB has the authority to place restrictions on a study or to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. The Chair may also temporarily suspend conduct of any research until the next meeting of the convened IRB. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly in a letter to the investigator, appropriate institutional officials and the Food and Drug Administration ("FDA") and/or Office of Human Research Protections ("OHRP") as appropriate.

4. The IRB has the authority to inspect research facilities, obtain records and other relevant information relating to the use of human subjects in research, and take such actions that are in its judgment necessary to ensure compliance with applicable federal and state law, and the policies and procedures to be established hereunder, including action to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

5. The IRB has the authority to observe or appoint a designee to observe the informed consent process and IRB approved research activities.

6. The IRB may determine that some research projects require verification from sources other than the investigator to confirm that no unapproved changes have occurred since the previous IRB review. The IRB may direct verification through the use of audits of research records, inquiries, and/or observing the informed consent process and conduct of the research. The IRB and IO and/or authorized HPHC /HPHCI officials have authority to monitor research reviewed by the IRB.

7. Non-exempt human subjects research conducted without IRB approval is an act of serious noncompliance with the federal regulations and HPHC/I policy. If non-exempt human subjects research is or has been conducted by HPHC/I investigators and/or staff without IRB approval, any person with knowledge about this shall immediately report it to the IRB and Institutional Official (IO). Corrective steps will be taken to ensure the investigator is aware of all federal, state, and local policies and procedures. Investigators will be asked to immediately stop all research and inform any journals, meetings, etc. where research was presented or where presentation is pending that the research was conducted without IRB approval. Reports to regulatory agencies will be made in accordance with the *Policy and Procedure on Reporting and Review of Adverse Events, Protocol Deviations, Protocol Violations, and Unanticipated Problems*.

8. The IRB functions independently of other HPHC/I committees that deal with human research protections, including:
- Conflict of Interest Management Committee (COIMC)
- Research Integrity Committee (RIC); and
- HPHCI Research Compliance Committee.

9. Reporting undue influence of IRB members and staff

When there is a perceived occurrence of undue influence of an IRB member or IRB staff, a verbal and/or written complaint shall be made to the IRB Chair, Senior Compliance Manager, IRB (SCM), or the Research Integrity and Compliance Officer (RICO) who will report the incident to the IO. The complaint can be anonymous. If an IRB member feels that the undue influence is coming from the IRB Chair or IRB staff, the complaint can be submitted directly to the IO. The RICO will conduct an investigation and document the outcome in a timely manner. When needed, a corrective action plan shall be employed.

REVISION HISTORY:

Department: OSP – Research Integrity & Compliance	**Title**: IRB Authority and Undue Influence of IRB Members
Effective Date: 05/06/19	**Owner:** Research Integrity and Compliance Officer
Replaces P/P Dated: P/P 01/21/19; IRB SOP (02/17)	
Related Documents: Investigators Handbook; HPHC IRB Authority Statement	
References: 45 CFR 46.109(a); 45 CFR 46.109(e); 45 CFR 46.112; 45 CFR 46.113; 21 CFR 56.109(a); 21 CFR 56.109(e); 21 CFR 56.112; 21 CFR 56.113; AAHRPP Element I.1.C; AAHRPP Tip Sheet 12.	