San Francisco Department of Public Health

Policy

Policy Title: HIPAA Compliance – Privacy and the Conduct of Research	
Category: Privacy	
Effective Date: April 1, 2003	**Last Reissue/Revision Date:** December 14, 2021
DPH Unit of Origin: Office of Compliance and Privacy Affairs	
Policy Contact - Employee Name and Title; and/or DPH Division: Margaret Rykowski, Office of Compliance and Privacy Affairs (OCPA)	
Contact Phone Number(s): 855-729-6040	
Distribution: DPH-wide ☒	**If not DPH-wide, other distribution:**

All sections in table required.

1. PURPOSE OF POLICY

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 in order to allow research to occur, while at the same time ensuring that it is conducted in an ethical and legally-compliant manner.

2. 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), the Common Rule, 42 CFR Part 2, California Health & Safety Code § 11845.5(c)(3), and all other applicable California and federal laws. Use of PHI for research purposes must also follow DPH requirements for obtaining approval to conduct research projects using DPH human subjects and their health information.

3. DEFINITIONS

Cal. Health & Safety Code § 11845.5(c)(3): States that the contents of a medical record may be made available to qualified personnel for the purpose of conducting scientific research, management audits, financial and compliance audits, or program evaluation, but the personnel may not identify, directly or indirectly, any individual client in any report of the research, audit, or evaluation, or otherwise disclose patient identities in any manner. For purposes of this paragraph, the term "qualified personnel" means persons whose training and experience are appropriate to the nature and level of work in which they are engaged, and who, when working as part of an organization, are performing that work with adequate administrative safeguards against unauthorized disclosures.

Client Identifiers: Information that identifies patients. The HIPAA Privacy Rule lists 18 identifiers (see section 4.III.2.A of this policy – Safe Harbor).

Common Rule: The "Common Rule" regulations govern research funded (or conducted) by the Department of Health and Human Services. General rules for use and disclosure of patient information (Federal Policy for the Protection of Human Subjects, 42 C.F.R. Part 46).

Decedent Subject: Health information of deceased individuals is protected by federal and state

regulations. IRB review is determined by the level of protected health information (PHI) associated with the data. Decedent research that will have direct access to PHI, even if identifiers will not be recorded, must be submitted for IRB approval.

De-identified Data Sets: A data set can be considered data de-identified when 1.) The data does not identify an individual (all 18 identifiers are removed); and 2.) If the covered entity releasing the data has no reasonable basis to believe it can be used to identify the individual. De-identified data is not considered PHI.

DPH Administrative Representative: DPH Divisional heads, or their designees.

DPH Partners: Refers to staff of community based organizations contracted by DPH, or staff of providers affiliated with DPH via memorandums of understanding and other agreements, and/or staff of UCSF working at DPH locations.

DPH Program Representative: Representative of the DPH department whose patients, staff, and other resources are most impacted by the research. May at times be the same person as Administrative Representative.

DPH Staff: Refers to DPH employees, students, interns, and volunteers.

Federal-wide Assurance: All human subject research activities undertaken by an institution must be guided by a statement of principles known as the Federal-wide Assurance for the Protection of Human Subjects. This may include federal codes, statements of ethical principles, or statements created by the institution.

(Source: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html)

Health Care Operations: Operations refers to financial, legal, administrative, and quality improvement activities that are necessary to run a healthcare organization. These activities include coordinating patient care, analyzing patient data, teaching, performing audits, or managing healthcare quality. (45 C.F.R. Section 164.501)

HIPAA: The Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 CFR Parts 160 and 164, Standards for Privacy of Individually Identifiable Health Information and Security Standards for the Protection of Electronic Protected Health Information. HIPAA includes provisions designed to save money for health care businesses by encouraging electronic transactions and also regulations to protect the security and confidentiality of patient information. The privacy rule took effect on April 14, 2001, with most covered entities (health plans, health care clearinghouse and health care providers who conduct certain financial and administrative transactions electronically) having until April 2003 to comply. The security rule took effect on April 21, 2003.

HIPAA Privacy Rule: creates national standards to protect individuals' protected health information. (45 CFR Part 160; and 45 CFR Part 164, Subparts A and E).

Human Subject: A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. (45 CFR 46.102(e)(1)).

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. IRBs follow the requirements promulgated by the Department of Health

and Human Services for the protection of human subjects known as the "Common Rule."

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(j).

Peer-reviewed journal: A publication featuring work reviewed and approved by others in the same field of work as the author prior to publication.

Principal Investigator: The Principal Investigator (PI) is defined as the individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant. The DPH Principal Investigator is a PI employed by the San Francisco Department of Public Health.

Privacy Officer: Person responsible for overseeing the development of and adherence to privacy policies in an organization. These privacy polices ensure that all applicable laws are followed in the safe handling of protected health information.

Protected Health Information (PHI): Individually identifiable health information maintained or transmitted in any medium: oral, written, or electronic. It involves any information that identifies an individual AND relates to: 1.The individual's past, present or future physical or mental health; OR 2.The provision of health care to the individual; OR 3. The past, present or future payment for health care.

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 counseling session and that are separated from the rest of the individual's medical record. (Psychotherapy Notes are not medical record progress notes.) DPH policy prohibits the use of psychotherapy notes (See CBHS policy "Restrictions of Psychotherapy Notes and Informal Memory Prompts": https://www.sfdph.org/dph/files/CBHSPolProcMnl/3.06-05.pdf).

Public Health Activities: Covered entities may disclose PHI without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. This would include the reporting of a disease or injury; reporting vital events, such as births or deaths; and conducting public health surveillance, investigations, or interventions. (See 45 CFR 164.512(b)(1)(i).)

Public Health Surveillance: Public Health Surveillance is activities that allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance that are conducted, supported, requested, ordered or required (by) and authorized by a Public Health Agency or authority.

Quality Improvement/Quality Assurance (QI/QA): Refers to activities to continually evaluate and improve performance in a clinical area or department. QI/QA activities include changes to clinical systems or processes, the development and implementation of guidelines, or the intersection of these activities with training and education.

Re-identification: The assignment of a unique code to de-identified data, which can be used to identify it if needed. The code cannot be derived from the data being de-identified, and it must not be disclosed for any other purpose than re-identification. (Source: https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html)

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to 'generalizable' knowledge (45 CFR 46.102(l)). 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.

University of California (UCSF) Human Research Protection Program Institutional Review Board (IRB): The IRB established by UCSF for approving and overseeing research. For a complete description of UCSF Human Research Protection Program Guidelines go to: https://irb.ucsf.edu/

4. Procedures

I. RESEARCH VERSUS HEALTHCARE OR PUBLIC HEALTH OPERATIONS

Quality Improvement/Quality Assurance Activities: Studies pursued in the Department of Public Health for the primary purpose of quality improvement, public health activities, and outcome evaluation fall under the definition of health care and/or public health operations rather than research, and therefore do not require IRB approval 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 activities; 2) Population-based activities related to improving health; 3) Evaluating provider performance; and 4) Training programs. (45 CFR 164.501)

It is expected that the findings of QI/QA activities and public health activities may warrant publication from time to time. The possibilities of publishing the findings of a QI/QA activity (as defined above) or public health activity does not in and of itself obligate prior IRB review of the activity. Sharing or generalizing the results of a QI /QA activity or public health activity does not imply that the original activity was in fact research and was conducted without appropriate review.

Quality Improvement/Quality Assurance Activities that Become Research: If, following a completed QI project, there is a desire to study it further and make it generalizable (research) or if publication of the findings of a QI/QA activity requires re-analysis of identifiable data, it may be necessary to submit an application to the IRB and DPH approval. If the IRB determines that IRB approval is required, then DPH approval will also be required.

Note: IRB approval would not be required if publication of the QI/QA activity did not require access to a data set with subject identifiers.

Public Health Surveillance Activities: Public health surveillance activities are deemed not to be research only if they are limited to activities necessary to directly allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, and patterns in diseases or injuries).

II. REVIEW AND APPROVAL OF RESEARCH

1. Administrative Approval: Before commencing, all research conducted at a DPH site, utilizing DPH Protected Health Information, or funded by DPH must be approved in the manner prescribed by DPH research approval procedure.

   A. Research shall not be conducted within DPH without first obtaining the appropriate approvals. Any individual conducting research within DPH without obtaining the appropriate approvals shall be liable for any and all adverse consequences as result of commencing the unapproved research.

2. Attestation: As part of the approval process, researchers must attest that they have read and agree with all DPH policies regarding research involving DPH staff, settings, clients/patients, data, including protected health information.

3. Disclaimer: When references to DPH 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."

4. Usage of Institutional Review Boards (IRB): All research conducted in 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. UCSF IRB: Usage of the UCSF IRB is available to the following:

      i. DPH staff with 50% full time employment (FTE) appointments or higher at University of California at San Francisco (UCSF) must use the UCSF IRB for review and approval, unless otherwise advised by the UCSF IRB.

      ii. Any project that includes a 50% FTE or higher UCSF staff or faculty member in any capacity (including in-kind) must use the UCSF IRB for review and approval.

      iii. Any DPH staff member designated as a DPH Principal Investigator (PI) is permitted to use the UCSF IRB. (DPH employees may apply for designation as a DPH Principal Investigator by applying to the designated DPH IRB Representative).

      iv. Unless otherwise recommended by the UCSF IRB, DPH PIs must use 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:

      - Funding is granted to or applied for through UCSF,
      - Subjects will be recruited at UCSF, ZSFG, Laguna Honda Hospital (LHH) or the San Francisco Veterans Administration Medical Center (SFVAMC),
      - Research will take place at a UCSF, ZSFG, 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.

      v. 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 ensure the quality and integrity of the research.

   B. Other IRBs: Usage of non-UCSF-affiliated IRBs that have been formally designated to review and monitor biomedical research involving human subjects is permitted for the following:

i. DPH PIs whose research projects do not meet the criteria in 4.A.iv. above.

ii. All other researchers.

5. Research Recruitment

A. Prior to contacting DPH client/patient human subjects, identified based on review of health records, to recruit them to participate in research, researchers must receive permission from a member of the patient's health care team, such as their primary care provider. Documentation of approval, such as an email, or an email confirming verbal approval, is required for auditing purposes. If this is not possible, such as in cases where no recent or meaningful provider relationship exists, details and reasoning must be included within the Research Proposal Approval form that is approved by DPH.

i. Prior to contacting individuals on a DPH site or using a public health data set that is the property of DPH, including data sets of non-DPH clients, researchers must obtain approval by the DPH site administrator or data set owner.

B. Approval of patient recruitment methods, materials and messaging is also required, and part of the DPH research proposal approval process. Whether recruitment is done via phone, letter, text, in-person, or other methods such as through the patient portal, DPH must approve the method and messaging used.

C. If the study requires researchers to review charts or access an electronic health record system (EHR) such as EPIC to identify prospective subjects who will then be contacted and asked to be in the study, a waiver of informed consent must be obtained from the IRB. The justification for the waiver to review charts/access the EHR must show why the study cannot be done without the waiver. The waiver covers collecting only the minimum amount of information needed to make contact; consent is obtained before additional information is gathered.

D Prior to recruiting DPH staff for research, researchers shall obtain approval from the staff members' supervisor or division head.

E. Bias, stereotyping, and prejudice perpetuate racial and cultural disparities in clinical research. All research at a DPH site, using DPH PHI, or funded by DPH shall be conducted in a manner to reduce disparities and encourage diversity. Researchers should support the participation of vulnerable populations by making materials at an accessible language and literacy level, and reducing practical barriers to participation (transportation, childcare, etc) whenever possible. Researchers should identify the methods in which they will address these barriers to participation. There is also a history of exploitation (extraction without benefit to the community or individual) and unequal risk when research is conducted with vulnerable populations. Researchers should describe their reasoning for including patients from marginalized communities, reasons for excluding other populations (or clarification they are included), and share of the benefits of the research expected to accrue to the individuals or populations involved.

III. USE OF DPH PHI FOR RESEARCH PURPOSES

The remaining sections of this policy regarding use of DPH PHI apply only to use of existing

PHI that was originally collected for non-research purposes. De novo research projects (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) are exempt from the following policies regarding data sets.

This policy integrates federal privacy rules and local requirements for the use of three types of health information:

1. **PHI Data with Client Identifiers**
2. **De-Identified Data Sets**
3. **Limited PHI Data Sets**

1. 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 and state law.

B. Waiver of Patient Authorization
An IRB (per HIPAA and the Common Rule), 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 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.

C. Protected Classes: Mental Health, Developmentally Disabled, Substance Use Disorder,

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 use disorder 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 Review Preparatory to Research

HIPAA's preparatory to research provision (45 CFR 164.512(i)(1)(ii) permits the release of PHI by covered entities to researchers without patient authorization for certain purposes under specific conditions. Purposes include using PHI to help inform a research protocol or grant, or to identify a pool of potential research participants. The following conditions apply for PHI to be released for reviews preparatory to research:

1. Researchers who are not DPH employees or DPH Partners may not use PHI for activities preparatory to research without IRB waiver of informed consent, and IRB and DPH approval.

2. Researchers employed by DPH and DPH partner agencies may use PHI for activities preparatory to research 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 PHI will not be further disclosed by the researcher without obtaining prior IRB and DPH 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.

1. All data sharing of SFDPH data for research with UCSF researchers will be done only through UCSF's Academic Research Services (ARS). When data fulfillment is not done by ARS, the Program Representative will also provide the name of a DPH Data Set Representative to fulfill the request, and any billing related details. The DPH Data Set Representative will then share the data through UCSF ARS, who will share the data with the UCSF researcher.

2. Researchers must obtain DPH approval for any DPH data transmitted from the researcher to a third-party.

F. PHI Sources Excluded from Inclusion in Research

The following PHI sources may not be used to gather PHI for research purposes:

1. Epic Care Everywhere Health Information Exchanges (HIE): The Care Everywhere HIE found within the Epic Electronic Health Record may NOT be used to gather PHI for

research purposes. Existing PHI gathered via Care Everywhere that has been previously integrated into a client's medical record may be included in research data sets, but actively requesting data from other Care Everywhere participants (i.e., other health care systems) for research purposes is not permitted.

2. **De-Identified Data Sets**

The Privacy Rule defines data as de-identified when 1.) the data does not identify an individual; and 2.) if the covered entity releasing the data has no reasonable basis to believe it can be used to identify the individual. De-identified data are no longer considered PHI, and thus do not require authorization from the patient or an IRB prior to release for research purposes.

A. Approved Methods for De-Identifying Data

To be considered de-identified under the Privacy Rule, one of two de-identification methods may be used, the Safe Harbor method or the Expert Determination method[1].

Safe Harbor Method: Requires removing all of the following 18 identifiers:

1. Names
2. 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)
3. The month and day of dates directly related to an individual, such as birth date, admission date, death date, or dates of service
4. All ages over 89 must be removed, or aggregated into a single category of age 90 or over;
5. Telephone numbers
6. Email addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate / license numbers
12. Vehicle serial numbers and other identifiers, including license plate numbers
13. Device serial numbers and other identifiers
14. Web URLs (Universal Resource Locators)
15. Internet Protocol (IP) addresses
16. Biometric identifiers, including finger prints and voice recordings
17. Full face photographs, and any comparably identifying images
18. Any unique identifying number, characteristic, or code

Expert Determination Method

De-identification is performed by an individual with the appropriate knowledge of accepted statistical and scientific methods for rendering information not individually identifiable

If after applying those methods to de-identify data, the expert determines that the risk

is very small that the data could be used, alone or in combination with other sources, to identify an individual who is a subject of the data; then the data can be released to researchers as de-identified data, and is not held to the standards of PHI.

B. Re-identification of De-identified Data

DPH may create and assign a code or other means of re-identifying de-identified data, so long as the code is not derived from or related to any information involving the individual and their data, and the mechanism for re-identification is not disclosed.

C. 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 is used to de-identify the PHI, the third party must have a Business Associate Agreement in place with DPH. After the de-identification of the PHI, the business associate may not retain the fully-identifiable PHI for research without obtaining DPH approval.

D. Approvals Required

Researchers who access, review, collect, or receive De-Identified DPH Data Sets do not require IRB approval, but must have prior DPH approval to conduct the research.

3. **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

To be considered a Limited PHI Data Set, 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.

B. Approvals Required

Researchers who access, review, collect, or receive Limited PHI Data Sets must have prior approval from an IRB and the appropriate Administrative and Program representative.