

**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 members of The Texas A&M University System (Texas A&M members) with access to, and use of, protected health information (PHI) for research purposes under certain conditions. This document provides guidance to Texas A&M members and their Chief Research Officers and Research Compliance Officers on the various ways that covered entities can disclose PHI 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 the:

1. 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. provision of health care to the individual; or
3. 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 (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 members for research purposes – with or without patient authorization.

A. WITH PATIENT AUTHORIZATION

Under HIPAA, covered entities may disclose PHI for research purposes with the individual’s written authorization (Authorization). HIPAA has specific requirements for what must be included in that Authorization, including a description of the PHI to be used, 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 member 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 members for research purposes 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 (LDS) to a Texas A&M member pursuant to a data use agreement (DUA) that governs how the Texas A&M member researcher can use the LDS for his/her research study. An LDS excludes 16 specific identifiers,¹ including names, email addresses, telephone numbers, and medical record numbers. HIPAA has specific requirements for what must be included in a DUA, including the permitted uses and disclosures of the LDS, who may use the LDS, and other stipulations for the protection of the LDS.

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

2. IRB Waiver

A Texas A&M member researcher 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. A Texas A&M member researcher 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 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

¹ The 16 specific identifiers that must be removed to create a limited data set are (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.

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 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 for research purposes 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. The covered entity may also request that the 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 for research purposes without any restrictions under HIPAA. HIPAA permits two methods for de-identifying a data set containing PHI; the covered entity can either (1) obtain an expert determination that the data set containing PHI has been de-identified, or (2) remove 18 specific identifiers² from the data set.

Texas A&M members may de-identify a data set containing PHI on behalf of the covered entity if the Texas A&M member and the covered entity enter into a "business associate agreement" (as described below) governing the de-identification. Once the data set containing PHI is de-identified, the Texas A&M member must return or delete all copies of the data set containing 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 (BAA) that ensures 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.

HIPAA does not permit a covered entity to disclose PHI for research purposes pursuant to a BAA, but Texas A&M members may enter into a BAA with a covered entity to create a LDS or de-identify PHI on behalf of the covered entity. The BAA must be incorporated into an underlying

² The 18 specific identifiers that must be removed to create a de-identified data set are (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.

services agreement between the Texas A&M member and the covered entity that governs the creation of the LDS or de-identified data set.

By entering into a BAA with a covered entity, Texas A&M members are 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 regarding conducting research with PHI.