

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

SCOPE

This policy & procedure (P/P) applies to 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.

PURPOSE

To provide for the development, implementation, review, revision and administration of P/P relating to the conduct of research, teaching or research administration activities in support of the charitable and educational mission of HPHC, Inc.

POLICY

1. The Department of the Office of Sponsored Programs (OSP) must have written P/Ps that address issues related to compliance with federal, state and local statutes and regulations (laws), applicable ethical and accreditation standards, and OSP and Department of Population Medicine (DPM) practices.
2. All OSP P/P must be prepared in the format provided in the **Appendix - Template**.
3. Changes to HPHCI OSP policies will be reviewed and approved by the Director of OSP and/or the Research Integrity & Compliance Officer (RICO), as applicable.
4. OSP P/P should be reviewed annually to ensure continued compliance with federal, state and local laws, applicable ethical and accreditation standards, and OSP and Department of Population (DPM) practices.
5. If, during the course of a year, an applicable law, standard, or 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.

PROCEDURE

Section I – 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 using the Times New Roman font. The font size should be 12 pitch. The grade level should be 12 or below.

3. The author of the P/P must follow the P/P Template available in the **Appendix - Template** to this P/P. The P/P Template is also available in electronic format on LiveWire.
4. When developing a new P/P, keep sentences short, focused and simple.
5. Describe the “SCOPE” of the P/P. The SCOPE used for most OSP P/P is: This policy & procedure (P/P) applies to all Harvard Pilgrim Health Care, Inc. (HPHC) and Harvard Pilgrim Care Institute, LLC (HPHCI) (collectively, HPHC/I) employees who conduct research, teaching or research administration activities in support of the charitable and educational mission of HPHC, Inc.”
6. Describe the “PURPOSE” of the P/P.
7. Describe the “POLICY.” The POLICY statement describes the P/P.
8. Document the “PROCEDURE.” The PROCEDURE is a step-by-step description of the performance of a task.
9. Complete the bottom section on the last page of the P/P Template by identifying the information below in the box on the last page of the document.
 - a. “Effective Date” will be the date the P/P is to be implemented.
 - b. “Version#.” is the version number.
 - c. “Reviewed On” indicates the year and month the policy was reviewed, even if not updated.
 - d. “Replaces P/P Dated” indicates the date of the policy replaced.
 - e. “Related Documents” lists all applicable documents (such as forms, checklists, reviewer sheets, etc.) used in performance the procedure.
 - f. “References” indicates the applicable laws or accreditation standards.
 - g. “Approved By” indicates approval by DOSP for Grants related P/P and the RICO for research integrity & compliance related P/P.

Department: OSP	Title: Policy and Procedure on Policy and Procedure Development and Implementation
Effective Date:	Version #:
Reviewed By/On:	
Replaces P/P Dated:	
Related Documents:	
References:	
Author:	
Approved By (Director of OSP or RICO):	

Section II – Approval

1. The completed P/P must be reviewed and approved by the Director of OSP – for Grants-related P/P and the Research Integrity & Compliance Officer (RICO) – for Research Integrity & Compliance- related P/P.

2. The Director of OSP or RICO, as applicable, shall present the P/P to the Committee.

Section III – Revising Existing Policies

1. The author of a P/P is responsible for reviewing and updating each P/P on an annual or as-needed basis. The P/P should redline each P/P and submit it for review to the Director of OSP and/or the RICO.
2. The Director of OSP and/or RICO, as applicable, shall present the P/P to the Committee.

Section IV – Retiring an Existing Policy

1. The author 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 authorize the retirement, 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.

Section V – Annual Review

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

Section VI – 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, as applicable.

Department: OSP	Title: Policy and Procedure on Policy and Procedure Development and Implementation
Effective Date: 5/1/2017	Version #:
Reviewed By On: Amy Hudspeth Cabell 7/19/17	
Replaces P/P Dated: “Updating Policies” 9/14; 11/11/16.	
Related Documents:	
References: Amended and Restated Certificate of Organization of HPHCI, LLC; HPHCI 2013 Annual Report	
Author:	
Approved By: Charlotte Johnson, Amy Hudspeth Cabell	

Appendix - Template

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

SCOPE

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PURPOSE

To provide for...

POLICY

PROCEDURE

Department:	Title:
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Author:	
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