**HIPAA AUTHORIZATION**

**FOR A RESEARCH STUDY**

**TITLE**:

**SPONSOR:**

**IRB:** North Texas Regional IRB

Office of Research Compliance /CBH-160

3500 Camp Bowie Blvd.

 Fort Worth, Texas 76107

 (817)-735-0409

**PRINCIPAL INVESTIGATOR:**

**SUB- INVESTIGATORS:**

**INSTITUTION:** JPS Health Network

 1500 S. Main Street

 Fort Worth, TX 76104

**Subject name** *(please print)* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**HIPAA AUTHORIZATION**

**A.** **What is the purpose of this HIPAA authorization?**

The purpose is to enable you to give your permission to the research team at John Peter Smith Health Network (“JPS”) to obtain, use or share your protected health information (PHI). This protected health information will be used to do the research named above. JPS 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 by signing this consent form. However, if you do not sign, JPS will not obtain, use or share your protected health information for research and 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.

**B. What is considered Protected Health Information (PHI)?**

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

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

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

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

4. Genetic information

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

If you sign this form, you give JPS permission to obtain, use or share some health and identifying information contained in your medical record as part of this research study.

JPS is required by law to protect your health information. By signing this consent form you authorize JPS 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.

**D. From whom, or where will you obtain my Protected Health Information?**

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

1. Researchers: Health information about you created or generated during the course of this research study;

2. The healthcare provider(s) who provided services to you or analyze your health information for clinic purposes

**E. 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. The research team for the research described in this research consent form;

2. Others with authority to oversee the research (i.e., Institutional Review Board (IRB), safety monitoring committee, research integrity team etc.);

3. Your health care providers who provide services to you or analyze your health information in connection to the study;

4. 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 \_\_\_\_\_\_\_\_\_\_\_, 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

**F. 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 any of the following ways:

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

**G. Am I required to sign this consent document?**

No, you are not required to sign this consent document. If you decide not to sign this consent form, 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.

**H. Does my permission expire?**

This permission to release your Protected Health Information expires when the research ends and

all required study monitoring is over.

**I. Can I cancel my permission or authorization?**

Yes, you can cancel your permission at any time.

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

\_\_\_MD

Department

Email:

817-702-\_\_\_\_

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 after enrolling in the study, 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.

**J. What if I have questions concerning my privacy rights**?

If you have any questions about your rights as a research participant, or you would like to obtain information to offer input, or you wish to speak with someone not directly involved with the research study, you may contact the Chairman,

 North Texas Regional IRB

 Office of Research Compliance / CBH-160

 3500 Camp Bowie Blvd

 Fort Worth, Texas 76107

 Or call (817) 735-0409 during regular business hours.

An IRB is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the study subject’s rights and welfare in mind. The IRB has reviewed and approved the research study described in this consent and authorization.

You may also call the JPS Research Integrity team at (817) 702-4186 with any concerns you may have.

**K. How do I provide my authorization?**

If you agree to the use and release of your PHI, please sign at the consent signature line at the end of this document.

**Signatures:**

 **YOU WILL BE GIVEN A COPY OF THIS HIPAA FORM TO KEEP AND THE ORIGINAL WILL BE KEPT BY YOUR RESEARCH TEAM.**

**Your** signature below certifies the following:

* You have read (or have been read to) the information provided above.
* You have received answers to all of your questions and have been told who to call if you have more questions.
* You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons.
* You authorize the release of your medical records and protected health information related to this study to the researchers, sponsors agencies and their representatives

Printed Name of Participant

Signature of Participant Date

 ***If applicable***

Printed Name of Legally Authorized Representative

Relationship Signature of Participant Date

**Person Obtaining HIPAA Authorization**

The person signing this consent form has had the study carefully explained, and the subject has been given the opportunity to ask any number of questions regarding the nature, risks, and benefits of his/her participation in this research study.

Printed Name of Person Explaining Consent

Signature of Person Explaining Consent Date