

Harvard Pilgrim Health Care, Inc.
Privacy & Security Database
Agreements Cover Sheet

Project title	
Principal Investigator:	
IRBNet #	
Oracle/GMS (Project#):	
Is HVMA data included under this agreement?	
Name of vendor representative & title:	
Vendor address & telephone #:	
Agreement activation date:	
Risk score:	
** Relationship Manager:	
Brief description of services:	

*****The person listed as Relationship Manager is responsible for the agreement. As Relationship Manager you will be asked to give quarterly updates as to the status of the agreement and you must notify OSP of any changes to the agreement, e.g., termination, change of Relationship Manager, etc.***

SUBMIT THE A COPY OF THIS FORM ALONG WITH THE FULLY EXECUTED AGREEMENT TO YOUR OSP GRANTS MANAGER.

DATA USE AGREEMENT

This Data Use Agreement (“Agreement”) is made and entered into as of this _____ day of _____, 20__ (“Effective Date”), by and between **HARVARD PILGRIM HEALTH CARE INSTITUTE** (“Research Entity”) and _____ (“Data Recipient”) (collectively referred to as the “Parties”).

WHEREAS, the Research Entity wishes to provide to the Data Recipient, and the Data Recipient wishes to receive from the Research Entity, certain Protected Health Information (“PHI”) in the form of a Limited Data Set as defined in 45 CFR Section 164.514(e) or in an otherwise agreed upon format, and Research Entity may also provide and Data Recipient receive Personal Information (“PI”) as defined by Massachusetts Regulations at 201 CMR 17:02 (the data described in this paragraph shall hereafter be called “Disclosed Data”); and

WHEREAS, the Parties understand that Use and Disclosure of Disclosed Data is governed by HIPAA, the HITECH Act, and related guidance and regulations, and applicable laws for the protection of PI; and

WHEREAS, as part of the HIPAA Regulations, the Privacy Rule requires the Research Entity to enter into a Data Use Agreement with the Data Recipient prior to the Disclosure of PHI in a Limited Data Set or other agreed upon format.

NOW THEREFORE, in consideration of the mutual promises below, and the exchange of PHI and/or PI pursuant to the terms of this Agreement, the Parties agree as follows:

1.0 DATA TO BE PROVIDED BY RESEARCH ENTITY

Under the terms and conditions set forth in this Agreement, Research Entity will Disclose to Data Recipient certain Disclosed Data, as described below (insert a meaningful description of the Disclosed Data, including the protocol title):

2.0 PROPOSED USES OF DATA

Except as otherwise specified herein, or as Required by Law, Data Recipient may only Use and Disclose the Disclosed Data in a manner that is consistent with the specific purposes described in the space below, which must be only for the purposes of research, public health, or health care operations. Any change to the proposed uses must be agreed to in writing in advance of any such change. (If there is insufficient space below to set forth all agreed upon purposes, the proposed uses of data may be appended to this Agreement as Appendix A):

3.0 NAMES OF PERSONS AUTHORIZED TO USE DISCLOSED DATA

In addition to the Data Recipient, only the individuals, or classes of individuals, and their organizational affiliations, listed below are permitted to Use or receive the Disclosed Data for the purposes described in section 2.0 of this Agreement. Disclosed Data will not be shared with anyone else.

4.0 OBLIGATIONS OF THE DATA RECIPIENT. In addition to the obligations imposed by 1.0, 2.0, and 3.0 above, Data Recipient agrees to the following:

- 4.1 Data Recipient agrees to use appropriate safeguards to prevent Use or Disclosure of the Disclosed Data other than as provided for by this Agreement. Upon request by the Research Entity, the Data Recipient will describe the safeguards being used to prevent unauthorized Use or Disclosure of the Disclosed Data.
- 4.2 Data Recipient agrees that Disclosed Data will be used only on the institutional premises of the individuals listed in Section 3.0.
- 4.3 Data Recipient agrees that it will not disclose any Disclosed Data to any agent, including a subcontractor, without prior written approval from the Research Entity, and only if such agent agrees to the same restrictions and conditions that apply to the Data Recipient.
- 4.4 Data Recipient will not seek to identify or contact anyone whose information is in the Disclosed Data, except when explicitly approved by the protocol.
- 4.5 Data Recipient shall indemnify and hold harmless the Research Entity from and against any and all losses, expense, damage or injury that the Research Entity sustains as a result of, or arising out of a breach of this Agreement by the Data Recipient or its agents or subcontractors, including but not limited to any unauthorized Use or Disclosure of Disclosed Data.
- 4.6 **Breach of Privacy or Security Obligations.** Consistent with the requirements of HITECH and any other security breach notification laws, Data Recipient shall comply with the following:
 - 4.6.1 **Notice to Research Entity.** Data Recipient will notify Research Entity following discovery and without unreasonable delay but in no event later than five (5) business days following discovery of any Breach of Unsecured Protected Health Information, or any Breach of Security (collectively “Breach”).
 - 4.6.2 **Reporting to Research Entity.** (i) For any Breach, Data Recipient, without unreasonable delay, but in no event later than ten (10) business days after Data Recipient learns of such Breach, shall provide Research Entity a written report that will identify:
 - (a.) each individual whose Data has been Breached;
 - (b) the nature and date of the Breach;
 - (c) the PHI or PI accessed;
 - (d) who

committed the Breach; (e) and corrective and mitigative action taken

5.0 TERMINATION OF AGREEMENT

- 5.1 This Agreement shall be effective from the Effective Date until all PHI and/or PI provided by Research Entity to Data Recipient is destroyed or returned to Research Entity. Data Recipient shall return all PHI and/or PI upon Research Entity's request.
- 5.2 This Agreement may be terminated by the Research Entity upon ten (10) days prior written notice to the Data Recipient if Data Recipient materially breaches any obligation of this Agreement and fails to cure the breach within such ten (10) day period.
- 5.3 Upon termination of this Agreement, the Data Recipient shall return to the Research Entity or destroy all PHI and/or PI in the Data Recipient's possession or in the possession of its agents or subcontractors. Data Recipient shall not retain any copies of PHI and/or PI, except when explicitly approved by the protocol.

IN WITNESS WHEREOF, the Parties hereto have duly executed the Agreement.

**HARVARD PILGRIM HEALTH
CARE INSTITUTE**

DATA RECIPIENT

BY _____

BY _____

Sheila Fireman
Director of Institute Administration

Name & Title

Date _____

Date _____

INSTITUTIONAL REPRESENTATIVE
(if required by Research Entity)

NAME (Print) DATE