

THE TEXAS A&M UNIVERSITY SYSTEM CONDUCTING RESEARCH WITH PROTECTED HEALTH INFORMATION

The Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (HIPAA) protect the privacy of individually identifiable health information. Entities that are subject to HIPAA can provide Texas A&M University System researchers (Texas A&M researchers) with access to, and use of, protected health information (PHI) for research purposes under certain conditions. This document provides guidance to Texas A&M researchers on the various ways that covered entities can disclose PHI to them for research purposes.

PROTECTED HEALTH INFORMATION

HIPAA applies to certain health care providers, health plans, and health care clearinghouses that electronically transmit health information in connection with certain healthcare-related transactions. These “covered entities” may only use and disclose PHI as permitted or required by HIPAA.

PHI is individually identifiable health information that is transmitted or maintained in any form and held or maintained by covered entities or their “business associates” (as such term is described below). PHI includes demographic information and other information that identifies an individual relating to:

1. the past, present, or future physical or mental health or condition of the individual (including genetic information and health information of non-U.S. citizens);
2. the provision of health care to the individual; or
3. the past, present, or future payment for the provision of health care to the individual.

HIPAA specifically excludes “education records” and “treatment records” governed by the Family Educational Rights and Privacy Act (or FERPA) from the definition of PHI.

USE AND DISCLOSURE OF PHI FOR RESEARCH

HIPAA provides various mechanisms for covered entities to disclose PHI to Texas A&M researchers – with or without patient authorization.

A. WITH PATIENT AUTHORIZATION

Under HIPAA, covered entities may disclose PHI to a Texas A&M researcher with the individual’s written authorization (Authorization). HIPAA has specific requirements for what must be contained in that Authorization, including a description of the PHI to be used and the purpose of the requested use, the names of the persons to whom the disclosure may be made, and the expiration date of the Authorization. Each individual whose PHI will be disclosed must sign an Authorization that permits the Texas A&M researcher to use the PHI for his/her specific research study.

B. WITHOUT PATIENT AUTHORIZATION

HIPAA permits covered entities to disclose PHI to Texas A&M researchers without the patient's authorization in the following circumstances:

1. Limited Data Set with a Data Use Agreement

A covered entity may disclose a limited data set to a Texas A&M researcher pursuant to a data use agreement (DUA). A limited data set excludes the following 16 identifiers from the PHI that the Texas A&M researcher receives: (1) names; (2) account numbers; (3) postal address information (other than town, city, state, and zip code); (4) certificate/license numbers; (5) telephone numbers; (6) vehicle identifiers and serial numbers, including license plate numbers; (7) fax numbers; (8) device identifiers and serial numbers; (9) email addresses; (10) web universal resource locators (URLs); (11) social security numbers; (12) Internet protocol (IP) address numbers; (13) medical record numbers; (14) biometric identifiers, including fingerprints and voiceprints; (15) health plan beneficiary numbers; and (16) full-face photos and any comparable images.

Texas A&M and the covered entity would enter into a DUA to govern how the Texas A&M researcher can use the limited data set for his/her research study. HIPAA has specific requirements for what must be included in that DUA, including the permitted uses and disclosures of the limited data set by the Texas A&M researcher, who is permitted to use the limited data set, and certain stipulations for the protection of the limited data set.

Texas A&M may create the limited data set on behalf of the covered entity if Texas A&M and the covered entity enter into a "business associate agreement" (as such term is described below) governing that creation. Once the limited data set is created, Texas A&M must return or destroy the data set that includes the 16 specific identifiers.

2. IRB Waiver

Texas A&M researchers may seek a waiver or alteration of the Authorization requirement from an Institutional Review Board (IRB) or a Privacy Board if it is not feasible to obtain a signed Authorization from all individuals whose PHI is needed for the study. An IRB or Privacy Board may approve a waiver in whole (i.e., no Authorization is required for a particular research study) or in part (e.g., PHI can be disclosed for subject recruitment purposes). An IRB or Privacy Board may also approve a request that alters the requirements for an Authorization.

To grant a waiver or alteration, the IRB or Privacy Board must determine that there is no more than a minimal risk to the privacy of the individuals and that the research could not be practicably conducted without (1) the waiver or alteration and (2) access to and use of the PHI. Texas A&M researchers should consult with the relevant IRB or Privacy Board to request a waiver or alteration of the Authorization requirement.

3. Activities Preparatory to Research

Covered entities may disclose PHI to a Texas A&M researcher for activities involved in preparing research, such as aiding in study recruitment or preparing a research protocol. For these activities, the covered entity must obtain oral or written representations that: (1) the use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar preparatory purposes, (2) the PHI will not be removed from the covered entity during the Texas A&M researcher's review, and (3) the PHI for which use or access is requested is necessary for the research.

4. Research with Decedents' Information

Covered entities may disclose PHI of deceased individuals to Texas A&M researchers if the covered entity obtains oral or written representations that: (1) the use and disclosure is sought solely for research on the PHI of decedents, and (2) the PHI for which use or disclosure is sought is necessary for the research. In addition, the covered entity may request that the Texas A&M researcher provide documentation showing that the individuals whose PHI is needed for the study are deceased.

DE-IDENTIFIED HEALTH INFORMATION

De-identified health information is not considered PHI for purposes of HIPAA, which means that a covered entity may disclose de-identified health information to a Texas A&M researcher without any restrictions under HIPAA. HIPAA permits two methods for de-identifying PHI – (a) the covered entity can obtain an expert determination that the PHI has been de-identified, or (b) the following 18 identifiers can be removed from the PHI: (1) names; (2) account numbers; (3) all geographic subdivision smaller than a state (e.g., street address, city, county, ZIP code, etc.); (4) certificate/license numbers; (5) telephone numbers; (6) vehicle identifiers and serial numbers, including license plate numbers; (7) fax numbers; (8) device identifiers and serial numbers; (9) email addresses; (10) web universal resource locators (URLs); (11) social security numbers; (12) Internet protocol (IP) address numbers; (13) medical record numbers; (14) biometric identifiers, including fingerprints and voiceprints; (15) health plan beneficiary numbers; and (16) full-face photos and any comparable images; (17) All elements of dates (except year) for dates that are directly related to an individual (e.g., date of birth, admission date, discharge date, death date, etc.); and (18) any other unique identifying number, characteristic, or code.

Texas A&M is permitted to de-identify PHI on behalf of the covered entity if Texas A&M and the covered entity enter into a "business associate agreement" (as such term is described below) governing the de-identification. Once the PHI is de-identified, Texas A&M must return or delete all copies of the PHI received from the covered entity.

BUSINESS ASSOCIATE AGREEMENTS

Under HIPAA, covered entities can disclose PHI to their business associates if they enter into a business associate agreement to ensure that the business associate will appropriately safeguard the PHI. A business associate is a person or entity that performs certain services or functions on behalf

of the covered entity, such as claims processing or administration; data analysis, processing or administration; utilization review; and quality assurance. Although HIPAA does not permit a covered entity to disclose PHI for research purposes pursuant to a business associate agreement, Texas A&M may enter into a business associate agreement with a covered entity to create a limited data set or de-identify PHI on behalf of the covered entity as described above. The business associate agreement must be incorporated into an underlying services agreement between Texas A&M and the covered entity.

By entering into a business associate agreement with a covered entity, Texas A&M is contractually obligated to comply with certain aspects of HIPAA and also directly liable for certain HIPAA violations, including impermissible uses and disclosures of PHI, failure to comply with HIPAA's Security Rule, and failure to make reasonable efforts to limit disclosures of PHI to the minimum necessary amount. The federal government can seek civil and criminal penalties for a business associate's violations of HIPAA.

QUESTIONS

Texas A&M members may contact Kate Pharr, Assistant General Counsel, in the Office of General Counsel (kpharr@tamus.edu) with questions relating to conducting research with PHI.