**LSUHSC-NO OPTIONAL BIOREPOSITORY CONSENT FORM TEMPLATE**

**Instructions for Using the Template**

* 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.
* 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.
* 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.
  + Use active voice rather than passive voice whenever possible.
  + Use short, simple sentences and short paragraphs.
  + Avoid medical and scientific jargon.

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

Louisiana State University Health Sciences Center - New Orleans

Optional Biorepository Consent

**STUDY TITLE:**

**PRINCIPAL INVESTIGATOR:**

**EMERGENCY CONTACT:**

**STUDY SPONSOR:**

1. Invitation to be Part of a Research Study

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.

2. Why is this study being done?

Things you should know:

* The purpose of the study is to collect and store blood and/or tissue samples and information [elaborate on the reason for storage of the samples]. Collectively, the samples and associated information is referred to as a biorepository.
* If you choose to participate, you will [briefly describe in lay language what will happen to the participant in the 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].
* Taking part in this biorepository is voluntary; you do not have to participate. If you do take part, you can stop at any time.

3. 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.

This study involves the collection of [list samples to be collected] samples and medical history.

Select one or more of the options below.

If you agree to take part in this study, we will

* collect a blood sample from you by drawing about [amount in lay terms, i.e. 1 teaspoon] of blood from a vein in your arm.

[and/or]

* collect a urine sample from you by [describe procedure].

[and/or]

* collect a [sample type] from you by [describe procedure].

[and/or]

* receive a portion of a sample that was collected from you during a previous [surgery/procedure] for research and storage.

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.

4. 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.

5. 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].

**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.

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

**Possible benefits to you**

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

**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.

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

The alternative is not to participate.

8. 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.

9. Will my information/specimens be used for future research?

Choose one of the following two 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].

Before sharing, we will remove all identifiable information (such as your name, medical record number, date of birth) so the researchers cannot identify you. Despite these measures, we cannot guarantee complete anonymity of your personal data. We will not ask you to provide additional informed consent.

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

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

There will be no costs to you for taking part in this study.

11. Will I be paid or 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.

12. Who can profit from study results?

**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 otherwise delete this section.]

**Use of My Specimens**

Select one or more of the following options

**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.

13. 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:  Address:  Phone #:  24-Hour Phone #: | **Co-Investigator**  Name:  Address:  Phone #:  Research Injury 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.

14. What if I no longer wish to participate in the study?

If participants can withdraw: You may decide to withdraw from participating in this study at some point in the future. You should contact the investigator and he/she will destroy any samples of yours that are currently being stored and have not already been used. However, information, material derived from processing of your original samples, and data generated up to the point of withdrawal may remain part of the study. You may not remove this data from the study database. We will keep this information confidential.

Or

If participants cannot withdraw: The samples you provided are not identified or linked to codes that can identify your samples; therefore, it is not possible to withdraw your samples once you have provided them and they have been stored.

15. 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.

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.

16. 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 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 his/her questions. I will give a copy of the signed consent form to the subject.*

Signature of Person Obtaining Consent Printed Name Date