TU HIPAA RELEASE FORM FOR RESEARCH

If research involves the use of protected health information (PHI), the researcher may need to comply with the requirements of the Health Insurance Portability and Accountability Act (HIPAA).

PHI is a person’s identifiable health information, that was created by the HIPAA-covered entity (CE), and relates to past, present or future physical or mental health or condition of an individual. Types of PHI include but are not limited to: patient name, social security number, medical record number, address, medical test results, prescriptions, diagnoses etc. Covered entities include health provider organizations, health plans and health plan clearinghouses that engage in electronic health care transactions, used to render care and bill for services provided.

HIPAA governs the use and disclosure of "protected health information" by "HIPAA-covered entities." HIPAA’s protections focus on a person’s personal & protected health information that is used to render care and bill for services provided. PHI can be transmitted or maintained by electronic media or in any other form or medium and applies to all patients, both living and deceased. In order to access this information, researchers must have each subject whose PHI is being gathered sign a HIPAA Authorization or HIPAA Release form. The TU Informed Consent Form must include a statement referencing the HIPAA Authorization form. For example, the TU Informed Consent Form could say "In order to do this research, you must also authorize us to access and use some of your personal health information by reviewing and signing the attached authorization form."

HIPAA Authorizations must be written in plain language and must include 6 core elements and three required statements.

Authorization Core Elements:

• A specific and meaningful description of the PHI to be used.
• The name(s) or specific identification of the person(s) or class of person(s) who will make the disclosure.
• The name(s) or specific identification of the person(s) or class of person(s) who will use the PHI or to whom the covered entity will make the disclosure.
• Description of each specific purpose of the requested disclosure. Once researchers have obtained PHI, it may not be used for any purposes except those described in the Authorization. (Authorizations are study-specific and may not be used for future unspecified research.)
• Authorization expiration date or event. Researchers may use the terms "end of the research study" or "none" if the PHI is collected for research.
• The individual’s signature and the date the Authorization is signed.
Authorization Required Statements:

- A statement of the individual's right to revoke the Authorization at any time in writing and a description of how to revoke the Authorization.

- A notice of the covered entity's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and, if applicable, the consequences of refusing to sign the Authorization. **NOTE: In most research at TU, this statement should simply indicate that refusing to sign the Authorization will not affect the subject's enrollment/services/care/benefits at the HIPAA covered center and will result only in the subject being excluded from the research study (if applicable).**

- A statement explaining that the researcher receiving the data could potentially re-disclose the PHI and that the HIPAA Privacy Rule does not apply to the re-disclosure.

The Office of Research and Sponsored Programs has developed this form for researchers to use. As with all templates, researchers may alter the format or wording of the document as long as the elements required by law remain.

For more information about HIPAA and research, please visit the [NIH HIPAA information page](#).
Researchers from the study, “_____” would like your permission to use your health information which will be gathered as a part of this study with your consent.

The researcher(s) are asking for the following health information to be gathered from your file [Note: this list should be tailored specifically to your research and state precisely which records are being requested. Delete what does not apply and include additional records as needed.]

*Please mark all the listed information requests that you are allowing the research(s) to receive:

☐ Demographic information, including your name, address, phone number . . .
☐ Information in your medical records related to . . .
☐ X-rays/laboratory results obtained by ____ laboratory.
☐ Information from mental health/substance abuse records.
☐ Other:
☐ Other:________________________________________________________________________
☐ Other:________________________________________________________________________
☐ None. I do not consent to sharing any of my health information from my file.

We will use the health information in your file to [ . . . Insert a purpose statement from the Informed Consent Form and describe each use of the requested information ]

The name(s) of the TU researcher(s) who will receive the above information from your file is/are: [insert the name(s) of all TU researchers starting with the lead researcher]:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

[Choose from one of the following sentences that best describes your time frame and delete the other 2 sentences]

This authorization will expire on (date).
This authorization will expire at the end of this research study, approximately (date).
This authorization will not have an expiration date.

Your health information may be shared with others who are working with the TU researchers on this study, institutes that are paying for this study or involved in any other way, or as required by law. The names of these other researchers (include name, affiliation, and role in the study) or institutions (name and role in the study) are listed below.

*If this does not apply to this study, please state “non-applicable” N/A*
The TU researchers and other researchers who work with TU will protect your health information in the following ways:

- Your health information will be kept private
- Your name or any other identifying information will not be made known
- Your health information may be shown in research papers or meetings without any information about you that will link it to you.
- Your health information will be given a special code for security
- Your health information will be grouped together with other people’s health information to form an average
- Your health information will be locked in a cabinet and kept safe

This authorization can be revoked at any time by delivering a revocation in writing to the Health Care Provider named above and that the revocation will be effective except to the extent (1) research has already been conducted in reliance on my previous authorization or (2) at the time of my request, my PHI has been de-identified and cannot be re-identified for removal or (3) if necessary to protect the integrity of the research (e.g., to account for a person’s withdrawal from the research).

I realize that [name of Principal Investigator] may not be bound by the Privacy Rule and therefore may not be required by that Rule to maintain the confidentiality of my personal health information.

The researchers can only use or disclose your health information for purposes approved by the Institutional Review Board at The University of Tulsa or as required by law or regulations and will continue to protect your personally identifiable health information as described in the attached Informed Consent Form.

I understand that if I refuse to sign this form I will be [describe consequences, i.e. excluded from the research] but that my relationship with [health care provider] will not be affected.

I understand what this document says and authorize release of my personal health information as stated above. I understand I will be given a signed copy of this Authorization for my records.

[The research participant should sign and date this form. If the research participant is a minor, the legally authorized representative should sign and date this form.]
*You can agree or not agree to sign this form.* This authorization to release your health information is voluntary. Treatment, payment, enrollment or eligibility for benefits/services will not be affected by signing or refusing to sign this authorization form. If you agree to sign this form but change your mind later, you can choose to stop being in the study at any time. If you decide to stop being in the study, you will need to contact the researcher [insert the name, telephone, and e-mail of the PI] or you may contact the Coordinator of Research Compliance, Carmen Schaar Walden at 918-631-3310

You will be given a copy of this form to keep.

If you have any questions or concerns about your rights as a research study participant, please contact: Carmen Schaar Walden, Coordinator of Research Compliance, Phone 918-631-3310 or email carmen-schaar-walden@utulsa.edu.

By signing your name below, you are saying that you understand what is being said in this form, you have received answers to all your questions, you have freely agreed to sign this form, you have been told who to contact if you have questions regarding your rights as a participant, and you have allowed The University of Tulsa to gather, use, and share your health information as described in the form.

Participant’s Name (please print): ________________________________

Participant’s Signature: ___________________________ Date: __________

Investigator’s Signature: ___________________________ Date: __________

**Legal Representative of Research Participant (if applicable):**

Legal Representative’s Name (please print): ________________________________

Relationship to research participant: ________________________________

I certify that I have the legal authority as a _____________________________ (e.g., parent, legal guardian, person with legal power of attorney, etc.) to make this authorization on behalf of the research participant named above.

Signature of the Legal Representative: ___________________________ Date: __________

Investigator’s Signature: ___________________________ Date: __________