UT TYLER HIPAA REQUIREMENTS

PIs, co-investigators and anyone else involved with protected health information must be knowledgeable about the federal regulations regarding protecting the privacy of research participant health information.

When health information is involved as a part of the research study, participants must sign a HIPAA Consent Form in addition to the written informed consent form.

I. Background

A. The Health Information Portability Accountability Act (HIPAA) Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes.

B. Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” See 45 CFR 164.501.

C. A researcher may use or disclose for research purposes health information which has been de-identified (in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule) without regard to the provisions below.

For example, if a list of diagnoses are being reviewed with no identifying information on them, including names, birthdates, and other personal information, then HIPAA policies do not apply.

D. Accounting for Disclosures: The Privacy Rule also defines the means by which individuals will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities.

E. 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. Currently, most research involving human subjects operates under the Common Rule (45 CFR Part 46, Subpart A) and/or the Food and Drug Administration’s (FDA) human subject protection regulations (21 CFR Parts 50 and 56), which have some provisions that are similar to, but separate from, the Privacy Rule’s provisions for research.
F. The Privacy Rule creates equal standards of privacy protection for research governed by the existing Federal human subject regulations and research that is not.

G. The Privacy Rule applies to all situations involving protected health information, regardless of research funding or setting.

II. Application of the Privacy Rule in Research

A. In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information with full disclosure of this intent to the IRB prior to these actions.

B. Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research under one of the following circumstances: (a) with individual authorization, or (b) without individual authorization under limited circumstances set forth in the Privacy Rule.

C. Research Use/Disclosure Without Authorization: To use or disclose protected health information without authorization by the research participant, the PI must first complete the UT Tyler IRB Approval Of Waiver Of Authorization To Use Protected Health Information form and submit to the IRB with the review application. In order to proceed with obtaining protected health information from an entity, e.g., health care facility, the investigator must have:

   a. Documentation that an alteration or waiver of research participants’ authorization for use/disclosure of information about them for research purposes has been approved by the UT Tyler IRB [See 45 CFR 164.512(i)(1)(i)].

   This provision of the Privacy Rule might be used, for example, to conduct records research, when researchers are unable to use de-identified information, and the research could not practically be conducted if research participants’ authorization were required.

   b. A covered entity (e.g., a health care facility that houses the protected health information) may use or disclose protected health information for research purposes following an approved waiver of authorization by the UT Tyler IRB, provided it has obtained documentation of all of the following:

   >Identification of the IRB approval and the date on which the waiver of authorization was approved;
> A statement that the IRB has determined that the waiver of authorization, in whole or in part, satisfies the three criteria in the Privacy Rule;

> A brief description of the protected health information for which use or access has been determined to be necessary by the IRB;

> A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and

> The signature of the chair or other member, as designated by the chair, of the IRB or the Privacy Board, as applicable.

c. The following three criteria must be satisfied for the UT Tyler IRB to approve a waiver of authorization under the Privacy Rule:

> The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

* an adequate plan to protect the identifiers from improper use and disclosure;

* 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;

* adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law--for example, authorized oversight of the research project by the IRB may necessitate review of the health information or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule.

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

> The research could not practicably be conducted without access to and use of the protected health information.
Other criteria that may meet waiver of authorization (must be in addition to the three listed above): Preparatory to Research; Decedents; Limited Data Sets

2. Access to PHI as Preparatory to Research

a. HIPAA provides a mechanism to access personally identifiable information for the purpose of "reviews preparatory to research". This provision might be used to design a research study, to assess the feasibility of conducting a study, or to assemble a database of individuals who indicate a willingness to be considered for participation in future research studies.

Note that this mechanism does not permit the collection of data for conducting actual research or the removal of information from a covered entity.

The following is needed from the PI:

b. HIPAA Disclosures from the researcher, either in writing or orally, that:

- the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purposes preparatory to research,

- the researcher will not remove any protected health information from the covered entity, and

- protected health information for which access is sought is necessary for the research purpose. See 45 CFR 164.512(i)(1)(ii).

3. Research on Protected Health Information of Decedents: The researcher must provide to the covered entity:

a. Representations, either in writing or orally, that the use or disclosure being sought is solely for research on the protected health information of decedents

b. Documentation that the protected health information being sought is necessary for the research

c. Documentation, at the request of the covered entity, of the death of such individuals. See 45 CFR 164.512(i)(1)(iii).
4. Limited Data Sets with a Data Use Agreement

   a. A limited data set excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual.

   b. A data use agreement must first be entered into by both the covered entity and the researcher. Following this, the covered entity may disclose a limited data set to the researcher for research, public health, or health care operations. See 45 CFR 164.514(e).

   c. The data use agreement must:

      >Establish the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research, and which may not include any use or disclosure that would violate the Privacy Rule

      >Limit who can use or receive the data; and

      >Require the recipient to agree to the following:

      * Not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law;

      *Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement;

      *Report to the covered entity any use or disclosure of the information not provided for by the data use agreement of which the recipient becomes aware;

      *Ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set agrees to the same restrictions and conditions that apply to the recipient with respect to the limited data set; and

      *Not to identify the information or contact the individual.

D. Research Use/Disclosure With Individual Authorization

1. The Privacy Rule also permits covered entities to use or disclose protected health information for research purposes when a research
2. In addition to the research protocol consent form, participants must sign a Research Participant Authorization To Use Protected Health Information form and have available for covered entity and IRB review.

3. Accounting for Research Disclosures.

a. In general, the Privacy Rule gives individuals the right to receive an accounting of certain disclosures of protected health information made by a covered entity. (See 45 CFR 164.528).

b. This accounting must include disclosures of protected health information that occurred during the six years prior to the individual's request for an accounting, or since the applicable compliance date (whichever is sooner), and must include specified information regarding each disclosure.

c. However, where the covered entity has, during the accounting period, made multiple disclosures to the same recipient for the same purpose, the Privacy rule provides for a simplified means of accounting. In such cases, the covered entity need only identify the recipient of such repetitive disclosures, the purpose of the disclosure, and describe the PHI routinely disclosed. The date of each disclosure need not be tracked. Rather, the accounting may include the date of the first and last such disclosure during the accounting period, and a description of the frequency of such disclosures.

d. A covered entity is not required to account for all disclosures of PHI.

e. An accounting is not required for

>Research disclosures made pursuant to an individual's authorization;

>Disclosures of the limited data set to researchers with a data use agreement under 45 CFR 164.514(e).