

City and County of San Francisco – Department of Public Health DPH Research Proposal Approval

TITLE OF STUDY	
Principal Investigator	

Research projects that are conducted at DPH facilities, use DPH clients as participants, use DPH staff to recruit participants or supply data, or use data generated from DPH programs, require approval from DPH administration. This form must be completed by researchers who propose to perform such projects.

Researchers are strongly encouraged to receive approval prior to submitting projects for funding, as the Department cannot guarantee that it will participate in projects without preapproval.

When completed, this form should be submitted along with applications for Institutional Review for the protection of human subjects (IRB). The completed form indicates that DPH administrators approve the proposal, pending institutional review.

By signing this form, the researcher for the study named above indicates that he or she:

- a. Has received approval for the project from the appropriate program representative and divisional administrator. Signatures from these DPH staff or their designees must be affixed to this form.
- b. Will comply with all applicable federal and state laws and regulations relating to acquisition of any necessary client/patient prior authorizations, maintenance of the PHI, safeguarding of the confidentiality of the PHI, and use and disclosure of the PHI. Violation of state and federal laws regarding patient privacy may result in substantial monetary penalties and/or subjection to civil or criminal action pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the California Medical Information Act, the Welfare and Institutions Code, and other federal and state privacy laws.
- c. Will provide a copy of the IRB application for DPH review to ensure that the treatment of research participants and data are consistent with DPH standards.
- d. Will provide a copy of the IRB letter of approval to DPH prior to commencing with research. Researchers' activities in the conduct of the research will be strictly limited to conform to those specified in the approved IRB application.
- e. Will inform DPH program personnel about significant alterations in the IRB protocol, including changes in key personnel.
- f. Will use and disclose the PHI only for the purpose(s) identified in the approved IRB protocol, or as otherwise required by law, and for no other purpose.
- g. Will use all appropriate safeguards to prevent the use and disclosure of the PHI, other than for a use or disclosure expressly permitted by approved IRB protocol.
- h. Will immediately report to SFDPH and the IRB any use or disclosure of the PHI other than as expressly allowed in the IRB application or any other serious adverse events that occur to DPH clients.
- i. Will ensure that, for the purposes of health care operations, if a third party (non-DPH employee) is used to analyze or review PHI, that party must also have a Business Associate Agreement in place with DPH.
- j. Will ensure that its employees and representatives comply with the terms and conditions of this Agreement, and ensure that its agents, Business Associates, and subcontractors to whom Recipient provides the PHI agree to comply with the same restrictions and conditions that apply to Recipient hereunder.



Principal Investigator

City and County of San Francisco – Department of Public Health DPH Research Proposal Approval

TITLE OF STUDY	
Principal Investigator	

- k. May not re-release PHI Data or share PHI learned about a patient or client to another party without prior authorization from the IRB and/or patient.
- I. Will indemnify, defend, and hold SFDPH harmless from all costs and expenses (including attorney fees) that relate to a breach of Recipient's obligations.

I verify that I have read and agree to comply with all DPH policies regarding research involving DPH affiliated staff, settings, clients/patients, and data, including protected health information. I commit that this research will be conducted with approval from a duly constituted IRB.

I further agree that if references to SFDPH participation, data, or subjects are made in publications or presentations to the public, the following disclaimer will be included: "The views expressed herein do not necessarily reflect the official policies of the City and County of San Francisco; nor does mention of the San Francisco Department of Public Health imply its endorsement."

PRINTED NAME			TITLE			
AGENCY			ADDRESS		PHONE:	
SIGNATURE			DATE SIGNED			
SFDPH Prog	ram or Dataset Re	epresentative)			
APPROVED COMMENTS:	☐ NOT APPROVED	☐ APPROVED, I	PENDING REVISIONS			
PRINTED NAME			TITLE			
AGENCY			ADDRESS			
SIGNATURE			DATE SIGNED			



City and County of San Francisco – Department of Public Health DPH Research Proposal Approval

TITLE OF STUDY	
Principal Investigator	

SFDPH Administrative Representative							
APPROVED COMMENTS:	☐ NOT APPROVED	APPROVED, F	PENDING REVISIONS				
PRINTED NAME			TITLE				
AGENCY			ADDRESS	PHONE			
SIGNATURE			DATE SIGNED				

- 1. <u>Community Programs</u>: Director of Community Programs designee, Director of the Office of Quality Management
- 2. <u>Laguna Honda Hospital</u>: Executive Administrator of Laguna Honda Hospital
- 3. San Francisco General Hospital Medical Center:
 - a. For UCSF researchers: Associate Dean for SFGHMC programs, UCSF
 - b. For all other SFGH researchers: Executive Administrator of SFGHMC
- 4. <u>Jail Health Services</u>: Director of Health Services
- 5. <u>Population Health and Prevention</u>: Each Section's Director

 $^{^{\}mathrm{i}\,\mathrm{i}}$ Appropriate divisional administrator, or their designees are as follows: