**Sample Consent Form**

**It is impossible to address all scenarios for the many types of research protocols conducted by MUSC researchers. This sample is designed to assist you in the preparation of consent forms. It is intended to show language preferred by the MUSC IRB to address the essential elements of informed consent. In many cases, the sample language will need to be modified, deleted, or expanded for the particular study.**

Shaded paragraphs like this one are instructions/guidance for you, the writer. Do not include them in the consent form you submit.

*Paragraphs in italics (like this) are intended to be copied and pasted verbatim into the consent form, when applicable.* Please take text out of italics after pasting into consent document.

**Use this sample consent form as a guide for writing consent and/or assent**

**Formatting Instructions:**

* For the participants’ ease of readability it is strongly recommended that you use no smaller than 12 point font.
* Write the consent form in the 2nd person (i.e. you) and keep the pronoun usage consistent throughout.
* Use page numbers (such as *Page X of Y)*
* Use the watermark provided on the IRB forms page and do not alter the watermark. Leave an area approximately 1 inch by 2 inches on the bottom of each page for the IRB approval stamp. (The watermark template on the forms page automatically provides the required margin.)

**Use understandable, non-technical language at an 8th-grade or lower reading level:**

* Do not use symbols (i.e. >, <)
* Provide standard measurements when describing the amount of samples to be used. Convert milliliters to teaspoons/tablespoons. Only one standard measurement is required. (Conversions: 5ml = 1 teaspoon; 15 ml= 1 tablespoon)
* Spell out acronyms the first time they are used.
* Avoid exculpatory statements such as “you understand.”
* Readability statistics can be displayed in Microsoft Word. Search Microsoft Office Help for “readability statistics” for further instructions.
* Make sure to use spell check and proof the document for grammar before submission.

[**Suggested lay terminology can be found Here**](https://sctrweb2.musc.edu/pups/files/0000/0092/MUSC_LAY_Terms_5-27-09.xlsx) (Hold down Ctrl and press Enter)

**Please also use the** [**Suggested Consent Language Library**](https://research.musc.edu/resources/ori/irb/forms/consent-language) **for sample language to be used to describe specific procedures and risks of those procedures.**

**DELETE THIS FIRST PAGE OF INFORMATION**

**IF YOU ARE USING THIS DOCUMENT**

**TO CREATE YOUR CONSENT FORM.**

**Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT**

**TITLE OF RESEARCH:** Insert study title

* The Consent form study title must match the title on all documents (i.e. protocol, grant application, eIRB application full title, HIPAA authorization, 1572, surveys, etc.).
* If the study involves using different consent forms for different populations, identify the population group as the subtitle of the study.

**RESEARCH INVOLVING CHILDREN:**

* If the study will enroll both minors and adults as participants (but not parent/ child pairs), insert the following language beneath the title of the study:

*If participants include those under 18 years of age: 1) The subject's parent or legal guardian will be present when the informed consent form is provided. 2) The subject will be able to participate only if the parent or legal guardian provides permission and the adolescent provides his/her assent. 3) In statements below, the word "you" refers to your child or adolescent who is being asked to participate in the study.*

* When a parent or guardian is providing consent for only the child participant who will sign a separate assent form or who will not provide written assent, use “your child” throughout the form.
* When a parent or guardian is providing consent for both him/herself and the child participant, specify throughout the consent form when you are referring to the parent and when you are referring to the child. This would allow for the use of “you,” “your child,” and “you and your child” throughout the form.

**SUMMARY**

* The new regulations require that each consent have a “concise summary”
* that provides information that a reasonable person would want to have in order to make an informed decision about whether or not to participate.

**Insert concise summary here. Summary must include the following:**

* The fact that consent is being sought for research and that participation is voluntary;
* The purpose(s) of the research, expected duration of the subject’s participation, and the procedures to be followed in the research;
* Reasonably foreseeable risks or discomforts;
* Benefits to subjects or others that may be reasonably expected from the research; and
* Appropriate alternative procedures or courses of treatment, if any that might be advantageous to the prospective subject

Examples of concise summaries may be found on the IRB website.

**A. PURPOSE OF THE RESEARCH**

**Note: To eliminate redundancy, only address those items that have not already been covered in the concise summary**

* Explain the purpose of the study in nontechnical language—
* Describe why the participant is being asked to join.
* State that the study involves research.
* Studies of drugs/devices or comparison of procedures should include a statement that the purpose of the study includes an evaluation of the safety and effectiveness of the article or procedure.
* If the study is using an investigational drug, drug combination, biologic and/or device, always indicate what is FDA approved and what is investigational. (Investigational means the study drug or device or biologic is still being tested in research studies and is not approved by the U.S. Food and Drug Administration.)
* If applicable, explain what a Pilot, Phase I, II, III, or IV drug study is.
* State the total planned number of participants to be enrolled by the MUSC investigator, and study wide for multicenter studies.
* If the study is a corporate sponsored study, include the following statement in the purpose section: “MUSC, the study team and the Principal Investigator will be paid to conduct the study.”
* If applicable, include the following language, “A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of the (PI’s name) and his/her research team’s salaries will be paid by this grant.”

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you are/have \_\_\_\_\_\_. The study is sponsored by \_\_\_\_\_\_\_\_. The investigator in charge of this study at MUSC is \_\_\_\_\_\_ (PI’s name). The study is being done at \_\_\_\_\_ (insert the number) sites. Approximately\_\_\_\_ people will take part study-wide and \_\_\_\_\_ will take part at this institution **OR** if this is a single site study: Approximately\_\_\_people will take part in this study.

**B. PROCEDURES**

**\*\***Refer to the [Suggested Consent Language Library](https://research.musc.edu/resources/ori/irb/forms/consent-language) for sample language to be used to describe specific procedures.

* Procedures should be listed in chronological order.
* Describe the research procedures to be followed. Give sufficient detail for the subject to understand the full extent of his/her participation.
* Standard of care procedures (SOC) do not need to be described in the consent document. There are certain types of studies (e.g. oncology studies, comparative effectiveness studies) where some description of SOC is inevitable.
* Identify all drugs, devices, and procedures that are experimental. This also includes all drugs or devices that have FDA approved indications but are being used in this investigation for non-approved indications.
* If applicable, describe randomization procedures and blinding for the participant.
* If the study will use a placebo, please define placebo. For example, “A placebo is an inactive substance given in the same form as the active drug.”
* Estimate the amount of time involved for the study visits.
* If both pregnancy testing and illicit drug testing will occur in the same study, the pregnancy test and a negative result from that pregnancy test should be obtained prior to performing the illicit drug test.
* If applicable, include a section that addresses the precautions that should be taken by women of childbearing potential and /or by men capable of fathering a child before, during, and/or after participation. List the specific acceptable methods of birth control for participants involved in the study. Use only the information that is applicable to the study population.
* For complex studies with many visits, include visit times in the procedures sections (lay out a timeline); or consider inserting a table/study calendar to assist in describing the study.
* If specimens (e.g., blood, tissue, body fluids) will be collected as part of the research procedures, describe the collection in this section. If the specimens will be stored for future research, describe the storage procedures later in this consent form under “Storage of Specimens for Future Use”.
* If research-only imaging studies are part of the protocol, address whether or not the images will be read for incidental findings. If the images will not be read for incidental findings, include the suggested risk language for incidental findings.
* If applicable, include a section outlining reasons why a participant may be withdrawn from the study or include the ramifications of a participant’s decision to withdraw from the research.
	+ Include procedures for orderly termination of participation (i.e. end of treatment visit, tapering schedule, exit interview).

If you agree to be in this study, the following will happen:

1. You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

 OR:

You will have the following tests and procedures to make sure that you are eligible:

* Physical exam and medical history
* Vital signs
* Blood tests

 OR:

 The researchers will check your medical records to gather information about ….

2. You will have a physical examination and blood and urine will be collected for laboratory tests. Approximately \_\_\_\_ teaspoons (or other commonly understood units such as tablespoons) of blood will be drawn for these tests to \_\_\_\_\_\_.

3. If the physical examination and test results show that you are eligible for the study, you will be randomly assigned to one of two groups. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice to which group you are assigned. The two groups are Group A (Drug \_\_\_\_) and Group B (placebo, an inactive substance).

OR, for studies with more than two arms:

You will be randomly assigned to one of ­­­\_\_\_\_ groups, like drawing numbers from a hat.

4. Group A will receive \_\_\_\_\_, the investigational drug, \_\_\_ times a day for \_\_\_ weeks for a total of \_\_\_\_weeks. Group B will receive placebo, according to the same schedule.

5. An imaging study of your \_\_\_\_\_\_ will be done once at the beginning of the study, and again at the end of the study, in order to check \_\_\_\_. Each procedure will take about \_\_\_\_ minutes/hour(s).

6. Once every two weeks, you will have a Magnetic Resonance Imaging (MRI) exam. For the MRI exam, you will …

7. If you are a woman of childbearing potential and /or a man capable of fathering a child before, during, and/or after participation precaution should be taken. Examples of acceptable methods of birth control for participants involved in the study includes: birth control pills, patch, IUD, condom, sponge, diaphragm with spermicide, or avoiding sexual activity that could cause you to become pregnant.

**C. DURATION**

If applicable, include additional detail about duration than what is in the concise summary. If there is no additional information, this section may be removed.

Participation in the study will take about \_\_\_\_\_visits over a period of \_\_\_\_\_days/weeks/months.

**D. RISKS AND DISCOMFORTS**

If applicable, include additional detail about risks other than what is in the concise summary. If there is no additional information, this section may be removed.

**\*\***Refer to the [Suggested Consent Language Library](https://research.musc.edu/resources/ori/irb/forms/consent-language) for sample language to be used to describe the risks of specific procedures.

* Include any foreseeable risks or discomforts to the participant including physical, social, financial, loss of employability, reputation, and breach of confidentiality.
* The risk section should only contain the risks associated with study procedures. Do not include risks or discomforts associated with drugs or interventions that are not being administered or performed as part of this study. Generally, risks of standard of care procedures should not be included in the consent form.
* Give details of all risks and or discomforts. List risks in order of relative frequency and provide the expected frequency.
* Use sub-headers if there are multiple types of risks

Common adverse events occurring in approximately \_\_\_% of subjects:

(List)

Less common adverse events occurring in \_\_\_% of subjects:

(List)

OR:

*There is a risk of a loss of confidentiality of your personal information as a result of participation in this study.*

OR:

There is a risk of loss of privacy as a result of participation in the group discussions.

**E. MEDICAL RECORDS and/or CERTIFICATE OF CONFIDENTIALITY**

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.

If the study is NIH funded, or an application has been submitted for a CoC from another entity (e.g. FDA) include one of the of the Certificate of Confidentiality paragraphs from the Suggested Language Library. Click here to access: [Certificate of Confidentiality](https://research.musc.edu/resources/ori/irb/forms/consent-language/certificate-of-confidentiality)

**F. BENEFITS**

If applicable, include additional detail about benefits other than what is in the concise summary. If there is no additional information, this section may be removed.

* State any potential benefits to the participant or to others (e.g. future patients) that may reasonably be expected to benefit from the research.
* Do not overstate benefits.
* If there is no potential for direct benefit to the participant, clearly state this.
* **Do not include** medication, treatment, devices, or compensation as a benefit.

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help in the treatment of future patients with conditions like yours/will help the researcher learn more about\_\_\_\_\_\_\_\_\_.

OR, if the subject is randomized:

The potential benefit to you is that the treatment you receive may prove to be more effective than the other study treatment or than other available treatments, although this cannot be guaranteed.

If you are in the group that receives Drug \_\_\_\_\_ and it is successful in treating your condition with fewer side effects than the current standard therapy, you may benefit from participating in the study; however, this cannot be guaranteed.

**G. COSTS**

* If any costs to the participant or the participant’s health insurance might result from the research (i.e. for tests, drugs, biologics, devices, or copayments) describe those costs. Any charges to subjects for investigational drugs or devices must be authorized by the Food and Drug Administration. Include information about any financial assistance that may be available.
* If there is no cost to the participant, this should be stated.

If the subject is responsible for costs and the research involves medical care and the use of a drug:

You or your insurance provider will be responsible for all costs related to your medical care, including the drugs/devices used in this study. You may wish to contact your insurance representative to discuss this further before making your decision about participating in the study. It is possible that your insurance company will refuse to pay for the costs associated with study participation in which case you will be held financially responsible. Please ask \_\_\_\_\_\_\_ (PI’s name) if you would like to know more about which tests and studies are being done solely for research purposes.

OR, if the sponsor is partially responsible for costs:

The study drug/device, \_\_\_\_\_\_\_ (Drug/Device name), will be provided to you at no cost. There will be no additional cost to you for procedures required in this research study that are for research purposes only. All routine clinical care that the Sponsor is not paying for that you would have undergone without participation in the study will be billed to you/your insurance company.

Some insurance plans will not pay for these services for people taking part in research studies. You will be responsible for any charges that your insurance does not cover including co-payments and deductibles. Please ask \_\_\_\_\_\_\_ (PI’s name) if you would like to know more about which tests and studies are being done solely for research purposes.

OR, if there will be no cost to the participant:

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

**H. PAYMENT TO PARTICIPANTS**

* Payment should be dispersed as the study progresses and cannot be contingent upon the subject completing the study.
* Include amount, payment schedule, and method of payment (checks, cash, gift certificates/cards, pre-paid debit card, personal property, and other items of value).
	+ If the intended method of payment is a pre-paid debit card via MUSC’s ClinCard program, include the ClinCard language from the Suggested Consent Language Library. Click here to access: [ClinCard](https://research.musc.edu/resources/ori/irb/forms/consent-language/greenphire-clincard).
* Describe prorated payments for participants who withdraw before the end of the study.
* If children are involved, specify whether the child or parent is being paid.

You will not be paid for participating in this study.

OR:

In return for your time and effort, you will be paid $\_\_\_\_\_ for participation in this study. If you do not complete the study, you will receive $\_\_\_\_\_for each completed visit.

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.*

**I. ALTERNATIVES**

If applicable, include additional detail about alternatives other than what is in the concise summary. If there is no additional information, this section may be removed.

* Describe all appropriate alternative treatment, if any, of treatment that might be advantageous to the subject.
* To enable a rational choice to participate in the research study, subjects should be aware of the full range of options available to them. The person obtaining the subject’s consent should be able to discuss available alternatives including side effects of these alternatives and answer questions that the subject may raise about them.
* One alternative should be to not participate in the study.

If you choose not to participate in this study, you could receive other treatments for your condition. The standard therapy for your condition is …

OR:

Your alternative is to not participate in this study.

1. **DATA SHARING**

One of the below two statements must be included. If you are unsure whether you may share either identified or de-identified data from this study select the first option.

*Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.*

OR

If there is no way you will EVER want to use the data for ANY other purpose, include the statement below. Note, if you choose the following statement, the data cannot be used for anything other than the current project, even if the data are de-identified:

*No information about you that is collected as part of this research (whether or not it is identifiable) will be used or distributed for future research studies under any circumstances.*

**K. DISCLOSURE OF RESULTS**

Include a statement regarding whether or not clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

**OPTIONAL SECTIONS:**

Include any of the following additional elements of consent as applicable. Continue to use outline format (L., M., N., etc.).

\_\_\_\_ **SIGNIFICANT NEW FINDINGS**

Usually applicable for treatment studies, the significant new findings section should indicate whether significant new findings developed during the course of the research that may relate to the participant’s willingness to continue participation would be provided to the participant by the principal investigator or his/her staff.

If there are significant new findings during the course of the study, you will be notified*.*

**\_\_\_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.*

\_\_\_**CLINICAL TRIALS.GOV**

For applicable clinical trials, include the statement below. It is the responsibility of the sponsors and investigators to determine if their clinical trial meets the definition of an “applicable clinical trial” and to ensure compliance with the most current applicable statutory and regulatory requirements.

*A description of this clinical trial will be available on* [*http://www.ClinicalTrials.gov*](http://www.ClinicalTrials.gov)*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.*

\_\_\_**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.

**\_\_\_\_COLLECTION OF SPECIMENS**

Below are the key issues that must be addressed regarding specimen collection. Please articulate whether the specimen collection will be used solely for the purposes of this study, for future use, and/or if the collection is optional.

At a minimum, address the following points:

* What kind of specimens will be collected and the means of collection
* What type of research will be done with the specimens
* Whether the specimens will be shared with other investigators
* Whether the specimens will be coded or anonymized (no way of tracing back to participant/uncoded or code destroyed)
* Whether the participant may be contacted for additional consent
* How long, if known, the biological specimens will be stored (short-term: current protocol only or other current research; long-term: future studies on this study disease or condition, other diseases/conditions unrelated to this study, repository, etc.)
* Foreseeable risks or benefits to participants in the collection, storage, and subsequent research use of specimens
* What will be done with the biological specimens if the participant refuses permission
* What will be done with the research results (research results should not be placed in the individual participant’s medical record)
* How to withdraw consent for future use (if specimens are identifiable)
* A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
* **Whole Genome Sequencing:** For research involving biospecimens include a statement whether the research will (if known) or might include whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

Please access the Suggested Consent Language Library for sample language to be used to describe specific scenarios for the collection of specimens. To access this language click here:

[Collection of Specimens](https://research.musc.edu/resources/ori/irb/forms/consent-language/collection-of-specimens)

**\_\_\_FUTURE CONTACT**

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

\_\_\_\_Yes, I agree to be contacted

\_\_\_\_No, I do not agree to be contacted

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

[Standard Paragraphs – Child AND Adult Not FDA Regulated (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.ashx)

[Standard Paragraphs – Child AND Adult FDA Regulated (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.ashx?la=en)