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

Policy and Procedure

TITLE: Quality Assurance and Quality Improvement Program

PURPOSE:

To describe the process for monitoring the quality, efficiency and effectiveness of the human research protection program (HRPP).

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 has established the Quality Assurance/Quality Improvement (QA/QI) component of the Research Integrity & Compliance Program to reflect its strong commitment to maintaining and improving the quality, integrity, efficiency and effectiveness of its HRPP intended to ensure the protections afforded to human research subjects. The HPHC/I Board of Managers has appointed a Research Compliance Committee (RCC) that will assist the Research Compliance and Integrity Officer ("RICO") and the Director of the Office of Sponsored Programs ("Director of OSP") in overseeing and monitoring the HPHC/I research compliance program for the purpose of:

- overseeing, monitoring and improving the HRPP;
- evaluating regulatory compliance and legal conduct;
- identifying and preventing non-compliance and unethical or illegal conduct;
- formulating and utilizing internal controls to promote ethical, regulatory, and procedural compliance;
- creating an environment that encourages personnel to report potential problems without fear of retaliation.

See HPHC/I **Board of Managers Research Compliance Committee Charter**.

DEFINITIONS:

Continuing noncompliance
A pattern of recurring or ongoing instances of actions or omissions which indicates an underlying deficiency in knowledge of the regulations and IRB requirements or willingness to comply with them.

Noncompliance
Conducting research in a manner that disregards or violates applicable laws or institutional policies and procedures applicable to human subjects research. Noncompliance with IRB and/or regulatory requirements may involve a range of issues from relatively minor or technical violations which result from inadvertent errors, inattention to detail, or inadequate training and supervision of research staff to more serious violations which pose risk to subjects and/or violations of their rights and welfare.

Serious noncompliance
Knowingly disregarding or violating applicable laws or institutional policies and procedures applicable to human subjects research, which, in the judgment of the IRB, could place subjects at an increased risk of harm.

PROCEDURE:

1. The RICO shall have sufficient resources, including funding and staff to develop, implement and maintain a research compliance program set out in an annual work plan and comprised of:
    - an effective leadership structure that involves collaboration between the Director of OSP and the RICO, the RCC, the Conflicts of Interest Management Committee ("COIMC"), the Research Integrity Committee ("RIC") and the IRB;
    - clearly stated standards responsive to HPHC/I's regulatory and risk environment including written policies and procedures and standards of conduct;
    - effective training and education programs for HPHC/I employees;
    - auditing and monitoring processes capable of reliably reporting performance, achievement of research compliance standards, and discovering material and previously undetected compliance gaps;
    - investigation of non-compliance including reported conflicts of interest or research misconduct and development of recommendations for active management of such cases, evaluation of deviations from study protocols, adverse events and unanticipated issues;
    - publication of reporting pathways for research study participants and staff for the voicing of concerns about the conduct of research;
    - enforcement procedures for ensuring prompt response to confirmed violations of regulatory requirements; and
    - the annual work plan which is intended to be flexible and adaptable to the needs of HPHC/I. The annual work plan shall be reviewed by the RCC and revised as deemed necessary.

2. IRB Post Approval Review Monitoring

The IRB shall implement/maintain a Post Approval Review (PAR) process to monitor approved research activities in order to ensure that ethical, technical and legal requirements are met and to improve the quality of research for the purpose of protecting human research subjects. The PAR

process will:

- assess active, ongoing IRB approved studies for compliance with approved protocols and with laws, regulations and HPHC/I policies and procedures;
- perform quality assurance reviews and audits of selected studies;
- monitor the informed consent process;
- detect errors and/or omissions that may occur during research activities;
- provide feedback to investigators, the IRB members and staff;
- respond to feedback from investigators, the IRB members and staff;
- develop strategies for improving the quality of research through self-assessments, policy development and educational programs;
- assist investigators to improve their research processes by sharing best practices; and
- protect the integrity of research by identifying and correcting significant deficiencies in approved research protocols.

3. The RICO and designated staff shall have the access to and the authority to review all documents and other information relevant to compliance monitoring and shall:

- conduct random, routine and for-cause audits; review reports, monitoring letters, and final audits of research studies by other institutions or sponsors;
- monitor the functioning of the IRB for efficiency and compliance with ethical standards, regulations and HPHC/I policies and procedures; and
- assess IRB meeting agenda and minutes to ensure regulatory, technical and ethical compliance as well as approval process efficiency.

4. All research activities, including exempt research, are subject to quality monitoring. Emphasis will be given to studies that:

- present greater than minimal risk to subjects;
- involve vulnerable populations;
- are initiated by the investigator;
- involve or may involve a conflict of interest;
- have known compliance problems; or
- involve the testing of a drug or device for which the investigator holds an IND or IDE.

5. QA/QI Measuring and Monitoring Tools include but are not limited to the following used to evaluate*:*

a. IRB Chair, members and staff:
   - IRB Chair and Members self-evaluation form;
   - IRB staff self-evaluation form;
   - Harvard Catalyst Minutes Quality Improvement Assessment form;
   - Harvard Catalyst Collaborative Quality Improvement Program (CQIP) Task Force assessment tools to review IRB meeting minutes and non-human subject determinations.

b. Investigators:
   - OHRP QA Program and Self-evaluation Tool;
   - Grant Managers Checklist;
   - Submission Screening worksheets and checklists

- Harvard Catalyst Post Approval Monitoring Program worksheet;
- PAR follow-up notification of findings, results and recommendations;
- Investigators self-evaluation form;
- Investigators feedback form.

c. Others:
- Grant Managers records review and assessment;
- Participants feedback form;
- Workstation Use and Security Monitoring form.

6. Allegations of non-compliance

The RICO or designated staff shall review and investigate allegations of non-compliance against investigators, staff, other personnel or the IRB in a timely manner. Reports of non-compliance may be submitted by anyone verbally, in writing, or by telephone via the Hotline: 1-800-807-6812, in accordance with the *Policy and Procedure on Concerns, Complaints, and Questions about the Human Research Protection Program*. If the RICO or designated staff determines that the allegation on non-compliance has a basis in fact, they will refer the matter to the Legal Department, the Institutional Official (IO) or the IRB chair, the Compliance Committee, RIC, FCOIMC, or appropriate regulatory agency, as circumstances dictate.

If the IRB Chair determines that the alleged non-compliance is minor or administrative in nature, they may decide that:

- no further action is needed;
- further action is necessary;
- the matter should be presented to the convened IRB.

When the IRB chair decides to present the matter to the convened IRB, the Senior Compliance Manager, IRB (SCM) shall distribute all the pertinent material as a *Special Project* submission in IRBNet to all IRB members. The IRB shall review these materials and discuss the matter at a convened meeting at which a quorum is present. The IRB may request advice from the RICO or outside legal counsel or request additional information.

When the convened IRB finds that the allegation of non-compliance is substantiated and the human subjects research involves serious or continuing non-compliance, they may consider the following actions:

- suspension or termination of IRB approval of research as per the *Policy and Procedure on Termination or Suspension of IRB Approval*;
- implementation of a corrective action plan including additional education and training;
- notification of current participants;
- provision of additional information to past participants;
- requirement for re-consent;
- requirement for investigators to modify the protocol;
- more frequent continuing review;
- additional monitoring and auditing.

In cases of serious or continuing non-compliance, the RICO shall prepare a report for submission to the IO and the Office of Human Research Protection (OHRP) and other applicable regulatory agencies. When research is FDA regulated, the IRB shall require the investigator to report to the sponsor who must report to the Food and Drug Administration ("FDA"). If the investigator is

also the sponsor, then the investigator is required to report directly to the FDA. The IRB can choose to prepare and send the report directly to the FDA, if deemed appropriate.

7. External Audits

Investigators shall notify the IRB office immediately upon receipt of notice of upcoming audit or investigation.

8. Sponsor Monitoring Reports

Investigators shall submit a copy of external sponsor monitoring reports in IRBNet within 10 (ten) days of receipt.

REVISION HISTORY:

Department: OSP – Research Integrity & Compliance	**Title**: Quality Assurance and Quality Improvement Program
Effective Date: 01/21/19	**Owner:** Research Compliance Specialist, QA/QI
Replaces P/P Dated: IRB SOP (02/17)	
Related Documents: Policy and Procedures: *Termination or Suspension of IRB Approval; Concerns, Complaints, and Questions about the Human Research Protection Program*; Forms: IRB Chair, Members and Staff self-evaluation; Grant Managers checklist; Reviewer Sheet: Reportable Events	
References: 45 CFR 46.103(b)(5)(i); 45 CFR 46.116(b)(5); 21 CFR 50.25(b)(5); 21 CFR 56.108(b)(2); AAHRPP Elements 1.5.A, 1.5.B and I.5.D; AAHRPP Tip Sheets: 14 and 21; Harvard Catalyst Post Approval Monitoring Program worksheet; HPHCI Board of Managers Research Compliance Committee Charter	