



**Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute, LLC**

Office of Sponsored Programs

Policy and Procedure

TITLE: Prep-to-Research Reviews of PHI Prior to Conducting Research

PURPOSE:

To provide a policy and procedure for preparatory-to-research (“prep-to-research”) reviews of protected health information (PHI) prior to conducting any research activities.

PERSONS AFFECTED:

This policy & procedure 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.

POLICY:

Research personnel may review PHI for prep-to-research purposes so long as they can provide to the institution from which the PHI is requested, representations that:

1. The PHI review is solely to review the minimum necessary amount of PHI to prepare a research funding application and/or research protocol;
2. No PHI shall be removed from the data source by the researcher during the prep-to-research review;
3. The PHI to be reviewed is necessary for the research purposes;
4. The PHI accessed during the prep-to-research review will not be written down or recorded prior to initiation of the research study; and
5. The information reviewed during the prep-to-research review will not be used for any other purpose including presentation or publication.

DEFINITIONS:

Health Information means any information, whether electronic media, oral, paper or in any other form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Individually Identifiable Health Information means information that is a subset of Health Information, including demographic information collected from an individual, and (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse (“covered entity”); and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (a) that identifies the individual; or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Protected Health Information means Individually Identifiable Health Information transmitted and/or maintained by electronic media, orally, by hard copy, or in any other form or medium.

Preparatory-to-Research means reviewing the minimum amount necessary of PHI of a covered entity to determine the feasibility of using the data for a funding application or to prepare a research protocol.

PROCEDURE:

1. Any researcher planning to engage in prep-to-research review of data must submit a completed **PREP-TO-RESEARCH ATTESTATION FORM** as follows:
 - (a) Any researcher (including HPHC/I and non-HPHC/I) requesting prep-to-research review of HPHC data must submit the completed **PREP-TO-RESEARCH ATTESTATION FORM** to the manager of RSDC; and
 - (b) A HPHC/I researcher requesting prep-to-research review of data from a non-HPHC/I institution, shall follow the prep-to-research attestation procedures of that institution.
2. The researcher shall include in the **PREP-TO-RESEARCH ATTESTATION FORM**,
 - (a) Purpose of the prep-to-research review; and
 - (b) Description of PHI to be reviewed.
3. The **PREP-TO-RESEARCH ATTESTATION FORM** shall include the following researcher’s attestation:
 - (a) The PHI review is solely to review the minimum necessary amount of PHI to prepare a research funding application and/or research protocol;
 - (b) I will not remove any PHI from the data source during the prep-to-research review;
 - (c) The PHI to be reviewed is necessary for the purpose described above;
 - (d) The PHI accessed during this prep-to-research review will not be written down or recorded prior to initiation of the research study; and
 - (e) The information reviewed during the prep-to-research review will not be used for any other purpose including presentation or publication.
4. After submission and approval of the **PREP-TO-RESEARCH ATTESTATION FORM** to the RSDC manager, the researcher may proceed with the prep-to-research review. However, the researcher must not remove any of the data, record or write down any of the data, or use

the data accessed during the prep-to-research reviewed for any purposes including presentation or publication.

5. Following the prep-to-research review, the researcher shall follow the applicable procedure for submitting the funding application to the grants manager and the research protocol to the IRB.

REVISION HISTORY:

Department: Office of Sponsored Programs	Title: Prep-to-Research Reviews of PHI Prior to Conducting Research
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Replaces P/P Dated: n/a	
Related Documents: PREP-TO-RESEARCH ATTESTATION FORM 45 CFR 164.512(i)(1)(ii)	
References: HIPAA Administrative Simplification Regulation Text, March 2013, 45 CFR 64.512(i)(1)(ii).	
Approved By: CAJ and AHC	

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