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I. PURPOSE

The Stanford University HIPAA Components (SUHC) have developed policies and procedures that establish administrative, technical and physical safeguards requirements to promote compliance with HIPAA and the HITECH Act. This document sets forth definitions of key terms that are frequently used in SUHC's HIPAA Privacy policies.

II. DEFINITIONS

Access

The ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource.

Affiliated Covered Entity

Two or more covered entities that are under common ownership or control and that have designated themselves as an "Affiliated Covered Entity" for purposes of compliance with HIPAA. SHC and LPCH, and specified entities under their common ownership or control, have joined with the Stanford University HIPAA Components to form a single affiliated entity, called the Stanford Affiliated Covered Entity, for purposes of compliance with HIPAA.

Authentication

The process of verifying the identity of a person or system.

Breach

The unauthorized acquisition, access, use, or disclosure of PHI which compromises the security or privacy of the PHI. Breach excludes the following:

A. Unintentional acquisition, access, or use of PHI by an SUHC workforce member or person acting under the authority of SUHC or its business associates, if such acquisition, access, or use was made in good faith, within the scope of authority, and does not result in further acquisition, access, use or disclosure of such PHI in a manner not permitted under the Privacy

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Rule;

- B. Inadvertent disclosure by a person who is authorized to access PHI at SUHC or a Business Associate to another person authorized to access PHI at SUHC or the same Business Associate, or at an organized health care arrangement in which the covered entity participates, and the PHI received as a result of the disclosure is not further used or disclosed in a manner not permitted under the Privacy Rule.,
- C. A disclosure of PHI to an unauthorized individual when the covered entity or Business Associate has a good faith belief that the individual does not remember and has not otherwise retained the PHI.

Breach Notification

Notification of a breach of unsecured PHI in accordance with 45 CFR 164.404 through 164.412, as applicable, and other applicable legal requirements.

Business Associate

A person or entity that is <u>not</u> a member of the SUHC's workforce and that:

- A. Acting on behalf of the SUHC or an organized health care arrangement in which the SUHC participates, creates, receives, maintains, or transmits protected health information for a function or activity regulated by the Privacy Rule. Examples of such activities and functions include, but are not limited to:
 - 1. claims processing or administration;
 - 2. data analysis;
 - 3. processing or administration;
 - 4. utilization review;
 - 5. quality assurance;
 - 6. billing;
 - 7. benefits management;
 - 8. practice management;
 - 9. re-pricing; or,
 - 10. information technology

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- B. Provides the following types of services to the SUHC or an organized health care arrangement in which the SUHC participates, where the provision of service involves the disclosure of protected health information:
 - ı. Legal;
 - 2. Actuarial;
 - 3. Accounting;
 - 4. Consulting;
 - 5. Data aggregation;
 - 6. Management;
 - 7. Administrative;
 - 8. Accreditation; or,
 - 9. Financial
- C. Business associates also include the following:
 - I. Health information organizations, e-prescribing gateways; or other persons/entities that provide data transmission services with respect to protected health information and that requires access on a routine basis to such information; for purposes of this definition, "access on a routine basis;"
 - 2. Person/entity that offers a personal health record (PHR) on behalf of the SUHC; or,
 - 3. A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.
- D. The SUHC may be a business associate of another covered entity.

Computing Device

An electronic device such as a server, desktop or laptop computer, any other device that performs similar functions and electronic media stored in its immediate environment.

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Covered Entity

- A. A health care provider who transmits any health information in electronic form in connection with a transaction;
- B. A health plan; or,
- C. A health care clearinghouse

Covered Functions

Those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

Custodian of PHI

Any department or person(s), including faculty members and researchers, responsible for maintaining, controlling access to, and managing release of protected health information that is recorded in any form or medium, paper or electronic (e.g., databases, spreadsheets, paper files), and maintained in any location (e.g., Stanford office or data center,

Data aggregation

With respect to protected health information created or received by a business associate in its capacity as business associate of a covered entity, the combining of such PHI by the business associate with the PHI received by the business associate in its capacity as business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.

DHHS

The United States Department of Health and Human Services.

Designated Record Set

A group of records:

A. That includes the medical records and billing records about individuals maintained by or for a covered health care provider; or

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B. That may be used, in whole or in part, by or for SUHC to make decisions about individuals when acting in its capacity as a covered entity (e.g., decisions when acting as a health care provider).

De-identified Information

Health information that cannot be used to identify an individual. HIPAA allows only two (2) means of de-identifying protected health information (See, De-Identification Policy).

Direct Treatment Relationship

A treatment relationship between an individual and a health care provider who delivers care directly to the individual.

Disclosure

The release of, transfer of, provision of access to, or divulging in any other manner of information outside the Stanford Affiliated Covered Entity. (for example, a transfer of information from SHC/LPCH to the Stanford University HIPAA Components, or vice-versa, is within the Stanford Affiliated Covered Entity and, accordingly, would constitute a "use" of information rather than a "disclosure".)

Electronic Media

- A. Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card;
- B. Transmission media used to exchange information already in electronic storage media.

Transmission media include the Internet (wide-open), intranet, extranet (using Internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission.

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Electronic Protected Health Information (ePHI)

Protected health information that is:

- A. transmitted by electronic media; or
- B. maintained in electronic media.

Encryption

The use of an algorithmic process to transform data into a form in which there is a low probability of assigning meaning without use of a confidential process or key, and such confidential process or key that might enable decryption has not been breached.

Facility

The physical premises and the interior and exterior of a building(s).

Genetic Information

A subset of health information that includes:

- A. The individual's genetic tests;
- B. The genetic tests of family members of an individual;
- C. The manifestation of a disease or disorder in family members of an individual;
- D. Any request for, or receipt of, genetic services; "genetic services" includes a genetic test, genetic counsel (including obtaining, interpreting, or assessing genetic information), or genetic education;
- E. Participation in clinical research that includes genetic services;
- F. Genetic information of a fetus carried by the individual or family member who is a pregnant woman; or,

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G. Genetic information of an embryo legally held by an individual or family member utilizing an assisted reproductive technology.

Genetic Information, cont.

Genetic information excludes information about the gender or age of an individual.

Genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. Genetic test excludes an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition.

"Manifestation" or "manifested," for purposes of "genetic information" definition, means with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. A disease, disorder, or pathological condition is not manifested I if the diagnosis is based principally on genetic information.

Group Health Plan

An employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg-91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

- A. Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C.1002(7)); or
- B. Is administered by an entity other than the employer that established and maintains the plan.

A Group Health Plan is a type of health plan and, therefore, a covered entity under HIPAA. Stanford University, as an employer, sponsors and maintains various ERISA health benefit plans that are Group Health Plans. These include the University's

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Educated Choices Flexible Benefits Program, the Post-retirement and Post-employment Benefit Plan, the Postdoctoral Affiliates Welfare Benefit Plan, and the Welfare Benefit Plan for Certain Affiliated Medical Faculty and these and other plans as modified, added, and eliminated in the future.

Health Care Operations

Any of the following activities of a covered entity, to the extent that the activities are related to covered functions:

- A. Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;
- B. Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, and conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improved their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing or credentialing activities;
- C. Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care unless such health insurance or health benefits are not placed with the health plan;
- D. Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;
- E. Business planning and development, such as conducting cost-management

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and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; or,

- F. Business management and general administrative activities including, but not limited to:
 - Management activities relating to implementation of and compliance with the Privacy Rule;
 - 2. Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that PHI is not disclosed to such policy holder, plan sponsor, or customer;
 - 3. Resolution of internal grievances;
 - 4. The sale, transfer, merger or consolidation of all or part of SUHC with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; or
 - 5. Consistent with HIPAA policies, the Privacy Rule, and state law, creating de-identified health information or a limited data set, and fundraising for the benefit of SUHC.

Health care operations exclude marketing.

Health Care Provider

A provider of medical or health services and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Health Information

Any information, including genetic information, whether oral or recorded in any form or medium that:

A. Is created or received by a health care provider, health plan, public health

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authority, employer, life insurer, school or university, or health care clearinghouse; and,

B. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual.

Health Services

As defined in section 186i(s) of the Act, 42 U.S.C. 1395x(s)

HIPAA

The Health Insurance Portability and Accountability Act of 1996.

HITECH

Health Information Technology for Economic and Clinical Health Act.

Hybrid Entity

A covered entity that performs both health-related and non-health-related functions and has segregated its various functions into health care components and non-health care components for purposes of compliance with HIPAA. Stanford University is a hybrid entity and has placed its health care components and selected support units (e.g., Information Security Office (ISO), Internal Audit, Office of General Counsel) into the covered entity known as the Stanford University HIPAA Components.

Indirect Treatment Relationship

A relationship between an individual and a health care provider in which:

- A. The health care provider delivers health care to the individual based on the orders of another health care provider; and,
- B. The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

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Individual

The person who is the subject of protected health information.

Information System

An interconnected set of information resources under the same direct management control that share common functionality. A system normally includes hardware, software, information, data, applications, communications, and people.

Integrity

The property that data or information have not yet been altered or destroyed in an unauthorized manner.

Limited Data Set

Protected health information that excludes all of the identifiers that must be omitted in order for the information to be considered de-identified information, except for the following identifiers of the individual or of the individual's relatives, employers or household members (refer to SUHC HIPAA Use and Disclosure of Protected Health Information policy):

- A. Town or city, State, and zip code or any equivalent geocodes, but not including a street/postal address; and
- B. Dates, including dates directly related to an individual, (e.g., birth date, health care service, admission and discharge dates, date of death).

Malicious Software

Software (e.g., virus, worm, Trojan horse or spyware) designed to damage, disrupt or compromise the security of an information system.

Marketing

Communication about a product or service a purpose of which is to encourage recipients of the communication to purchase or use the product or service. Please refer to the HIPAA Use and Disclosure of Protected Health Information policy, Appendix I for exclusions from the definition of marketing.

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Mental Health Information

Information and records, or discrete portions thereof, specially relating to evaluation or treatment of a mental disorder, including all alcohol and drug abuse records and all records obtained in the course of providing mental health services to inpatients or outpatients subject to the California Lanterman-Petris-Short Act or the California Confidentiality of Medical Information Act.

Outpatient Psychotherapy Treatment Information

Information that is a subset of mental health information that relates to outpatient psychotherapy treatment regulated by the California Confidentiality of Medical Information Act and that may contain psychotherapy notes.

Password

The character string that a user enters with a User ID to authenticate the individual to an information system.

Payment

The activities undertaken to obtain or provide compensation or reimbursement for the provision of health care.

Personal Representative

Any person authorized under applicable law to act on behalf of the individual with respect to the individual's health care. For example, a personal representative may include the parent or guardian of a minor patient (unless the minor has the authority under California law to act on his or her own behalf), the guardian or conservator of an adult patient, or the representative of a deceased patient.

Privacy Rule

A regulation established under HIPAA and which sets national standards to protect the privacy of certain health information. The Privacy Rule became effective on April 14, 2003 and applies to health plans, health care clearinghouses and health care providers who conduct certain health care transactions electronically.

Protected Health Information (PHI)

Individually identifiable health information, including demographic information, that is created or received by a covered entity and that relates to the past, present, or

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future physical or mental health of an individual, provision of health care to an individual, or past, present, or future payment for the provision of health care to an individual.

Under HIPAA, protected health information does <u>not</u>include:

- A. Education records covered by the Family Educational Rights and Privacy Act (FERPA);
- B. Employment records held by a covered entity in its role as employer;
- C. Information relating to blood banking activities, including procurement, testing, and other procedures; or,
- D. Individually identifiable information regarding a person who has been deceased for more than 50 years.

Psychotherapy Notes

Information that is a subset of mental health information and in some cases a subset of outpatient psychotherapy treatment information, and defined by HIPAA as notes recorded in any medium:

- A. By a health care provider who is a mental health professional;
- B. Documenting or analyzing the contents of conversation during a counseling session (private, joint, group or family); and,
- C. That are separated from the rest of the individual's medical record.

Psychotherapy notes do <u>not</u> include medication prescription and monitoring information, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

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Remuneration

For purposes of the prohibition on sale of PHI, remuneration is prohibited (unless subject to a legal exception). Remuneration includes both financial benefit and nonfinancial benefit (including, for example, in-kind benefits, or other benefits such as through an access, license, or lease agreement). Remuneration also includes direct and indirect pathways (including remuneration from another party on behalf of the recipient of PHI).

Research

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Secretary

The Secretary of the United States Department of Health and Human Services.

Security Incident

Any attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.

Stanford Affiliated Covered Entity (SACE)

The single affiliated entity created by the joining of Stanford Health Care, Louise Packard Children's Hospital, ValleyCare, and University Healthcare Alliance, and the Stanford University HIPAA Components for the purposes of compliance with HIPAA. See, privacy.stanford.edu/covered-entity for a current listing of the SACE.

Stanford University HIPAA Components (SUHC)

The health care components of Stanford University that are its health care providers (e.g., School of Medicine, Vaden Health Center, etc.) and selected support units, as designated by the University Privacy Officer. For a list of departments and groups that are included in the Stanford University HIPAA Components, refer to_http://hipaa.stanford.edu/covered_entity.html.

Subcontractor

A person to whom a business associate delegates a function, activity, or service (other than a person in the workforce of the business associate).

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TPO

Treatment, payment, health care operations.

Transaction

The transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions:

- A. Health care claims or equivalent encounter information;
- B. Health care payment and remittance advice;
- C. Coordination of benefits;
- D. Health care claim status;
- E. Enrollment and change of enrollment status in a health plan;
- F. Eligibility for a health plan;
- G. Health plan premium payments;
- H. Referral certification and authorization;

Transaction, cont.

- First report of injury;
- J. Health claims attachments; and,
- K. Other transactions that the Secretary may prescribe by regulation

Treatment

The provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of

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health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

Unsecured PHI

PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology in compliance with NIST standards.

Use

With respect to protected health information, the sharing, employment, application, utilization, examination, or analysis of such information within the Stanford Affiliated Covered Entity (See, privacy.stanford.edu/covered-entity for a current list of SACE entities). For example, a transfer of PHI amongst SACE entities, e.g. from Stanford Health Care to Stanford University School of Medicine is a "use." A transfer of PHI from and entity within the SACE to an entity outside of the Stanford Affiliated Covered Entity constitutes a "disclosure" of information rather than a "use."

Workforce

A covered entity's employees, medical staff, volunteers, trainees, and other persons whose conduct, in the course of work for SUHC is under SUHC's direct control, whether or not they are paid by SUHC.

III. DOCUMENT INFORMATION

A. Legal Authority/References

- Federal Register, Vol. 65, No. 250, December 28, 2000, pages 82798 to 82829
- Federal Register, Vol. 67, No. 157, August 14, 2002, pages 53181 to 53273
- Federal Register, Vol. 68, No. 34, February 20, 2003, pages 8333 to 8381
- Health Information Technology for Economic and Clinical Health Act, enacted on February 17, 2009

B. Review and Renewal Requirements

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This policy will be reviewed and/or revised every three years or as required by change of law or practice.

c. Review and Revision History

Note: SUHC Policies were restructured September 2013

- (Version 3.0) September 2010
- (Version 4.0) September 2013, Privacy Office and Office of the General Counsel
- (Version 5.0) November 2014, Privacy Office
- (Version 6.0) January 2017 Office of the General Counsel; March 2017 Privacy Office

D. Approvals

• April 15, 2017, Stanford University Privacy Office

E. Contact for Questions Related to this Policy

Stanford University Privacy Office privacy@stanford.edu (650) 725-1828

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