PURPOSE

To define terms used in standard operating procedures implementing the HIPAA Research Compliance Program.

REVISIONS FROM PREVIOUS VERSION

1. Effective date: 9/6/2005
2. Revision #1 date: 6/12/2014
3. Revision #2 date: 5/6/2020

DEFINITIONS

Accounting of Disclosures of PHI: Information that describes a covered entity's disclosure of Protected Health Information (PHI) that has taken place within six (6) years of the date of the request (excluding any disclosures taking place prior to the compliance date). An accounting of disclosures is not required in the following situations:

- disclosures for treatment, payment, or health care operations ("TPO");
- disclosures made pursuant to valid authorizations;
- disclosure of limited data sets;
- disclosure of de-identified data;
- disclosures of PHI prior to April 14, 2003.

Authorization: An individual's written permission (signed by the individual or his/her legally authorized representative (LAR)) to allow a covered entity to use/disclose specified PHI for a particular research study. Except as otherwise permitted by the Privacy Rule, a covered entity may not use or disclose PHI for research purposes without a valid authorization.

Business Associate: With respect to a covered entity, a person who:

1. On behalf of such covered entity or of an organized health care arrangement in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

    a. A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or

    b. Any other function or activity regulated by 45 CFR 160; or

2. Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associated of such covered entity or arrangement, to the person.

Compliance Date: The date by which a covered entity must comply with the requirements mandated by the Privacy Rule. Covered entities must have completed implementation of, and be in compliance with, the Privacy Rule by April 14, 2003.

Covered Component: Components of a covered entity that engage in covered functions and any component that engages in activities that would make such component a business associate of a component that performs covered functions if the two components were separate legal entities.

Covered Entity:

1. A health plan;

2. A health care clearinghouse; and

3. A health care provider who transmits any health information in electronic form.

University of South Florida (USF) providers who render health care are covered entities according to the Privacy Rule.

Covered Functions: Functions that make an entity a health plan, a health care provider, or a health care clearinghouse.

Data Use Agreement: An agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected. This agreement may take the form of a formal contract or of a confidentiality agreement.

De-identified Data: Data that does not identify an individual and with respect to which there is no reasonable basis to believe that information within the data can be used to identify an individual.

The Privacy Rule provides two (2) routes by which data may be de-identified.

1. The first is the “Expert Determination” method:

a. A covered entity may determine that health information is not individually identifiable health information only if:

    i. A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

        1) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and

        2) Documents the methods and results of the analysis that justify such determination.

2. The second is the "Safe Harbor" method:

    a. Remove a list of eighteen (18) direct identifiers that could be used to identify the individual, or the individual's relatives, employer or household members. These identifiers are enumerated in the Privacy Rule (see list below).

    b. The covered entity must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is the subject of the information.

    <u>Direct Identifiers:</u>

    1. Names

    2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geographical codes, except for the initial three digits of a ZIP code if, according to the current publicly available data from the Bureau of the Census:

        a. The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and

        b. The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people are changed to 000.

    3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.

4. Telephone numbers
5. Facsimile numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web universal resource locators (URLs)
15. Internet protocol (IP) address numbers
16. Biometric identifiers, including fingerprints and voiceprints
17. Full-face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code.

Designated Record Set: A group of records maintained by or for a covered entity that includes:

1. Medical and billing records about individuals maintained by or for a covered health care provider;
2. Enrollment, payment, claims adjudication, and case or medial management record systems maintained by or for a health plan; or
3. Used, in whole, or in part, by or for the covered entity to make decisions about individuals.

A record is any item, collection, or grouping of information that includes PHI and is maintained, collected, used, or disseminated by or for a covered entity.

Disclosure -- The release, transfer, provision of access to, or divulging of information in any manner outside the covered entity holding the information.

FDA: The United States Food and Drug Administration.

FDA Regulations: A set of regulations intended to protect the rights, safety, and welfare of participants involved in studies subject to FDA jurisdiction.

HHS Regulations for the Protection of Human Subjects: Regulations intended to protect the rights and welfare of human subjects involved in research conducted or supported by the Department of Health and Human Services (HHS).

Health Information: Any information, whether oral or recorded in any form or medium, that:

1. Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

2. 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 Care Operations: Any of the following activities of the covered entity:

1. Conducting quality assessment and improvement activities, population-based activities related to improving health or reducing health care costs, and case management and care coordination;

2. Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, conducting training programs, accreditation, certification, licensing, or credentialing activities;

3. Conducting or arranging for medical review, legal services, and auditing functions, including compliance programs;

4. Business planning and development; and

5. Business management and general administrative activities.

Health Care Provider: Providers of medical or health care. Investigators who provide health care are health care providers.

Health Insurance Portability and Accountability Act of 1996 (HIPAA): This act requires, among other things, under the Administrative Simplification subtitle, the adoption of standards, including standards for protecting the privacy of individually identifiable health information.

HIPAA Privacy Regulations/Privacy Rule: A set of regulations adopted by the Department of Health and Human Services, as required by HIPAA, which are intended to protect the privacy and confidentiality of patients and study subjects.

HIPAA Research Privacy Officer: The individual employed by USF Research Integrity & Compliance who is charged with the responsibility of ensuring that USF investigators use and disclose PHI in research activities only in accordance with the Privacy Rule.

Hybrid Entity: A single legal entity that is a covered entity, performs business activities that include both covered and non-covered functions, and designates its health care components as provided in the Privacy Rule. USF is designated as a hybrid entity with both covered and non-covered components.

Individually Identifiable Health Information: Information that is a subset of health information, including demographic information collected from an individual, and:

1. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

2. 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; and

    a. That identifies the individual; or

    b. With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Investigator: Collective term denoting the Investigator, sub-investigator or co-investigator (including faculty, staff, students or agents) who are responsible for the design, conduct, implementation, evaluation, subject safety, and/or reporting of the proposed or ongoing research project. Investigators include individuals employed by USF or USF Affiliates and those who fall under a contractual agreement (including an Individual Investigator Agreement) or IRB Authorization Agreement with the USF IRB.

Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a potential subject to the subject's participation in the procedure(s) involved in the research.

Limited Data Set: A data set of PHI that excludes sixteen (16) of the eighteen (18) direct identifiers and may be used or disclosed, for the purposes of research, public health, or health care operations without obtaining either an individual's authorization or a waiver or alteration of authorization.

Minimum Necessary: The least information reasonably necessary to accomplish the intended purpose of the use, disclosure, or request.

Modified Accounting System: A method of accounting that can be utilized only in research studies that involve more than fifty (50) individuals, where the covered entity must provide the individual requesting the accounting with just the following information:

- The name of the protocol or research activity.
- A plain-language description of the research protocol or activity, purpose of the research, and criteria for selecting particular records.
- A description of the type of PHI disclosed.

- The date or period of time during which the disclosure(s) occurred or may have occurred, including the date of the last disclosure during the accounting period.
- The name, address, and telephone number of the entity that sponsored the research and of the researcher who received the PHI.
- A statement that the individual's PHI may or may not have been disclosed for a particular protocol or research activity.

If the covered entity uses this modified accounting method, it must, if requested by the individual, assist the individual in contacting the research sponsor and the researcher. Such assistance, however, is limited to those situations in which there is a reasonable likelihood that the individual's PHI was actually disclosed for the research protocol or activity.

Non-Covered Component Investigator: Investigators who are not employed by any of the University's covered components.

Payment: The activities undertaken by:

1. A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or

2. A health care provider or health plan to obtain or provide reimbursement for the provision of health care.

The above activities relate to the patient to whom health care is provided.

Privacy Board: A Board established to review and approve requests for waivers or alterations of authorizations in connection with a use or disclosure of PHI. A Privacy Board consists of members with varying backgrounds and appropriate professional competencies as necessary to review the effect of the research protocol on an individual's privacy rights and related interests. The Board must include at least one member who is not affiliated with either the covered component (covered entity) or with the entity that is conducting or sponsoring the research, and not related to any person who is affiliated with any such entities. Also, it must not have any member participating in a review of any project in which the member has a conflict of interest. At the University of South Florida, the Institutional Review Board (IRB) serves as the Privacy Board for issues related to the HIPAA Privacy Rule.

Protected Health Information (PHI): Individually identifiable health information transmitted or maintained in any form or medium (electronic, oral or paper) by a covered entity or its business associates. Education records covered by FERPA, records described at 20 U.S.C. 1232g(a)(4)(B)(iv) and employment records held by a covered entity in its role as an employer are excluded from this definition.

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 or family setting, that are separated from the patient's

medical records. See 45 C.F.R. Section 164.501 for elements of the record that are excluded from the definition of psychotherapy notes.

Reliance Exception to Revocation of Authorization by Subject: Permits the continued use/disclosure of PHI already obtained with an authorization, despite a written revocation of the individual's authorization, to the extent necessary to preserve the integrity of the research. For example, the reliance exception permits the use/disclosure of PHI: to account for a subject's withdrawal from the study; as necessary to incorporate the information as part of a marketing application submitted to the FDA; and to conduct investigations of scientific misconduct, or to report adverse events.

Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge**.**

Research as Defined by FDA: Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

1. Must meet the requirements for prior submission to the FDA under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;

2. Must meet the requirements for prior submission to the FDA under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; or

3. Any activity the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

Reviews Preparatory to Research: Using/reviewing PHI for the purpose of developing a research protocol or a similar activity in preparation for formulating a research hypothesis or identifying potential research subjects.

TPO Exception: Use and disclosure of PHI without an authorization or a waiver of HIPAA authorization, but only if such use and disclosure falls within treatment, payment, and/or health care operations activities, as such activities are defined in 45 CFR 164.501.

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 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 provider to another.

Use: The sharing, application, utilization, examination, analysis, or employment of individually identifiable health information within an entity or health care component that maintains such information.

USF Affiliate: An entity other than the University of South Florida (USF) with which USF has a contractual relationship.

USF Research Integrity & Compliance: The area responsible for facilitating research-related assurance and compliance programs for the conduct of research at the University. Research Integrity & Compliance reports to the Senior Vice President for Research, Innovation & Knowledge Enterprise.

USF Covered Component: College of Medicine (COM), Physical Therapy School, College of Pharmacy, USF Student Health Services, the Johnnie B. Byrd, Sr. Alzheimer's Center and Research Institute, the USF College of Behavioral and Community Sciences Department of Communication Sciences and Disorders, University Medical Services Association (UMSA) / Medical Services Support Corporation (MSSC), USF St. Petersburg Family Study Center, Infant Family Center, and certain administrative units to the extent these units engage in covered functions involving use/disclosure of PHI.

Waiver, Partial Waiver, or Alteration of Authorization – The documentation that the covered entity (covered component, for USF) obtains from the Privacy Board and/or its designee, which states that the Privacy Board has waived or altered the requirement of the HIPAA Privacy Rule that an individual must authorize the use or disclosure of his/her PHI for research purposes.

Workforce: Employees, volunteers, trainees, and other persons whose conduct in the performance of work for a covered entity (covered component) is under the direct control of that covered entity (covered component), whether or not they are paid by that entity or component.

REFERENCES

45 CFR 164