It is impossible to address all scenarios for the many types of research protocols conducted by RALPH H. JOHNSON VA HEALTH CARE SYSTEM researchers. It is intended to show language preferred by the VA and 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.

Information highlighted in blue is required by the VA and cannot be changed. Please remove the highlighting.

New information is in **RED**.

**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. 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](https://sctrweb2.musc.edu/pups/files/0000/0092/MUSC_LAY_Terms_5-27-09.xlsx)** [**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**](http://academicdepartments.musc.edu/research/ori/irb/Suggested_Consent_Language) **for sample language to be used to describe specific procedures and risks of those procedures.**

**DELETE THE ABOVE SECTION OF INFORMATION AFTER COMPLETION**

**SUMMARY**

(start typing here)

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 in research.

**Insert concise summary above. A concise 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 [MUSC IRB website](http://academicdepartments.musc.edu/research/ori/irb/forms.html) under “Concise Summary Examples.”

**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 VA investigator, and study wide for multicenter studies.
* If the study is a corporate sponsored study, include the following statement in the purpose section: “the VA, 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 the Ralph H. Johnson VA Health Care System 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](http://academicdepartments.musc.edu/research/ori/irb/Suggested_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).

**Make sure references to all research locations are accurate, e.g. Ralph H. Johnson VA Health Care System; MUSC.** If recruitment, screening, or consenting is at one location and interventional procedures at another location, it must be clearly noted in the procedure section.

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.

8. You may be withdrawn from the study without your consent if the researchers believe it is in your best interest of if you fail to follow study procedures. (State specific reasons why subjects may be withdrawn from the study as outlined in the protocol.)

While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

**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](http://academicdepartments.musc.edu/research/ori/irb/Suggested_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.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your healthcare providers if you have any questions about the risks of usual care.

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

If no information will be placed in the subject’s medical record at Ralph H. Johnson VA Health Care System, 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 your Ralph H. Johnson VA medical record.

**OR:**

If information will be placed in the subject’s medical record at Ralph H. Johnson VA, include the following*:* If you are a Ralph H. Johnson VA Health Care System patient, you have a VA medical record.  If you have never been a Ralph H. Johnson VA Health Care System patient, a VA medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your VA 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:[Suggested Consent Language: Certificate of Confidentiality | MUSC Research](https://research.musc.edu/resources/ori/irb/forms/consent-language/certificate-of-confidentiality) **REPLACE MUSC WITH VA.**

**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 participants must bear any additional costs (e.g. transportation, time away from work, health costs, etc.) it must be disclosed in this section. Any such costs must be consistent with Federal laws concerning Veterans' eligibility for medical care and treatment.

*Any charges to subjects for investigational drugs or devices must be authorized by the Food and Drug Administration.*

You or your insurance will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these copayments for VA care and medications that are not part of 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, personal property, and other items of value).
* Describe prorated payments for participants who withdraw before the end of the study.
* Note: VA policy prohibits paying human subjects to participate in research when the research is integrated with a patient’s medical care and when it makes no special demands on the patient beyond those of usual medical care. Any payment offered should be commensurate with the time and inconvenience of the participant incurred by the participant that they otherwise would not have incurred, as well as to cover travel expenses

*You will not be paid for participating in this study*

OR

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

*In return for your time, effort, and travel expenses, you will be paid $\_\_\_\_\_ for participation in this study. If you do not complete the study, you will receive $\_\_\_\_\_for each completed visit. The IRS requires a tax form be filed if your compensation exceeds $600.00/year. However, if the payment for participation will be made through Austin Financial Services Center. This will require the use of your Social Security Number and it may generate IRS Form 1099 automatically, regardless of amount.*

**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.).

**\_\_\_ PHOTOGRAPHS, VOICE AND/OR VIDEO RECORDING**

Please state why photographs, or voice or video recordings are being taken for the research, who will have access to them, and what their disposition will be after the research is completed

\_\_\_\_ **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 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/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

**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.**

**CONSENT**

Your privacy is very important to us and the researchers will make every effort to protect it. Results of this research will be used for the purposes described in this study. These results may be published, but you will not be identified.

The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. 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. There are times when we may have to show your records to other people from Federal agencies that oversee our research such as the Department of Health and Human Service’s Office of Human Research Protections (OHRP), the Food and Drug Administration (for FDA regulated research only), the Government Accountability Office (GAO), the VA Office of the Inspector General (OIG), the VA Office of Research Oversight (ORO), our local VA Research and Development Committee, and other study monitors may look at or copy portions of records that identify you. Also, all records in South Carolina are subject to subpoena by a court of law. Any information shared with these outside groups may no longer be protected under federal law.

The VA will provide necessary medical treatment to a research subject injured by participation in a research project. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by the Ralph H. Johnson VA Health Care System. Financial compensation is not available for such things as lost wages, disability or discomfort due to an injury.

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.

**VOLUNTEER STATEMENT**

Dr./Mr./Ms\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (or indicate a study role that has been delegated by the PI to obtain informed consent) has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

If I have any more questions about my participation in this study or study related injury, or if I have comments, concerns or complaints, I may contact: **insert PI’s name and phone number here**.

If I have questions about my rights as a study participant, or I want to make sure this is a valid VA study, I may contact the Medical University of South Carolina’s Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. I may call the MUSC IRB (843) 792-4148, or the Ralph H. Johnson VA Health Care System Research Compliance Officer at (843) 789-7399, if I have questions, complaints or concerns about the study or if I would like to obtain information or offer input.

By signing this document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it.

(Include the following if the VA informed consent document will be scanned to the Veteran’s medical record): A copy of this signed consent will also be put in my medical record.

|  |  |  |
| --- | --- | --- |
| **I agree to participate in this research study as has been explained in this document.** | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Participant’s Name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Participant’s Signature | \_\_\_\_\_\_\_\_\_\_\_  Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of person obtaining consent | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of person obtaining consent | \_\_\_\_\_\_\_\_\_\_\_\_  Date |

Note: The use of a witness signature is optional. If the IRB determines that a witness signature is required, an additional line for the witness signature must be added above the name of the person obtaining consent. Usually, a witness is solely witnessing the signature of the participant, but the IRB may determine that the witness must witness the entire consent process. A note should be added below the signature of the witness indicating what the role of the witness is.

IMPORTANT: The below signature block for Legally Authorized Representatives (LAR) is only used for populations unable to provide informed consent. Only use the LAR signature block in place of the participant’s signature block if it has been explained in the new study application (subject to approval by the IRB) that these types of populations are going to be used in the study). Delete this if you do not plan to enroll participants using an LAR.

|  |  |  |
| --- | --- | --- |
| **The participant is unable to give informed consent. I, as the legally authorized representative of the participant, give consent for their participation in this study.** | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Legally Authorized Representative | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Legally Authorized Representative | \_\_\_\_\_\_\_\_\_\_  Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of person obtaining consent | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of person obtaining consent | \_\_\_\_\_\_\_\_\_\_\_\_  Date |
| **Indicate below your authority to act as the participant’s legally authorized representative:**  ☐ Spouse  ☐ Parent  ☐ Adult Child (18 years of age or over) for his or her parent  ☐ Adult Sibling (18 years of age or over)  ☐ Grandparent  ☐ Adult Grandchild  ☐ Guardian appointed to make medical decisions for individuals who are incapacitated  ☐ Other per local or state law. Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |