In addition to requesting your consent to participate in the research entitled, [Title Must Match Consent Title], IRB number [IRB Number] we are also requesting your permission to use your protected health information for research.

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Federal and state privacy laws protect the release and use of your health information. Under these laws, your health care provider, Louisiana State University Health Sciences Center - New Orleans (LSUHSC-NO) cannot release or use your protected health information (PHI) for research purposes unless you give your permission. The purpose of this form is to inform you of the information that will be released and how it will be used or shared, and also for you to give permission.

If you decide to give your permission, you must provide verbal authorization. Your information will be released to the research team which includes [PI Name], the principal investigator; other researchers hired by the sponsor or LSUHSC-NO; and people with authority to oversee the research. This research team will use and protect your information as described by me and as was outlined during the consent. However, once your health information is released by LSUHSC-NO it may not be protected by the privacy laws and might be shared with others.

If you do not provide verbal authorization, LSUHSC-NO will not obtain, use or share your PHI for research but you will not be able to participate in the research study. Your decision to not provide verbal authorization will not affect any treatment, medical care, enrollment in health plans or eligibility for benefits. If you have questions, please ask a member of the research team.

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By providing verbal authorization, you are allowing those involved in providing your care and treatment to release the PHI. Your PHI includes health information in your medical records, financial records and other information that can identify you. We will be releasing the following PHI:

INSTRUCTIONS: Choose one of the following statements to include in this section.

Your complete Medical record

**[OR]**

Your [remove any that are not applicable] Ambulatory Clinic Records, Progress Notes, Hospital Inpatient Records, Other Test Reports, Dental Records, Operative Reports, Discharge Summary, Consultations, Emergency Department Records, Imaging Reports, Photographs, Videotapes, History & Physical Exams, Psychological Tests, Lab & Pathology, Reports, Financial Records, Diagnosis & Treatment Codes, and [Describe Other, if applicable].

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There are specific uses of your PHI that can only be released with your specific permission. Please confirm if you agree to the:

Release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

□ Agreed □ Did Not Agree

Release of HIV/AIDS testing information.

□ Agreed □ Did Not Agree

Release of genetic testing information.

□ Agreed □ Did Not Agree

Release of information pertaining to mental health diagnosis or treatment.

□ Agreed □ Did Not Agree

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Your Protected Health Information may be obtained, used or shared with these individuals or organizations for the following purposes:

* To the Principal Investigator and the research team;
* To others with authority to oversee the research such as the Institutional Review Board (IRB), safety monitoring committee, oversight board, and others;
* To healthcare providers who provide services to you or analyze your health information in connection with the research study;
* To insurance companies or others responsible for your medical bills in order to secure payment;
* 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 or the sponsor’s representatives; other federal or state agencies; or government agencies in other countries.

LSUHSC-NO is required by law to protect your health information. By providing your verbal authorization, you are allowing LSUHSC-NO to collect, release 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.

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If you agree to be in this study, the research team may share your PHI in order to perform the research; use it to improve the design of future studies; and File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

The research team may also share it with researchers in the U.S. or other countries; and with business partners of the sponsor.

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You are not required to provide your authorization. If you decide not to provide authorization, you will still receive the same clinical care, or any services you were already entitled to receive. However, if you do not provide authorization, you will not be able to participate in this research study.

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[Do not discuss if not applicable]

If the research you are 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 you in the informed consent process, you can choose to agree or not agree to have my information shared for those activities.

Do you agree to allow your information to be disclosed for the additional optional research activities explained in the informed consent process?

□ Agreed □ Did Not Agree

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This permission to release, retain, use or share your Protected Health Information:

INSTRUCTIONS: Choose one of the following statements to include in this section.

Expires when the research ends and all required study monitoring is over.

**[OR]**

Does not expire. [***NOTE:*** *If researchers want to retain PHI indefinitely, a justifiable rationale for doing so must be described in the IRB application*.]

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**You can cancel your permission at any time.** You can do this by contacting a member of the research team. Please send your written request to [contact name] by phone or email at [phone number and/or email address].

If you cancel your permission, you will no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment.

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 medical records to review the quality or safety of the study.

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Any privacy rights not specifically mentioned in this form are contained in the Notice of Privacy Practices that you received or will receive from the Principal Investigator or at the facility that you attend.

**Signature of Person Obtaining Verbal HIPAA Authorization:**

*The subject or their LAR has agreed to the release and use of the subject’s Protected Health Information.*

Signature of Person Obtaining Consent Printed Name Date

*Verbal HIPAA Authorization was obtained*:

□ In person

□ Over the phone

□ By other electronic means: ­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Verification of Legally Authorized Representative**:

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Relationship to Participant/LAR Type