**Louisiana State University Health Sciences Center - New Orleans & Our Lady of the Lake Hospital**

Permission to Use Protected Health Information for Research

**STUDY TITLE:** Click or tap here to enter text.

**STUDY IRB#:** Click or tap here to enter text.

**PRINCIPAL INVESTIGATOR:** Click or tap here to enter text.

**SPONSOR/FUNDING AGENCY:** Click or tap here to enter text.

1. What is the purpose of this form?

Federal and state privacy laws protect the release and use of your health information. Under these laws, your health care providers, Louisiana State University Health Sciences Center - New Orleans (LSUHSC-NO) and Our Lady of the Lake Hospital, Inc d/b/a Our Lady of the Lake Regional Medical Center (OLOL) 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 and to participate in the research study named above, you must sign this form as well as the Consent Document. Your information will be released to the research team which includes the principal investigator listed above; other employees and researchers hired by the sponsor, OLOL, or LSUHSC-NO; and people with authority to oversee the research. This research team will use and protect your information as described below and in the Consent Document. However, once your health information is released by LSUHSC-NO or OLOL it may not be protected by the privacy laws and might be shared with others.

If you do not sign this form, LSUHSC-NO and OLOL 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 sign this form 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.

2. What Protected Health Information will be released or used?

If you give your permission and sign this form, you are allowing those involved in providing your care and treatment to release the following PHI. Your PHI includes health information in your medical records, financial records and other information that can identify you.

1. **Complete Medical Record** (Complete health record(s) may contain all of the records, as well as “other” notes or documents relating to my treatment or hospitalization, as listed below);

**OR**

1. **One or more of the specific records checked below.**

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

Other

Describe “Other”: Click or tap here to enter text.

3. Do I have to give my permission for certain specific uses?

**Yes.** Please place your initials on the line(s) corresponding to the information, if any, for which you are giving permission to release.

\_\_\_\_\_\_\_\_ 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 DO NOT agree to the release of information listed above.

4. Who will release and/or receive my Protected Health Information?

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

* To the Principal Investigator listed above, OLOL and the research team described in the Consent Document;
* To others with authority to oversee the research (i.e., Institutional Review Board (IRB), safety monitoring committee, oversight board, etc.);
* 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 and OLOL are required by law to protect your health information. By signing this form you authorize LSUHSC-NO and OLOL and their researchers and other workforce members 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.

5. How will my Protected Health Information be shared for the research?

If you agree to be in this study, the research team may share your PHI in the following ways:

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

6. 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.

7. What about optional research activities?

The research study you are agreeing to participate in may have additional, optional research activities such as the creation of a database, a tissue repository or other projects, as explained to you in the informed consent process. If this is the case, please indicate your approval or disapproval for sharing your information for these optional activities by placing your initials on the appropriate line.

This study does not have any optional research activities.

\_\_\_\_\_\_\_\_ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

\_\_\_\_\_\_\_\_ I DO NOT agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

8. Does my permission expire?

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

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

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

9. Can I cancel my permission?

**You can cancel your permission at any time.** You can do this by writing to a member of the research team. Please send your written request to:

Name: Click or tap here to enter text.

Title/Role: Click or tap here to enter text.

Physical Address: Click or tap here to enter text.

Email Address: Click or tap here to enter text.

Phone Number: Click or tap here to enter text.

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.

10. What if I have more questions about my privacy rights?

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.

If you still have further questions about your privacy rights, you may contact the individual listed in Section 9.

11. Permission(s)

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| **Participant:**  If you agree to the release and use of your Protected Health Information, please print your name and sign below. You will be given a signed copy of this form.  Participant Name (Print) – ***Required***  Participant Signature Date |

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| **Parent or Legally Authorized Representative (LAR):**  If you agree to the release and use of the above named participant’s Protected Health Information, please print your name and sign below.  Parent or LAR Name (Print) Relationship to Participant/LAR Type  Parent or LAR Signature Date |

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| **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 |