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

Policy and Procedure

TITLE: Collaborations and Agreements with Non-Federal Sponsors

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PURPOSE:

To contribute to the protection of human research subjects in research collaborations with non-federal sponsors.

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 is an ideal environment in which to conduct research in collaboration with non-federal sponsors, including, but not limited to, private and for-profit entities such as pharmaceutical and biotechnology companies. Such collaborations shall be guided by the principles ("Collaboration Guiding Principles") set forth in the next section.

In order to ensure the safety and welfare of human research subjects during collaborative research activities with non-federal sponsors, HPHC shall include sample language in the funding agreement templates that addresses the following:

- medical care and payment in cases of research-related injury;
- mechanism of prompt reporting of adverse events to HPHCI when the sponsor conducts research site visits or remote monitoring;
- provisions for monitoring the data to ensure the subjects' safety and for providing data and safety monitoring reports to HPHCI in cases when the sponsor has the responsibility to conduct data and safety monitoring;
- the roles of investigators and sponsors in publication, dissemination and disclosure of study results; and

- sponsor notification to HPHCI and investigators of study results which may directly affect the subjects' safety to allow HPHCI to consider informing past subjects of potential harm after a study's closure.

PROCEDURE:

A. Agreements with Non-Federal Sponsors.

1. All research collaborations with non-federal sponsors shall be conducted in conformance with agreements prepared by the Grants Managers (GMs) and signed by the Director of the Office of Sponsored Programs (OSP).

2. GMs and others involved in negotiating agreements with non-federal funders, the Institutional Review Board (IRB) staff, and the IRB shall be trained on the requirements in this policy and procedure.

3. GMs shall be able to explain the required provisions to sponsors so that they understand the requirements and include them in the funding agreements.

4. The GMs shall use the *Grant Manager Project Checklist* that indicates whether each item of required language from the Sample Language Template:

- is present in the funding agreement;
- not applicable to the specific research protocol with justification; or
- the sponsor refused to include the language with evidence attached (e.g., e-mails).

5. If the non-federal sponsor refuses to include the requested language, the GMs shall inform the Director, OSP. For example, if the sponsor will not provide data and safety monitoring reports, the IRB will have no basis to assess risk at continuing review and thus the research cannot be approved.

6. GMs shall consult with the Director of OSP and/or the Research Integrity & Compliance Officer (RICO), as appropriate, regarding the appropriate provisions in each agreement on a case-by-case basis.

B. Collaboration Guiding Principles

1. **Value.** Research should serve a public purpose and be conducted for the broadest possible audience. While research studies may be intended to support marketing purposes, there must also be a clear value to the general public.

2. **Strategic.** Collaborative research with non-federal sponsors must be consistent with HPHC/I's business goals and objectives, including being in the public interest.

3. Scientific Merit. Collaborative research studies must be designed to allow the full range of relevant and likely results to be observed. The aims and methods used must be clearly stated in advance. Protocols must have adequate statistical power to provide an informative answer to the questions being posed. Situations in which the study design may be modified should be stated in advance. All protocols must be capable of passing peer review.

4. Participation. Every investigator is expected to take an active role in the development, implementation and reporting of research. Exceptions may be considered when there exists a life-threatening condition and no satisfactory alternative therapy is available, when the proposed therapy is perceived to be a major advance, or when small numbers of subjects from multiple sites are necessary. Collaboration with HPHC/I does not imply HPHC/I's endorsement of a sponsor's product.

5. Publication. HPHCI investigators must retain the right to present and publish any findings. A sponsor may not retain right of approval of the content or timing of publication or presentation, except to protect the sponsor's proprietary information.

6. Data Sharing. HPHC/I investigators shall not provide analyzable datasets to sponsors or others unless pursuant to a written agreement in which the analysis to be performed or proposed use of the data is clearly specified. No additional use will be made of the data without the approval of the HPHC Office of Sponsored Programs.

C. Collaboration Agreement Language

1. Reference to Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) sample language shall be included in the *Grant Manager Project Checklist*.

2. The Senior Compliance Manager (SCM) shall maintain contact with the GMs to ensure consistency between the consent document and the funding agreement.

3. The SCM may review all funding agreements to ensure that the IRB will be aware that its decisions do not conflict with requirements set forth in the agreements.

4. The IRB shall ensure that it has the necessary information to assess risk and to ensure consistency between the consent document and the funding agreement.

5. Prior to finalizing the agreement, GMs shall ensure that written agreements with non-federal sponsors contain the appropriate template language regarding the subject matter described in this policy.

REVISION HISTORY:

Department: OSP – Grants and Contracts Administration	**Title**: Agreements with Non-Federal Sponsors
Effective Date: 02/01/20	**Owner:** Director, Office of Sponsored Programs
Replaces P/P Dated: new; 01/21/19	
Related Documents: Grant Manager Project Checklist; Sample Language Template Regarding Additional Requirements for Agreements with Non-Federal Sponsors	
References: 45 CFR 46.116(a)(6) and (a)(7); 21 CFR 50.25(a)(6) and (a)(7); AAHRPP Element I.8 – A-E; AAHRPP Tip Sheet 25	