This document contains editable (highlighted) and un-editable (not highlighted) text. To remove the highlight, click the **Review** tab and then click **Restrict Editing**. Uncheck the box labeled *“Highlight the regions I can edit.”* Do not click **Stop Protection**.

**LSUHSC-NO CONSENT AND HIPAA AUTHORIZATION TEMPLATES**

This document contains both informed consent and HIPAA authorization templates. The consent template is fully editable whereas editing of the HIPAA template is limited to filling form fields. Please complete one or both templates based on the expected requirements of the study for submission to, and review by, the IRB. *Please note that the HIPAA form cannot be deleted from the document. If HIPAA is not applicable or is waived, please simply complete and print only the informed consent form.* This document also contains an emergency/evacuation card to be completed by the study team for the participant to keep.

**Instructions for Using the Consent Template**

Informed consent is required to provide potential participants or their legally authorized representatives with the information necessary for them to make a decision about participating in research. Use of this template, and the instructions provided below, will help you create a consent document that is organized and written to facilitate comprehension by potential participants. It also will speed up IRB review and approval of your consent form. If you submit a new or revised consent form that does not comply with these instructions, your submission may be returned without review.

**General Instructions**

* Regulations now require that consent forms contain a concise and focused presentation of the key information that is most likely to help potential participants understand why they might or might not want to participate in the study. If your project is complex, involves numerous research procedures, and is more than 3 pages in length, this information section is required. In this template, the key information section is labeled **“Important Information about this Research Study.”**
* Unless otherwise indicated, all sections of this template are required. If necessary, you may insert additional sections not included in this template. This version of the informed consent template contains, after the signature page(s), a contact information card for safekeeping and use by the participant during emergencies and evacuations. Please make sure to complete the card and instruct the participant to cut and keep the card on their person.
* **DO NOT** change existing text of title, header & footers, headings, subheadings, signature blocks, and the information for contacting the Office of the Chancellor.
* 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 is otherwise optional.
* In each section, **black** text is suggested language. While not mandatory, we highly recommend using this language to maintain consistency across consent forms. This text is optimized for readability and grade-level comprehension using the tools described below.
* Additional instructions and sample language are found in the [**LSUHSC-NO Consent Form Supplemental Instructions**](https://www.lsuhsc.edu/administration/academic/ors/docs/HRP-2655_Supplemental%20Instructions%20for%20Consent%20Form_v1.0_6.8.20.pdf)document.
* Insert the LSUHSC IRB # for the study and your consent version date in the header. Consent forms must have the IRB #, a version date, and page numbers.
* Before you submit your consent document to the IRB, delete the instruction pages.Delete all **blue,** **red** and yellow-highlighted 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.

**Formatting Instructions**

* Maintain existing formatting of the template:
* Section headings- calibri, font 18
* Section subheadings- arial, font 12
* Body text- cambria, font 12
* Existing header and footer
* Maintain existing margins: 0.9 inch left & right margins, left justified only.
* Use subheadings to break up large amounts of text.
* Use bullets for long lists of procedures or risks.

**Language/Style Instructions**

* As much as possible, write in common, everyday language that can be understood by a participant with an 8th to 10th grade education, similar to the style used in popular news magazines and newspapers.
	+ Check the readability level of the document or a subset of the document in [Word](https://support.office.com/en-us/article/test-your-document-s-readability-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2#__toc342546555) or [StoryToolz](https://storytoolz.com/readability).
* Use active voice rather than passive voice whenever possible; for example, use “We will draw a blood sample”, not “A sample of blood will be drawn.” The Grammar tool in Word can identify sentences written in passive voice.
* Use short, simple sentences and short paragraphs.
* Whenever possible use words with three syllables or less.
	+ Use [wordify.com](https://rewordify.com/index.php) to identify simpler alternatives to non-technical but still sophisticated, high-grade level words.
* Avoid medical and scientific jargon.
	+ A searchable database of informed consent language is located [here](https://www.nccn.org/icl/default.aspx).
	+ Other glossaries of lay language for common medical and scientific terms are found [here](https://hso.research.uiowa.edu/medical-terms-lay-language) and [here](https://www.med.upenn.edu/ocrobjects/PM/2_glossary.of.lay.terms.pdf).
	+ Additional resources are found in the [PRISM Readability Tool Kit](http://ora.research.ucla.edu/OHRPP/Documents/Consent/PRISM.pdf).
* Avoid details that do not help participants make a decision about being in the study.
* Avoid unnecessary duplication of information.
* If a technical term is used, define or explain it in lay language the first time.
* Spell out abbreviations or acronyms the first time they are used.
* Maintain question and answer format as much as possible. This format is considered best practice for improving readability in consent forms. Write the consent form in conversational style, as if you were speaking to the reader.
	+ Whenever possible section headings should be in question format as if the participant were asking the question (e.g., Are there any benefits if I participate?).
	+ Answers should be in second person (‘You” instead of “I”, as if the researcher were answering the questions).
* Additional formatting and language instructions are found in the [**LSUHSC-NO Consent Form Supplemental Instructions**](https://www.lsuhsc.edu/administration/academic/ors/docs/HRP-2655_Supplemental%20Instructions%20for%20Consent%20Form_v1.0_6.8.20.pdf)document.

**Consent/HIPAA Revocation**

As indicated in this document, the participant has the right to withdraw at any time their consent to participate in the research study and release of protected health information. The HRPP Office has prepared and posted a [letter template](https://www.lsuhsc.edu/administration/academic/ors/irb/participant_information.aspx) that the participant may use to submit a written letter of withdrawal. If appropriate, please complete and provide a copy of the letter, along with the signed consent document, for the participant’s potential use. Alternatively, you may guide the participant to the online location of the template.

**DELETE THE INSTRUCTION PAGES FROM THE CONSENT AND HIPAA TEMPLATES PRIOR TO SUBMITTING TO THE IRB**

Louisiana State University Health Sciences Center - New Orleans

Consent to Participate in Research

**STUDY TITLE:** Click or tap here to enter text. [Title must match title of protocol]

**PRINCIPAL INVESTIGATOR:** Click or tap here to enter text. [Name and credentials]

**EMERGENCY CONTACT:** Click or tap here to enter text. [Duplicate research injury phone # here. Use for greater than minimal risk studies; otherwise delete.]

**STUDY SPONSOR:** Click or tap here to enter text. [List all sources of monetary/non-monetary support. If none, delete this item.]

1. Invitation to be Part of a Research Study

[Insert name and degrees of the Principal Investigator], andassociates from the [insert department affiliation] at the Louisiana State University Health Sciences Center in New Orleans (LSUHSC-NO) are conducting a research study. A research study is a scientific way to improve or develop new methods of health care. Studies are designed to answer specific questions on how to prevent, diagnose, or treat diseases and disorders. This study is being funded by[insert Sponsor name, if any, and include if the Sponsor is also the manufacturer of the drug/device being studied, if applicable. **If no sponsor, delete this sentence**].The research team is asking you to be in this study because [describe in one sentence why the potential participant qualifies for this study]. **Research studies are voluntary and include only people who choose to take part.** The researchers will explain this study to you and this consent form will help you decide if you want to participate. Before deciding:

* You can discuss this study with friends and family.
* You can also discuss it with your health care doctor or request a second opinion.
* If you have any questions, you can ask the researchers for more information before deciding to participate.
* Even if you choose to participate, you can decide to stop participating at any time.

In this consent form, “you” always refers to the participant. If you are a legally authorized representative, please remember that “you” refers to the study participant.

**Consult the** [**LSUHSC-NO Consent Form Supplemental Instructions**](https://www.lsuhsc.edu/administration/academic/ors/docs/HRP-2655_Supplemental%20Instructions%20for%20Consent%20Form_v1.0_6.8.20.pdf) **for additional instructions and/or example text for completing this section**

2. Important Information about this Research Study

**INSTRUCTIONS: P**rovide a **concise and focused** presentation of key information that is most likely to help potential subjects understand the full scope of the study to determine whether or not to participate. Organize and simplify information to facilitate comprehension.

This section lists the key characteristics of this study and the basic reasons why you may or may not want to take part. It is only a summary. The sections following this summary have more details, including contact information for people who can answer any questions or concerns you may have. Please take time to read this whole document and ask questions before deciding if you want to take part in this research study.

Things you should know:

* The purpose of the study is to [briefly explain in lay language of why the study is being conducted].
* In order to participate, you must be [briefly describe the main eligibility criteria].
* If you choose to participate, you will [briefly describe in lay language what will happen to the participant in the study]. You will be in the study for [xx days, weeks, months] if you decide to stay for the whole study.
* The main risks of being in the study are [identify the most important risks, not necessarily all risks; or state that the risks involved in this study are not greater than everyday life].
* You might benefit from being in the study because [a brief overview in lay language of the benefits that are most relevant to the potential subject’s decision about whether or not to join the study; or state that there is no direct benefit for participating in this study].
* [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].
* 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.

3. Why is this study being done?

**INSTRUCTIONS:** Insert a concise (1-2 paragraphs) explanation of why the study is being conducted. If you have used the summary above, provide additional details in this section. Include as appropriate, the background to the research problem, the rationale for the study, and/or a description of the study’s hypothesis or research question. If applicable, include the FDA status of any drug(s) or device(s). Also include a description of the type of participant that would be included; e.g., adult diabetics with hypertension. Write this section in language easily understood by potential participants. Do NOT copy from a grant application, a scientific protocol or other scientific description.

**Consult the** [**LSUHSC-NO Consent Form Supplemental Instructions**](https://www.lsuhsc.edu/administration/academic/ors/docs/HRP-2655_Supplemental%20Instructions%20for%20Consent%20Form_v1.0_6.8.20.pdf) **for additional instructions and/or example text for completing this section**

4. What will happen if I take part in this study?

**INSTRUCTIONS:** Provide a concise description of study procedures in enough detail to give a clear picture of what the subject will experience during the study. Explain the overall design of the study. Describe procedures to be followed (including pregnancy testing if applicable), the location and length of time for the procedures, the frequency of procedures, and, as appropriate, such study details as how subjects will be assigned to study groups, the method, dose, and frequency of medication administration, and specific tasks subjects will be expected to complete on their own. Use lists, tables and charts to show complex schedules and study designs. Differentiate procedures that are experimental from standard treatments. Do not use technical language unfamiliar to the subject population. If necessary, insert subheadings to make this section more readable. The subject and the family must be able to get an overall picture of what will happen during the study, when it will happen and how long they could be involved.

**Before you begin the study**

Before you begin the study, you will need to [explain any exams, tests, procedures, etc. that are required for screening or determining eligibility. Use bullets or numbering where appropriate].

**During the study**

If you agree to take part in this study, you will be asked to [provide a detailed description of what the subject will be asked to do in chronological order (what, when, where, how)].

Include the following if the study includes photography, video-taping, audio-recording, or use of other media; otherwise delete this part:

With your permission, we will [describe the context and process for audio/video recording; describe how participant’s identity will be protected, how the recordings will be used and what will happen to the recordings at the end of the study]. You may review and edit the media at your discretion. You do not have to agree to audio/video recording in order to participate in the study.

**Consent to be Audio/video Recorded**

*I agree to be audio/video recorded. I may withdraw my consent at any time by submitting a request in writing to the researcher.*

[ ] YES [ ] NO Initials \_\_\_\_\_\_\_\_

If applicable, include the following statement; otherwise delete.

Results of research testing on you or your sample(s) may be given to you or your doctor. This will be done only if the results may be necessary for your care.

**Consult the** [**LSUHSC-NO Consent Form Supplemental Instructions**](https://www.lsuhsc.edu/administration/academic/ors/docs/HRP-2655_Supplemental%20Instructions%20for%20Consent%20Form_v1.0_6.8.20.pdf) **for additional instructions and/or example text for completing this section**

5. What should I know about genetic research?

**INSTRUCTIONS:** This is an **OPTIONAL** section that applies only to studies generating, using, or analyzing participant’s genetic information. **If not applicable to this study, delete all the text in this section and type “Not Applicable.”**

**Genetic information and privacy risk**

The samples collected during this research will be used to extract your genetic information. We plan to [describe how genetic information will be generated, used and/or analyzed].

[If genetic analysis includes whole genome sequencing, include this or similar statement; otherwise delete.] Research testing on your sample will include whole genome sequencing. This means we will map your entire genetic code. If you have questions about this ask the study staff.

Your genetic information is unique to you. It is possible for someone to use genetic information in research records to identify you even if there are no other identifiers such as your name or address in the records. The researchers believe this risk is very small. However, the risk may increase in the future as people come up with new ways of tracing genetic information.

**Discrimination based on genetic information**

Health insurance companies, group health plans, and most employers may not treat you differently based on your genetic information. This is because of a federal law called the Genetic Information Nondiscrimination Act. This law protects you in the following ways:

* Health insurance companies and group health plans may not:
	+ ask for your genetic information that we get from this research, or
	+ use your genetic information when making decisions about your eligibility or premiums.
* Employers with 15 or more workers may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you, or when setting the terms of your employment.

All health insurance companies, group health plans, and all employers with 15 or more employees must follow this law.

Federal law does not prevent companies that sell life insurance, disability insurance, or long-term care insurance from treating you differently based on your genetic information. It also does not prevent different treatment because of a genetic disease or disorder that you already know about.

According to Louisiana law, your genetic information is your property. Insurance companies or employers may not get samples containing your genetic information without first getting your written permission. Insurance companies or employers also cannot use your genetic information to treat you differently when you are looking for a job or buying insurance.

6. How many people will take part in this study and how long will it last?

XX people will take part in this study at LSUHSC-NO. In total, approximately xx people will participate in this study [describe geographical extent: e.g., locally, in the state, nationally, or internationally].

If you complete the entire study, your participation will last [explain the full duration of the study, or how long the study will last. Include, if applicable, if you intend to collect follow-up information and how often this will occur. For example, “We will follow up with you once a month for the next 6 months.”].

 7. What are the risks of taking part in this study?

**Known risks and discomforts**

**INSTRUCTIONS:** Include one of the two following statements.

We do not anticipate any risks from participating in this research.

**[OR]**

The known risks and discomforts from the study procedures are [categorize the risks by severity and the likelihood of the risk occurring. A bulleted list should be used. Be sure to consider all types of risks – psychological, social, economic, legal and physical].

**INSTRUCTIONS:** If this is an interventional, biomedical study, include the following section; otherwise delete section:

**Unknown risks and discomforts**

The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about continuing to take part in the study.

**Consult the** [**LSUHSC-NO Consent Form Supplemental Instructions**](https://www.lsuhsc.edu/administration/academic/ors/docs/HRP-2655_Supplemental%20Instructions%20for%20Consent%20Form_v1.0_6.8.20.pdf) **for additional instructions and/or example text for completing this section**

8. Are there any benefits to participating in this study?

**Possible benefits to you**

**INSTRUCTIONS:** Include one of the two following statements.

There will be no direct benefit to you from participating in this study.

**[OR]**

The possible benefits to you include [provide a fair, reasonably detailed and easily comprehensible description of any potential direct benefits to participants from taking part in this study; use bullets and numbering where appropriate. Incentives such as monetary compensation should not be mentioned here].

For greater than minimal risk studies, include the following statement; otherwise delete:

We cannot guarantee these benefits to you because results from a research study are unpredictable.

**Possible benefits to others or society**

This study will help the researchers learn more about [procedure/drug/ intervention/ device]. This information may help in the treatment of future patients with [disease /condition] like yours.

9. What other choices do I have if I don’t take part in this study?

**INSTRUCTIONS:** Use one of the options below.

**OPTION 1**

The alternative is not to participate.

**OPTION 2:** For studies that involve an intervention that might treat or improve a condition or a disease, include one of the following statements.

You do not have to take part in this research study. At this time, however, there are no alternative treatments for [medical condition being studied].

**[OR]**

You do not have to take part in this research study to be treated for [medical condition being studied]. Other treatments available for your condition include: [state other available treatments; use bulleted list when appropriate].

**[OR]**

There may be other ways of treating your condition if you do not wish take part in this research. Check with your health care provider to discuss other options.

**OPTION 3:** For non-clinical protocols where alternative actions are available:

You do not have to take part in this research study. Other options for you include [state other options such as private weight loss clinics, private counseling, special courses, etc.; use bulleted list when appropriate].

10. How will my information be kept confidential?

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.

The results of the study may be released to the funding agency [provide the name of the funding agency, if known]. If any publications and/or presentations result from this study, they will not identify you by name.

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11. Will my information or specimens be used for future research?

**INSTRUCTIONS:** This section is required for any research that involves the collection of identifiable private information or biospecimens. **If not applicable to this study, delete all the text in this section and type “Not Applicable.”**

Choose one of the following options to include in this section.

**OPTION 1:** We will not use or share any of your information and/or samples collected as part of this study for future research, even if identifiers are removed. Any samples obtained for this study will be discarded or destroyed once they have been used for their intended purpose(s) in this study. [Describe any special conditions for the destruction of the material; e.g., after a specific period of time, once all data has been analyzed, after publication, etc.].

**OPTION 2:** Your information and/or samples collected as part of this study may help advance science and health if used in future studies. If you give us permission, we may store, use, and/or share with other researchers, your information and/or samples for future research. [Provide a brief description of potential future research including permitted usages, length of time information/samples will be stored, and disposition/destruction of these materials].

Your information and/or samples may be shared with outside labs, collaborators or researchers. Your information and/or samples [will/will not] be identifiable.

You do not have to agree to let us use your information and/or samples for future research to participate in this study.

**Consent to Use Data and/or Biospecimens for Future Research**

*I agree that my information and/or samples may be shared with other researchers for future research studies that may be similar to this study or may be completely different. The information and/or samples shared with other researchers [will/will not] include any information that can directly identify me. I may withdraw my consent at any time by submitting a request in writing to the researcher. Researchers will not contact me for additional permission to use this information and/or samples.*

[ ] YES [ ] NO Initials \_\_\_\_\_\_\_\_

12. Will there be any costs to me for taking part in this study?

**INSTRUCTIONS:** Use one or more of the following options as appropriate.

**OPTION 1:** If the participant is NOT responsible for ANY research-related expenses, use one of the following statements:

[For studies NOT involving medical or billable intervention] There will be no costs to you for taking part in this study.

**[OR]**

[For studies involving medical or billable intervention] If you take part in this study, you will not have any expenses beyond the routine costs for patients with similar conditions. The drugs, procedures, examinations and all other research-related activities are provided free of cost.

**OPTION 2:** If research-related expenses are a shared responsibility:

If you take part in this study, you will need to pay for [list any specific costs subjects will have to pay (such as parking)].

The study sponsor will supply or pay for the cost of: [list any items covered by the sponsor, preferably using bullet points; general examples are listed below]

* Study drug(s); name(s)
* Visits; describe
* Procedures; describe
* Complications
* Other

**OPTION 3:** If ALL research-related expenses are the responsibility of the participant:

You are responsible for the costs of all drugs, visits, procedures and study related or unforeseen side effects. The required treatments are part of good medical care and usually covered by most insurance companies.

**OPTION 4:** Use of this statement is required for almost all studies involving medical or billable intervention, as it allows us to bill for research related costs permissible under Medicare billing rules. If not applicable to the study, delete section.

We will bill you and/or your insurance company (or healthcare plan) for the costs of any standard medical care you receive during your participation in the study. This includes standard medical care to treat any known or unknown side effects you may experience. There is a possibility that your insurance company may not cover these costs because you are in a research study. If this happens you might have unexpected expenses. If the insurance company does pay for the standard care, you may be responsible for any co-payments and deductibles.

We [select: do/do not] have money to pay for any disability, damages such as lost wages, or similar outcomes that you may experience.

13. Will I be paid for taking part in this study?

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

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

**[OR]**

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.

The study team will release your name, address, social security number and amount of payment to Accounting Services. If the total payment for your participation in research is greater than $600 in a year, Accounting Services will report this amount to the Internal Revenue Service as income as required by law.

14. Who can profit from study results?

**INSTRUCTIONS:** Include this section only if a researcher conflict of interest has been identified or if biospecimens are collected. **If not applicable to this study, delete all the text in this section and type “Not Applicable.”**

**Researcher Financial Interests in this Study**

[If a member of the study team has a personal financial interest in the outside entity funding this study or other personal financial interests in entities that might reasonably be affected by the research, the LSUHSC-NO COI Committee will provide required language to be included in the consent document.]

**Use of My Specimens**

If the study involves collection of specimens, use one or more of the following options; otherwise delete this section:

**OPTION 1:** If specimens will be kept by LSUHSC-NO and there is a potential for commercialization of the research:

Any specimens (for example: tissue, blood, urine) obtained for the purposes of this study will become the property of LSUHSC-NO. Once you provide the specimens you will not have access to them. The Health Sciences Center may share your specimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of LSUHSC-NO. The specimens will be used for research, possibly including genetic research. Such use may result in inventions or discoveries that could become the basis for new medical tests or products. In some instances, these inventions and discoveries may have commercial value and may be patented and licensed by the Health Sciences Center. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

**OPTION 2:** If specimens will be provided to an outside entity, such as the study sponsor or national group and there is a potential for commercialization:

Any specimens (for example: tissue, blood, urine) obtained for the purposes of this study will be provided to [the Sponsor of this study (company name optional) or the name of the national group]. These specimens will not include information that identifies you directly. Once you provide the specimens you will not have access to them. The specimens will be used for research, possibly including genetic research. Such use may result in discoveries that could become the basis for new medical tests or products. In some instances, these discoveries may have commercial value and may be patented and licensed by one or more of the organizations involved in the research. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

**OPTION 3:** If specimens will be used in research with no possibility or intention of commercial profit:

Your samples will not be used for commercial profit.

**OPTION 4:** If specimens will be discarded:

Any specimens (e.g., tissue, blood, urine) obtained for routine lab testing will be discarded or destroyed once they have been used for the purposes described in the protocol.

15. What should I do if I get sick or injured during the study?

**INSTRUCTIONS:** This section may be omitted for certain minimal risk research studies (e.g., research limited to questionnaires/surveys) wherein injury associated with study participation is unlikely to occur. **If not applicable to this study, delete all the text in this section and type “Not Applicable.”**

If you believe the research procedures have made you sick or caused an injury to you, immediately seek medical advice and/or treatment by:

* Contacting the Principal Investigator and/or the Co-Investigator whose phone numbers are listed in the next section; and/or
* Calling the Research Injury phone number listed in the next section; and/or
* Contacting your regular medical doctor; and/or
* Contacting the treatment center of your choice.

In the event of study-related harm, [describe which party (or parties) is responsible for arranging medical care, who will pay for the cost of care, and under what conditions (if any) that such payments will be made].

**Consult the** [**LSUHSC-NO Consent Form Supplemental Instructions**](https://www.lsuhsc.edu/administration/academic/ors/docs/HRP-2655_Supplemental%20Instructions%20for%20Consent%20Form_v1.0_6.8.20.pdf) **for additional instructions and/or example text for completing this section**

If cost of care will be billed to the participant’s insurance company or third party payor, include the following statement; otherwise delete:

If the insurance company does pay for the care and treatment of study-related injury, you may be responsible for any co-payments and deductibles.

16. Who 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: Click or tap here to enter text.Address: Click or tap here to enter text.Phone #: Click or tap here to enter text.24-Hour Phone #: Click or tap here to enter text. | **Co-Investigator**Name: Click or tap here to enter text.Address: Click or tap here to enter text.Phone #: Click or tap here to enter text.Research Injury Phone #: Click or tap here to enter text. |

**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.

[Include the following paragraphs if this is an applicable clinical trial of a drug, device, biologic or other product regulated by the FDA; otherwise delete.]

**Public information about this study:**

*ClinicalTrials.gov* is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available at [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/), as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

The National Clinical Trials number for this study is NCT     .

17. 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.

18. Your participation in this study is voluntary

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason or no reason at all. No matter what you decide, there will be no penalty to you and you will not lose any services, benefits or rights you would normally have. 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 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.

19. Your consent

**INSTRUCTIONS:** Include the following signature blocks as appropriate to the subject population and consent process described in the protocol documents. **Delete those signature blocks that are not applicable.**

By signing this document, I acknowledge or am aware that:

* The researcher(s) discussed the study with me and answered all my questions.
* I will receive a copy of the consent form.
* I do not waive any of my legal rights by signing this consent document.
* I can contact the study team or the Chancellor’s Office using the contact information provided above if I have any questions or concerns after signing the consent form.

**INSTRUCTIONS:** Include this signature block when informed consent and authorization for participation of some or all subjects will be obtained directly from the subjects. **Otherwise, delete.**

**Signature of Participant:**

*I agree to take part in this study.*

Participant Signature Printed Name Date

**INSTRUCTIONS:** Include this signature block when you anticipate enrolling adult subjects who cannot read. **Otherwise, delete.**

**Signature of Reader & Witness to Consent of Subjects Who Cannot Read:**

*The study subject has indicated to me that he/she is unable to read. I represent that the consent form was presented orally to the subject in the subject’s own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent for participation by completing the signature line above.*

Reader Signature Printed Name Date

Witness Signature Printed Name Date

**INSTRUCTIONS:** Include this signature block when informed consent and authorization for participation of some or all adult subjects will be obtained from a legally authorized representative (LAR) of the subject. **Otherwise, delete.**

**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

**INSTRUCTIONS:** Include this signature block if you anticipate that a subject initially enrolled by an LAR will regain capacity to consent for themselves. **Otherwise, delete.**

**Consent for Continued Participation:**

*At the time that you became ill, you were not able to make a decision about participating in a research project. The person making medical decisions on your behalf during your illness agreed for you to be in this research study. Now that you are again able to make decisions, you can choose whether or not to remain a participant.*

*If you decide to stay in the study, you will be asked to review and sign the full consent form for this research.*

*If you decide to end your participation, your personal and medical information gathered since the start of the research project may still be used for this research.*

Please check below to indicate your decision:

\_\_\_\_\_ I wish to stay in the study

\_\_\_\_\_ I wish to end my participation in the study

Participant Signature Printed Name Date

Signature of Person Obtaining Consent Printed Name Date

Witness Signature Printed Name Date

**INSTRUCTIONS:** Include this signature block when assent of the child (7 to 17 years of age, inclusive) and parental/guardian permission will be obtained. Please contact the IRB Office to obtain the age-appropriate assent form. If assent was not obtained, document the reason for not obtaining assent. **Otherwise, delete.**

**Signature of Parent(s)/Guardian for Child:**

*I certify that I am the child’s legal guardian and agree for my child to take part in this study.*

Mother’s Signature Printed Name Date

Father’s Signature Printed Name Date

Legal Guardian’s Signature Printed Name Date

Name of Child (Please print) Age of Child

**Reason for not obtaining child assent:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**INSTRUCTIONS:** This signature block is mandatory.

**Signature of Person Obtaining Consent:**

*I have explained the research to the subject and answered all their questions. I will give a copy of the signed consent form to the subject.*

Signature of Person Obtaining Consent Printed Name Date

20. Who can I contact during evacuations or emergencies?

Please keep this card with you at all times for use during evacuations or other emergencies. Please cut along the dotted lines, fold along the solid line.

|  |  |
| --- | --- |
| **CONTACT INFORMATION***If you need to get in touch with researchers during an evacuation or other emergency, please contact:***Name:** Click or tap here to enter text.**Phone**: Click or tap here to enter text.**Email Address:** Click or tap here to enter text.*If you are unable to contact the person named above, please call the Office of Research Services at:* **504-568-4970** or (toll-free) **866-957-8472** | **STUDY INFORMATION****Sponsor:** Click or tap here to enter text.**LSUHSC-NO IRB #:** Click or tap here to enter text.**PI:** Click or tap here to enter text.**Site:** Click or tap here to enter text.**Participant ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***Please be prepared to provide this information to your healthcare provider during routine or emergency medical service.* |

INTENTIONALLY LEFT BLANK

**Louisiana State University Health Sciences Center - New Orleans**

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 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 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 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 below and in the Consent Document. 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 sign this form, 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 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) include all records, except those listed in Section 3, as well as “other” notes or documents relating to my treatment or hospitalization);

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

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?

**Yes, 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)

|  |
| --- |
| **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 |

|  |
| --- |
| **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 TypeParent or LAR Signature Date |

|  |
| --- |
| **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 |