Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute, LLC
Office of Sponsored Programs and Office of Research Integrity & Compliance

Policy and Procedure

TITLE: Data and Safety Monitoring Plans

PURPOSE:

To provide a policy and procedure for Institutional Review Board (IRB) review of each data and safety monitoring plan (DSMPs) to ensure adequate protection of research subjects.

PERSONS AFFECTED:

This policy and 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/I.

POLICY:

The IRB protects the safety of research subjects and research data by ensuring that investigators submit a comprehensive DSMP that makes adequate provision for monitoring the data collected. Review and approval by the IRB of the DSMP is necessary for greater than minimal risk research and clinical research funded and/or monitored by the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). For clinical, behavioral and social science research involving no more than minimal risk where provisions for data and safety monitoring are not needed to protect subjects, IRB members shall be able to:

- articulate when provisions for data safety and monitoring are required; and
- determine that research protocols or plans include adequate provisions for monitoring the data to provide for the safety of subjects.

PROCEDURE:

1. Investigators conducting greater than minimal risk research must include a comprehensive DSMP in the protocol when submitting their research package for initial IRB review.

2. During initial review, the IRB evaluates the DSMP to ensure that the provisions for monitoring data are adequate and protect the safety of research subjects. The IRB may consider provisions such as:

a. what safety information will be collected, including serious adverse events;
b. how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with subjects);
c. the frequency of data collection, including when safety data collection starts;
d. the frequency or periodicity of review of cumulative safety data;
e. whether the protocol includes a provision for requiring a Data and Safety Monitoring Board (DSMB) and a plan to report DSMB findings to the IRB;
f. whether a DSMB is needed for studies that are not required to have or do not include a DSMB for research projects that are blinded, have multiple sites, enter vulnerable populations, or employ high-risk interventions;
g. assurances that communication among multiple sites, when the lead PI is employed by HPHC/I, adequately protects human subjects and others;
h. if not using a DSMB, and if applicable, statistical tests for analyzing the safety data to determine whether harm is occurring; and
i. conditions that trigger an immediate suspension of the research, if applicable.

3. After initial review, the IRB may request additional information from the investigator regarding the DSMP.

4. When the protocol does not include a provision for a DSMB, the IRB may decide that one is needed in order to adequately protect the well-being of subjects.

5. It is the investigator's responsibility to report DSMB findings to the IRB in a timely manner for continuing review.

REVISION HISTORY:

Department: Office of Research Integrity & Compliance	**Title**: Data and Safety Monitoring Plans
Effective Date: 05/17/24	**Owner:** Director, Research Integrity & Compliance Officer
Replaces P/P Dated: IRB SOP (2/8/17), P/P (1/21/19)	
Related Documents: Reviewer Sheets: Initial, Continuing Review, Amendment; Initial Application; Continuing Review Form	
References: 45 CFR 46.111(a)(6); 21 CFR 56.111(a)(6); AAHRPP Elements II.3.B. and III.1.C; AAHRPP Tip Sheets 1, 6, 11 and 20	