Medical University of South Carolina
Relying Institution Consent Language Requirements

This document contains only the MUSC local institutional language requirements for use in sponsor-provided informed consent form templates for external IRB studies. Please see the MUSC IRB Forms and Guidance website for the applicable full MUSC Informed Consent templates.

Instructions are highlighted in yellow.

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INSTITUTION NAME

"Medical University of South Carolina" must be included at the top of the consent form.

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SOURCE OF FUNDING

"The study is sponsored by_____"

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CONFLICT OF INTEREST

Language as applicable must be included 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.

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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GENETIC RISKS

The following language must be included 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.

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INFECTIOUS DISEASE REPORTING

The following language must be included if there is infectious disease testing:

Per South Carolina law, if you test positive for [Name the qualifying disease], 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. This language must be included in the consent.

OR, if there is no cost to the participant, the following language must be included:

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 must be included 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.

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AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

HIPAA language should be included in every ICF. The site's HIPAA should replace the sponsor's template HIPAA. In addition, the HIPAA should be placed above the signature blocks so that there is only one signature for both the consent and HIPAA.
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.

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OPTIONAL RESEARCH LANGUAGE

The following language must 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

The following language must be included if the study will be enrolling students of the institution:

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.

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EMPLOYEE PARTICIPATION

The following language must be included if the study will be enrolling employees of the institution:

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

MUSC prefers that this language be included in the consent form together. This language should appear just before the signature lines in the consent form. The paragraphs cannot be edited or altered without prior approval of general counsel.

- Exceptions to edits: "your child" and "you and your child" may be added without prior approval of general counsel.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact ***PI NAME at PHONE NUMBER***. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the

Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

Standard Signature Block for Enrolling Adult Participants

_____ _____
Signature of Participant Date Name of Participant

_____
Signature of Person Obtaining Consent Date

Signature Block for Enrolling Decisionally Impaired Adult Participants - LAR consent

_____
Name of Participant

Participant's Personal Representative:

_____
Name of Personal Representative *(Please print)*

_____
Signature of Personal Representative Date

Relationship: ___ Spouse ___ Parent ___Next of Kin ___Legal Guardian* ____ DPOA for Healthcare*
**(If you are the health care agent or guardian, please provide proof of your authority to act on behalf of the patient)*

_____
Signature of Person Obtaining Consent Date

Signature Block for Enrolling Minor Participants - Parent/Guardian Permission

_____
Name of Participant

Participant's Personal Representative:

_____
Name of Personal Representative *(Please print)*

_____
Signature of Personal Representative Date

Relationship: ___ Spouse ___ Parent ___Next of Kin ___Legal Guardian* ____ DPOA for Healthcare*
**(If you are the health care agent or guardian, please provide proof of your authority to act on behalf of the patient)*

*For Minors 12-17 years of age: "My participation has been explained to me, and all of my questions have been answered. I am willing to participate."

Signature: _____

_____
Signature of Person Obtaining Consent Date

Signature Block for Enrolling Adults and Minors as Participants

_____ _____
Signature of Adult Participant Date Printed Name of Adult Participant

_____
Printed Name of Minor Participant

Participant's Personal Representative:

_____
Signature of Participant's Personal Representative (if applicable) Date

_____
Printed Name of Personal Representative (if applicable)

Relationship: ___ Spouse ___ Parent ___Next of Kin ___Legal Guardian* ____ DPOA for Healthcare*

**(If you are the health care agent or guardian, please provide proof of your authority to act on behalf of the patient)*

*For Minors 12-17 years of age: "My participation has been explained to me, and all of my questions have been answered. I am willing to participate."

Signature: _____

_____
Signature of Person Obtaining Consent Date