

TITLE RECIPIENT

This form, "DPH Health Information Data Use Agreement," must be completed by researchers who propose to perform research using datasets generated from DPH sources.

This Agreement is entered into by and between the City and County of San Francisco Department of Public Health ("SFDPH") and a Data Recipient ("Recipient") named on Schedule 1, as of the Effective Date noted on Schedule 1.

- A. SFDPH is providing certain health information regarding its patients and clients to Recipient for the purpose(s) identified in **Schedule 1**. Data sets may be provided in the following format:
 - a. SFDPH DE-IDENTIFIED Health Information, or
 - b. SFDPH Protected Health Information (PHI) in the form of:
 - i. Full PHI Data Set
 - ii. LIMITED PHI Data Set

With the provision of that PHI, pursuant to the Health Insurance Portability and Accountability Act (HIPAA) and regulations, SFDPH is required to obtain assurances from Recipient that Recipient will only use or disclose PHI as permitted herein. The provisions of this Agreement are intended to meet the Date Use Agreement requirements of HIPAA.

B. The parties enter into this Agreement as a condition to SFDPH furnishing the health information to Recipient, and as a means of Recipient's providing assurances about use and disclosure.

NOW THEREFORE, the parties agree as follows:

- 1. **Definitions.** Each capitalized term used in this Agreement and not otherwise defined, shall have the meaning given it in HIPAA.
- 2. **Term.** This Agreement shall commence on the Effective Date and continue until terminated in accordance with Section 4 below.
- 3. Recipient's Obligations for DPH Protected Health Information (PHI) Data Sets. Recipient shall:
 - a. Complete and abide by the requirements of the DPH Research Proposal Approval form.
 - b. Not identify or attempt to identify the information contained in the Full or LIMITED Data Set, nor contact any of the individuals whose information is contained in the Full or LIMITED Data Set.
 - c. Not attempt to re-identify any client for whom identifying information has been removed to create a de-identified database.
 - d. (For researchers) Obtain IRB and DPH approval before re-releasing PHI. (For others) Not re-release PHI Data Sets or share PHI learned about a patient or client to another party.
 - e. Not request use of or disclose more PHI than the minimum amount necessary to perform its functions pursuant to the purpose identified in **Schedule 1**.
 - f. "Activity Preparatory to Research" includes access to PHI for purposes of preparing a protocol or grant or to determine the size of the research pool, etc.
 - i. Researchers outside the DPH Safety Net: May <u>not</u> use PHI for activities preparatory to research without IRB waiver of informed consent.



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- ii. DPH Safety Net¹ researchers may use PHI for activities preparatory to research if <u>all</u> of the following conditions are met:
 - 1. The use or disclosure is sought solely to review PHI as necessary to prepare for research or grant;
 - The researcher meets the requirements set forth in the DPH Electronic Data Security policies² <u>if</u>, in the course of the review, PHI is removed from the premises from which it is obtained,
 - 3. The PHI will not be further disclosed by the researcher without obtaining prior IRB approval; and
 - 4. The researcher has provided a written representation with respect to the foregoing conditions and attaches to **Schedule 1**.
- g. As part of the approval process, researcher attests that they have read and agree with all DPH policies regarding research involving DPH affiliated staff, settings, clients/patients, and data, including protected health information.

4. Termination.

- a. SFDPH may terminate this Agreement without cause at any time.
- b. Return or destruction of Protected Health Information (PHI) Data Sets, whether full or LIMITED:
 - i. <u>Upon Completion</u>, Recipient shall return or destroy the PHI data sets received from SFDPH on the completion date on **Schedule 1**. If destroyed, Recipient shall notify DPH. If IRB approval stipulates retention of research data beyond the completion of the study, Recipient shall continue the protections required under this Agreement for the PHI consistent with the requirements of this Agreement and applicable HIPAA privacy standards during the time period.
 - ii. <u>Violations</u>. If Recipient violates or breaches any material term or condition of this Agreement, SFDPH may terminate this Agreement and any disclosures of PHI data sets identified in **Schedule 1** immediately. Recipient agrees to return or destroy all PHI contained in the Data Set received from SFDPH within 10 business days of notice. If destroyed, Recipient shall notify DPH.
 - iii. <u>Ceasing To Do Business</u>. If Recipient ceases to do business or otherwise terminates its relationship with SFDPH, Recipient agrees to return or destroy all PHI contained in the Data Set received from SFDPH within 10 business days. If destroyed, Recipient shall notify DPH.
- 5. **Governing Law and Venue**. This Agreement shall be governed by the laws of the State of California. Venue for any claim, action or suit, whether state or federal, between Recipient and SFDPH, shall be the City and County of San Francisco, California.

¹ DPH Safety Net Providers are listed at <u>http://www.sfdph.org/dph/comupg/oservices/medSvs/HIPAA/</u>

² DPH Data Security Policies are located at <u>http://www.sfdph.org/dph/comupg/healthliv/yourRights/</u>



City and County of San Francisco – Department of Public Health DPH Health Information Data Use Agreement

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IN WITNESS WHEREOF, the parties have executed this Agreement effective on the approval date by the SFDPH Administrative Representative.

Recipient				
PRINTED NAME		TITLE		
AGENCY		ADDRESS		
SIGNATURE		DATE SIGNED		

SFDPH Program or Dataset Representative				
APPROVED COMMENTS:	D NOT APPROVED	APPROVED, F	PENDING REVI	SIONS
PRINTED NAME			TITLE	
AGENCY			ADDRESS	
SIGNATURE			DATE SIGNED	

SFDPH Administrative Representative				
APPROVED COMMENTS:	D INOT APPROVED	APPROVED, F	PENDING REVI	SIONS
PRINTED NAME			TITLE	
AGENCY			ADDRESS	
SIGNATURE			DATE SIGNED	



City and County of San Francisco – Department of Public Health DPH Health Information Data Use Agreement

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EFECTIVE DATE			TERM	INATION DATI	Schedule 1			
DATA FULL NAME								
RECIPIENT (Individual	TITLE							
completes this	AGENCY		DPH Safety Net?					
form)	ADDRESS		YES NO					
	PHONE	EMAIL						
PURPOSE OF DISCLOSURE	HEALTH CARE C	H CARE OPERATIONS RESEARCH ACTIVITY PREPARATORY TO RESEARCH dissertations)						
	TITLE							
	PURPOSE						If PHIInformed	
	IF RESEARCH, TITLE OF STUDY	PRINCIPAL INVESTIGATOR NAME				Consent Obtain		
		IRB # (Attach documents)					Authorization waived by IRB?	
		SPONSOR						
DATA	DATABASE NAME							
SOURCE	MED REC NAME							
	OTHER							
DATA	DATASET	PROTECTED HEALTH INFORMATION				DE-IDENTIFIED HEALTH		
REQUESTED	CATEGORY	G FULL ID						
	NAME		<u>NO</u> NAMES		NO NAMES			
	IDENTIFIABLE NUMBERS		Any other unique identifying number or code that is not expressly listed under De- Identified Dataset.		NO SS#, MR#, Health Plan Beneficiary #, Account #, Certificate & License #, Vehicle ID #, Device ID #, Serial #, URLs and IP addresses, biometric identifiers, identifiable photographs, or any other unique identifiers. *			
	ADDRESS		<u>NO</u> Telephone, Fax, Email		Email	<u>NO</u> Telephone, Fax, Email		
			Geographic Destinations above the Street Level or PO Box		NO geographic designations smaller than a state (except for the initial three digits of zip codes if the first three digits cover an area having more than 20,000 people) **			
	DEMOGRAPHICS					NO DATES OF BIRTH are okay) and NO AGE all persons over 89 may into a single category) *	over 89 (although be aggregated *	
	OTHER (LIST DATA TYPES REQUESTED)					Must <u>Ex</u> clude Dates	s (years are okay)	

* DPH may code the identifiers prior to accessing and releasing the data. The code must not be derived from any information about the patient, such as a record number or SS#. No means of re-identification may be disclosed with the de-identified information or subsequent to its analysis.

** DPH may have a qualified statistician determine that the risk is very small that the identifiers present could be used alone, or in combination with other available information, to identify the patient. The statistician must be knowledgeable and experienced with accepted methods for rendering information non-individually identifiable, and must document the methods and results of the analysis that justifies the conclusion of very small risk. The HIPAA covered entity must keep this documentation for six years.



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Instructions – Data Use Agreement and Schedule 1

1. Data Recipient:

- a. Completes Schedule 1
- b. Completes and signs "Recipient" box on last page of the Data Use Agreement
- c. Sends the completed forms to the DPH Data Set Representative assigned to the data set being requested.

2. DPH Data Set Representative:

Completes and signs "Data Set Representative" box on last page of the Data Use Agreement

a. If "Approved":

i. Sends the completed forms to the DPH Administrative Representative assigned to the Division within which the DPH data resides

b. If "Approved, Pending Revisions":

- i. Notes the revisions needed in Comments section
- ii. Files copy and returns original to Data Recipient
- iii. If desired, Data Recipient revises <u>Schedule 1</u> and revises and submits a new <u>Data Use</u> <u>Agreement</u>

c. If "Not Approved":

- i. Notes the reasons in the Comments section
- ii. Files copy and returns original to Data Recipient

3. DPH Administrative Representative:

Completes and signs "Data Set Representative" box on last page of the Data Use Agreement

- a. If "Approved":
 - i. Copies and sends the completed forms to the Data Set Representative and the Data Recipient

b. If "Approved, Pending Revisions":

- i. Notes the revisions needed
- ii. Files copy and returns original to Data Set Representative and Data Recipient
- iii. If desired, Data Recipient revises <u>Schedule 1</u> and revises and submits a new <u>Data Use</u> <u>Agreement</u>
- c. If "Not Approved":
 - i. Notes the reasons
 - ii. Files copy and returns original to Data Set Representative and Data Recipient