**RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM**

**STUDY TITLE:** [Insert the official title of the study, as it is given in the IRB application]

**VCU INVESTIGATOR:** [Insert the full name, title, and phone number of the VCU Principal Investigator]

**SPONSOR:** [Insert the full name of the funding sponsor. If there is no sponsor for this research, delete this item]

*TEMPLATE INSTRUCTIONS: This template is based on a drug or device research study.*

* Instructions and comments are indicated in orange or blue boxes and [yellow highlighting].
* Delete the instructions and comments after reading and following.
* Required information is indicated in the instruction boxes. You may delete the optional sections and language if they are not applicable to your study.
* Example text should be edited to be appropriate for your study.
* Use lay language at an 8th grade reading level.
* If it is necessary to use technical terms, a lay definition of the term must be provided.
* Define all acronyms at first use.
* Page numbers must be included in the format “Page \_\_ out of \_\_\_\_”.
* Replace “drug name” with the actual generic name of the drug if it exists and any brand, chemical, or slang name you will be using later in the consent. Subsequent replacement of “drug name” may be with the generic, brand, chemical, or slang name of the drug, in a consistent manner.
* Replace “disease name” with the actual disease or condition.
* If the study enrolls only children, consider replacing “you” with “your child” and “consent” with “parental permission”
* Replace “study doctor” with “investigator” if this is not a treatment study.

*[Include if appropriate:] NOTE: In this consent form, “you” always refers to the research participant. [Include if this study will enroll decisionally impaired subjects:]* *If you are a legally authorized representative, please remember that “you” refers to the study participant. [Include if this study will enroll child subjects:]* *If you are a parent or legal guardian, please remember that “you” refers to the child study participant.*

**ABOUT THIS CONSENT FORM**

**The following text is relevant to all research studies and may be modified as appropriate.**

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the study doctor or the study staff to explain any information in this consent document that is not clear to you.** [Insert if applicable:] You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

**Basic element of consent 46.116(b)(8):**“A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled”

**\*\*The following text is required for all studies and modifications are not recommended:**

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

**AN OVERVIEW OF THE STUDY AND KEY INFORMATION**

INSTRUCTIONS: This Key Summary section is a required section for all studies and may not be waived. Sub-headers in this section are optional, but may improve reading comprehension.

**Required section 46.116(a)(5)(i):** “Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist the prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.”

As explained in guidance provided with the Final Rule (Federal Register Vol. 82, No. 12, January 19, 2017, page 7214), if the information included in this Overview section contains sufficient detail to also satisfy the required Basic and Additional Elements of informed consent, then the information included at the beginning does not need to be repeated later in the informed consent.

**Why is this study being done?**

INSTRUCTIONS: Insert a concise overview (1-2 paragraphs) of the study’s purpose written in lay language. This could be a description of the study’s hypothesis or research question.

**Basic element of consent 46.116(b)(1):** “A statement that the study involves research [and] an explanation of the purposes of the research”

**\*\*This is required information for all studies and may be modified as appropriate.**

[Example 1] The purpose of this research study is to test the safety, tolerability, and effectiveness of the drug name when used to treat disease name. You are being asked to participate in this study because you have been diagnosed with disease name, and may meet the study entry requirements.

[Example 2] Disease causes symptoms or condition, which may involve [insert short discussion of how or why the drug might affect the disease or condition. Do not promise efficacy or safety.]

[If conducting the study in a prison setting with research project involving prison staff or inmates as participants, also include a description of the anticipated uses of the results of the research.] The results of this study will be used to \_\_\_.

**What will happen if I participate?**

INSTRUCTIONS: Insert a concise overview (no more than 1/2 page) of the research procedures explained from the participant’s perspective. This information must be organized and presented in a way that facilitates comprehension.

This should briefly outline all the types of activities that they will be asked to do because full details can be given in a later section. Do not include activities that are done for usual care or other purposes (e.g. QI, regular education, etc.).

**Basic element of consent 46.116(b)(1):** “the expected duration of the subject's participation, a description of the procedures to be followed, identification of any procedures that are experimental”

**Additional element of consent 46.116(c)(6):** “The approximate number of subjects involved in the study”

**\*\*This is required information for all studies and may be modified as appropriate.**

[Example 1] Drug name is an investigational drug, which means it has not been approved by the U. S. Food and Drug Administration (FDA). In this study, drug name will be compared to \_\_\_\_, an approved drug, and to placebo (a look-alike inactive substance, a “sugar pill”).

[Example 2] Usual care for your disease or condition involves \_\_\_\_\_. In this study, you will receive usual care, and in addition, you will be asked to \_\_\_\_\_\_\_. [Or, if usual care will be replaced with another treatment/procedure/test, use “instead of \_\_\_\_, you will \_\_\_\_\_.”]

[If randomization occurs, insert:] You will be randomly assigned (like the flip of a coin) to receive either \_\_\_ or \_\_\_\_. [Can also list as bullets if several arms.] You have \_\_\_ chance in \_\_\_\_ of being assigned to placebo, and \_\_\_\_\_ chance in\_\_\_ of receiving \_\_\_\_. [Or can say] You have an equal chance of being assigned to any one of the groups.

[Example 3] In this study, you will be asked to do the following things:

1. Visit [location] \_\_ times for study visits
2. Take either drug name or the placebo, depending upon which group you are assigned to
3. Have your blood drawn \_\_ times
4. Have an MRI/EKG/ultrasound/CT \_\_ times
5. Keep a diary at home
6. Take surveys and answer questions about [describe general topics]
7. Give permission for the researchers to collect information about [describe general topics] from your medical records.

Your participation in this study will last up to [insert length of time]. Approximately [insert how many total] individuals will participate in this study.

INSTRUCTIONS: Insert the language of either Option A or Option B if the study will involve biospecimens. If there is any chance that whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome of that specimen) could be done in this study or future research studies, insert Option A.

**Additional element of consent 46.116(c)(9):** “For research involving biospecimens, 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).”

**\*\*This is required information for all studies that involve biospecimens and may be modified as appropriate.**

[Option A – Studies that will or might perform whole genome sequencing, insert:] This study [will or might] use your samples to sequence all or part of your DNA.

*Deoxyribonucleic acid (DNA) is the “blueprint” or “recipe” that gives the body’s cells instructions on how to do their jobs. Scientists can use a test called whole genome sequencing to determine the order of all or part of the molecules that make up your DNA, like reading all the letters in a book. Sequencing is usually done to look for changes in the molecules of DNA that may cause health problems.*

[Option B – Studies that will not perform whole genome sequencing, insert:] This study will not use your samples to sequence all or part of your DNA.

**What alternative treatments or procedures are available?**

INSTRUCTIONS: Insert a concise overview (1-2 paragraphs) of the alternatives or other options that would be available to individuals who do not participate in this study.

Identify whether any of the study’s procedures and treatment options would be available outside of the study to individuals who do not want to participate (e.g. psychological treatment, coaching, drugs, devices).

If participants have an alternative way of completing a study procedure (e.g. filling out a paper instead of an online questionnaire, taking a survey home, going to a different location for a test, having a MRI instead of a CT, etc.), describe that option.

**Basic element of consent 46.116(b)(4):** “A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject”

**\*\*This is required information for all studies that have an alternative available and may be modified as appropriate. If the participant’s only option is to not participate in this study, then this information may be deleted.**

[If this is a treatment study:] If you decide not to enter this study, you can receive the usual care that you would receive even if you were not in the study. This includes [List the major drugs and/or therapies that are part of usual care]. The study doctor will discuss these options with you. You do not have to participate in this study to be treated for [disease name].

[If the study involves a marketed drug or device or common activity:] You could receive [e.g. drug or device/yoga classes/weight loss coaching] without being in the study. Talk to the study staff or your regular doctor to see if this would be a good option for you.

[If participants have an alternative way of completing a study procedure (e.g. filling out a paper instead of an online questionnaire, going to a different location for a test, having a MRI instead of a CT, etc.), describe that option.]

**What are the risks and benefits of participating?**

INSTRUCTIONS: Insert a concise overview (no more than 1/2 page) of the most common risks or discomforts and of the anticipated benefits of being in the study. The template uses a table format to facilitate comprehension. Paragraph form may be used instead.

Risks must be described using lay terms. If the study involves many potential side effects, include only the most common side effects here and give a full description of all risks later in this consent form.

**Basic element of consent 46.116(b)(2):** “A description of any reasonably foreseeable risks or discomforts to the subject”

**Basic element of consent 46.116(b)(3):** “A description of any benefits to the subject or to others that may reasonably be expected from the research”

**\*\*This is required information for all studies and may be modified as appropriate.**

There are both risks and benefits of participating in research studies. [Insert if applicable:] We want you to know about a few key risks right now. We will give you more information in the “WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?” section.

|  |  |
| --- | --- |
| **Risks and Discomforts** | **Benefits to You and Others** |
| [Example 1 – example of experimental drug risks]   1. There is a risk that study drug may not be as good as the usual approach for disease name. 2. There is also a risk that you could have side effects from taking study drug. Below are some of the most common side effects:  * [Insert the most important risks in a bulleted list. This should be similar to the information that a doctor might deliver in the clinical context. It should be a brief list (i.e. generally around 5, although more may be necessary).]  1. There may be some risks that the study doctors do not know about yet, so we will let you know of any new findings.   [Example 2 – examples of procedural risks]   * Blood draws may cause pain, bleeding, and/or bruising. You may faint and could develop an infection at the site where blood is drawn. * Mild to moderate physical activity may cause sore or pulled muscles, heart problems, physical discomfort, and/or accidental injuries such as falling. You may also experience some physical discomfort such as increased heart rate, chest pain, shortness of breath, headache, nausea, and/or fatigue. * The study questionnaires ask questions that are [sensitive/personal/upsetting/ offensive/disturbing/etc.] in nature and may make you feel uncomfortable.   [Example 3 – example of data storage risks]  Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you. | [Example 1 – potential direct benefits] There is some evidence that [insert intervention] is effective in [insert description of how it may help]. However, it is unlikely that it will work with everyone, and we cannot promise that it will help you. This study may help the study doctors learn things that may help other people in the future.  [Example 2 – potential direct benefits] There is no guarantee that you will receive any medical benefits from being in this study. However, possible benefits include \_\_\_\_. We hope the information learned from this study will provide more information about \_\_\_\_.    [Example 3 – no anticipated direct benefits] This study is not likely to help you. However, the information learned in this research may help the study doctors understand how \_\_\_ works.  [Example 4 – no anticipated direct benefits] This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study. The information from this research study may lead to a better treatment in the future for people with disease name.  [If this study will include prisoners as subjects, insert:] If you are or should become involuntarily detained, confined or incarcerated (in a jail, prison, or alternative facility), you should be aware that your participation in this research project will have no effect on consideration of sentencing, length of sentence, or parole. |

[For longer consent forms, insert the following if a break/transition is needed between the key summary and a full description of the study:] Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you don’t understand, be sure to ask the study staff.

**WHY IS THIS STUDY BEING DONE?**

INSTRUCTIONS: Include in this section a full and complete description of the study’s purpose and any necessary background information about why the study is being done.

**Basic element of consent 46.116(b)(1):** “An explanation of the purposes of the research”

**\*\*This is required information for all studies and may be modified as appropriate. However, if a full description of the study’s purpose is given in the Overview above, then this section can be deleted.**

[Example 1:] The purpose of this study is to test \_\_\_\_\_\_. [Identify any experimental interventions or interactions including use of randomization. Any investigational drugs or devices to be used in the study should be noted and named along with an explanation about their FDA approval status and indications for use.] Drug name is an investigational drug, which means it has not been approved by the U. S. Food and Drug Administration (FDA).

[Example 2:] Disease causes symptoms or condition, which may involve [insert short discussion of how or why the drug might affect the disease or condition. Do not promise efficacy or safety.]

**WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?**

INSTRUCTIONS: Include in this section a full and complete description of the study procedures explained from the participant’s perspective. After reading this section, the participant should have a good understanding of what they will experience and be asked to do and allow during the study.

1. Include information about timing and duration of activities, locations where activities will take place, and what uncommon procedures will be like. Also include a description of any secondary data that will be collected about participants.
2. Include only information about the research activities in this study, not activities that would be done for usual care or other purposes (e.g. normal education, routine psychiatric care, quality improvement, etc.) regardless of participation in study. Explain what aspects of usual care will be altered or omitted because of the study.
3. As appropriate, and particularly for complex studies, include study schemas, study calendars or other tables, figures or graphics to assist the subject in understanding what will be asked of them.
4. Use lay language to facilitate the participant’s understanding. Do not copy technical language from the IRB application or a grant.
5. If the study involves genetic research, be sure to explain what genetic information will be used, generated, or obtained.

**Basic element of consent 46.116(b)(1):** “A description of the procedures to be followed and identification of any procedures that are experimental”

**\*\*This is required information for all studies and may be modified as appropriate. However, if a full description of the study’s procedures is given in the Overview above, then this section can be deleted.**

[What follows is an example.]

At your first study visit (Visit 1), your medical history will be taken and a physical exam will be performed. This exam will include measurements of your weight and vital signs (pulse, blood pressure and temperature). Blood (approximately 1 to 2 tablespoons) and urine samples will be collected for routine lab tests. [If a pregnancy test will be done:] Women of childbearing potential will have a pregnancy test done. Finally, you will have an electrocardiogram (ECG), where sticky pads will be placed on your chest and a machine will trace the electrical activity of your heart. These screening tests and procedures are done to see if you are eligible to be in the study.

If you qualify for the study, you will be given study drug and you will be instructed on how to take your study drug. [If randomization occurs:] You will be randomly assigned (like the flip of a coin) to receive either \_\_\_\_ or \_\_\_\_\_. [Can also list as bullets if several arms.] You have\_\_\_\_ chance in \_\_\_\_ of being assigned to placebo, and \_\_\_\_ chance in \_\_\_\_ of receiving \_\_\_\_. [Alternative explanation for randomization:] You have an equal chance of being assigned to any one of the groups.

[If double blind:] Neither you nor the study doctor will know which study drug (or procedure or treatment, etc.) you are receiving. This information is available to the study doctor if needed in an emergency. This is called blinding, and it is done so that a fair evaluation of results may be made.

[If single blind:] You will not know which study drug you are receiving. This is called blinding, and it is done so that a fair evaluation of results may be made.

Visit 2 will take place \_\_\_\_ days/weeks after Visit 1. Your vital signs will be measured, and...

Visits 3 through 6 will be scheduled at \_\_\_\_. At each visit except Visit 6, your vital signs will be checked, and ... You will be asked about your health since the last visit. You will receive a new supply of study drug and ... You will also complete questionnaires about [insert topics].

Visit 6, the last visit, will include a physical exam, ECG and blood (1 to 2 tablespoons) and urine samples for lab tests. You will be asked about your overall experience with the study drug.

At each visit, you should bring all of your remaining study drug supply to the research clinic.

The investigators will also collect information from your medical records about [insert a description of what types of information will be abstracted]. Medical record information will be collected during your participation in the study and for 5 years after you finish taking the study drug.

**WHAT ALTERNATIVE TREATMENTS OR PROCEDURES ARE AVAILABLE?**

INSTRUCTIONS: Identify any other treatment options, services, or procedures that would be available to individuals who do not participate in this study.

If participants have an alternative way of completing a study procedure (e.g. filling out a paper instead of an online questionnaire, taking a survey home, going to a different location for a test, having a MRI instead of a CT, etc.), describe that option.

If this is not a treatment study, remove “Treatments” from section title.

**Basic element of consent 46.116(b)(4):** “A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject”

**\*\*This is required information for all studies and may be modified as appropriate. However, if a full description of the alternatives is given in the Overview above, then this section can be deleted.**

[If this is a treatment study:] If you decide not to enter this study, you can receive the usual care that you would receive even if you were not in the study. This includes [List the major drugs and/or therapies that are part of usual care]. The study doctor will discuss these options with you. You do not have to participate in this study to be treated for [disease name].

[If the study uses a marketed drug or device or common activity:] You could receive [study drug/study device/yoga classes/weight loss coaching] without being in the study. Talk to your regular doctor to see if this would be a good option for you.

[If participants have an alternative way of completing a study procedure (e.g. filling out a paper instead of an online questionnaire, going to a different location for a test, having a MRI instead of a CT, etc.), describe that option.]

[Example:] You can receive extra credit without being in the study by [explain the alternative way to earn credit].

**WHAT ARE THE BENEFITS OF BEING IN THE STUDY?**

INSTRUCTIONS: Include in this section a full and complete description of any direct benefits participants may reasonably expect to experience as well as a description of the benefits to others from the scientific knowledge to be gained.

**Basic element of consent 46.116(b)(3):** “A description of any benefits to the subject or to others that may reasonably be expected from the research”

**\*\*This is required information for all studies and may be modified as appropriate. However, if a full description of the benefits is given in the Overview above, then this section can be deleted.**

[Example 1 – potential direct benefits] There is some evidence that [insert intervention] is effective in [insert description of how it may help]. However, it is unlikely that it will work with everyone, and we cannot promise that it will help you. This study may help the study doctors learn things that may help other people in the future.

[Example 2 – potential direct benefits] There is no guarantee that you will receive any medical benefits from being in this study. However, possible benefits include \_\_\_\_. We hope the information learned from this study will provide more information about \_\_\_\_.

[Example 3 – no anticipated direct benefits] This study is not likely to help you. However, it may help the study doctors understand how \_\_\_\_\_ works.

[Example 4 – no anticipated direct benefits] This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study. The information from this research study may lead to a better treatment in the future for people with disease name.

**WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?**

INSTRUCTIONS: Include in this section a full and complete description of all reasonably foreseeable risks and discomforts the participant might experience. It is not acceptable to say that there are no risks.

**Basic element of consent 46.116(b)(2):** “A description of any reasonably foreseeable risks or discomforts to the subject”

**\*\*This is required information for all studies and may be modified as appropriate. However, if a full description of all anticipated risks and discomforts is given in the Overview above, then this section can be deleted.**

1. Include only risks of the research activities in this study, not the risks of activities that would be done for usual care or for other purposes (e.g. normal education, routine psychiatric care, quality improvement, etc.) regardless of participation in study.
2. For comparative effectiveness research, the risks and benefits of both/all treatments or procedures must be discussed.
3. Include physical, psychological, social, and research data risks. The information in this section should be a lay description of the risks given in the IRB submission.
4. If there are more than 3-4 side effects in a list, please present in a vertical, bulleted format with the most significant risks first.
5. Use lay language (the non-technical meaning), rather than a medical term (ex, use dizziness” instead of “vertigo” or “weakness” instead of “asthenia”)
6. The NCCN Informed Consent Language (ICL) database is a comprehensive resource to assist researchers and clinical operations personnel with writing and amending informed consents for study participants. **For standardized lay language descriptions of risks and events associated with clinical research, see:** [**https://www.nccn.org/clinical\_trials/informed\_consent.aspx**](https://www.nccn.org/clinical_trials/informed_consent.aspx).

[If this is a treatment study, insert:] Your condition may not get better or may become worse while you are in this study.

**Possible Risks Associated with Study Drug/Device/Intervention**

[What follows is only an example.]

Likely [If applicable, add:] (More than a 50% chance that this will happen)

* Headache
* Dizziness
* Sleepiness

Frequent [If applicable, add:] (Between a 10-50% chance that this will happen)

* Nausea

Occasional [If applicable, add:] (Between a 1-10% chance that this will happen)

* Indigestion

Rare [If applicable, add:] (Less than a 1% chance that this will happen)

* Allergic reaction todrug name is possible, but rare. Severe allergic reactions can be life threatening.

**Possible Risks Associated with Having a MRI with Gadolinium-Based Contrast**

[What follows is an example.]

Magnetic Resonance Imaging (MRI) Procedure

* The machine will produce a loud knocking noise, so you will be given earplugs to protect your ears.
* Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner.
* During the MRI, you may feel mild vibrations throughout your body or a twitching sensation from the strong magnetic field. You may feel warm if the MRI lasts for a long time.
* The magnetic field used in MRI scanning may harm people who have metal in their bodies. It may cause problems with devices, such as pacemakers. If you have metal in your body or a pacemaker, you should not have an MRI.

IV Insertion to Inject the MRI Contrast Dye

* IV injections may cause slight discomfort, light-headedness, fainting, bleeding, infection, soreness and/or bruising. Multiple needle-sticks may be necessary.

Gadolinium-Based Contrast Dye

*The MRI contrast dye used in this study is a medicine that contains a metal called gadolinium.* *Your healthcare provider will explain more about the risks and side effects of the specific medicine that you will receive.*

* The contrast dye may cause allergic reaction, headache, nausea, vomiting, dizziness, rash, itching, discomfort, tingling or warmth in the lips, metallic taste in the mouth, or numbness or tingling in the arm, hands or feet.
* Gadolinium can stay in your body for a long time (several months to years), including in the brain and other parts of your body. It is not known how gadolinium may affect you, but so far, studies have not found harmful effects in patients with normal kidneys. More studies on the safety of gadolinium are being done.
* Some people with kidney problems who get gadolinium medicines can develop a condition with severe thickening of the skin, muscles and other organs in the body (nephrogenic systemic fibrosis).
* MRI contrast crosses the placenta, and risks to the developing fetus are not known.

[Also include risks of drug interactions, drug withdrawal, receiving placebo, sham treatment, washout periods, randomization, etc. Include risks and side effects for each comparator drug, if any].

[If study drug is taken home, insert:]Only the study participant can take the study drug. It must be kept out of the reach of children and persons who may not be able to read or understand the label.

[List risks of all other research and sample collection procedures. Also include any language from the Radiation Safety Committee regarding radiation exposure that does not have a direct clinical benefit.]

**The following sub-section is relevant to all studies:**

**Non-Physical Risks**

Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.

[Example:] Questionnaires may contain questions that are [sensitive/personal/upsetting/offensive/disturbing/etc.] in nature. You may refuse to answer any question that makes you feel uncomfortable.

[Example:] This study will ask you questions about personal topics that might be embarrassing to talk about and that could affect your family relationships if this information were to become known outside of the study. You will also be asked about illegal activities, which could have legal and financial consequences if this information were to become known outside of the study.

**Include the following sub-section if the study involves genetic analyses or clinical genetic testing. Modifications are not recommended.**

**Genetic Risks:**

If known to employers or insurance companies, the results of genetic tests might affect a person's ability to obtain a job or health or life insurance. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job.

A federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, this legal protection still may not keep someone from trying to discriminate against you in this way

**Additional element of consent 46.116(c)(5):** “A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject”

**\*\*** **Include the following sub-section if the study is longitudinal or interventional. Modifications are not recommended.**

**Unknown or Unforeseeable Risks**

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

**Additional element of consent 46.116(c)(1)** “A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable”

**\*\*The following information is required for all studies that:**

1. **involve investigational drugs or devices**
2. **involve any research-related interventions for which the risk profile is not well known**

[Insert name of investigational drug/device/treatment/procedure] involves risks that are currently unknown or unforeseeable. [If any of the treatments or procedures have not been well studied in pregnant women, insert:] If you are or may become pregnant, [insert name of study treatment or procedure] might involve risks to the embryo or fetus that are currently unforeseeable.

**\*\*The following sub-section should be included when applicable and may be modified as appropriate:**

**Reproductive Risks**

[For studies enrolling only women:]

As the study procedures might injure an unborn child, pregnant women may not participate. Women who might become pregnant should use a medically accepted form of birth control such as total abstinence, birth control pills, an IUD, diaphragm, progesterone injections or implants, or condoms plus a spermicide. Methods of birth control other than total abstinence are not 100% effective, and should a women become pregnant there is a risk of injury to an unborn child. For similar reasons, women who are nursing an infant may not participate.

[For studies with women and men:]

As the study procedures might injure an unborn child, pregnant women may not participate. Women who might become pregnant should use a medically accepted form of birth control such as total abstinence, birth control pills, an IUD, diaphragm, progesterone injections or implants, or condoms plus a spermicide. Methods of birth control other than total abstinence are not 100% effective, and should a women become pregnant there is a risk of injury to an unborn child. For similar reasons, women who are nursing an infant may not participate.

For men, the study procedures might increase the risks for birth defects of any child conceived during treatment and several months after treatment is stopped. Men in this study who have the potential of fathering children should be aware of this possibility and consider using a medically accepted form of birth control. For men this would include total abstinence and condoms plus a spermicide, or for the female partner, birth control pills, an IUD, diaphragm, progesterone injections or implants. Methods of birth control other than total abstinence are not 100% effective, and should a women become pregnant there is a risk of injury to an unborn child.

[For studies enrolling only men:]

For men, the study procedures might increase the risks for birth defects of any child conceived during treatment and several months after treatment is stopped. Men in this study who have the potential of fathering children should be aware of this possibility and consider using a medically accepted form of birth control. For men this would include total abstinence and condoms plus a spermicide, or for the female partner, birth control pills, an IUD, diaphragm, progesterone injections or implants. Methods of birth control other than total abstinence are not 100% effective, and should a women become pregnant there is a risk of injury to an unborn child.

**WHAT ARE THE COSTS?**

INSTRUCTIONS: Include in this section a description of all costs that the participant or their insurance will be responsible for paying. Use your cost coverage analysis to determine which items are billed to the patient.

**Additional element of consent 46.116(c)(3):** “Any additional costs to the subject that may result from participation in the research”

**\*\*This is an optional section. It applies only to studies where there will be costs to the participant or their insurance and may be modified as appropriate.**

[Example:] Study drug will be provided by the sponsor at no cost to you. You will not be charged for any study visits, tests, or procedures.

[Example:] You and your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your condition. This includes:

* The costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and to prevent and treat side effects.
* The costs of getting study drug ready and giving it to you
* Your insurance co-pays and deductibles.

[Example:] You and your insurance plan will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. This includes:

* The extra blood draws in this study done at every study visit
* The biopsy for testing \_\_\_\_ at the beginning of the study.

[Example:] You will have to pay for the following items, which are done for research purposes only and are not covered by the study. This includes:

* The cost of the cell phone used in this study
* The activity workbook and supplies
* Membership at the YMCA for 6 months

**WILL I BE PAID TO PARTICIPATE IN THE STUDY?**

INSTRUCTIONS: Include in this section a description of any planned compensation that will be given to participants. Use straightforward language and include the amount paid per visit.

**\*\*This is an optional section. It only applies to studies that plan to compensate participants and may be modified as appropriate.**

[Example:] You will be paid $\_\_\_\_\_ in cash/by check/by gift card for each study visit, and if you complete all scheduled study visits, you will have received a total of $\_\_\_\_. If you withdraw before the end of the study, you will be paid $\_\_\_\_\_ per completed study visit.

[Include if paying money to participants:] Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

[Include if appropriate] Please be aware that the investigative team and the University may receive money for the conduct of this study.

**WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?**

**Basic element of consent 46.116(b)(6):** “For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained”

**\*\* This is a required section for all greater than minimal risk studies and modifications are not recommended. Modified text will need to be reviewed by the Office of Sponsored Programs to ensure consistency with the grant contract.** This section is not required, and generally not appropriate, for expedited research.

If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

**CAN I STOP BEING IN THE STUDY?**

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

**Additional element of consent 46.116(c)(4):** “The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject”

**\*\*The following information is required if any adverse consequences (physical, social, economic, legal, or psychological) may result from a participant's decision to withdraw from the research**

If you leave the study before the final regularly scheduled visit, [Insert any procedures for orderly termination of participation by the subject (i.e., tapering off of study drug(s), follow-up visits with study team or patient’s physician).] Stopping the study drug/device/intervention early may result in \_\_\_\_.

**Additional element of consent 46.116(c)(2):** “Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent”

**\*\*The following information is required if there are any anticipated circumstances under which the investigator might stop a participant from continuing in the study (early withdrawal) and may be modified as appropriate.**

Your participation in this study may be stopped at any time by the study doctor without your consent. The reasons might include:

* the study doctor thinks it necessary for your health or safety
* you are found to not be eligible for the study [delete not applicable]
* the sponsor has stopped the study [delete if the study is unfunded]
* you have not followed study instructions
* administrative reasons require your withdrawal
* [insert any other reasons why the study team would take a participant out of the study]

[If this study will include prisoners as subjects, insert:]

If you are or should become involuntarily detained, confined or incarcerated (in a jail, prison, or alternative facility) during your participation in this study, you should be aware that your continuation would need to be reconsidered given your status as a prisoner.

[If this is an FDA-regulated study, insert:]

If you withdraw from the study, data that has already been collected about you will remain part of the study database and may not be removed.

**HOW WILL INFORMATION ABOUT ME BE PROTECTED?**

INSTRUCTIONS: Include in this section a description of how the study staff will keep research data secure and identify all individuals and groups who may access the data.

**Basic element of consent 46.116(b)(5):** “A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained”

**\*\* This is required information for all studies and modifications are not recommended:**

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases according to VCU’s policies (i.e. for a minimum of 5-6 years). It is only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

* The study Sponsor, representatives of the sponsor and other collaborating organizations [delete if there is no Sponsor]
* Representatives of VCU and the VCU Health System/VCU Dental Care
* Officials of the Department of Health and Human Services [insert any other federal funding agencies such as the Departments of Defense, Justice or Education] or the Federal Food and Drug Administration [reference to the FDA may be deleted if this is not an FDA regulated study]
* [If research is conducted in foreign countries include the following statement:] This research is also being conducted in foreign countries, so personal information pertaining to you may be shared or copied by authorized agents of governmental agencies in those countries.

[If this is a clinical research study that has the potential for clinical billing, is a clinical trial, or if research information will be placed in the participant’s electronic health record at VCU Health, insert:] It will be noted in your protected electronic health record at VCU Health that you are in this study. Information about the study [insert if applicable: including any medications you may receive,] will be included in the record. This information is protected just as any of your other health records are protected.

**Additional element of consent 46.116(c)(8):** “A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions”

**\*\* The following text is required for all studies and may be modified as appropriate.**

In general, we will not give you any individual results from the study. [Insert if the study may have clinically relevant findings:] If we find something of medical importance to you, we will inform you, [or explain another method of communicating the information] although we expect that this will be a very rare occurrence. [Insert if participants will receive aggregate study results:] Once the study has been completed, we will send you a summary of all of the results of the study and what they mean.

**\*\*The following paragraph is required for all clinical trials and for studies that will voluntarily post on the ClinicalTrials.gov website. It may not be modified.**

For more information about CT.gov requirements, see <https://cctr.vcu.edu/support/consultation/clinical-trials-gov/>

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 Website will include a summary of the results. You can search this Web site at any time.

As employees of an institution of higher education in Virginia, VCU faculty and staff are all mandated reporters and are obligated to report child and elder abuse. If there is the potential for any participant to disclose that they may cause injury to themselves or others, you should state in this section that you are required by law to report that information to the appropriate authorities.

Note: When research is supported by the Department of Justice, in order to report child abuse, the researcher must obtain a separate consent to allow child abuse reporting. The National Institute of Justice provides a consent template for this purpose.

**\*\*The following information is required if there is the potential for you to discover suspected child or elder abuse or any other conditions that have mandated reporting during the course of the study and may be modified as appropriate.**

[Example:] We will not tell anyone the answers your child/loved one gives us. However, if your child/loved one tells us that someone is hurting them, or that they might hurt themself or someone else, the law says that we must let people in authority know so they can protect your child/loved one.

[Example:] If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

**[If tests are done that require reporting of positive results to the Health Department (e.g. hepatitis, HIV, STDs, COVID, see** [**https://www.vdh.virginia.gov/surveillance-and-investigation/commonwealth-of-virginiastate-board-of-health/**](https://www.vdh.virginia.gov/surveillance-and-investigation/commonwealth-of-virginiastate-board-of-health/)**), these must be mentioned, along with that information.**

[Example:] Your blood sample will be tested for [insert name of disease]. Virginia state law requires the study staff to report the results of positive tests for [disease name] to a local public health agency.

**\*\*The following text is required if the study will include prisoners as subjects and modifications are not recommended.**

If you are or should become involuntarily detained, confined or incarcerated (in a jail, prison or alternative facility), you should be aware that confidentiality regarding your status as a prisoner cannot be guaranteed. Personal information about you might be shared with or copied by authorized representatives of the prison facility and/or prison system.

All research involving human participants conducted within the Bureau of Prison system must comply with additional requirements established by the Bureau of Prisons in order to be approved by the IRB. Consent requirements are outlined in 28 CFR 512.16 and [WPP XVII-19](https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/).

**\*\*The following information is required if the study is conducted in a prison setting involving prison staff or inmates as participants:**

[Describe any exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself/herself, or, if the subject is an inmate, indicates intent to leave the facility without authorization] If you tell us \_\_\_\_, then we are required to report that information to \_\_\_\_.

All non-exempt research involving human participants supported through a funding award from the Department of Justice (DoJ), including the National Institute of Justice, must comply with additional requirements established by the DoJ in order to be approved by the IRB. Consent requirements are outlined in 26 CFR 46.116 and [WPP XVII-18](https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/).

**\*\*The following information is required for all studies funded by the Department of Justice:**

Private, identifiable information will only be used for research and statistical purposes. However, if you indicate future criminal intent, the researchers are required by law to report this to the authorities. [Any other intended disclosures for research purposes must be explicitly identified in the informed consent document including what will be disclosed, under what circumstances, and to whom.]

Project findings and reports prepared for dissemination will not contain information that can reasonably be expected to be identifiable. [If findings in a project cannot, by virtue of sample size or uniqueness of subject, be expected to totally conceal subject identity, this must be included in the informed consent.] [If the study is funded by the National Institute of Justice, insert:] At the end of the study, a copy of all the data (without any information that could identify you) will be submitted to the National Archive of Criminal Justice Data.

**Additional element of consent 46.116(c)(7):** “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”

**\*\*The following text is required for all studies that involve biospecimens and modifications are not recommended.**

There are no plans to share any money or profits with you if the use of your sample(s) results in inventions or discoveries that have commercial value. [Or, if the participant will share in profits, revise to give an explanation of the commercial profit that would/will be given to the participant.]

INSTRUCTIONS: Insert the language of either Option A or Option B. If there is any chance that information or biospecimens could be used in future studies, insert Option A.

**Basic element of consent 46.116(b)(9):** “One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:  
 (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or  
 (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.”

**\*\*The following text is required for all studies with identifiable or de-identified information or specimens (i.e. studies that do not involve completely anonymous data and/or specimens). Modifications are not recommended.**

[Option A – Studies that will or might use information or biospecimens for future research studies, insert:] In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking you for additional consent.

[Option B – Studies that will not use information or biospecimens for future research studies, insert:] The information and samples collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

**Certificate of Confidentiality**

**\*\*This sub-section is required for all studies funded in whole or in part by the NIH, that were commenced or ongoing, on or after December 13, 2016. It is also required for all non NIH-funded studies that will voluntarily seek a Certificate of Confidentiality (note: all human subject research qualifies for a CoC). Modifications are not recommended.**

To help us protect your privacy, we have obtained [or insert: will apply for] a Certificate of Confidentiality from the National Institutes of Health. If this certificate is obtained, it will offer the protections described here. A Certificate of Confidentiality helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited, or if the information is required by the Food and Drug Administration (FDA).

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

[If you intend to make voluntary disclosure about things such as child abuse, intent to hurt self or others, or other voluntary disclosures, insert:] The researchers may share information about you or your participation in the research project without your consent if: [State here the conditions under which voluntary disclosure would be made, such as child or elder abuse or neglect, or harm to self or others.]

**HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?**

INSTRUCTIONS: This section includes all of the required elements of valid HIPAA Authorization. Include this section if the study will use Protected Health Information (PHI) associated with or derived from a healthcare service event (e.g. treatment, payment, operations, medical records, etc.) as either secondary data or direct report from participants.

**\*\*This is an optional section that applies only to studies accessing, using, or maintaining PHI AND if the study’s HIPAA pathway is “Signed Authorization Combined with Consent.” Remove this section if a separate HIPAA Authorization form will be used. Modifications are not recommended.**

VCU researchers can ensure all of the HIPAA authorization requirements are being met by utilizing this template language as directed. **If you choose not to include all of the required elements, you must request a Partial Waiver of Some Elements of Authorization and list the elements that you want to waive.**

Researchers also have the option to draft their own authorization language. If drafting your own language, the HIPAA language in the consent form must include 8 elements in order for the authorization to be valid (elements listed at [WPP XII-3](https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/)). A Partial Waiver should be requested for any omitted elements.

As part of this research study, we will ask you to permit us to access existing information from your healthcare records. [Insert if applicable: New health information will also be added to your healthcare records from study-related tests, procedures, visits, and/or questionnaires.] This type of information is considered “Protected Health Information” that is protected by federal law.

**What type of health information will be used or shared with others during this research?**

[Double click on the boxes to insert a check mark. Or, you may delete the table and provide a list in paragraph form:]

The following types of information may be used for the conduct of this research:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Complete health record | Diagnosis & treatment codes | | Discharge summary | |
| History and physical exam | Consultation reports | | Progress notes | |
| Laboratory test results | Medical imaging reports | | Imaging films/scans/pictures | |
| Photographs, videotapes | Complete billing record | | Itemized bill | |
| Information about drug or alcohol abuse | | Information about Hepatitis B or C tests | |
| Information about mental health | | Information about sexually transmitted diseases | |
| Other physical or mental health information (specify): | | | |

**Who will use or share protected health information about me?**

VCU and VCU Health VCU Dental Care are required by law to protect your identifiable health information. By consenting to this study, you authorize [insert either: VCU/VCU Health or VCU/VCU Dental Care] to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

|  |  |
| --- | --- |
| * Principal Investigator and Research Staff | * Study Sponsor [delete if none] |
| * Health Care Providers at VCU Health/VCU Dental Care | * Data Coordinators [delete if none] |
| * Institutional Review Boards | * Research Collaborators [delete if none] |
| * Government/Health Agencies | * Data Safety Monitoring Boards [delete if none] |
| * Others as Required by Law |  |

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

**When will this authorization (permission) to use my protected health information expire?**

[Insert ONE of the following options:]

[Option 1:] This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

[Option 2:] This research study involves a Data Registry or Sample Repository and the authorization will expire [specify other expiration time point]

[Option 3:] This authorization will expire when [specify other expiration time point].

### Statement of Privacy Rights

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at [insert VCU PI’s full name and mailing address].

**OPTIONAL STORAGE FOR FUTURE RESEARCH STUDIES**

INSTRUCTIONS: Include in this section a description of what data or samples will be stored for future unspecified research in a registry or repository, either at VCU or at another institution (e.g. sponsor’s registry or biobank, collaborator’s registry, etc.).

The following information is considered key information that participants should be told in this section so that they can make an informed decision about participating in the registry/repository:

* The purpose of creating or contributing to a registry/repository
* What data/samples will be stored, where, and by whom
* The potential secondary uses of the data/samples
* Risks of re-identification and potential loss of confidentiality
* Whether/how participants can withdraw their data/specimens from the registry.

Additional information about the registry/repository, such as benefits, ownership of the data, costs, etc. should also be added if/when it is relevant to the subject’s decision about participation.

**\*\*This is an optional section that applies only to studies that plan to create or contribute to a research registry or repository and may be modified as appropriate.**

**Data Submission to an NIH-Designated Controlled-Access Database or Repository**

For NIH-funded research, investigators are frequently expected to obtain unrestricted consent for future uses and sharing of data and/or samples, particularly genomic and phenotypic data. Template language may be available at the funding institute or center’s website.

Unrestricted consent:

Participants can be asked to agree to storage of their samples and/or data and to the use of their samples/data in any future unspecified research on any topic ("general research use"). Unrestricted consent maximizes the utility of collected samples and/or data.

Specific consent:

Sometimes, it may be appropriate to seek consent for more narrowly defined research uses of participant samples and data. This consent approach may increase participation of people who have concerns about privacy or do not want their samples and data used for research on certain topics.

To advance science, it is helpful for researchers to share information. They do this by putting data or samples into one or more scientific databases (called registries or repositories), where it is stored along with information from other studies. Researchers can then study the information in other ways and combine information from many studies to learn even more about health and disease.

[Example – general VCU registry/repository] As part of this study, we would like to keep the information and/or samples that you provide, along with your [describe the identifiers that will be part of the registry (name, phone, email, etc.)] in a registry/repository to be available for other research studies in the future. Your information and samples would be stored at [VCU] by [full name of investigator who will oversee the registry] and could be used for other research studies about any topic [If future research will be limited to specific types of studies/diseases, indicate here; otherwise leave open-ended]. Your data/samples will be protected, but there is always a possibility that information could be accessed by individuals without authorization. There is no limit on the length of time we will store your information/samples.

[Example - Unrestricted consent for sharing] Your samples, genomic data and/or health information will be stored indefinitely by \_\_\_\_ in one or more scientific databases, and shared with other researchers. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from. This information will not be labeled with your name or other information that could be used to easily identify you. However, it is possible that the information, when combined with information from other public sources could be used to identify you, though we believe it is unlikely that this will happen.

[Example – Contribution to a controlled access NIH genetic database:] Your individual genomic data and health information will be put in a controlled-access database at the National Institutes of Health. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. However, it is possible that the information from your genome, when combined with information from other public sources could be used to identify you, though we believe it is unlikely that this will happen. Researchers approved to access information in the database will agree not to attempt to identify you.

[Insert for all studies with registries:] In the future, if you decide that you don’t want to be part of this registry, you can request that your information/samples be removed and destroyed by contacting [name of investigator who should be contacted (e.g. the PI at VCU)]. However, information that has already been shared with other researchers will continue to be used.

**Include the following paragraph if the registry involves children. It may be modified to reflect this study’s plan for re-consenting children in the registry who reach the age of majority.**

[Example:] When your child reaches age 18, we will try to contact them to ask whether they want to continue to participate in this research registry. If we cannot find your child, we will remove all identifying information, and continue to use their samples, genomic data and health information in research. [Or describe your plan for recontacting the child to obtain consent]

**Permission to Store Data and/or Samples for Future Research Studies**

*Please circle your answer:* I agree that my data and/or samples may be stored and used for future research as described above.

YES NO

**WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?**

INSTRUCTIONS: Include in this section the names and contact information for

1. The VCU Principal Investigator
2. The study doctor to contact if injury occurs (if different from the VCU PI), and
3. The person/office at VCU to contact with questions about rights as a participant.

**46.116(b)(7):** “An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject”

**\*\*This is required information for all studies**

Provide at least 2 methods of directly contacting the PI (e.g. mail, phone, email, pager). For greater than minimal risk treatment studies, a 24-hour phone number should be provided.

In addition to the PI, other relevant contact people may be listed in order of priority. Other contact persons might include the student investigator carrying out the project, a medically responsible investigator, or a research coordinator.

**The following language applies to all research studies and modifications are not recommended:**

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

**[Insert name and two forms of contact information of VCU Principal Investigator.]**

and/or

**[Insert name and two forms of contact information of additional contact person/people for study]**

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research

800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298

Phone: (804) 827-2157   
<https://research.vcu.edu/human-research/hrppirb/research-participants/>

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

**STATEMENT OF CONSENT [AND/OR PARENT/LEGAL GUARDIAN PERMISSION]**

I have been provided with an opportunity to read this consent form [permission form] carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form [permission form], I have not waived any of the legal rights or benefits to which I [and/or my child] otherwise would be entitled. My signature indicates that I freely consent to participate [and/or give permission for my child to participate] in this research study. I will receive a copy of the consent form [permission form] for my records.

INSTRUCTIONS: Include one or more signature blocks depending upon what type(s) of participants will be enrolled.

**VCU requires that the following three signature lines are included in all consent documents unless a waiver of consent documentation is approved in the IRB application**:

1. **Subjects or the subject’s legally authorized representative** must sign and date the consent form, as required by 46.117(a).
2. **The person conducting the informed consent discussion** must sign and date the consent form, as required by the VCU IRB and to meet International Conference on Harmonization (ICH) guidelines.
3. **The Principal Investigator or equally qualified Sub-Investigator** must sign and date consent forms, which is required by the VCU IRB because it is the responsibility of the investigator to ensure that consent is obtained from each subject as required.

**Try to format the signature lines so that the entire signature block fits on a single page.**

**Delete this block of signatures if the study does not enroll adult participants.**

**Signature Block for Enrolling Adult Participants**

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

Adult Participant Name (Printed)

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

Adult Participant’s Signature Date

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

Name of Person Conducting Consent Discussion (Printed)

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

Signature of Person Conducting Consent Discussion Date

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

Principal Investigator Signature (if different from above) Date

**Delete this block of signatures if the study does not enroll decisionally impaired adult participants.**

**Signature Block for Enrolling Decisionally Impaired Adult Participants – LAR Consent**

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

Name of Adult Participant (Printed)

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

Name of Legally Authorized Representative (Printed) Relationship to Participant

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

Legally Authorized Representative Signature Date

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

Name of Person Conducting Consent/Assent Discussion (Printed)

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

Signature of Person Conducting Consent/Assent Discussion Date

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

Principal Investigator Signature (if different from above) Date

**Delete this block of signatures**

1. **if the study does not enroll decisionally impaired adults,**
2. **if decisionally impaired adults will not provide signed assent, or**
3. **if a separate Assent Form for decisionally impaired adults will be developed.**

INSTRUCTIONS: Assent should be obtained from the adult participant whenever possible to show respect for their autonomy.For decisionally impaired adults who are capable of providing assent, it may be appropriate to explain the study to them verbally using this consent document and appropriate language. In this situation, the adult participant’s assent should be documented on the following line.

**Signature Block for Assent by Enrolling Decisionally Impaired Adult Participant**

**STATEMENT OF ASSENT BY ADULT PARTICIPANT**

The person doing this research study has explained what will happen to me if I participate in this study. My signature below means that I want to be in this study. I can decide not to be in this study if I do not want to. Nothing will happen to me if I do not want to participate.

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

Adult Participant’s Signature Date

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Name of Person Conducting Assent Discussion (Printed)

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Signature of Person Assent Discussion Date

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Principal Investigator Signature (if different from above) Date

**Delete this block of signatures if the study does not enroll children OR if a separate Parental Permission Form will be developed.**

INSTRUCTIONS: For research conducted under **Children’s Categories 404 and 405**, the IRB will determine whether one or two parents/guardians must sign the parental permission form. It is recommended that the form allow signature lines for 2 signatories even if only 1 parent/guardian is required to sign.

**Signature Block for Enrolling Child Participants - Parent/Guardian Permission**

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

Name of Child/Youth Participant

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

Name of First Parent/Legal Guardian (Printed)

*Study team – verify that this individual is the child’s parent or legal guardian.*

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

**Required** First Parent/Legal Guardian Signature Date

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**Optional**Second Parent /Legal Guardian’s Signature Date

INSTRUCTIONS: Both parents are required to sign the parental permission form in the following situations:

1. For research conducted under **Children’s Category 406**

2. For research conducted with **nonviable neonates** after delivery [45 CFR 46.204(c)(5)]

3. For research that **involves pregnant women AND** **holds out the prospect of direct benefit solely to the fetus** [45 CFR 46.204(e)]

**REPLACE the “Optional Second Parent/Legal Guardian” signature line above with the following Required Parent/Legal Guardian lines if any of the above situations apply:**

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

Name of Second Parent/Legal Guardian (Printed)

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**Required** Second Parent /Legal Guardian’s Signature Date

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

Name of Person Conducting Parental Permission Discussion (Printed)

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Signature of Person Conducting Parental Permission Discussion Date

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Principal Investigator Signature (if different from above) Date

**Delete this block of signatures if any of the following situations apply:**

1. **the study does not enroll children,**
2. **all children will be under age 7,**
3. **all children will not provide signed assent, or**
4. **if a separate Child Assent Form will be developed.**

INSTRUCTIONS: Depending on the nature of the study, it may be appropriate to explain the study to the child or teen verbally using the parental permission form and age-appropriate language. In this situation, assent could be documented in this form**. A separate Assent Form could be proposed.**

**Signature Block for Enrolling Child Participants (Ages \_\_-\_\_) – Assent by Child**

**STATEMENT OF ASSENT BY CHILD PARTICIPANT**

The person doing this research study has explained what will happen to me if I participate in this study. My signature below means that I want to be in this study. I can decide not to be in this study if I do not want to. Nothing will happen to me if I do not want to participate.

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

Child Participant’s Signature Date

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

Name of Person Conducting Assent Discussion (Printed)

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Signature of Person Assent Discussion Date

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Principal Investigator Signature (if different from above) Date

**Delete this block of signatures if the study will only enroll English-speaking participants OR if the consent document will be translated.**

INSTRUCTIONS: In order to provide equitable access to research, it may be appropriate to enroll subjects who are not fluent in English (LEP) using the “short form consent” process. For more instructions, see [WPP XI-5](https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/).

* The short form process is intended only for situations where the likelihood of encountering eligible LEP individuals is small (i.e., <5% of the patient population typically served).
* If the targeted population is anticipated to include 5% or more of LEP subjects, investigators should submit translated consent forms to the VCU IRB for approval.

**Signature Block for Short Form Consent – Participants with Limited English Proficiency**

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Name of Participant (Printed)

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Witness or Interpreter’s Signature Date

*(NOTE: The witness may be the interpreter or a family member of the LEP subject who can speak both English and the participant’s language. The witness cannot be the member of the study team conducting the consent process.)*

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Name of Person Conducting Consent/Assent Discussion (Printed)

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Signature of Person Conducting Consent/Assent Discussion Date

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Principal Investigator Signature (if different from above) Date