HIPAA Privacy Rule
in Research Policy

Guidelines for this policy were taken from the DHHS at the following site: http://www.hhs.gov/ocr/hipaa/guidelines/research.pdf  new link: https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html

Definitions: Selected definitions are below; if any other terms are not clear, please contact the IRB Chair for clarification. The Health Information Portability Accountability Act (HIPAA) Policy may also be referred to as the "Privacy Rule" and is directed toward privacy of individual protected health information (PHI)

Accounting for Disclosures:
This is also known as "tracking disclosures"
Upon request, a covered entity must provide the individual with an accounting of each disclosure by date, the Protected Health Information (PHI) disclosed, the identity of the recipient of the PHI, and the disclosure. Additional information is found below in II.D.3. https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html

Covered Entity (CE):
Under HIPAA, this is a health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form in connection with a HIPAA transaction. Also see Part II, 45 CFR 160.103.

Covered Workforce:
Any UT Tyler employee, full time, part time, or adjunct, student, or person with a research-associated contract

Data Element:
Under HIPAA, this is the smallest named unit of information in a transaction. Also see Part II, 45 CFR 162.103.

De-identified information:
Health information that has no identifiers with it and cannot be linked to an individual

Disclosure: Release or divulgence of information by an entity to persons or organizations outside of that entity. Also see Part II, 45 CFR 164.501.

Forms and Policies Relating to Enforcement of the UT Tyler Privacy Rule:

- Protected Health Information Use In Research (policy): This policy is a general policy for using PHI in research at UT Tyler.

- Waiver Of Authorization To Use Protected Health Information (policy): This policy presents guidelines to use when requesting permission to use PHI without participant authorization
• **Protected Health Information Use IRB Application (form):** This is a form that all PIs must complete and submit with their review applications to the IRB when participants are authorizing release of PHI from the covered entities to the PI.

• **Research Participant Authorization To Use Protected Health Information (form):** This form is an amendment to the written informed consent form that participants sign when health information is to be collected and used during a study. It does not include obtaining PHI from a covered entity; it only authorizes use of PHI during the study and authorizes release of PHI to other entities, e.g., study sponsors, the FDA, or any other regulatory agency.

• **Request for IRB Approval of Waiver of Authorization to Use Protected Health Information (form):** This form is to be submitted with the review application to the IRB when requesting PHI without participant authorization. Review of the [Waiver Of Authorization To Use Protected Health Information policy](https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html) is required.

**Identifiers:**

- Names
- All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code and their equivalent geocodes
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers & serial number, including license plate numbers
- Device identifiers & serial numbers
- Web universal resource locators (URLs)
- Internet protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic or code

**Minimum Necessary:**
The Privacy Rule stipulates that covered entities limit the amount of information disclosed to the minimum necessary to achieve the specified goal [45 CFR 164.514(d)(1)]. This requirement would not apply if the disclosure were required by law, authorized by the individual, or for treatment purposes.

**Protected Health Information (PHI):**
The Privacy Rule defines PHI as "…as individually identifiable health information, held or maintained by a covered entity or its business associates acting for the covered entity, that is transmitted or maintained in any form or medium (including the individually identifiable health information of non-U.S. citizens). This includes identifiable demographic and other information relating to the past, present, or future physical or mental health or condition of an individual, or the provision or payment of health care to an individual that is created or received by a health care provider, health plan, employer, or health care clearinghouse. For purposes of the Privacy Rule, genetic information is considered to be health information."

[https://privacyruleandresearch.nih.gov/pr_07.asp](https://privacyruleandresearch.nih.gov/pr_07.asp)

Health information held by a covered entity that is NOT considered protected is individually identifiable health information that is maintained in education records covered by the Family Educational Right and Privacy Act (as amended, 20 U.S.C. 1232g) and records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records containing individually identifiable health information that are held by a covered entity in its role as an employer.

**Treatment:**
Is the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.