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

Policy and Procedure

TITLE: Risk-to-Benefit Analysis

PURPOSE:

To describe the policy and procedure for:

- identifying and analyzing risks and identifying measures to minimize the risks associated with human subjects research; and
- ensuring that these risks are reasonable in relation to the potential benefits to the subjects and to society.

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:

The rights, safety, and well-being of subjects of research are the most important considerations and should prevail over interests of science. Before research is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual subject and for society. Research should be initiated and continued only if the anticipated benefits justify the risks.

When considering risks to subjects of research, investigators and the Institutional Review Board (IRB) must consider the physical, psychological, social, economic and legal risks, including invasion of privacy and loss of confidentiality. In addition, investigators and the IRB must evaluate special considerations of risk to vulnerable populations and groups. When reviewing benefits, investigators and the IRB must consider direct benefits such as therapy, education,

information, resources, or empowerment and indirect benefits such as the importance of knowledge that is likely to result from the research.

DEFINITIONS:

For the purposes of this policy:

Risk: The probability of harm or injury (physical, psychological, social, legal, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

PROCEDURE:

1. Criteria for IRB approval of research.
   a. The convened IRB or reviewer using the expedited procedure must determine that the research satisfies all the requirements set forth below.
   b. The criteria for review must be used to approve research for initial review, continuing review and review of modifications or changes.

2. To approve research, the IRB must determine that all the following requirements have been satisfied by the investigators:
   a. Risks to subjects are minimized:
      (1) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
      (2) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
   b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
   c. Where and when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

3. When assessing risks and benefits, the IRB must conduct a thorough review of the application (including supplements), protocol, and study materials.

4. The IRB may discuss any risk/benefit matters as a committee and call on consultants, as needed.

5. The IRB must assign a risk level as part of the review of each protocol. Based on the risk level, the IRB determines the appropriate review period. When risk is great in relation to the risk associated with alternative procedures, and for certain behavioral studies in which the degree of discomfort to the subject may be greater than minimal, the IRB may require that continuing review be conducted in less than one year.

6. Investigators should not commence a research study without adequate resources to protect subjects and should stop a research study if resources become unavailable.

7. Investigators are responsible for ensuring and the IRB shall review prior to initial approval and during continuing review whether adequate resources include:

a. adequate time for the investigators to conduct and complete research;
b. adequate facilities;
c. adequate number of qualified staff;
d. access to a population that will allow recruitment of the necessary number of subjects;
e. availability of medical or psychological resources that subjects may need as a consequence of the research; and
f. a process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.

8. The IRB must document the results of their review and assessment in the applicable reviewer worksheet and in the IRB meeting minutes, as appropriate.

9. IRB members and IRB staff shall be trained on this *Policy and Procedure on Risk-to-Benefit Analysis* annually.

REVISION HISTORY:

Department: OSP - Research Integrity & Compliance	**Title**: Risk-to-Benefit Analysis
Effective Date: 01/21/19	**Owner:** Senior Compliance Manager, IRB
Replaces P/P Dated: IRB SOP (02/17)	
Related Documents: Initial Application; Initial Application Data Health Information Only Studies; Amendment Short and Long Forms; Continuing Review Form; Reviewer Sheets: Initial Review, Continuing Review, Amendment	
References: 45 CFR 46.111(a)(1); 45 CFR 46.111(a)(2); 45 CFR 46.111(a)(6); 21 CFR 56.111(a)(1); 21 CFR 56.111(a)(2); 21 CFR 56.111(a)(6); ICH-GCP: 2.2, 2.3, 3.13,4.2.1, 4.2.2, 4.2.3; AAHRPP Elements II.3.A, III.1.C and III.1.D; AAHRPP Tip Sheets 1, 11and 20	