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 purposes pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

PURPOSE

To set forth the standards and procedures that investigators shall follow when using DPH PHI for research purposes.

DEFINITIONS

1. **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. Any investigation with a current or future intent to publish findings is considered by the DPH to be research.

2. **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).

3. **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.

4. **Privacy Board/Data Governance Committee**: A board that has members with varying backgrounds and appropriate professional competency as necessary to review the effect of research protocols on the individual's privacy rights and related interests. A Privacy Board must include at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring research, and not related to any person who is affiliated with any of such entities. A member of a Privacy Board may not participate in a review of any project in which the member

has a conflict of interest. The DPH Data Governance Committee shall serve as the DPH Privacy Board.

5. **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. 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 classification as "psychotherapy notes" but are still classified as mental health documentation.

BACKGROUND

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. Prior to the enactment and implementation of HIPAA, DPH already had measures in place to protect the rights of human subjects who participated in research and whose medical records were used for research purposes.

DPH has required that an established Institutional Review Board (IRB) approve all research. Additionally, DPH has a Data Governance Committee that sets policy regarding the use and disclosure of medical information, both in written and electronic formats. HIPAA mandates some of the measures that DPH already has in place to ensure the proper conduct of research, but also has some new requirements.

The HIPAA Privacy Rule requires that the use or disclosure of PHI for research purposes be authorized in writing by the individual whose health information is protected. A waiver of the individual's authorization may be obtained from an IRB or a Privacy Board under specified circumstances, as set forth below. Additionally, HIPAA regulations provide a transition period for research that began before the HIPAA implementation date of April 14, 2003.

PROCEDURE

I. AUTHORIZATION REQUIREMENTS

A. A covered entity that creates PHI for the purpose of providing health care to an individual must obtain a written authorization from the individual for the use or disclosure of that PHI if it is to be used for research purposes. The

authorization must contain all of the elements required under HIPAA (see DPH policy "Authorizing Release of Protected Health Information").

B. Human subjects who participate in research must be provided with a copy of the DPH Notice of Privacy Practices and acknowledge receipt of the Notice.

II. Waiver of Authorization for Research by the Privacy Board (DPH Data Governance Committee)

A. The Privacy Board may waive the requirement of an individual's authorization for the use or disclosure of PHI for research purposes (excluding psychotherapy notes as defined in HIPAA) if the Privacy Board makes a determination that all of the following criteria are met:

1. The use or disclosure of PHI involves no more than minimal risk 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;

   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.

* Identifiers include any of the data elements described in Section VII.B. below.

III. Review and Approval Procedures

A. IRBs

All research involving human subjects conducted in San Francisco Department of Public Health facilities shall be reviewed and approved by an institutional review board.

B. Privacy Board Review: DPH Data Governance Committee

1. Subsequent to IRB approval, all research involving human subjects and their protected health information shall be reviewed by the DPH Data Governance Committee.

2. The DPH Data Governance Committee shall adhere to the following review and approval procedures:

   a. The review of the research must be conducted at a convened meeting at which the majority of members are present, including at least one member who satisfies the non-affiliation criteria;

   b. The majority of members must approve the waiver or alteration of the authorization, unless the Committee elects to use an expedited review. An expedited review may only be used if the research involves no more than minimal risk to the privacy of the human subjects.

   c. If the DPH Data Governance Committee elects to use expedited review, the Chair of the DPH Data Governance Committee or his/her designee, may carry out the review and approval.

IV. Documentation of Approval of the Waiver of Individual Authorization

A. If an IRB and the DPH Data Governance Committee approve a request to waive the requirement of obtaining individual authorization, then such approval must be documented as follows:

1. Identification of the IRB and the date of approval;

2. The date of approval by the DPH Data Governance Committee;

3. A statement that the IRB and the DPH Data Governance Committee have determined that the waiver of authorization satisfies all of the criteria set forth in Section II herein above;

4. A brief description of the PHI determined to be necessary for research;

5. A statement that the IRB and the DPH Data Governance Committee have conformed to the normal or expedited review procedures described in Sections III.A and III.B herein above; and

6. The signature of the chair of the IRB or his/her designee and the signature of the chair of the DPH Data Governance Committee or his/her designee.

V. Transition Period

A. PHI may be used or disclosed for research purposes if any of the following occurred prior to April 14, 2003:

1. The individual gave a written authorization or other express permission to use or disclose his/her PHI for research and no agreed-upon restriction is in place;

2. The individual gave his/her informed consent to participate in the research in which the PHI was created or received; or

3. An IRB waived the informed consent for research in accordance with the Common Rule (45 CFR 46) or the FDA regulations on the protection of human subjects.

VI. Protected Classes: Mental Health, Developmentally Disabled, Substance Abuse, and HIV/AIDS

A. 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.

B. To use DPH PHI pertaining to treatment for mental health, developmental disabilities, and substance abuse, researchers must sign the following oath of confidentiality:

"As a condition of doing research concerning persons who have received services from the San Francisco Department of Public Health, I, _____, agree to obtain the prior informed consent of such persons who have received services to the maximum degree possible as determined by the appropriate institutional review board or boards for protection of human subjects reviewing my research, and I further agree not to divulge any information obtained in the course of such research to unauthorized persons, and not to publish or otherwise make public any information regarding persons who have received services such that the person who received services is identifiable.

"I recognize that the unauthorized release of confidential information may make me subject to a civil action under provisions of the Welfare and Institutions Code of the State of California."

C. HIPAA excludes the use of 'psychotherapy notes' for research purposes without the specific authorization of the patient. Neither an IRB nor the Privacy Board (the DPH Data Governance Committee) may waive the requirement for authorization for the use of "psychotherapy notes," as defined in the Privacy Rule.

D. With respect to HIV-related research or AIDS-related research, California law mandates that research records, when patient-identifiable, are confidential and shall be disclosed only in accordance with prior written consent of the human subject. Additionally, any approved disclosure must be accompanied by a written statement containing substantially the following language:

"This information has been disclosed to you from a confidential research record, the confidentiality of which is protected by state law and any further disclosure of it without specific prior written consent of the person to whom it pertains is prohibited. Violation of these confidentiality guarantees may subject you to civil or criminal liabilities."

VII. De-Identified Information

A. De-identified information may be used or disclosed as long as no means of re-identification is disclosed.

B. In order to meet the definition of "de-identified" under the Privacy Rule, all of the following specified identifiers must be removed: names, 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), dates (other than years), ages over 89 (although all persons over 89 may be aggregated into a single category), telephone and fax numbers, e-mail addresses, 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.

C. If all of the required identifiers are not removed, information can still be treated as de-identified if a qualified statistician determines that the risk of re-identification is very small. This analysis must be documented.

VIII. Limited Data Set

A. General Rule

Use and disclosure of a "Limited Data Set" in connection with research is permissible if the researcher has signed a "Data Use Agreement."

B. Removal of Facially Identifiable Information

To create a Limited Data Set, all of the following facially identifiable information must be removed: name, postal address information (other than town, city, state and zip code), telephone and fax numbers, e-mail addresses, social security numbers, medical record numbers, health plan numbers, account numbers, certificate/license numbers, vehicle identifiers, serial numbers and license plate numbers, device identifiers and serial numbers, URLs and IP addresses, full face photos, full face photographic images, and biometric identifiers.

C. Data Use Agreement

A Limited Data Set of PHI may be disclosed to a researcher who has signed a data use agreement that provides satisfactory assurance that the Limited Data Set of PHI will not be used or disclosed in any way that would violate the HIPAA Privacy Rule.