The Health Insurance Portability and Accountability Act (HIPAA)

Excerpted from the UTC IRB Policy

- The University of Tennessee at Chattanooga

Office of Grants and Research

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Table of Contents

Policy Statement

This policy defines the parameters for the use of protected health information (PHI) in biomedical, behavioral and social science research. Research being conducted at this institution that involves a HIPAA covered entity will adhere to the regulations set forth in the HIPAA Privacy and Security rules (45 CFR 160 and 164). PHI can only be used in research if the following conditions have been met:

- The research project has been reviewed and approved by UTC's IRB and the patient has provided written authorization for the research use or disclosure.
- The research project has been reviewed and approved by UTC's IRB and the patient authorization has been waived by the IRB.
- The PHI being requested is limited to that of descendants and conforms to the minimum information necessary to conduct the research.
- The PHI is being sought for preparatory research and no PHI information will be removed from the covered entity.
- The research project has been approved by the UTC's IRB, the PHI requested constitutes a limited data set and a Date Use agreement has been signed by the Investigator and the Institution.
- Disclosures of patient information will be limited to the terms on an investigator's patient authorization, certifications, IRB waiver, or Data Use agreement, as applicable.
- No investigator can use patient information to initiate contact with a patient for recruitment.

PART V: THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

Federal guidelines establish the conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes [45 CFR §§ 164.501, 164.508(f), 164.512(i)]. The Privacy Rule outlined in HIPAA defines the means by which individuals/human research subjects are informed of how medical information about them will be used or disclosed, and their rights with regard to gaining access to information about them when such information is held by covered entities. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time, ensuring that researchers continue to have access to medical information necessary to conduct vital research.

In the course of conducting research, researchers may create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose PHI for research with individual authorization, or without individual authorization under limited circumstances.

All research involving health information and/or records of the same should complete a Form H and attach it to any relevant IRB proposal.

5.1 DISCLOSURE WITH AUTHORIZATION BY THE RESEARCH SUBJECT

The Privacy Rule permits researchers to use and disclose PHI for research when participants authorize the use or disclosure of information about themselves. Typically, a research participant's authorization will be sought for clinical trials and some research involving records. In these instances, specific elements must be included in the informed consent form.

5.1.1 Informed Consent under HIPAA

1. Certain language is required to ensure HIPAA compliance with respect to informed consent and PHI. This language is reproduced in the Authorization Template attached in the Appendix. This template must be inserted into the confidentiality section of the informed consent form exactly as written in the Appendix.
2. A valid authorization for the release of PHI for research also must contain the following required elements in the informed consent form:

1. A description of the information to be used or disclosed that identifies the information in a specific and meaningful manner;
2. The name of the covered entity or person(s) authorized to make the requested use or disclosure;
3. The name or other specific identification of the person(s) or entities, which may include the covered entity itself, to whom the covered entity may make the request for use or disclosure;
4. An expiration date and a signature and date;
5. The authorization must be written in plain language;

6. If the authorization is executed by a legal representative authorized to act for the individual, a description of his/her authority to act for the individual must be specified as well as the relationship to the individual;

7. A statement that the individual acknowledges that he/she has the right to revoke the authorization except to the extent that information has already been disclosed under the authorization;

8. A statement that the individual acknowledges that information used or disclosed to any entity other than a health plan or health care provider may no longer be protected by the federal privacy law;

9. A description of the purpose(s) of the requested use or disclosure;

10. A statement that the individual may inspect or copy the protected health information to be used or disclosed; and

11. A statement that the individual may refuse to sign the authorization.

3. Consent forms for actual or potential subjects in a research study must be retained for at least six years from the date permission is granted.

5.2 RESEARCH USE: DISCLOSURE WITHOUT AUTHORIZATION BY THE RESEARCH SUBJECT

There are four circumstances that allow researchers to use and disclose PHI for research purposes without authorization by research subjects. These are:

1. Waiver of authorization

2. Review of PHI preparatory to research

3. Research involving a decedent's information

4. Use involving limited data sets

All of these situations require IRB approval.

5.2.1 Application Process for Disclosure of PHI without Authorization by Research Subjects

All applications for disclosure of PHI without authorization by research subjects will require a full board hearing. At such time the IRB will consider the type of PHI which is being considered for waiver and whether the investigators have met the criteria for waiver outlined in the following sections. Normal procedures for full board hearings will be used in hearing waiver applications (see Section 2.3.3). Investigators should submit applications to the Director of Research Integrity. Application forms and contact information for the Director of Research Integrity can be found at the IRB Website (http://www.utc.edu/irb). They also are on file at the Office of Grants. Electronic submission is required.

The IRB full-board meets on an ad hoc basis; therefore, investigators should consult the Director of Research Integrity to ensure that they are scheduled for review. Every attempt will be made to

schedule a meeting to hear these applications within 3-5 weeks from the time the application is received by the Director of Research Integrity (provided there are no modifications or clarifications needed to the application). The Director of Research Integrity will notify the applicant in writing of all decisions. The IRB approval letter will include the following elements:

1. Identification of the IRB and the date on which the waiver of authorization was approved;

2. A statement that the IRB has determined that the waiver satisfies the pertinent criteria;

3. Provide a brief description of the PHI for which use or access has been determined to be necessary by the IRB; and

4. Note that the request was approved based on a hearing by the full board.

5.2.1.a Securing a Waiver of Authorization

A waiver of authorization may be sought for three specific research uses of PHI:

1. To identify potential research subjects through review of their PHI;
2. To contact potential subjects in order to determine their interest in research participation; and
3. To receive or collect PHI during the conduct of research studies.

A covered entity is permitted to disclose PHI for research purposes without a written authorization from the research subject if approval is obtained from the IRB. A covered entity also may use or disclose PHI without individuals' authorizations for the creation of a research database, provided they have documentation that an IRB has determined that the specified waiver criteria were satisfied.

5.2.1.b Criteria to Determine if a Waiver is Authorized

A waiver of authorization form is attached in the Appendix (Form G). The investigator must provide information about the research study that enables the IRB to determine that three requirements are satisfied:

1. There must be no more than minimal risk to the privacy of individual subjects based on the presence of the following elements:

    i. An adequate plan to protect the identifiers from improper use and disclosure;

    ii. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research (unless there is a health or research justification for retaining identifiers or such retention is otherwise required by law);

    iii. An adequate written assurance that the PHI will not be reused or disclosed to any other person or entity (except as required by law, or for authorized oversight of the research study, or for other research for which the use or disclosure is permitted without authorization).

2. It must not be practicable to conduct the research without the waiver or alteration of the authorization requirement; and

3. It must not be practicable to conduct the research without access to and use of the PHI.

5.2.1.c Documentation Required to Secure a Waiver

An investigator may use or disclose PHI for research purposes pursuant to a waiver of authorization by the IRB with documentation of all of the following:

1. The use or disclosure of PHI involves no more than minimal risk to the individuals;

2. The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;

3. The research could not practicably be conducted without the alteration or waiver;

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

5. The privacy risks to individuals whose PHI is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;

6. There is an adequate plan to protect the identifiers from improper use and disclosure;

7. There is 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

8. There are 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 PHI would be permitted by this subpart.

Investigators seeking a waiver of authorization for PHI disclosure without consent of subjects must complete a Form G and submit it to the Director of Research Integrity who will schedule a full board review.

5.2.2 Reviews Preparatory to Research

Investigators may review PHI without authorization to prepare a research protocol (i.e., limited to designing a study and/or determining the feasibility of completing a study). Neither recruitment nor patient contact is considered preparatory activity. Under this provision of the regulations, the investigator must provide the following assurances to the covered entity:

1. The investigator shall not remove any protected health information from the covered entity;

2. The use/disclosure of PHI is sought solely for the purpose of preparing a research protocol; and

3. The PHI for which use or access is sought is necessary for research purposes.

In addition, reviews preparatory to research must not involve making copies of PHI or making notes that include PHI. However, medical records of interest to investigators in preparing a study may be flagged for future reference.

Investigators seeking to use PHI in preparation for research must complete a Form G and submit it to the Director of Research Integrity who will schedule a full board review. Investigators must certify that they have complied with the provisions outlined above.

5.2.3 Research on Decedent's Information

A investigator is not normally required to secure IRB approval for research involving deceased individuals, unless other living individuals (such as family members) could be affected (i.e., genetic markers of certain diseases). If the research has no impact upon other living individuals, the investigator may use PHI of deceased individuals without authorization from the decedent's estate. If the research has an impact upon other living individuals, IRB review is necessary. Investigators who are not sure about this determination should err on the side of caution and submit an application for IRB approval.

Qualifications under this provision require that the researcher provide the covered entity:

4. Assurance that the use or disclosure is being sought solely for research on the PHI of decedents;

5. Documentation, at the request of the covered entity, of the death of such individuals; and

6. Assurance that the PHI is necessary for research purposes.

Investigators may use PHI in research on decedent's information if the investigator certifies they have met the provisions outlined above. Investigators must submit a Form J and submit it to the Director of Research Integrity who will schedule a full board review.

5.2.4 Research Involving the Use of Limited Data Sets

Regulations permit covered entities to use or disclose PHI for research purposes without subject authorization if the use or disclosure only involves a "limited data set" and the covered entity enters into a data use agreement with the investigator. A "limited data set" is PHI that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual subjects:

1. Names

2. Postal address information, other than town or city, state and zip code

3. Telephone numbers

4. Fax numbers

5. Email addresses

6. Social security numbers

7. Health plan beneficiary numbers

8. Account numbers

9. Certificate/license numbers

10. Vehicle identifiers and serial numbers

11. Medical device identifiers and serial numbers

12. Web universal resources locators (URLs)

13. Internet protocol (IP) address numbers

14. Biometric identifiers, including finger and voice prints

15. Full face photographic images and any comparable images

16. All elements of dates (except year) directly related to individuals; unless the individuals are <89 and which point even the year must be removed.

17. Any other unique identifying numbers, characteristics, or codes, except those a covered entity might use to re-identify the previously de-identified information.

A limited data set may, however include other indirect identifiers, especially dates of birth, treatment, discharge, or death.

Investigators may use a limited data set for research without subject authorization if they have completed a Limited Data Use Agreement with the entity releasing the data. Investigators in this situation should complete a Form K and provide it and the Limited Data Use Agreement to the Director of Research Integrity. (Normally, the entity releasing the data should provide the Limited Data Use Agreement; however, if the entity does not have such a form the investigator should contact the Director of Research Integrity for examples of acceptable forms.)

5.3 USE OF DE-IDENTIFIED DATA IN CLINICAL RESEARCH

Under HIPAA, PHI can be released freely if it does not contain "individually identifiable information" as defined in the section above. PHI is not individually identified if the subject is not identified, directly or indirectly, and if the subject has no reasonable basis to believe that the information can be used to identify them. Research using De-Identified Data is exempt from the requirements. To be exempt, none of the subject identifiers identified in the previous section can be reviewed or recorded by the research team. In order to de-identify PHI, investigators must comply with one of the two following procedures.

5.3.1 Procedures to De-indentify Datasets

HIPAA regulations allow researchers to use two procedures to de-indentify data sets so that they may conduct research without securing waivers. These procedures are:

5.3.1.a Use of a Statistician:

Researchers may obtain the services of a person with appropriate experience and knowledge who applies generally acceptable statistical and scientific principles and methods to determine that the information is not individually identifiable; there is a very small risk that the information could be used by itself or in combination with other available information by the anticipated recipient(s) to identify the subject with the information; and who will document the methods and results in making such a determination.

5.3.1.b Removal of Identifiers

Investigators may ensure that all identifiers listed above have been removed and certify that they have no actual knowledge that the information remaining could be used alone or in combination with other information to identify the patient who is the subject of the information.

Investigators who choose to "de-identify" PHI data must complete and submit a Form K to the Director of Research Integrity who will schedule a full board review. The IRB shall determine if the PHI has been adequately de-identified in accordance with the privacy laws. If so, the IRB will notify the researcher in writing that the research has been approved as a de-identified health information data set. The investigator may then use the IRB approval notice to access and create the de-identified database.

5.4 INVESTIGATORS' RESPONSIBILITES MAINTAINING DATABASES

If an investigator maintains a database containing PHI, then the investigator has an obligation to ensure that the use and disclosure of PHI is in compliance with policies. The investigator is responsible for:

1. Maintaining applicable security for the database, including physical security and access control;

2. Controlling and managing the access, use and disclosure of PHI, including verifying appropriate IRB approvals and patient authorizations; and

3. Ensuring that any PHI in the database used for treatment or payment purposes must be a duplicate and the original must be included in the patient's medical record.

In order to use a research database containing PHI, one must have authorization or a waiver from the IRB. Another pathway to using PHI in a research database is by utilizing a limited data set.

5.5 STUDIES AND DATABASES INITIATED PRIOR TO HIPAA REGULATIONS

Databases created prior to April 14, 2003 are grandfathered in and do not have to meet the Privacy Act policies. Studies involving subjects that have enrolled prior to April 14, 2003 will not be required to re-consent. Investigators may continue to collect and use data gathered from these subjects and no new documentation is required.

5.6 RESEARCH PARTICIPANT'S RIGHT OF ACCESS TO RESEARCH RECORDS

With few exceptions, the Privacy Rule gives patients the right to inspect and obtain a copy of health information about themselves that is maintained in a "designated record set." A designated record set is a group of records that a covered entity uses to make decisions about individuals, and includes a health care provider's medical records and billing records, and a health plan's enrollment, payment, claims adjudication, and case or medical management record systems. Research records or results maintained in a designated record set are accessible to research participants unless one of the Privacy Rule's permitted exceptions applies.

One of the permitted exceptions, however, applies to PHI created or obtained by a covered health care provider/researcher for a clinical trial. The Privacy Rule permits the individual's access rights in these cases to be suspended while the clinical trial is in progress, provided the research participant agreed to this denial of access when consenting to participate in the clinical trial. In addition, the health care provider/researcher must inform the research participant that the right to access PHI will be reinstated at the conclusion of the clinical trial.