**LSUHSC-NO INFORMATION SHEET INSTRUCTIONS**

For research that involves interaction with human participants where you are requesting a waiver of documentation of informed consent and use of verbal consenting, LSUHSC institutional standards require researchers to uphold the ethical principle of respect for persons by providing a brief description of the research that includes the basic elements of informed consent. This typically is accomplished via an information sheet/cover letter or an oral script. In general, informed consent is required to provide potential participants the information necessary to make a decision about participating in research. Use of this template will help you create an information sheet document that is organized and written to facilitate comprehension by potential participants. It also will speed up IRB review and approval of your study.

There is a separate example information document showing how a completed information sheet for a survey should look.

Specific instructions for completing the form are in **blue** or **red** text. In general, blue text references required information. Red text references information that may or may not be applicable to your study or there is an option for alternate text.

In each section, **black** text is suggested language. While not mandatory, we highly recommend using this language to maintain consistency across information sheets.

Before you submit your information sheet to the IRB, delete the instruction page. Delete all blue and red text before finalizing the document. The font color of the finished consent document should be black. The finished document should reflect what you will give to the subject.

**DELETE THE INSTRUCTION PAGES FROM THE CONSENT FORM PRIOR TO SUBMITTING TO THE IRB**

Louisiana State University Health Sciences Center in New Orleans

Information on Participating in Research

**STUDY TITLE:**       [Title must match title of protocol]

**PRINCIPAL INVESTIGATOR:**       [Name and credentials]

**Why is this study being done?**

The purpose of the study is to [an explanation in lay language of why the study is being conducted]. You are being asked to participate in this study because you are [describe type of participant].

**What will happen if I take part in this study?**

Provide a concise description of study procedures in enough detail to give a clear picture of what the participant will experience during the study.  Describe procedures to be followed and the location and length of time for the procedures.

**What are the risks of taking part in this study?**

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

Although we are asking for [list identifiers, other information as appropriate] it is [unlikely/likely] that someone could identify you. However, we will be [list measures to protect confidentiality such as encryption, passwords, locked offices, other data storage methods as appropriate]. We do not think there are any other risks.

**[OR]**

We believe that this study presents no risks greater than those experienced in everyday life.

**Are there any benefits to participating in this study?**

There [will/will not] be direct benefits to you from participating in this study. This study may help researchers learn more about [study topic, benefit to society].

[Include and complete if there is a potential direct benefit to subjects; otherwise, omit entire bullet point] You could get these benefits without being in the study by [a brief overview in lay language of the alternatives].

**How will you keep my private information confidential?**

INSTRUCTIONS: Include this section only if there is identifiable information involved in the study. Otherwise, delete this section.

The researchers will protect your information by [briefly describe how the study staff will keep research data secure and identify who may access the data]. We will make every effort to maintain your privacy but we cannot guarantee complete confidentiality. For example, there is always a risk of someone breaking into a computer system where your information may be stored. Federal or state law also may require us to disclose your records. Loss of confidentiality is a potential risk of taking part in this study.

The following people or groups may review your study records for purposes such as quality control or safety:

* The study sponsor and/or representative of the sponsor [delete if there is no sponsor]
* Representatives of LSUHSC-NO and the LSUHSC-NO Institutional Review Board
* Other collaborating organizations [list other orgs or delete if not applicable]
* Officials of the Department of Health and Human Services or the Federal Food and Drug Administration [FDA may be deleted if this is not an FDA regulated study]
* Authorized government officials of foreign countries where this study also is taking place. [Replace “foreign countries” with names of specific countries if the study is being conducted in only a few such countries; delete if not applicable]
* Other organizations or agencies if required by law.

If any publications and/or presentations result from this study, they will not identify you by name.

**Will I be paid for my participation?**

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

You will receive [nature and total amount of incentive/compensation] for your participation in this study. Payments will occur [explain disbursement/conditions of payment; include circumstances, if any, where partial payment or no payment may occur; payments must be in equal amounts at each visit throughout the course of the study]. You will be responsible for any taxes assessed on the compensation.

**[OR]**

You will not receive any type of payment for taking part in this study.

**Whom can I contact if I have questions about this study?**

* **The research team:**

You may contact the following individuals with any questions or concerns about the research or your participation in this study.

|  |  |
| --- | --- |
| **Principal Investigator**  Name:  Address:  Phone #: | **Co-Investigator**  Name:  Address:  Phone #: |

* **Office of the Chancellor, LSU Health Sciences Center - New Orleans:**

You may contact the Office of the Chancellor by phone at (504) 568-4801, if

* you have questions about your rights while taking part in this study, or
* you have any concerns or suggestions, and
* want to talk to someone other than the researchers about the study.

**What will happen if I cannot complete the study?**

There are several reasons why you may not complete the study.

The researchers or the study sponsor might decide to stop the study at any time.

The researchers may end your participation in this study, without your permission, for a number of reasons including:

* Your safety and welfare are at risk.
* You do not follow instructions.
* You miss scheduled visits.
* You fail to complete study activities.

You also may decide on your own to stop participating in the study. If you are thinking about withdrawing, let the researcher know so he/she may remove you from the study safely. You also should seek medical advice for alternative treatments. The researcher will inform you of any significant new findings during the study that may impact your willingness to continue participation.

If you decide to stop being in the study, or the study is stopped, or you are removed from the study, the researcher will ask you to: [list steps the subject should complete, preferably in bullet point]

* Example: return for a final close-out visit or evaluation
* Example: return unused study medication
* Example: complete an exit telephone interview

You are not required to complete these tasks but some of them may be for your own safety.

Information collected about you up to the point of withdrawal will remain part of the study. You may not remove this data from the study database. We will keep this information confidential.

**Your Participation in this Study is Voluntary**

Taking part in this research study is voluntary; you do not have to participate. If you do take part, you can stop at any time. If you want more information about your rights as a research participant, please visit <https://www.lsuhsc.edu/administration/academic/ors/participant_information.aspx>.

Add the following paragraph if the potential participant may be a LSUHSC-NO student or faculty/staff member; otherwise delete this paragraph.

If you are a LSUHSC-NO student or faculty/staff member, you may choose not to be in the study or to stop being in the study before it is over at any time. Your decision will not affect your grades or job status at LSUHSC-NO. You will not be offered or receive any special consideration if you take part in this research study.

**Your Consent**

By choosing to participate in this study, I acknowledge or am aware that:

* The researcher(s) discussed the study with me and answered all my questions.
* I can contact the study team or the Chancellor’s Office using the contact information provided above if I have any questions or concerns as the study commences.

**INSTRUCTIONS:** Include this signature block when a waiver of documentation of informed consent is granted under 45 CFR 67.117(c)(i) The only record linking the subject and the research would be the signed informed consent form, and the principal risk would be potential harm resulting from a breach in confidentiality, and each subject or LAR will be asked whether the subject wants documentation linking them to the research.

**Signature of Participant:**

*I agree to take part in this study.*

Participant Signature Printed Name Date

Participant was given the option to sign this form and elected not to, as allowed under 45 CFR 67.117(c)(i). \_\_\_\_\_\_\_\_\_\_

Consenter Initials

**INSTRUCTIONS:** Include this signature block when a waiver of documentation of informed consent is granted under 45 CFR 67.117(c)(i) The only record linking the subject and the research would be the signed informed consent form, and the principal risk would be potential harm resulting from a breach in confidentiality, and each subject or LAR will be asked whether the subject wants documentation linking them to the research.

**Signature of Legally Authorized Representative for Adult:**

*I am a legally authorized representative of the person named below. I agree for this person to take part in this study.*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

Name of Participant (Please print)

**Type of LAR (Check applicable box):**

Court-appointed Guardian

Health Care Proxy

Durable Power of Attorney

Family Member/Next-of-Kin. Relationship: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

LAR Signature Printed Name Date

Participant’s LAR was given the option to sign this form and elected not to, as allowed under 45 CFR 67.117(c)(i). \_\_\_\_\_\_\_\_\_\_

Consenter Initials

**Signature of Person Obtaining Verbal Consent:**

*I have explained the research to the subject and answered all his/her questions.*

Signature of Person Obtaining Consent Printed Name Date

*Verbal consent was obtained*:

□ In person

□ Over the phone

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