

**Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute, LLC
Office of Sponsored Programs
Policy & Procedure**

TITLE:

Policy & Procedure on Policy & Procedure Development and Implementation

PURPOSE:

To provide for the development, implementation, review, revision and administration of policies and procedures (P&P) relating to the conduct of research, teaching or research administration activities in support of the charitable and educational mission of Harvard Pilgrim Health Care, Inc. (HPHC).

PERSONS AFFECTED:

All HPHC and Harvard Pilgrim 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 Department of the Office of Sponsored Programs (OSP) must have written P&Ps, in the format provided in the **Appendix – Template**, that address issues related to compliance with federal, state and local statutes and regulations (applicable laws), applicable ethical and accreditation standards of the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP standards), and OSP and Department of Population Medicine (DPM) practices.

OSP P&P should be reviewed annually to ensure continued compliance with applicable laws, applicable AAHRPP standards, and OSP and Department of Population (DPM) practices. Changes to HPHCI OSP P&Ps will be reviewed and approved by the Director of OSP and/or the Research Integrity & Compliance Officer (RICO), as applicable.

If, during the course of a year, an applicable law, AAHRPP standard, or OSP/DPM practice is revised or a need is discovered to update a specific P&P, the P&P should be reviewed and updated as soon as possible.

DEFINITIONS:

This section intentionally left blank.

PROCEDURES:

Development of P&Ps

1. Before drafting a new P&P, determine if there is an existing P&P that addresses the issue. If one exists, ascertain if it is valid and current. If one does not exist or it is invalid, proceed with developing a new P&P. If the existing P&P is not current, proceed with a revision.
2. The P&P should be created in a document with 1-inch margins, using the Times New Roman and 12 pitch fonts. The grade level should be 12 or below. P&P sentences shall be short, focused and simple.
3. The Author/Owner of the P&P must follow the P&P Template available in the **Appendix - Template** to this P&P.
4. Each P&P must include the six headings: **PURPOSE; PERSONS AFFECTED; POLICY; DEFINITIONS; PROCEDURE;** and **REVISION HISTORY**. These six headings will always appear in the sequence presented in the Template. Subsequent sections within the PROCEDURE section will be by sequential numbers. For example: 1, 2, 3, etc.
5. Describe the “PURPOSE” of the P&P by explaining the objective(s) for writing the document. Abbreviations or acronyms should not be used if they have not been explained yet.
6. Describe the “PERSONS AFFECTED” as set forth in the Template.
7. Describe the “POLICY” and provide a statement that reflects the organization’s attitude, objectives, goals and or vision, as applicable.
8. Describe the “DEFINITIONS” used in the PROCEDURE section of the document, including abbreviations, acronyms, forms, words infrequently used, and technical terms.
9. Document the “PROCEDURE” with a step-by-step description of the performance of the task(s).
10. Insert and complete a REVISION HISTORY box using the same format as set forth at the end of this document.

Approval

The completed P&P must be reviewed and approved by the Director of OSP – for Grants & Contracts Administration-related P&P and the RICO – for Research Integrity & Compliance-related P&P.

Revising Existing Policies

1. The Author/Owner of a P&P is responsible for reviewing and updating each P&P on an annual or as-needed basis. The Author/Owner/reviewer should redline each P&P and submit it for review to the Director of OSP and/or the RICO.

2. Each P&P should be reviewed for compliance with the most current reference materials, including statutes, regulations, AAHRPP accreditation standards, and other requirements, as applicable.
3. The REVISION HISTORY should be updated to include updated citations to the reference materials reviewed.
4. The Director of OSP and/or RICO, as applicable, shall present new P&P and P&P with substantive revisions to the Research Compliance Committee.

Retiring an Existing Policy

1. The Author/Owner of a P&P is responsible for providing the Director of OSP and/or the RICO with notice of the need to retire an existing P&P.
2. The Director of OSP and/or the RICO shall review and retire the P&P, as applicable.
3. Retired P&Ps may be deleted from the system or may be moved to a section designated for retired P&P and filed by date.

Annual Review

1. The Department of OSP will review all P&P annually.
2. The P&P Author/Owner should prepare revisions, retirements, and new P&Ps as required based on the annual review.

Implementation of Policies and Procedures

1. The OSP Training Coordinator will distribute the approved P&P via LiveWire, the HPHCI website, an email blast, and the Institute’s monthly newsletter, as applicable.
2. The OSP Training Coordinator will be responsible for conducting the P&P implementation training plan along with the P&P Author/Owner, as applicable.

REVISION HISTORY:

| | |
|---|---|
| Department: OSP | Title: Policy and Procedure on Policy and Procedure Development and Implementation |
| Effective Date: 7/1/2019 | Author/Owner/Owner: Charlotte Johnson |
| Reviewed By/On: Amy Hudspeth Cabell 6/7/2019 | |
| Replaces P&P Dated: “Updating Policies” 9/14; 11/11/16; 5/1/2017. | |
| Related Documents: | |
| References: Amended and Restated Certificate of Organization of HPHCI, LLC; HPHCI 2013 Annual Report | |
| Approved By: Charlotte Johnson, Amy Hudspeth Cabell | |

Appendix - Template

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

or

[Office of Sponsored Programs – Grants & Contracts Administration]

or

[Office of Sponsored Programs - Research Integrity & Compliance]

Policy and Procedure

TITLE:

PURPOSE:

To ...

PERSONS AFFECTED:

All Harvard Pilgrim Health Care, Inc. (HPHC) and Harvard Pilgrim 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, Inc.

POLICY:

DEFINITIONS:

Sample: Use italics for the defined term, acronym or abbreviation.

PROCEDURE:

Procedure steps shall be numbered

1. For example
2. For example

REVISION HISTORY:

| | |
|--------------------------------|----------------------|
| Department: | Title: |
| Effective Date: | Author/Owner: |
| Reviewed By/On: | |
| Replaces P&P Dated: | |
| Related Documents: | |
| References: | |
| Approved By: | |