UNLV **Office of Research Integrity**

Human Subjects Research and HIPAA

Responsible Administrator: Data Privacy Officer
Responsible Office: Office of Research Integrity
Originally Issued: 2024
Revision Date:

Approvals: David W. Hatchett 09/19/2024

David Hatchett, Ph.D., Vice President for Research — Date

Statement of Purpose

The intention of this policy is to provide guidance in regard to permissible uses and disclosure of Protected Health Information ("PHI") for research purposes pursuant to the Health Insurance Portability and Accountability Act ("HIPAA") Privacy Rule.

Entities Affected by this Policy

All UNLV faculty, staff, and students involved in research and all programs and departments of UNLV that are identified as covered entities under HIPAA and/or included in the health care component of NSHE.

Who Should Read this Policy

All UNLV faculty, staff, and students.

Policy

The HIPAA Privacy Rule ("Privacy Rule") describes ways in which PHI can be used or disclosed by a covered entity for research purposes. In general, the Rule allows PHI to be used or disclosed for research purposes pursuant to:

- Individual's authorization;
- Documented Institutional Review Board ("IRB") waiver of an individual's authorization or alteration of an authorization;
- Data Usage Agreement ("DUA") for sharing a limited data set;
- Activities involved in preparing for research when the PHI is not removed from the covered entity;
- Complete de-identification of the PHI; and/or
- Research studies involving decedent's PHI in limited situations

The Privacy Rule applies when: 1) The Researcher relies on a covered entity as the source of PHI; or 2) The Researcher works for a covered entity.

A. Research Use or Disclosure of PHI with Authorization (may include any and all individual identifiers)

    a. A covered entity must obtain a signed authorization from all participants in research prior to the internal use or external disclosure of PHI for any research related purpose that is not otherwise permitted or required under HIPAA. The research may include a clinical trial or records research.

    b. The IRB, Office of Research Integrity and/or Covered Entity will ensure that the authorization complies with the Privacy Rule for use or disclose of PHI for research purposes.

    c. Special note: An Authorization is always required for access, disclosure or use of psychotherapy notes.

B. Research Use or Disclosure of PHI with Waiver of Authorization by IRB (may include any and all individual identifiers approved by the IRB in its waiver)

    a. In some circumstances, an authorization for use of PHI for research may be waived by the IRB, provided the following three criteria are satisfied and documented (generally in addition to satisfaction of waiver of informed consent requirements pursuant to 45 CFR 46.116):

        i. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on HIPAA-prescribed criteria which are:
            1. an adequate plan to protect the identifiers from improper use and disclosure;
            2. an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
            3. adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

        ii. The research could not practicably be conducted without the waiver; and

iii. The research could not practicably be conducted without access to and use of the PHI.

b. A request for Waiver of Authorization must be completed by the researcher and submitted to the IRB for prior review and approval.

c. Uses or Disclosures of PHI made pursuant to a Waiver are subject to the HIPAA Minimum Necessary rules.

d. Since a researcher cannot practicably obtain a potential research participant's authorization for review of PHI in advance of contacting the potential participant, the IRB may issue a limited waiver of authorization permitting specified access and use of PHI solely for prescreening and recruitment contact pursuant to an approved protocol.

e. Individuals responding to an advertisement or otherwise initiating contact and indicating interest in participating in a research study may be given an explanation of the study (including, but not limited to, the name of the principal investigator and description of the study) without Authorization or Waiver of Authorization; however, either their Authorization or a Waiver of Authorization is required to review their PHI in health care records to determine potential eligibility.

C. Research Use of a Limited Data Set

a. A researcher may use, obtain or disclose a Limited Data Set from a covered entity for research without an Authorization or IRB Waiver of Authorization. A limited data set as defined in HIPAA is described below. Although a Limited Data Set is nearly de-identified, this limited amount of PHI consisting of certain geographic data and dates may be adequate for a broader array of research studies than completely de-Identified data.

b. A Limited Data Set is described as health information that excludes certain, direct identifiers. A Limited Data Set may include the following information:

i. State, county, city, town, census track, precinct, zip code or any other geocodes above the level that would identify an individual household; and/or

ii. All elements of dates directly related to an individual, including birth date, admission date, discharge date, dates of health care procedures or other services, and date of death.

c. The Limited Data Set must exclude the following direct identifiers : names, street addresses (other than town, city, and zip code), telephone numbers, fax numbers, email addresses, social security numbers, medical record numbers, health-plan insurance beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers, including license plate numbers, device identifiers and serial numbers, web universal resource locators (e.g. URLs), Internet Protocol (IP) address numbers, biometric identifiers including finger, retinal and voiceprints, full face photographic images and comparable image.

d. A Limited Data Set may be used or disclosed only if there is a DUA between the covered entity providing the data and the recipient of the limited data set. A researcher should contact the Data Privacy Officer in ORI if he/she needs or receives a DUA for a Limited Data Set.

e. A researcher may find the need to access full PHI in order to abstract from a Limited Data Set for research use. Because this abstraction activity requires access to PHI, a researcher may ONLY engage in this abstraction activity under the following circumstances:

    i. The researcher must have an IRB waiver of authorization; or

    ii. In addition to a DUA, the researcher must enter into a Business Associate Agreement with the Covered Entity to create the Limited Data Set on the covered entity's behalf for the researcher's use. IMPORTANT: Contact the Office of Research Integrity's Data Privacy Officer for assistance in this situation.

D. Access to PHI solely for Preparation for Research

a. Researchers may access PHI in the records of covered entities without an Authorization or IRB Waiver of Authorization for the purposes of development of a research protocol or assessment of feasibility of a research protocol, provided that the researcher documents to the satisfaction of the data privacy officer and covered entity's PHI data custodian (e.g. the medical records manager):

    i. The use or disclosure of PHI is solely to prepare or assess feasibility of a research protocol;

    ii. The researcher will not record individually identifiable PHI or remove PHI from the records reviewed (for example, researcher may review

identifiable PHI but may only record aggregate data or individual data that does not include any individual identifiers);

iii. The PHI sought is necessary for the purposes of the research; and

iv. The researcher shall not contact or recruit patients under this provision.

b. Physicians and other health care professionals who have a direct treatment relationship with an individual may review that individual's PHI for eligibility with respect to a research protocol and may initiate a discussion with the individual about potential participation as a research subject in a protocol relevant to the treatment relationship. This scenario does not require an Authorization or a Waiver of Authorization.

E. Use or Disclosure of "De-Identified" Health Information

a. The Privacy Rule permits a covered entity or business associate to create information that is not individually identifiable by following the de-identification standard.

b. Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.

c. The Privacy Rule provides two de-identification methods: 1) a formal determination by a qualified expert; or 2) the removal of specified individual identifiers as well as absence of actual knowledge by the covered entity that the remaining information could be used alone or in combination with other information to identify the individual.

d. Individual health information that conforms to the HIPAA definition of de-identified is exempt from HIPAA and may be used or disclosed for research purposes without an Authorization or Waiver of Authorization or DUA.

e. The HIPAA definition of de-identified PHI is not the same as what many researchers have been accustomed to consider "anonymized" data. While de-identified data, as defined by HIPAA, may not be adequate for many research studies, it presents no risk of privacy violation. De-identified data is not subject to the HIPAA Privacy Rule. Therefore, it requires relatively

little documentation for research access or use and is not subject to any restrictions on downstream use and disclosure.

F. Use and Disclosure of Decedent's Individually Identifiable PHI Without Authorization

a. Researchers may use and disclose a decedent's individually identifiable PHI for research without an Authorization or IRB Waiver, provided that the researcher documents that all the following criteria are satisfied:

i. The use will be solely for research on the PHI of a decedent; and

ii. The researcher has documentation of the death of the individual about whom information is being sought; and

iii. The PHI sought is necessary for the purposes of the research.

b. The researcher will provide documentation in the protocol and/or data safety management plan that all of the above criteria are satisfied in accordance with the data management registration process.

c. Uses or Disclosures of a decedent's PHI for research purposes are subject to the minimum necessary rule.

The Privacy Rule allows for certain rights of individuals with respect to their health information such as a right to receive a notice of privacy practices and privacy rights from the covered entity. Additionally, the Rule permits individuals to gain access to PHI, request amendment of, request restrictions on, request confidential communications, receive an accounting of disclosures of PHI and report to the Secretary of Health and Human Services if the individual believes a violation of the Rule has occurred. However, during clinical trials, the individual's right of access can be suspended while the research is in progress if, in consenting to participate in research, the individual agreed to temporary denial of access and that access will be restored upon conclusion of the clinical trial.

Exceptions where PHI is not protected under the Rule include data that is de-identified and Family Educational Rights and Privacy Act (FERPA) data that is considered "education records."

Related Documents

Appendix A- Decision Tree: When does HIPAA apply to Research

Research Responsibilities Memo

NSHE Manual, Cpt 4, Section 11

Summary of the Privacy Rule

Privacy Rule and Research

IRBs and the HIPAA Privacy Rule

Contacts

Office of Research Integrity: Data Privacy Officer

Definitions

Defer to Research Glossary

APPENDIX A
DECISION TREE: WHEN DOES HIPAA APPLY TO RESEARCH

Does your research involve protected health information (PHI)[1] about living participants or about deceased persons, regardless of how it will be collected (from intervention, interaction, chart review, and/or stored in databases or repositories)?

NO →

Your research does not use health information covered under HIPAA

YES ↓

Will you be accessing, collecting, recording, or using heath information linked to personal identifiers (at any time)?

NO → HIPAA does not apply.

YES ↓

Does your research only involve data/specimens from deceased persons?

YES → An IRB application is not required as deceased individuals are not human subjects under Research. HIPAA does not apply.

NO ↓

Does your study involve obtaining/recording health information with identifiers?

NO → Research data is considered <u>de-identified.</u> HIPAA does not apply.

YES ↓

Is your research a chart review in which only limited identifiers are recorded (age, individual dates (DOB, dates of service), and city, state, zip codes?

YES → Research data is considered a <u>limited dataset</u>. An internal or external DUA is required to be executed. Contact the Data Privacy Officer for assistance.

NO ↓

Will the study involve obtaining/recording of health information that can be linked to an individual directly or through a code that can be linked to a master list?

YES → Research data is considered identifiable per HIPAA. Prepare and submit a HIPAA Authorization Form to use in your study or request a **Waiver or Alteration** in your IRB application.

[1]Protected Health Information (PHI) = Health Information + Identifiers

Name, Address, All elements (except years) of dates related to an individual, telephone numbers, fax number, email address, social security number, medical record number, health plan beneficiary number, account number, certificate/license number, vehicle identifiers & serial numbers, including license plate numbers, device identifiers & serial numbers, web URL, IP address, finger or voice print, photographic image, any other characteristic that could uniquely identify the individual

Version Date: 07/2024