



# San Francisco Department of Public Health

Policy Title: HIPAA Compliance – Privacy and the Conduct of Research

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**TITLE: HIPAA COMPLIANCE: PRIVACY AND THE CONDUCT OF RESEARCH**

## **POLICY**

It is the policy of the San Francisco Department of Public Health (DPH) to maintain the privacy of Protected Health Information (PHI) used for research<sup>1</sup> purposes pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

## **PURPOSE**

Research is an important element of the DPH mission, both in its role of improving the health of the residents of San Francisco as well as through its affiliation with the University of California. The purpose of this policy is to set forth the standards and procedures investigators shall follow when requesting approval to conduct research at the DPH and when using DPH PHI for research purposes. This policy document applies the HIPAA Privacy Rule, the Common Rule<sup>2</sup>, and DPH requirements for obtaining approval to conduct research projects using DPH human subjects<sup>3</sup> and their health information.

## **SCOPE OF POLICY**

Studies pursued in the Department of Public Health for the primary purpose of quality improvement and outcome evaluation fall under the definition of health care operations rather than research, and therefore do not require Institutional Review Board<sup>4</sup> (IRB) approval (45 CFR 164 501) or prior authorization from patients/clients for use of their Protected Health Information. Health Care Operations include 1) Quality assessment and improvement activities, outcomes evaluation, and the development of clinical guidelines, provided that the obtaining of “generalizable” knowledge is not the primary purpose of any studies resulting from such

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<sup>1</sup> Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to ‘generalizable’ knowledge (45 CFR 46.102(d). Research differs from treatment in that the end goals of treatment are to benefit the individual being treated, while research is performed for the benefit of obtaining general knowledge.

<sup>2</sup> The “Common Rule” regulations govern research funded (or conducted) by the Department of Health and Human Services or research subject to an institution’s Federal-wide Assurance. General rules for use and disclosure of patient information for research can be found in 42 C.F.R. Part 46.

<sup>3</sup> Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. (45 CFR 46.102(f).

<sup>4</sup> Institutional Review Board (IRB): A board established for the protection of human subjects. This board is responsible for initial and continuing review and approval of research that involves subjects in an institution or conducted by an individual affiliated with an institution that agrees to assume responsibility for the study. Federal regulations establish standards for the membership, organization and functions of IRBs and criteria for IRB review and approval of research. California law requires that the IRB either be approved by the state Department of Health Services or meet the requirements of federal law. IRBs follow the requirements promulgated by the Department of Health and Human Services for the protection of human subjects known as the “Common Rule.”



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activities; 2) Population-based activities related to improving health; 3) Evaluating provider performance; and 4) Training programs. (45 CFR 164 501)<sup>5</sup>

Results of these studies may be communicated at general professional practice forums regarding improvements in practice or evaluation methods. However, if the authors of a quality improvement or program evaluation study wish to publish their results in a peer-reviewed journal or other published format, they must receive approval from the appropriate divisional administrator identified in Section I.A. of this policy.

All privacy policies and regulations apply to the use and disclosure of PHI received for the purposes of health care operations. If a third party (non-DPH employee) is used, that party must have a Business Associate Agreement<sup>6</sup> in place with DPH. Clarification regarding whether or not a specific data request using DPH protected health information falls under Health Care Operations or Research should be directed to your DPH Privacy Officer.

## REVIEW AND APPROVAL OF RESEARCH

- I. **Before commencing and prior to IRB review, all research conducted by DPH staff, at a DPH site, or utilizing DPH Protected Health Information shall be approved by the appropriate divisional administrator as outlined in Appendix A.** Administrative approval authorizes the researcher to utilize DPH data, staff, and other resources as outlined in the request, if and when IRB approval is obtained. (See [DPH Research Proposal Approval Form](#) in Appendix B and online)
- II. As part of the approval process, researchers must attest 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.
- III. If and when references to SFDPH participation, data, or subjects are made in publications or presentations to the public, the following disclaimer must 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."
- IV. All research conducted in the DPH involving human subjects and/or existing DPH PHI that was originally collected for non-research purposes shall be reviewed and approved by a duly-constituted institutional review board as follows:
  - A. DPH staff with 50% FTE appointments or higher at University of California at San Francisco (UCSF) must use the UCSF Committee on Human Research (CHR) for review and approval. Any project that includes a 50% FTE or higher UCSF staff or

<sup>5</sup> The definition of health care operations is found in 45 CFR 164 501. This entire section of the DHHS privacy rule can be found at the following webpage: [http://www.access.gpo.gov/nara/cfr/waisidx\\_02/45cfr164\\_02.html](http://www.access.gpo.gov/nara/cfr/waisidx_02/45cfr164_02.html)

<sup>6</sup> For a copy of the DPH HIPAA Business Associates Agreement, go to <http://dphnet/Privacy/default.htm#Forms> or <http://www.sfdph.org/dph/comupg/oservices/medSvs/HIPAA/default.asp>



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faculty member in any capacity (including in-kind) must use the UCSF CHR for review and approval.<sup>7</sup>

- B. Any researcher who is not specifically designated as a DPH Principal Investigator, including DPH staff with less than 50% FTE appointment at UCSF, non-UCSF-affiliated DPH staff, staff members of the DPH Safety Net, independent researchers, and researchers affiliated with a post-secondary educational institution other than UCSF, shall use a duly-constituted IRB for review and approval. DPH employees who are not designated PIs may submit their research proposals to the UCSF IRB only if a designated DPH PI or a UCSF faculty member has agreed to sponsor the project, be the PI of record, and insure the quality and integrity of the research.
- C. UCSF is the IRB of record for designated DPH principal investigators (PIs) who are not UCSF staff. Designated DPH PIs must go through the UCSF IRB if they collaborate with UCSF faculty with 50% FTE appointments or higher, or are conducting research where any of the following apply:
  - 1. Funding is granted to or applied for through UCSF,
  - 2. Subjects will be recruited at UCSF, SFGH, Laguna Honda Hospital (LHH) or the San Francisco Veterans Administration Medical Center (SFVAMC),
  - 3. Research will take place at a UCSF, SFGH, LHH or SFVAMC facility, or at a UCSF-affiliated institution that holds a Federalwide Assurance that identifies the UCSF CHR as the IRB of record for all its human research.
- D. DPH PIs may choose to use a non-UCSF-affiliated duly constituted IRB if none of the conditions in C. above apply.
- V. Prior to contact with DPH client/patient human subjects, the researcher will inform the attending physician or primary provider of the study. If DPH PHI is used in the targeting and recruitment of human subjects, a member of the health care team, not the researcher, will ask the potential human subject regarding his or her desire to participate in the study before the researcher approaches the client/patient.

### USE OF DPH PHI FOR RESEARCH PURPOSES

The HIPAA Privacy Rule states that Protected Health Information (PHI) includes information relating to an individual's health, the care received and/or payment for services, including demographic data, which can be individually identified as belonging to a particular person. The Privacy Rule applies to both paper documents and electronic data sets that include PHI.

This remaining sections regarding use of DPH PHI described in this document apply to a researcher's use of existing PHI that was originally collected for non-research purposes. DPH staff conducting de novo research; that is, independent research that does not use pre-existing PHI in any form, but collects PHI as part of the research study itself (for example from interviews and testing with human subjects) must have their studies IRB-approved and all relevant HIPAA regulations apply; however, the following sections on Data Sets do not apply.

<sup>7</sup> For a complete description of UCSF Human Research Protection Program CHR Guidelines go to: <http://www.research.ucsf.edu/chr/guide/chrpriorapproval.asp>



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This policy integrates federal privacy rules<sup>8</sup> and local requirements for the use of three types of health information:

- I. **PHI Data with Client Identifiers**
- II. **De-Identified Data Sets**
- III. **Limited PHI Data Sets**

## I. **PHI Data with Client Identifiers**

The HIPAA Privacy Rule requires that the use or disclosure of PHI with client identifiers for research purposes be prior authorized (in writing) by the individual whose health information is protected. However, a waiver of the individual's authorization may be obtained from an Institutional Review Board (IRB) under specified circumstances.

### A. **Patient Authorization**

A covered entity that creates Protected Health Information (PHI) for the purpose of providing health care to an individual must obtain a prior written authorization from the individual for the use or disclosure of that PHI if it is to be used for research purposes. The authorization form must contain all of the elements required under HIPAA (see DPH Privacy Policy "Authorizing Release of Protected Health Information").

### B. **Waiver of Patient Authorization**

An IRB (per HIPAA and the Common Rule), and only an IRB (per DPH Policy), may waive the requirement of an individual's authorization for the use or disclosure of PHI for research purposes if it is determined that all of the following criteria are met:

1. The use or disclosure of PHI involves no more than minimal risk<sup>9</sup> to the privacy of individuals based on the following three elements:
  - a. There is an adequate plan to protect the identifiers from improper use or disclosure (identifiers include any of the data elements described in Section II.A.1. below).
  - b. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of research, unless there is a health or research justification for retaining the identifiers or retention is required by law; and
  - c. There are adequate written assurances that the PHI will not be re-used or disclosed to any other person or entity except (i) as required by law, (ii) for oversight of the research project, or (iii) for other research as permitted by HIPAA regulations;
2. The research cannot practicably be conducted without the waiver; and
3. The research cannot practicably be conducted without access to and use of the PHI.

HIPAA excludes the use of "psychotherapy notes"<sup>10</sup> for research purposes without the specific authorization of the patient. Neither an IRB nor DPH staff may waive

<sup>8</sup> Rosati, K.B. (2006-2007). HIPAA and the Common Rule: Handling Health Information in Research. Coopersmith, Gordon Schermer & Brockelman PLC, pp. 2-4.

<sup>9</sup> Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(i)).



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the requirement for authorization for the use of "psychotherapy notes," as defined in the Privacy Rule.

C. Protected Classes: Mental Health, Developmentally Disabled, Substance Use, and HIV/AIDS

In addition to HIPAA, there are other federal and state laws that protect records pertaining to treatment for mental health, developmental disabilities, substance abuse and HIV/AIDS. DPH PHI containing such information will not be used or disclosed to researchers without assuring that such use or disclosure is permissible under state and federal law.

D. Use of PHI for Activity Preparatory to Research

"Activity Preparatory to Research" includes access to PHI for purposes such as to prepare a protocol or grant or to determine the size of the research pool.

1. Researchers outside the DPH Safety Net may not use PHI for activities preparatory to research without IRB waiver of informed consent.
2. DPH Safety Net<sup>11</sup> researchers may if all of the following conditions are met:
  - a. The use or disclosure is sought solely to review PHI as necessary to prepare for research;
  - b. The researcher meets the requirements set forth in the DPH Data Security policies<sup>12</sup> if, in the course of the review, PHI is removed from the premises from which it is obtained, and
  - c. The PHI will not be further disclosed by the researcher without obtaining prior IRB approval.

E. Approvals Required

Researchers who access, review, collect, or receive PHI Data Sets must have prior approval from an IRB and the appropriate division representative (Appendix A).

## II. De-Identified Data Sets

De-identified data sets have all identifiers and potentially identifiable information removed, and is no longer considered PHI. De-identified health information may be used or disclosed for research purposes as long as the requirements set forth below are completed. In this case, the data disclosed would no longer be considered "protected health information" as defined by HIPAA, and thus do not require authorization from the patient/client or an IRB prior to their release for research purposes.

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<sup>10</sup> Psychotherapy Notes: Notes recorded in any medium by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. (Psychotherapy Notes are not medical record progress notes.) Medication prescription and monitoring, counseling session start and stop times, modalities and frequencies of treatment furnished, results of clinical tests, and any summary of diagnosis, functional status, treatment plan, symptoms, prognosis, and progress to date are excluded from this classification as "psychotherapy notes" but are still classified as mental health documentation.

<sup>11</sup> DPH Safety Net Providers are listed at <http://www.sfdph.org/dph/comupg/oservices/medSvs/HIPAA/>

<sup>12</sup> DPH Data Security Policies are located at <http://dphnet/Privacy/ISPrivacyProc.htm>



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### A. Methods for De-Identifying

The HIPAA Privacy Rule permits three methods for de-identifying information. Only one of the three methods must be used:

#### 1. Remove all of the following specified identifiers:

- a. names;
- b. 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);
- c. the month and day of dates directly related to an individual, such as birth date, admission date, or dates of service;
- d. ages over 89 (although all persons over 89 may be aggregated into a single category);
- e. telephone and fax numbers; e-mail addresses;
- f. social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate and license numbers; vehicle identification numbers, device identifiers and serial numbers, URLs and IP addresses, biometric identifiers, identifiable photographs, and any other unique identifiers.

#### 2. Or, 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 social security number. No means of re-identification is disclosed with the de-identified information or subsequent to its analysis.

#### 3. Or, 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.

### B. Who May De-Identify PHI

1. DPH may have one of its employees (or a third party) de-identify the Protected Health Information (PHI) for research purposes. The process of de-identifying PHI is considered a “health care operation” and therefore does not require the individual’s authorization.
2. If a third party (non-DPH employee) is used to de-identify the PHI, the third party must have a Business Associate Agreement in place with the covered entity. After the de-identification of the PHI, the business associate may not retain the fully-identifiable PHI for research without following one of the previously described HIPAA options for obtaining identified PHI for research, and without obtaining DPH approval.

### C. Approvals Required

Researchers who access, review, collect, or receive a De-Identified DPH Data Sets do not require IRB approval, but must have prior approval from the appropriate division representative (Appendix A).





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### III. Limited PHI Data Sets

Limited PHI data sets do not include client identifiers but may contain some information that are required to be excluded in De-Identified Data Sets (as noted in Section II.A.1. above).

A. Limited PHI Data Sets include partially de-identified patient information.

All of the identifiers listed under De-Identified Data Sets above (Section II.A.1.) must be removed, except for the following (that is, the following may be included in a Limited Data Set):

1. geographic designations greater than the street level or PO Box;
2. dates directly related to a patient, such as dates of service, birth date, admission and discharge dates, or date of death;
3. any other unique identifying number or code that may is not expressly listed as an "identifier" in Section II.A.1 above.

B. Approvals Required

Researchers who access, review, collect, or receive Limited PHI Data Sets must have prior approval from an IRB and the appropriate division representative (Appendix A).



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## APPENDIX A

### REVIEW AND APPROVAL BY DPH ADMINISTRATION

- A. All research conducted by a DPH staff, at a DPH site, or utilizing DPH Protected Health Information shall be approved by the appropriate divisional administrator, or their designees, as follows:
  1. Community Programs: Director of Community Programs
  2. Laguna Honda Hospital: Executive Administrator of Laguna Honda Hospital
  3. San Francisco General Hospital Medical Center:
    - a. For UCSF researchers: Associate Dean for SFGHMC programs, University of California, San Francisco
    - b. For all other SFGH researchers: Executive Administrator of SFGHMC
  4. Jail Health Services: Director of Health Services
  5. Population Health and Prevention: Each Section's Director
  
- B. DPH employees may apply for designation as a DPH Principal Investigator by applying to the DPH IRB Representative. For contact information, please ask your Privacy Officer.





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## APPENDIX B



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

TITLE OF STUDY	
Principal Investigator	

**DO NOT USE THIS APPENDIX AS THE FORM YOU SUBMIT. GO TO ACTUAL FORM.**

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:

- Has received approval for the project from the appropriate program representative and divisional administrator.<sup>1</sup> Signatures from these DPH staff or their designees must be affixed to this form.
- 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.
- 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.
- 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.
- Will inform DPH program personnel about significant alterations in the IRB protocol, including changes in key personnel.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- Will indemnify, defend, and hold SFDPH harmless from all costs and expenses (including attorney fees) that relate to a breach of Recipient's obligations.



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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."

**DO NOT USE THIS APPENDIX AS THE FORM YOU SUBMIT. GO TO ACTUAL FORM.**

Principal Investigator		
PRINTED NAME	TITLE	
AGENCY	ADDRESS	PHONE:
SIGNATURE	DATE SIGNED	
SFDPH Program or Dataset Representative		
<input type="checkbox"/> APPROVED <input type="checkbox"/> NOT APPROVED <input type="checkbox"/> APPROVED, PENDING REVISIONS COMMENTS:		
PRINTED NAME	TITLE	
AGENCY	ADDRESS	
SIGNATURE	DATE SIGNED	
SFDPH Administrative Representative		
<input type="checkbox"/> APPROVED <input type="checkbox"/> NOT APPROVED <input type="checkbox"/> APPROVED, PENDING REVISIONS COMMENTS:		
PRINTED NAME	TITLE	
AGENCY	ADDRESS	PHONE
SIGNATURE	DATE SIGNED	

<sup>ii</sup> Appropriate divisional administrator, or their designees are as follows:

1. Community Programs: Director of Community Programs designee, Director of the Office of Quality Management
2. Laguna Honda Hospital: 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. Jail Health Services: Director of Health Services
5. Population Health and Prevention: Each Section's Director