|  |  |  |
| --- | --- | --- |
| **UNTHSC.jpg** |  | Authorization to Use Protected Health Information for Research Template |
|  |
|  |

**DO NOT SUBMIT THIS first Page To the IRB**

**this PAGE IS NOT FOR USE WITH RESEARCH SUBJECTS**

**THIS FORM DOES NOT NEED TO BE PRINTED IN COLOR**

|  |  |
| --- | --- |
| PURPOSE | The purpose of this template is to create the HIPAA Authorization form that human subjects, parents, and/or legally-authorized representatives of human subjects sign to give you permission to obtain, use and disclose protected health information for research purposes. This University of North Texas Health Science Center HIPAA Research Authorization form may be combined with the informed consent document, or may be presented as a separate document. If combined, both the consent form and the HIPAA Authorization forms must be signed. |

|  |  |
| --- | --- |
| INSTRUCTIONS | * The text in yellow-highlighted [brackets] provides instructions/guidance and indicates information that either must be inserted or may be needed depending on the research.
* When you have finished providing all of the requested information:
* Delete the instructions that are in the brackets, and delete the brackets.
* Remove the yellow highlighting (by changing it to white).
* **This is an official form of the University of North Texas Health Science Center. Do NOT delete or revise any content. Do NOT re-organize or re-format this form. Such changes will be disapproved by the IRB or its agents. NOTE: Researchers from John Peter Smith Health Network should utilize the HIPAA Authorization form authorized by their institution.**
* However, additional content may be inserted as necessary. Indicate the additions by providing one extra copy of the form on which the additions were made using Word’s “track changes” feature.
* This form does not need to be printed in color.
 |

**DO NOT SUBMIT THIS PAGE FOR REVIEW…**

**THIS IS THE INSTRUCTION PAGE**

|  |  |  |
| --- | --- | --- |
| **UNTHSC.jpg** |  | Authorization to Use Protected Health Information for Research |
|  |
|  |

Study Title: [Insert study title below.]

Principal Investigator Name: [Insert Principal Investigator’s name below.]

## What is the purpose of this form?

The purpose of this form is to give your permission to the research team at [the University of North Texas Health Science Center (“UNTHSC”) to obtain, use or share your protected health information (PHI).  This protected health information will be used to do the research named above.  UNTHSC understands that information about you and your health is personal and we are committed to protecting the privacy of that information in accordance with state and federal privacy laws. Because of this commitment, we must obtain your written authorization before we may collect, use or share your protected health information for the research study listed above. This form provides authorization and helps us make sure you are properly informed of how this information will be used or disclosed. You do not have to sign this permission form. If you do not sign, UNTHSC will not obtain, use or share your protected health information for research. Please note though that you will not be able to participate in the research study. Your decision to not sign this permission will not affect any treatment, health care, enrollment in health plans or eligibility for benefits.

*[Delete this paragraph and/or the next paragraph if they do not apply to your research.]*

*“This document is also used for parents to provide permission to obtain the individual health information of their minor children, and for legally-authorized representatives of subjects (such as an appropriate family member) to provide permission to obtain individual health information of individuals who are not capable themselves of providing permission. In such cases, the terms “you” and “your health information” refer to the subject rather than the person providing permission.*

*A minor’s signature is required to release the following information about the minor: 1. Age 14 and older – information relating to reproductive care, including but not limited, to birth control and pregnancy-related services and sexually-transmitted diseases, including HIV/AIDS and 2. Age 13 and older – substance abuse diagnosis or treatment, and mental health information.”*

## What is considered Protected Health Information (PHI)?

In this form, “protected health information” (PHI) refers to any health information that identifies you, such as:

Your past, present, or future physical or mental health or condition (e.g., lab results)

Health care provided to you (e.g., x-rays)

The past, present, or future payment for providing your health care (e.g., billing/payment information).

Genetic information

1. **What Protected Health Information will be obtained, used or shared?**

If you sign this form, you give UNTHSC permission to obtain, use or share the following health information as part of this research study:

List the types of health information that will be collected, used, and disclosed as part of this research study (*including any PHI obtained about the subject or PHI generated from the subject during the course of the research*) in a way that will be meaningful to the subject.

For example, type of test results, prior treatments, physical and mental history, and information collected as part of the research. Note that identifiable health information obtained and/or generated through surveys or interview should also be included. Below are some examples.

**NOTE: BY LAW**, the information **must be** limited to the ***minimum*** necessary information needed to accomplish the purpose of the research.

**EXAMPLES ONLY**: (Eliminate those that are not applicable to your research project)

* Medical history / treatment
* Physical exam
* Radiology films (like X-rays or CT scans)
* Laboratory / diagnostic tests
* Psychological testing
* Diagnostic imaging reports
* Other test reports
* All medical records
* Your research record
* Health information generated from surveys and interviews
* Other health information collected about you during this study
* Hospital discharge summary
* Progress notes
* Emergency department records
* Financial/Billing records
* Radiology records
* Consultation
* EKG report
* EEG report
* Pathology reports
* Operative reports (about an operation)
* Pathology specimen(s) and/or slide(s)
* Dental records
* Ambulatory clinic records
* [specify other here]

**Additional Note:** Any “sensitive” information, such as HIV status, illegal drug use, pregnancy testing, genetic testing, mental health information (e.g., psychotherapy notes) require specific consent for use. If your project includes these items, insert the authorization section titled “Consent for Specific Health Use” on the signature page.

UNTHSC is required by law to protect your health information. By signing this form you authorize UNTHSC to obtain, use or share your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them.

## From whom, or where will you obtain my Protected Health Information?

The health information described above may be generated or obtained from:

[Below select the option that applies to your research project.

* If PHI will be generated only through the course of the research study, select the first option (#1).
* If PHI will be obtained from a healthcare provider (e.g., medical records), select the second option (#2) **and** name the healthcare organization(s) or provider(s).
* If PHI will be obtained through the course of the research study and from a healthcare provider(s)/organization(s), list first and second options (#1, #2 and name the healthcare provider/organization).
* The last option can be inserted **if** there is another source where researchers plan to request the release, or obtain PHI. Be sure to specify the location/source]
1. Researchers: Health information about you created or generated during the course of this research study.

AND/OR

1. The following healthcare provider(s) who provided services to you or analyzes your health information for clinic purposes: [Name of health care organization(s) or provider(s)].

AND/OR

1. Other source: [Be specific in naming any other organization or institution that may release health information about the subject to UNTHSC researchers for research].
2. **Who may obtain, use or share my Protected Health Information?**

Your protected health information may be obtained, used, or shared with these individuals or organizations for the following purposes:

* 1. To the research team for the research described in the Research Consent Form;
	2. To others with authority to oversee the research (i.e., Institutional Review Board (IRB), safety monitoring committee, oversight board, etc.)
	3. Health care providers who provide services to you or analyze your health information in connection to the study. [Insert specific name if required]
	4. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor [insert the name of the sponsor], or the sponsor’s representatives [including but not limited to (*insert the name of \_\_\_\_\_\_),*], other federal or state agencies, and government agencies in other countries.

Any protected health information disclosed pursuant to the authorization may be subject to re-disclosure by the recipient and is no longer protected.

## How will my Protected Health Information be used or shared for the research?

If you agree to be in this study, the research team may use or share your protected health information in the following ways:

*[Remove any of the options below that are not applicable to your research study.]*

* 1. To perform the research
	2. Share it with researchers in the U.S. or other countries; business partners of the sponsor
	3. Use it to improve the design of future studies;
	4. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

## Am I required to sign this document?

**No**, you are **not** required to sign this document. If you decide not to sign this document, you will still receive the same clinical care, or any services you were already entitled to receive. However, if you do not sign the document, you will not be able to participate in this research study.

## Does my permission expire?

This permission to release your Protected Health Information expires when the research ends and all required study monitoring is over. [NOTE: If researchers want to retain PHI indefinitely, a good rational for doing this must be descried in the IRB application.]

## Can I cancel my permission?

**You can cancel your permission at any time.**

You can do this by writing to the researcher. Please send your written request to:

[Name of researcher or appropriate research staff person]

[Address information]

You have the right to take back your permission at any time, except to the extent that the research team has already taken action in reliance on your permission. If you cancel your permission, you may no longer be in the research study.

. If you cancel, no more health information about you will be collected. However, information that has already been collected and disclosed about you may continue to be used as necessary to maintain the integrity of the study (i.e. complete the research). Also, if the law requires it, the sponsor and government agencies may continue to look at your protected health information to review the quality or safety of the study.

1. **QUESTIONS CONCERNING YOUR PRIVACY RIGHTS?**

Please call us at [phone number] with any questions.

## Authorization

## If you agree to the use and release of your Protected Health Information, please sign below.

|  |
| --- |
| [Insert the following yellow-highlight section if appropriate. Delete the types of information you do not need for your research.]**Consent for Specific Health Information and Use**The following information will only be released if you give your specific permission, which is required by Federal and state laws, by putting your initials on the line(s). The federal rules bar any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient. I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment. I agree to the release of HIV/AIDS testing information. I agree to the release of genetic testing information. I agree to the release of information pertaining to mental health diagnosis or treatment.  I agree to the release of information pertaining to psychotherapy notes.  |

|  |
| --- |
| *[Insert the following yellow-highlight section if appropriate. Delete the types of information you do not need for your research.]*Optional research activityIf the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for these activities or not. \_\_\_\_ I agree, by initialing this section, to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.  |

## *Required Signature for HIPAA Authorization*:

## Subject name (print)

## Subject signature: Date

## \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[If HIPAA authorization may be obtained from a legally authorized representative (for example, a parent, legal guardian, or family member) and you have (or are requesting) approval from the IRB for doing so, the following information must be included. **Otherwise, delete this section.**]

## Parent or Legally Authorized Representative

If you agree to the use and release of the above named subject’s Personal Health Information, please print your name and sign below.

|  |  |
| --- | --- |
|  |  |
| Parent or Legally Authorized Representative’s Name(print) | Relationship to the Subject |
|  |  |
| Parent or Legally Authorized Representative’s Signature | Date |

[If not applicable, delete.]

**Witness**

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

|  |
| --- |
|  |
| Witness’ Name (print) |
|  |  |
| Witness’ Signature | Date |

**You will receive a copy of this signed form. Please keep it with your personal records**.