**Medical University of South Carolina Relying Institution Consent Language Requirements**

**This document contains only the MUSC institutional language requirements. See the** [**MUSC consent form template**](https://research.musc.edu/-/sm/research/resources/ori/irb/forms-files/revised-informed-consent-template-with-hipaa-05112023.ashx) **for the applicable full template.**

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# SOURCE OF FUNDING FOR THE STUDY

The study is sponsored by \_\_\_\_\_\_\_\_

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# CONFLICT OF INTEREST

Include language as applicable if there is a management plan in place.

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# MEDICAL RECORDS

If no information will be placed in the subject’s medical record at MUSC and no external monitors will access the medical record for this study, include the following*:*

Information about your study participation will not be in your medical record.  This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

OR*:*

If information will be placed in the subject’s medical record at MUSC or any of the following apply: 1) an external research monitor will access a participant’s medical record, 2) utilization of recruitment tools in the EHR, 3) utilization of MyChart to communicate with participants, 4) research participation will be indicated in Epic with a research header, 5) the study will utilize any of the Epic Research Functionality (i.e. event notifications, adverse event documentation, research notes, electronic task lists, etc.), include the following*:*

If you are an MUSC patient you have an MUSC medical record.  If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Documentation of your participation in this study will be included in the medical record and results of research tests or procedures may be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law.

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**RISKS**

Include the following text in the consent form if there is Genetic Testing:

Genetic research studies may present unique risks to human subjects and their relatives. These involve medical, psychosocial, and economic risks, such as the possible loss of confidentiality (private information), loss of insurability and employability, paternity, and social stigmas. Knowledge of one’s genetic make-up may also affect one’s knowledge of the disease risk status of family members. Genetic research raises difficult questions about informing you and other subjects of any results, or of future results. Some people feel anxious about the possibility of having a defective gene that would place them or their children at risk. Some people want to know what is found out about them; others do not. The risks of knowing include anxiety and other psychological distress. The risks of not knowing what is found include not being aware if there is treatment for the problem being studied. But these risks can change depending on whether there is a treatment or cure for a particular disease and on how clear the results are. If there is a medical reason to seek specific information from you, your doctor will tell you this. A process called “genetic counseling” is often appropriate in such cases; you should ask your doctor or nurse about this if you have any questions.

South Carolina law, mandates that your genetic information obtained from any test or from this research, be kept confidential. Our state law prohibits an insurer using this information in a discriminatory manner against your or any of your family in issuing or renewing insurance coverage for you or your family. Our state law further prohibits our sharing your genetic information with anyone except in a few narrow circumstances, one of these being a research project of this type, approved by the Institutional Review Board and then we must take all steps to protect your identity. You will still be responsible for paying for health care, however. The Medical University of South Carolina will not be responsible for such costs, even if care is needed for a condition revealed during research or clinical testing.

Include the following text in the consent form if there is infectious disease testing:

Per South Carolina law, if you test positive for [\_\_\_[Name the qualifying disease]](http://academicdepartments.musc.edu/research/ori/irb/Standard%20Consent%20Language/Infectious%20Disease%20Testing#Procedure), the results of your test must be reported to the South Carolina Department of Health and Environmental Control.

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# COSTS

If the study has costs, language will be provided to the study team by the OCR-PRA committee. Language is provided by the OCR-PRA committee in a memo uploaded in the eIRB history section.

OR, if there is no cost to the participant:

There will be no cost to you as a result of participation in this study.

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**PAYMENT TO PARTICIPANTS**

The following language is required if subjects are being paid for participation:

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

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**SPONSOR COMMITMENT**

Sponsoring companies often request that their own wording be used for treatment and compensation for study related injuries. Sponsors may include a description of what the sponsor will cover in this section only.

The wording of MUSC’s standard paragraphs at the end of the consent form was formulated with the advice of legal counsel with the intent of adhering to the requirements of Federal and State regulations and cannot be changed.

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**Authorization to Use and Disclose (Release) Medical Information**

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

* The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
* Other institutions and investigators participating in the study;
* Data Safety Monitoring Boards;
* Accrediting agencies;
* Clinical staff not involved in the study whom may become involved if it is relevant;
* Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
* Health insurer or payer in order to secure payment for covered treatment;
* Federal and state agencies and MUSC committees having authority over the study such as:
* The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company’s application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC’s Privacy Officer at (843) 792-8740.

*OPTIONAL LANGUAGE- to be included in the consent if the participant is being asked to participate in optional research.*

*In addition to the main study, you have the option of participating in (insert the optional types of research that may be performed). Your protected health information may be used or shared with others outside of MUSC for this research as well. Please initial below if we may use/disclose your protected health information for the optional research portion/s of this study.*

 *\_\_\_\_Yes, you may use my protected health information for the optional research portions of this study.*

 *\_\_\_\_No, you may not use my protected health information for the optional research portions of this study.*

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**STUDENT PARTICIPATION**

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution*.*

**EMPLOYEE PARTICIPATION**

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

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**MUSC STANDARD PARAGRAPHS:**

* The following information must be included in all informed consents as required by Federal regulations and MUSC IRB policies. They are commitments and/or responses to Federal regulations by this Institution. **The paragraphs cannot be edited or altered without prior approval of general counsel.**
* Click on the appropriate Standard Paragraphs, copy and paste the information into this document and delete the links below.

[Standard Paragraphs - Not FDA Regulated HIPAA (MUSC)](https://research.musc.edu/-/media/sites-media/research-media/resources-media/ori-media/irb/forms-files/standard-paragraphs/sp-not-fda-regulated-hipaa.ashx)
[Standard Paragraphs - FDA Regulated HIPAA (MUSC)](https://research.musc.edu/-/media/sites-media/research-media/resources-media/ori-media/irb/forms-files/standard-paragraphs/sp-fda-regulated-hipaa.ashx)
[Standard Paragraphs - Child Not FDA Regulated HIPAA (MUSC)](https://research.musc.edu/-/media/sites-media/research-media/resources-media/ori-media/irb/forms-files/standard-paragraphs/sp-child-not-fda-regulated-hipaa.ashx)
[Standard Paragraphs - Child FDA Regulated HIPAA (MUSC)](https://research.musc.edu/-/media/sites-media/research-media/resources-media/ori-media/irb/forms-files/standard-paragraphs/sp-child-fda-regulated-hipaa.ashx)

[Standard Paragraphs – Child AND Adult Not FDA Regulated HIPAA (MUSC)](https://research.musc.edu/-/media/sites-media/research-media/resources-media/ori-media/irb/forms-files/standard-paragraphs/sp-child-and-adult-not-fda-regulated-hipaa.ashx)

[Standard Paragraphs – Child AND Adult FDA Regulated HIPAA (MUSC)](https://research.musc.edu/-/media/sites-media/research-media/resources-media/ori-media/irb/forms-files/standard-paragraphs/sp-child-and-adult-fda-regulated-hipaa.ashx)