

**Harvard Pilgrim Health Care Institute, LLC  
Board of Managers  
Research Compliance Committee  
Charter**

**I. Purpose**

The Board of Managers of Harvard Pilgrim Health Care Institute, LLC (“HPHCI” or “Institute”) will appoint a Research Compliance Committee (“Committee”) that will assist the Research Integrity and Compliance Officer (“RICO”) and the Director of the Office of Sponsored Programs (“Director of OSP”) in overseeing and monitoring the research compliance program of Harvard Pilgrim Health Care, Inc. (“HPHC”) and HPHCI.

The Committee will strive to enhance the quality, productivity and efficiency of the compliance program while reducing the probability of improper or unethical conduct and legal liability for HPHC and HPHCI. The RICO, the Director of OSP and the Committee will develop, implement and oversee HPHC’s and HPHCI’s research compliance program. They will seek to guide the HPHC and HPHCI community regarding the responsible conduct of research by:

- articulating and demonstrating a commitment to regulatory compliance and legal conduct;
- identifying and preventing unethical or illegal conduct;
- formulating and utilizing internal controls to promote compliance with internal policies and procedures, state and federal laws and regulations;
- creating an environment that encourages employees to report potential problems without fear of retaliation by other employees or management; and
- developing, implementing and overseeing HPHC’s and HPHCI’s research compliance program.

**II. Membership and Roles**

The Committee will be co-chaired by the RICO and the Director of OSP who are together accountable for:

- providing leadership of the Committee to ensure its purposes are achieved;
- responding to research compliance concerns, violations and initiatives;
- convening meetings, creating agendas and facilitating proceedings;
- assuring documentation of discussion, decisions and next steps;
- facilitating communication among Committee members, and
- communicating with management on issues/progress as needed.

The Committee shall include as many members of the HPHC Board of Managers as required to comply with the Board of Managers Operating Agreement as well as the following individuals who have the skills, responsibility and seniority necessary to represent HPHC’s and HPHCI’s research program:

- the RICO (co-chair);
- the Director of OSP (co-chair);
- a scientist/researcher on the Institute’s faculty;
- the Director, Institute Administration;

- the Manager, Administration;
- HPHC Legal Counsel;
- HPHC Vice President of Corporate Compliance; and
- Such other individuals with other expertise (e.g., human resources) in the judgment of the Committee, would be able to assist the Committee on specific matters from time to time.

### III. Responsibilities

The Committee shall oversee the development, implementation and maintenance of:

1. an effective **structure** to manage the research compliance function including collaboration between and among the Director of the OSP and the RICO, the Committee, the Conflicts of Interest Management Committee, the Research Integrity Committee and the Institutional Review Board;
2. clearly stated **standards** and expectations responsive to HPHC's and HPHCI's regulatory and risk environments including written policies, procedures, and standards of conduct which articulate the organization's commitment to comply with all applicable state and federal requirements;
3. effective **training and education** programs for HPHCI and HPHC employees including initiatives designed to provide consultation for Institute faculty and staff on the development of compliant research protocols, promote detection of potential violations, an emphasis on compliance with pertinent requirements, general and specific training focused on standards and expected behaviors, and options for responding to compliance questions from staff;
4. **auditing and monitoring** processes capable of reliably reporting performance, achievement of research compliance standards, and discovering material and previously undetected compliance gaps;
5. **investigation** of 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;
6. publication of **reporting** pathways for research study participants and staff for the voicing of concerns about the conduct of research, including allegations of noncompliance with the law, research misconduct or alleged violations of HPHCI's Code of Conduct. Promote and maintain effective lines of communication between and among the RICO and the Director of the OSP, and employees, including options for anonymity; and
7. **enforcement** procedures for ensuring prompt response to confirmed violations of regulatory requirements and HPHCI's Code of Conduct, policies and procedures in accordance with a violator's employment status for applying corrective actions involving sanctioned individuals.

### IV. Meetings

Internal Use Only

Regularly scheduled meetings will occur at least on a quarterly basis. Ad-hoc meetings may be called as needed. Agenda and supporting documentation will be distributed in advance and minutes will follow within one week of each meeting.

## **V. Documentation**

Committee co-chairs will document Committee activities through meeting agenda, minutes, work plans and any corrective action plans, and assure that all documentation supporting the Committee's activities is maintained.

## **VI. Reporting**

Committee co-chairs will report to the HPHCI's Board of Managers at each of its meetings, including their annual recommendations for edits to the Committee's Charter and any membership changes.

## **VII. Approval**

Revised Section II to provide flexibility in reference to Board of Managers roles except for HPHC Vice President of Corporate Compliance who is also the research Institutional Official. "

Pending approval by HPHCI's Board of Managers on December 17, 2020