



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

**Policy and Procedure**

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**TITLE:** Community Outreach

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**PURPOSE:**

To enhance the public's understanding of research.

**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 provides information and resources designed to enhance the understanding of human subjects research by participants, prospective participants and their communities and performs annual evaluation of these outreach activities for improvement.

**DEFINITIONS:**

*Community Outreach*

Information designed to enhance the understanding of human subjects research activities involving participants, prospective participants and their community and may be provided by pamphlets or brochures, web site information, educational outreach such as a "Research Day," a mini-medical school, speakers bureaus, evaluation reports, and quality improvement plans. These activities may be performed by HPHCI alone or in collaboration with other organizations.

**PROCEDURE:**

1. Provision of outreach activities to participants, potential participants and their communities  
Information on community outreach activities may be provided in the following ways, depending on particular research activities.

- a. HPHC web site <https://www.harvardpilgrim.org/public/home>
  - (1) Hotline telephone #
  - (2) IRB Office contact information (email and telephone #)
  - (3) Research Integrity & Compliance Officer (email and telephone #)
  - (4) Office for Human Research Protections (OHRP) website link.
  - (5) Food and Drug Administration (FDA) website link.
  - (6) Training and Education Program information managed by the Training Coordinator.
  - (7) Office of Research Integrity (ORI) website link.
  - (8) Harvard Catalyst website, Research Subject Advocacy Link:  
<https://catalyst.harvard.edu/services/rsa>
  - (9) Office of Civil Rights (OCR) website link.
  - (10) Massachusetts Department of Public Health (DPH) website link.
- b. Department of Population Medicine web site ([www.populationmedicine.org](http://www.populationmedicine.org)):
  - (1) The external website [www.populationmedicine.org](http://www.populationmedicine.org) and the HPHCI LiveWire page both contain information about faculty blogs, publications, trainings etc.
  - (2) Faculty pages on [www.populationmedicine.org](http://www.populationmedicine.org) include faculty participation on state and national committees, committees at Harvard Medical School, etc.
  - (3) Presentations are included on the faculty pages as well.
  - (4) The external website provides links to Division pages (TIDE, CoRAL, CHeRP, HPI) and Centers (PRoMoTR, CARPe) and publications.
  - (5) Faculty Trainings.

## 2. Development and Assessment of Community Outreach

- a. In December of each year, an HPHCI team of individuals consisting of: the Office of Sponsored Programs (“OSP”) Training Coordinator; the Director of OSP; the Senior Compliance Manager, Institutional Review Board (IRB); the Research Integrity & Compliance Officer; the IRB Chair; the Research Compliance Specialist, QA/QI; the Manager of Communications and Training; the Manager, Institute Administration; the Executive Director, Institute Administration; and a member of the DPM Diversity Committee or delegate shall meet to develop a community outreach plan for the upcoming year.
- b. The group shall consider efforts that inform the community at large about HPHCI’s research activities and methods to increase inclusiveness and ethnic and language diversity. Depending on the activity, the group may consider additional HPHC/I collaboration with community partners such as Harvard Catalyst, Public Responsibility in Medicine and Research (“PRIM&R”), etc.
- c. The group shall describe how the outcome(s) will be measured and reported.
- d. The group may also recommend revising website information geared toward research participants that includes some variation of the following Frequently Asked Questions:
  - (1) What is research?
  - (2) Where can I find more information about research at HPHC/I?
  - (3) How can I get more information about my rights or if I have a problem?
  - (4) Who can I contact if I have a complaint or concern about a study?
  - (5) What happens when the study ends?
  - (6) What happens if I leave a study?
  - (7) Who else will know that I am participating in research?

- (8) How do I protect my rights if I volunteer as a research participant?
  - (9) How will I know if my data is being used in research?
  - (10) Will I be paid for participating in research?
  - (11) What are the benefits of participating in research?
  - (12) What questions might I want to ask before agreeing to participate?
  - (13) What information should the investigator give to me?
  - (14) How does HPHC/I protect research participants?
  - (15) How does HPHC/I protect research participant data?
  - (16) What are participants commonly asked to do?
- e. In November of each year, the community outreach efforts of the current year shall be evaluated by that group to determine effectiveness. The group shall describe the quantitative and qualitative tools and techniques it will employ to measure the outcome(s) and how the “lessons learned” will be identified and documented. This team shall consider any complaints, concerns, suggestions, and other input from the public, participants or others within the research community. Metrics used to measure effectiveness may include:
- (1) number of effective collaborations with other entities such as other educational institutions or research organizations;
  - (2) number of effective collaborations with HPHC/I alumni;
  - (3) number of IRB members involved with the community in research-related outreach activities;
  - (4) increase in the number of recruited and involved research participants as IRB members;
  - (5) measurement of HPHC/I’s participation in programs that introduce human research protection programs and/or community engagement in research;
  - (6) program descriptions in the HPHC Annual Community Benefits Report; and
  - (7) tracking activities designed to reach out to diverse communities.

**REVISION HISTORY:**

<b>Department:</b> OSP - Research Integrity & Compliance	<b>Title:</b> Community Outreach
<b>Effective Date:</b> 06/22/20	<b>Owner:</b> Research Integrity & Compliance Officer
<b>Replaces P/P Dated:</b> 01/21/19	
<b>Related Documents:</b> none	
<b>References:</b> AAHRPP Element I.4.B and I.4.C.	