INFORMED CONSENT Form AND
Authorization FOR RESEARCH

[Insert Title of Study]

***Note to investigators:*** *this template encompasses all of the required and some additional elements of informed consent, as required by federal regulations.*

*In the header above, enter the appropriate information for your department, and title of your study. For non-Wright State PIs, please either delete the logo or replace with the appropriate logo or letterhead. You must leave at least 1.5-inch header on each page that is blank on the right side. This is where the IRB stamp will be generated on approved forms.*

*Text that does not apply to your research should be deleted or modified as appropriate. The text is intended to be instructional rather than declarative. Be sure to delete all instructive text, which is in red, italicized font throughout the document, before submitting the informed consent for IRB review. Sections in brackets, highlighted, and/or italics are meant for you to fill in. Examples are given in select selections for illustrative purposes and will need to be deleted if not being utilized..*

### About This Research Study

You are asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future. This consent form will give you information about the study to help you decide if you want to participate. The study staff will discuss this study with you and explain everything in detail. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

**This study is being conducted by:** [Name of researcher, department/college, affiliation.]

***\*\*****If the Researcher is a Student, add the following:* ,under the direction of [Name of Faculty Adviser, department, affiliation.]

*All consent forms should disclose which agencies, institutions, cooperative groups, foundation or industry sponsors are funding the research. If the study is not being funded by an external agency, then the internal founding source should be identified. Delete if there is no funding.*

**This study is being funded by:** The study will be funded by [Insert Sponsor or Funding Agency.] Wright State/Premier Health will be compensated for conducting the study.

OR

This study is being carried out with funds received from the [WSU Department of Psychology.]

**Key Information**

*Key Information: Studies are required to begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant in understanding the reasons why one might or might not want to participate. Feel free to be creative with format and language, and consider including non-text elements like pictures, or icons to describe your study.*

*Focus on five items: (1) Statement that consent is being sought for research and that participation is voluntary; (2) the purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research; (3) common risks or discomforts to the prospective subject and* ***include statement to indicate where complete list of risk is within the consent form****; (4) the benefits to the prospective subject or to others that may reasonably be expected from the research; and (5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. This should be accomplished in 2-3 short paragraphs. It should fit on the first page.*

[Insert Key Information Summary]

**Why is This Study Being Done?**

The purpose of this study is to [Insert general statement about the study].

*Example:*

The purpose of this study is to compare standard treatment, combined with drug X, to standard treatment plus a placebo. The use of drug X in this study is considered investigational, meaning it has not been approved by the FDA for marketing in the United States for the use being testing in this research. A placebo is an inactive substance which looks like the active drug, i.e. a “sugar pill”.

**Why Am I Being Asked to Participate in This Research Study?**

You were selected as a possible participant because [Explain how participant was identified as people often wonder why they are chosen to participate and may be fearful, confused, or concerned.]

*Example:*

You are being asked to take part in this study because you haveseizures that have not responded well to the medications currently available.

**How Many People Will Take Part?**

If you agree to participate, you will be one of [insert number of participants] *Use local number of subjects if the study involves only one site or insert local, national, and international numbers of subjects if the study involves multiple sites. It may be appropriate to include number of subjects in different cohorts or groups*.] participants taking part in this study.

*Example:*

A total of 1,000 subjects will participate in this study at 30 sites internationally. Wright State University would like to enroll 10 subjects.

**Taking Part in this Study is Voluntary**

You may choose not to take part in this study or choose to leave the study at any time. Deciding to not participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled. *If your study involves an interview or a survey:* You can skip any questions that make you uncomfortable and can stop the interview/survey at any time. *(If applicable)* Your decision whether or not to participate in this study will not affect your current or future relationship with Wright State or Premier Health, nor will it affect your health care.If you decide to participate, you are free to withdraw at any time without affecting that relationship. Please read this entire consent form and take your time to make your decision. We encourage you to talk to your doctor, your family, and/or your friends before you decide.

**What Will Happen During the Study?**

*After reading this section, the subject must be able to understand what will happen to them and what they will be expected to do as part of the research. Provide a detailed description of what participants will be asked to do, taking care to use easily understandable language and terms (i.e., eighth grade level). Please consult “Lay Language for Consent Forms” document for assistance. It may be helpful to use pictures, tables, and/or flowcharts to improve participant comprehension of the procedures involved. If the participant will be photographed, audio taped, or videotaped, include a description in this section. Designate which activities are experimental and which activities are standard of care.*

*Procedure Description: (e.g., randomization, assignment to study groups, study visits, administration of study medications, X-rays or imaging, blood draws, surveys and questionnaires, focus groups, audio or video recordings, etc.)*

*Include the following:*

* *Where the procedures are performed and how frequently they are performed*
* *The expected amount of time each procedure and/or visit will last*
* *The length or duration of subject participation*
* *Which procedures are experimental and which are standard of care*
* *If blood is to be drawn, explain how and from where the blood will be drawn (e.g., from a vein in your arm) and indicate the total number of times blood will be drawn, the amount of blood to be drawn, and the total amount of blood to be drawn over the course of the study. Translate the amount of blood to be drawn to common measurement terms (e.g., teaspoons, cups)*
* *If medical records will be reviewed/accessed: The study team will collect information about you from your medical records and use it for this study.]*

If you agree to be in this study, we would ask you to do the following things:[Insert explanation of all procedures/tests that are included in the study.]

*Example:*

**Before you begin the study – Screening Procedures**

You will need to have the following exams, test or procedures to find out if you can be in the study. These items will take about 1 hour to complete:

*List only the tests and procedures conducted for research purposes do not include a description of standard of care (SOC) tests and procedures. However, if SOC tests and procedures will be reviewed and recorded as part of the research, include a statement to that effect.*

* History and physical examination which will include checking your heart rate, blood pressure and temperature.
* Height and weight measurements.
* Blood tests (about 1 tablespoon) to measure blood counts, blood mineral levels, and check liver and kidney function.
* A pregnancy test if you are capable of becoming pregnant.
* Review of medications and supplements you are currently taking.

During the Study

This research will take place at [Insert Location]. *OR* [If different procedures will take place at different locations, specify accordingly.]

If the screening exams, tests or procedures show that you can continue to be in the study, and you choose to take part, then the following will be done.

If you agree to take part in this study, you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance (like pulling numbers out of a hat). A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group (also referred to as an “arm”) you will be in. You will have anequal chanceof being placed in any group.

If you are in **Arm A** you will be given the current standard treatment for this type of cancer plus Drug X. Side effects and quality of life information will also be collected and compared with Arm B.

If you are in **Arm B** you will be given the current standard treatment for this type of cancer plus a placebo. Side effects and quality of life information will be compared with Arm A.

You will receive study treatment for 48-weeks, returning for visits at week 1, 4, 8, 20, 24, 32, 44 and 48 after the first dose of study drug. These visits will last approximately 1 hour.

The following procedures will be completed:

* You will be asked questions about your medical history, and information about any drugs that you are taking from your last visit.
* A physical exam including vital signs (blood pressure and heart rate), will be performed.
* Your hips and waist circumferences will be measured by the research study staff.
* An electrocardiogram (ECG) will be collected. An ECG is a test that measures the electrical activity of your heart. Electrodes will be attached to the outer surface of the skin.
* You will have blood drawn for routine lab work. (About 6mL or 2 teaspoonfuls of blood will be drawn).

*Example Language for Select Procedures: This is not an all-inclusive list.*

**Ultrasound:**

Ultrasound (or sonography) is a test that uses high-frequency sound waves to show what is inside your body. You will lie on a cushioned table and gel will be applied to your skin; the gel acts as a conductor. A transducer, a hand-held device that sends and receives ultrasound signals, is moved over the area of the body being imaged. Images are seen on a television-like monitor and sent to film or videotape for a specialist to review and interpret. Depending on the type of exam, it can take anywhere from 20-60 minutes.

**DEXA Scan:**

A DEXA is a type of x-ray used to measure bone strength. During this test, pictures of your body will measure how much bone, fat and muscle are present. You will lie flat on a table and a machine will collect pictures of different areas of the body. This test will last about 15 minutes.

**CT Scan:**

You will have a computed tomography (CT) scan of your [insert body part] to check for [insert reason]. A CT scan uses special x-ray equipment to make detailed pictures of body tissues and organs. For the CT scan you will lie still on a table with your [insert body part] inside a large donut-shaped machine. [Explain what will happen during the procedure, what the patient will experience, how long it will take, etc. If using a contrast agent, explain what it is, why it is being used and how it will be given.]

**Biopsy:**

During a biopsy a small piece of skin or muscle is removed from [site] and looked at under the microscope for: [state use]. First you will be given [state numbing medicine]to numb the area and reduce the pain. Then a small cut will be made in the skin.

**Caliper Test:**

A tool called a caliper (like a pincher) grasps a small fold of flesh on the back of the arm, shoulder blade, or waist to measure the amount of body fat.

**EEG:**

An electroencephalogram (EEG) measures the electrical activity in the brain (brain waves) using electrodes (small metal discs or sensors) placed on the head with gel. The test does not hurt and usually takes about an hour.

**EKG/ECG**:

An electrocardiogram (EKG) is a test that gives us a measure of the heart’s electrical activity. You will be asked to lie flat on a table and several small electrode pads (like stickers) will be placed on the body. This test takes about 10 minutes.

**MRI:**

You will fill out a safety screening form to assess whether there are any factors which could affect whether you may enter the magnetic resonance imaging (MRI) room. You may also be asked to fill out study specific background questionnaire(s). You will then be asked to remove any metallic objects you may be carrying (for example, wallets, watches, earrings or piercings) and possibly to change clothing into a gown that we will provide (if deemed necessary because of large zippers, etc.). If you are female of reproductive age and are able to get pregnant (i.e. not postmenopausal, have not had a hysterectomy, and do not have a physical condition that prevents you from becoming pregnant), you will be asked to take a urine pregnancy test before the MRI scan. If you report pregnancy or have a positive pregnancy test result you will not be allowed to proceed with the MRI study.

If you meet the eligibility requirements, then you will be asked to enter the MRI scanner, which is a large, tunnel-shaped machine. MRI does not involve any ionizing radiation (i.e., does NOT involve exposure to radioactive materials). MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the inside of the body. You will first be asked to lie still on a table outside of the MRI scanner. Your [head or other body part, as appropriate] will be kept still with padding so it cannot move; you should, however, be comfortable at all times. Once you are comfortable, the table on which you are lying will be moved inside the MRI scanner. The MRI scanner does not collect images at all times. You will know when the MRI scanner collects images because you will hear the thumping noise of the electrical switching of the magnetic field, and feel the associated vibrations. Make sure to stay as still as possible during these times (no sneezing, scratching, stretching, etc.). **You will be able to communicate with the scanner operator and/or researcher at any time, and you will be in view of the researcher.** An alarm squeeze-ball will be provided to you to alert the scanner operator at the control console at any time even with loud scanner noise. **If you feel discomfort at any time, notify the operator.**

*Describe the use of other approved peripheral devices here. If applicable, include:*

The scanner's built-in optical pulse oximeter will be placed around your fingers and the pneumatic respiratory belt will be strapped around your upper abdomen, respectively, to record cardiac and respiratory waveforms during functional scans. You will hold a button box in your right hand to make manual responses during the task.

Your participation is expected to take approximately a total of \_\_\_\_\_\_ hour(s), including \_\_\_ minutes/hours in the scanner.

*Include for research subject to GDPR (Study takes place in the European Union). Otherwise delete.*

The study staff will collect identifiable information about you, such as your name, demographic information, the information you give to study staff as part of the study, and the results of any tests, surveys or procedures described in this informed consent form. It may also include information about your *insert as applicable: past and present health conditions and medications, genetics, sexual activity, HIV/AIDS status, tuberculosis status, substance use disorders, mental health disorders, race, ethnicity, religious beliefs, genetic information, sexuality, sexual orientation, political beliefs, and trade union membership* [Insert Description.]

*Include for research subject to FERPA. Otherwise delete.*

As part of this study, researchers will be collecting data that is protected by the Federal Educational Records Protection Act. The records will be collected for [state the purpose of the disclosure]. These records will include: [Specify the exact records to be disclosed] *(must be very specific)*.These records will be collected [state how often records will be disclosed *(e.g. once per semeste*r) ], and disclosed to only [to identify the party to whom the disclosure is to be made.]

*If using Biospecimens:*

**Biospecimen Sampling for Research:**

Research using biospecimens (saliva, blood, tissues, etc.) is an important way to try to understand human disease and functioning. There are several things you should know before allowing your biospecimens to be studied.

The type of specimens that will be stored and where they will be stored: [Sample Storage]

*Example: Your blood and saliva will be stored at a facility located on the Wright State campus.*

Identifiability of Biospecimens: [Sample Identifiablility] . *Describe how samples will be labelled and how samples will be linked - e.g., under diagnosis and medical record, code number, no link to names, etc*. *Example: The sample will be assigned a code that does not contain your name, initials, SSN, date of birth or any other unique identifier. The sample will be linked to your survey responses via a random code.*

The length of time your biospecimen will be stored until they are destroyed: [Sample Storage Time]

*For example: your samples will be stored until the analyses are completed, but no longer than 5 years after completion of the study. At that time, they will be destroyed. If they will not be destroyed, please state so.*

How to withdraw your biospecimens from the study:

*If linked*: You have the right to refuse to allow your biospecimen to be studied. You may withdraw your specimen from this study at any time by contacting the Principal Investigator.

*OR*

*If unlinked:* Because your samples will not be linked to your name after they are stored, you cannot withdraw your consent to the use of the samples after they are taken.

**Future Use of Biospecimens:**

*Include the following language if samples in study will be used in future research:*

Information or specimens for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, we cannot ask for your additional consent.

The types of analyses/studies the biospecimens will be used for:

*Example: Your samples will be used to study proteins in the blood that could indicate heart disease.*

*Include the following language if samples in study will NOT be used in future research:*

Information or specimens collected from you will not be used for future research studies or shared with other researchers for future research.

*Include the following language if samples in study will be used for genetic testing or if future research on samples will include genetic testing.*

**Biospecimen Sampling for Genetic Testing:**

As part of the analysis on your samples, the investigators [may/will] do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

When results will be given to you: [The results of the study of your samples will be used for research purposes only and you will not be told the results of the tests.] *Or* [You will be told the results of tests that are part of your clinical care, but you will not be told the results of the research tests, including any future research tests.]

*For research involving biospecimens, if 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), include a statement stating so.*

This research involves whole genome sequencing (i.e., looking at your entire genetic inheritance). You may be concerned that someone could get access to your genetic information and that it could be misused. For example, if your information suggests something serious about your health, it could be used to make it harder for you to get a job or health insurance. Also, by having genetic information about people from your ethnic group, researchers may make statements about your group identity that you or members of your community may disagree with.

You should discuss any concerns or questions regarding use of your genetic information with Dr. XX, members of the study team and your family before deciding to participate.

*For In-person studies:*

### What Steps Are Being Taken to Reduce Risk of Coronavirus Infection?

The following steps are being taken to address the risk of coronavirus infection:

**Screening:** Researchers and participants who show potential symptoms of COVID-19 (fever, cough, shortness of breath, etc.) will NOT participate in this study at this time.

**Physical distancing**: Whenever possible, we will maintain at least 6 feet of distance between persons while conducting the study.

**Mask/Covering**: Researchers will wear a mask and participants *(SELECT ONE)* will be advised *or* will be required to shield their mouth and nose with a cloth face cover or mask during the study, even when maintaining at least 6 feet of distance. Tissues will be available to cover coughs and sneezes.

**Handwashing**: Researchers and participants will wash hands before/during [activity] or use a hand sanitizer.

**Disinfecting materials:** When feasible, researchers will clean and disinfect surfaces between participants, using an EPA-registered disinfectant or a bleach solution (5 tablespoons of regular bleach per gallon of water) for hard materials and by laundering soft materials. Disinfected materials will be handled using gloves, paper towel, plastic wrap or storage bags to reduce the chance of re-contamination of materials.

**Electronics:** Alcohol-based wipes or sprays will be used to disinfect shared touch screens, mice, keyboards, etc. Surfaces will be dried to avoid pooling of liquids.

**How Long Will I Be in This Research Study?**

*Include a statement about the time commitments of the research for the subject including both the duration of the research and follow-up, if relevant. If there is a wash-out period, address this in lay terms specifying the length of time. This information could be included in a table which might be easier for the subject to understand.*

[Insert Description.]

*Examples:*

If you choose to take part, you will be on the study for a minimum of 59 weeks from the first Screening Visit through the final follow-up procedures.

*OR*

You will receive the study intervention for 8 weeks and if randomized to Arm B you will receive an additional 12 weeks of study intervention.

*OR*

After you are finished with treatment on the study, you will need to visit the office for follow-up exams every 3 months for the first two years and then every 6 months for the next three years after completion of your study treatment. If for any reason you are not able to complete study treatment we will still ask you to visit your doctor’s office for follow up exams and we will continue to collect data on your health status from your medical records during this period.

**Can I Stop Being in This Research Study? What Happens if I Change My Mind?**

*Explain the procedures for the orderly termination of participation by the subject. If applicable, explain the consequences of a subject's decision to withdraw from the research. List any reasons specific to the study that a patient could be removed, if applicable. Describe any other circumstances for withdrawal.*

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without any penalty. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled. If you withdraw from the study, *if applicable* [or the study medication is stopped] for any reason:

* Add anticipated consequences, if any, of discontinuing the study drug or device.
* Clearly state the protocol-specific termination procedures.
* Instruct subjects that they must return all study-related supplies, including unused study drug.

The principal investigator or study staff may also withdraw you from the study, without your consent for one or more of the following reasons

* Failure to follow the instructions of the research study staff.
* Pregnancy.
* You need treatment not allowed in the study.
* The study is cancelled.
* The principal investigator believes it is in your best interest.

### Is There Any Way Being in This Study Could Be Bad for Me? What are the Risks?

*Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk. The risks of procedures may be presented in a table form.*

* Physical risks
* Psychological risks
* Privacy risks
* Confidentiality risks
* Legal risks
* Social risks
* Economic risks
* Group or community risks

Distinguish between the risks presented by participation in the research and the risks associated with any procedures or treatments that would occur regardless of participation in the research.

This research may hurt you or cause discomfort in the following ways: [Insert explanation of the risks, side effects, and/or discomforts of each of the procedures completed in the study using language understandable to the subject (i.e., eighth grade level)]. In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

A risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information). The researchers have procedures in place to lessen the possibility of this happening. See the section, titled “How Will my Information be Protected.”

*Examples of risk/side effect statements include:*

* A risk of completing the survey is being uncomfortable answering the questions.
* There is a risk of possible loss of confidentiality.
* The risks of drawing blood include pain, bruising, and, rarely, infection.
* The side effects associated with taking [Insert study medication] are mild diarrhea, confusion, sleepiness, depression, anxiety, and headaches. In rare instances, side effects may include hair loss, rash, and a decrease in the number of red and white blood cells and blood platelets, which could cause fatigue and an increase in infection and/or bleeding.

*Example Language for Select Procedures: This is not an all-inclusive list.*

**Loss of Privacy:** A risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information). *Should be included in all studies.*

**Psychological Risks:**

Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question. OR

There could be a risk of discomfort and harm [Risk(s)] (Example: to psyche, reputation, employability, insurability, social status, criminal or civil liability) that may occur as a result of participation. If you do not wish to answer a question, you may skip it and go to the next question.

**Blood Draw/Insertion of IV Catheter/Heplock:**

A blood draw may lead to lightheadedness or fainting. It may also cause bruising, prolonged bleeding, and infection at the site where the blood was drawn. In order to minimize these risks, we will swab the site of the blood draw with alcohol to disinfect the area, use disposable sterile needles and tubes to collect blood, and apply pressure to the site following the blood draw to minimize bruising. *If applicable:* The longer an IV catheter is left in place, the more common it is for redness or infection to develop.

To protect against infection, we will also provide instructions on how to care for the wound and watch it for signs of infection. It is important to know that these blood tests performed in the study are strictly for research purposes. The researcher using your blood sample is not a physician and therefore not qualified to make clinical recommendations. Furthermore, no physicians will review the results of these blood tests, as the researchers are not using this test to make a diagnosis.

**Finger Stick:**

**There is a minor risk associated with this project in that you may experience slight pain when we pierce the skin on your finger; however the puncture and blood collecting equipment are part of the commercially available s**ystems that have been approved by the FDA.

Drawing blood from a finger stick may, in rare cases- cause discomfort, bruising, prolonged bleeding and infection at the site of puncture. To minimize risk, we will swab the site of puncture with alcohol to disinfect the area, use disposable lancet and capillary tubes to collect blood and apply pressure to the puncture site following the blood draw to minimize bruising. We will cover the puncture with an appropriate dressing and provide you with information on how to monitor for signs of infection.

**Electrocardiogram (EKG/ECG):**

This is a small risk of that redness or swelling could develop from the ECG electrodes (pads) that will be placed on your chest. The test may cause some itching where the pads are placed.

**Flow Mediated Dilation (FMD):**

Occlusion of blood flow is required for the assessment of vascular vessel function via FMD. The process of occlusion may cause pain, including a numb feeling in the arm. It is possible that bruising may occur as a result of this procedure.

**Ultrasound:**

The gel may be sticky, but the test should not cause any pain or discomfort.

**Biopsy:**

The biopsy may cause some pain and discomfort. It is possible, but not likely that you could get an infection. In very rare cases, people might have an allergic reaction to the numbing medicine. The allergic reaction could include rash/hive, flushing of the face, itching, wheezing and tightness in the throat. There will be a small scar from the biopsy.

**Caliper Test:**

There might be a little pain or discomfort from a pinch.

**EEG:**

The gel used to put the discs on your head is sometimes sticky and the discs may scratch a little bit.

**MRI:**

Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MRI scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator

*Include the following language if appropriate. The Radiation Safety Officer may require modification and/or additions to this sample language as deemed appropriate in your application to the Radiation Safety Committee for this study.*

**Use of Radiation:**

In this study, you will be exposed to a small amount of radiation called "ionizing radiation." Studies have shown that getting a lot of radiation at one time or getting many small doses over time may cause cancer. The risk of getting cancer from the small radiation dose in this study is very small. The amount of radiation you will get in the study is approximately [state amount] mrem (a “mrem” is how we measure radiation dose). In comparison, one regular chest x-ray would give you 10 mrem. The natural radiation we are exposed to all the time – like from the sun – gives you about 300 mrem each year. Neither chest x-rays nor background radiation have been found to harm most healthy adults. At doses much higher than you will receive, radiation is known to increase the risk of developing cancer after many years. At the doses you will receive, it is unlikely that you will see any effects at all.

Tell us now if you have been in other research studies where you had ionizing radiation. Also tell us if you have been exposed to radiation in other ways, like on your job or in radiation therapy. If you are pregnant or nursing, you cannot be in this research study because the radiation may harm your baby. If you are able to have a baby and are not pregnant now, and you want to be in this study, we will give you a free pregnancy test. Use if appropriate for longer term studies: If you join in this study, you should use contraception to keep from getting pregnant while you are in the study. If you get pregnant while you are in this study, or if you think you are pregnant, please tell the researchers right away.

*Example:*

**Risks and side effects for Arm B:**

**Likely:**

* Fatigue
* Low white blood cell counts which may make you more susceptible to infection
* Low red blood cell counts which may cause tiredness or shortness of breath
* Decrease in kidney function causing extra fluid and toxins to build up in your body
* Loss of appetite and weight loss
* Diarrhea, constipation, nausea and vomiting, and abdominal pain
* Numbness and pain of the hands and feet
* Skin rash
* Changes in taste
* Ringing in the ears and hearing loss
* Changes in electrolytes in the blood such as magnesium and potassium which may cause muscle weakness or twitching, irregular heartbeat, confusion or blood pressure changes

**Less Likely:**

* Allergic reactions which may be life-threatening with wheezing and low blood pressure
* Chills and fever with aches and pains
* Low platelet count which may make you bruise more easily and bleed longer if injured
* Sores in mouth and throat (that can lead to difficulty swallowing and dehydration)
* Vision changes: blurred vision, sensation of flashing lights or spots, inability to distinguish colors, blindness
* Complete hair loss

**Unknown:**

There may be risks from the [study drug/device] that are not known at this time.

Include for research that involves pregnant women or women of childbearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known. Otherwise, delete.

## **What Do I Need to Know About Reproductive Health and/or Sexual Activity if I Am in This Study?**

## The procedures in this research are known to harm a pregnancy or fetus in the following ways: [Insert Description]. The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death**.** [Omit the previous two sentences for research whose risk profile in pregnancy is well known.]

You should not be or become pregnant *[include as applicable “*or father a baby” and/or “breastfeed” and/or “donate eggs/sperm”] while on this research study. [If applicable, also include the amount of time a participant should wait after participation to become pregnant or father a child.]

Include if applicable. Otherwise, delete.

If you are sexually active, both men and women should use at least one effective means of birth control while participating in this research study. According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable but least effective methods of birth control include male condoms (with or without spermicide) and female condoms.

If you or your partner become pregnant while participating in this research study or for \_\_\_\_\_\_ months after you complete the study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.

Include if participants are postmenopausal women. Otherwise, delete.

If you or your partner [are/is] considered to be postmenopausal, you are not required to use contraception while participating in this research study. Postmenopausal women rarely become pregnant. If you or your partner become pregnant while participating in this research study or for \_\_\_\_\_ months after you complete the study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.

### What are the Potential Benefits of Taking Part in the Study?

**The benefits to participation are:** *List direct benefits to subjects. This section must be consistent with the benefits as explained in the protocol submitted to the IRB. DO NOT include compensation, payments, or extra credit in this section.* The benefits which may reasonably be expected to result from this study are [explain direct benefits]. We cannot guarantee or promise that you will receive any benefits from this study.

*OR*

You may not receive any personal benefit from being in the study. The researchers hope that information learned from your participation in this study will increase knowledge about which way is best to treat patients like you. This knowledge will help make it possible to provide the best type of treatment for patients in the future. While you may or may not personally benefit from being in this study, your participation will provide a benefit to others with this condition and to society.

*OR*

*If no direct benefits:*

There are no direct benefits to you. More broadly, this study may help the researchers learn more about [explain topic] and may help [future populations with a similar issues/future researchers design intervention to help with topic.].

*If research involves treatment, insert the following:*

### What Are the Other Treatment Options?

There may be other options for treatment of your [Insert applicable condition. Insert details regarding other possible treatment options such as surgery, drug treatment, management of symptoms, palliative care, etc.].

If you decide not to participate in this study, there is other care available to you, such as:

* Getting treatment or care without being in a study
* Taking part in another study
* Getting no treatment

The study doctor will discuss these with you.

### Will I Receive My Research Results?

*Insert appropriate statement.*

We may learn things about you from the study activities which could be important to your health or well-being. [Insert a description under what circumstances participants will be provided research results and how participants will be notified.] You may need to meet with professionals with appropriate expertise to help you learn more about your research results. The study team will not cover the costs of any follow-up consultations. We will share the following information with you: *[Pick one bullet point below]*

* *[If your study will generate information critical to the management of a participant’s health in the immediate/near future]*Any information that might be immediately critical to your health will be shared with you or your health care provider.
* *[If your study will generate information that has known implication for health or risk AND is clinically actionable]*We will share information that may be helpful for your health in the future: [genes that may suggest you have an increased risk of [DISEASE]; lab tests, x-rays, or other images that could suggest you have a disease that could be treated]. Getting this information could help you protect your health, but you will decide to take action or not. [Include appropriate language for participants to indicate whether they want to receive information, per your plan. See guidance for details.]
* *[If your study will generate information that is not clinically actionable OR not known to have any implication for health or risk]*During this study, we will learn things about you that you may find interesting but probably will not help you. Health care providers may not know what the information means or what to do about it. Examples include [describe]. Some people find this kind of information confusing or stressful. You can choose whether to receive this information. [Include appropriate language for participants to indicate whether they want to receive information, per your plan. See guidance for details.]

*OR*

We may learn things about you from the study activities which could be important to your health or well-being; however, we do not plan to share any of these results with you.

**Will I Be Told About New Information That May Affect My Decision to Participate in This Research Study?**

During the course of the study, you will be informed of any significant new research information (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the research. If new information is provided to you, you may be asked to sign a consent form that includes the new information.

**Will I be Paid to Participate in the Research?**

*If participants will receive a small token or chance in a drawing, include that information here. Explain when disbursement will occur and conditions of payment. For example, if monetary benefits will be prorated due to early withdraw. If using a Drawing: Describe the odds of winning the drawing.*

You will receive [describe compensation] as payment for your participation.You will be given this payment [describe distribution method]. *If compensation is over $600:* You may need to provide your social security number to receive payment. This information will be given to Accounts Payable in order to issue an IRS Form 1099 Misc at the end of the year. *If necessary:* To be eligible to receive the compensation, you need to [describe prorated payment plan].

*OR*

*If no compensation:* You will receive no payment for participating in this study.

*Include for Department of Defense (USDOD) research that targets military personnel where participants will be paid. Otherwise, delete.*

Military personnel should check with their supervisor before accepting payment for participation in this research.

*Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise, delete.*

If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

*If the study involves subjects’ biospecimens, include a statement that his/her biospecimens (even if identifiers are removed) may be used for commercial profit and whether he/he she will or will not share in this commercial profit.*

Your biospecimens (i.e., blood, tissue collected during the study) may be used for commercial profit and there is no plan for you to share in this profit.

*OR*

Your biospecimens (i.e., blood, tissue collected during the study) may be used for commercial profit and [insert description of how profits will be shared with subjects].

**Will It Cost Me Anything to Participate?**

*Insert one of the following:*

There is no cost to you for taking part in this study.

*OR*

Taking part in this study may lead to added costs to you or your insurance company. You or your insurance company will be responsible for the following costs: [Insert a list of the procedures, tests, office visits, medications, etc. for which the subject or the subject’s insurance is responsible. If appropriate, state that all standard of care procedures, drugs, tests, etc., will be the responsibility of the subject or his/her insurance. Also, include what is considered standard of care procedures.].

You will not be responsible for these study-specific costs: [Insert a list of the procedures, tests, visits, medications, etc. for which the study will pay. If appropriate, include the following: “If during the study, [Insert name of study drug] becomes commercially available, you may have to pay for the amount of drug needed to complete the study.”]

*OR*

If you decide to participate in this study, the sponsor will pay for the expenses of all study tests and procedures that are not part of your regular medical care. You and your insurance carrier will be responsible for the costs associated with the regular diagnosis and treatment of your medical condition. You should check with your insurance company to verify coverage or payments of these procedures.

**Who Will Pay for My Treatment If I Am Injured?**

If you feel that you have been injured as a result of participating in the research, contact the researcher [Insert principal investigator] at [Insert phone number] to talk to them about your illness or injury. *Emergency contact information should also be included here.*

*Standard Injury Statement:*

In the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

*OR*

*If sponsor would pay:*

The study sponsor will pay the reasonable and necessary medical expenses needed to treat an illness or injury caused by the study drug or device or procedures required to be done as part of the research study.

The study sponsor does not plan to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illness or injury. By signing this form, you will not give up any legal rights.

*OR*

*If there would be no sponsor payment:*

You or your insurance company will be billed for this medical care. Your insurance company may not pay for some or all of this medical care because you are participating in a research study. By signing this form, you will not give up any legal rights.

*If applicable, insert the following:*

If you are participating in research that is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

**How Will my Information Be Protected?**

*Use this section to describe how you will keep the participant’s data private and confidential. This should include a brief statement about how you will collect their data, store it, and use it in your study.*

*Select the text appropriate for your particular study. Address then delete instructional text once complete. These examples will not cover all situations, please adjust as needed for your study.*

*Coded Data/Pseudonym linked with identifying information:*

The information that you give in the study will be handled confidentially. Your information will be assigned a code number/pseudonym. The list connecting your name to this code will be kept in a locked file separate from the research data. When the study is completed and the data have been analyzed, this list will be destroyed. Your name will not be used in any report

*OR*

*Confidentiality cannot be Guaranteed:*

*In some cases it may not be possible to guarantee confidentiality (e.g. an interview of a prominent person, a focus group interview, ethnographic research, oral history projects).*

Because of the nature of the data, I cannot guarantee your data will be confidential and it may be possible that others will know what you have reported. The researchers will make every effort to ensure that information about you remains confidential, but cannot guarantee total confidentiality. Your identity will not be revealed in any publications, presentations, or reports resulting from this research study. *If applicable:* However, it may be possible for someone to recognize your particular story/situation/response. *If your research is in a group setting:* While we will ask all group members to keep the information they hear in this group confidential, we cannot guarantee that everyone will do so.

*OR*

*Clinical Studies:*

The people who will know that you are a research subject are members of the research study staff, and if appropriate, your physicians and nurses. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare or if required by law.

AND

Your data will be stored *(Examples: a locked drawer in a restricted-access office, on an encrypted flash drive/external hard drive, in a restricted access folder on Dropbox.com, an encrypted, cloud-based storage system, etc.)* [insert data storage method]. *If the data has identifiers that will be separated and destroyed, state the timeframe for doing so:* When the study is completed and the data have been analyzed, all code lists linking names to study numbers will be destroyed. This is expected to occur no later than [state time frame]. *If the data has audio/visual recording, please state the timeframe for destruction of the recording and what, if anything, will be kept:* The audio/video recording will be transcribed. The recording will be deleted after the transcription is complete and verified. This process should take approximately [state time frame]. *OR* The audio/video recording will be kept as part of the study records *(example: indefinitely until no longer useful, for five years, etc.)* [state time frame]. *All:* This informed consent form will be kept for [state time frame] *(Required minimum is 3 years, 6 years for HIPAA)* years after the study is complete, and then it will be destroyed.

*Include the following text if using an online survey or data collection tool. Delete if not:*

The research team works to ensure confidentiality to the degree permitted by technology. It is possible, although unlikely, that unauthorized individuals could gain access to your responses because you are responding online. However, your participation in this online survey involves risks similar to a person’s everyday use of the internet. If you have concerns, you should consult the survey provider privacy policy at [insert link to online privacy policy].

It is unlikely, but possible, that others responsible for research oversight may require us to share the information you give us from the study to ensure that the research was conducted safely and appropriately. Organizations, in addition to the Wright State Institutional Review Board (IRB) and research investigators, that may inspect your research records include [ if federally funded add Office of Human Research Protections (OHRP), Food & Drug Administration (FDA), and Sponsor, as appropriate.] We will only share your information if law or policy requires us to do so. *If working with children, the elderly, disabled persons, or other vulnerable populations that carries a reporting requirement, please modify the bracketed language appropriately and include the following statement:* If the researchers learn that you are [describe condition. Examples: abusing/neglecting/going to engage in self-harm/intend to harm another], state law requires the researchers report this [behavior/intention] to the authorities. Finally, confidentiality could be broken if materials from this study were subpoenaed by a court of law.

*Use if you HAVE received an NIH Certificate of Confidentiality: this section below is required for all NIH funded research, and any other research, with a NIH Certificate of Confidentiality.*

**Certificates of Confidentiality**

To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we can’t be forced by a court order or subpoena to disclose information that could identify you in any civil, criminal, administrative, legislative or other proceeding.

There are circumstances where the Certificate doesn’t protect against disclosure of your personally identifiable information:

* when the US government is inspecting or evaluating federally-funded studies
* when information must be disclosed to meet FDA requirements
* if you give someone written permission to receive research information or you voluntarily disclose your study information
* if the researcher reports that you threatened to harm yourself or others
* in cases of child abuse reported by the researcher
* if the investigator reports cases of contagious disease (such as HIV) to the state

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

*If the study is an FDA-regulated or NIH-funded clinical trial, insert the following:*

**FDA Clinical Trial Registry**

*If the research study is an “applicable” clinical trial listed on www.clinicaltrials.gov website the following statement must be included verbatim in the consent form:*

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

*The following section is required if you will be accessing, using or creating PHI for this study via a covered entity (e.g., Premier Health, physician office, Dayton Children’s etc…) Delete if not needed.*

**Authorization to Use and Disclose Your Health Information**

State and Federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect the privacy of your health information. This section of the consent form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information (PHI) for this research study. **Please read this section of the consent form carefully.**

If you sign this document, you give permission to (insert name of PI) and his (or her) Wright State/Premier Health/Dayton Children’s/Wright State Physicians research team to use or disclose (release) the following protected health information: *(List PHI to be used, created or disclosed for this study in a specific and meaningful way, customize example below to match your study)*

* Your medical records for past medical conditions and medications related to your XX health/condition
* All information (research records and medical records) created during your participation in this research study
* All information related to illness or hospitalizations that occur during your participation in this study

The research team needs this information to conduct the study.This is a study to test (add simple language describing the purpose of the study. For example, whether a device called an XYZ can increase the likelihood of survival in patients at risk of a stroke or heart attack.)

To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally would have access to your health information.

**Disclosure of your protected health information**

If you sign this form, the researchers may share your health information during the conduct of the study with:

* Non- (insert appropriate covered entity name) researchers or organizations working with (insert appropriate covered entity name) researchers, including Wright State University researchers
* Law enforcement or other agencies, when required by law
* Wright State University Institutional Review Board (or other IRB of record), which oversees our research
* The sponsor (the organization paying for) of this research study: insert name(s) here
* Representatives of government agencies in the United States and other countries (i.e. Food and Drug Administration and the Office of Human Research Protection)
* Other authorized WSU/(insert covered entity name) Officials who oversee research and clinical care

The people listed above will use and share your health information to review the quality, safety, and results of the research and may also do additional research.

Please understand that these persons/organizations who may receive your health information may not be required by U.S. Federal privacy laws (such as HIPAA) to protect it and may share your information with others without your permission.

This authorization does not have an expiration date*.*

However, you can change your mind and cancel this authorization at any time. To cancel this authorization, you must write or email the principal investigator at (insert email and mailing address).

If you cancel this authorization, you will no longer be allowed to take part in the research study. If you cancel this authorization, health information you had already allowed us to obtain may still be used and disclosed by researchers in order to maintain the integrity and reliability of the research, and to report any adverse (bad) effects that may have happened to you.

If study involves optional activities use the following language, if not delete next sentence

You can cancel your authorization for the optional part(s) of the study and remain in the main study.

**Right to refuse to sign this Authorization**

You have the right to refuse to sign and give your authorization. If you do not sign this form, your non-research related treatment, payment or enrollment in any health plans, or your eligibility for other medical benefits at (insert covered entity name) will not be affected in any way.

However, if you do not sign this form, you will not be able to participate in this research study.

If study includes optional activities use the following language, if not delete next sentence. You can still be in the main part of the study even if you do not authorize the use and sharing of your information for the optional part(s) of the study.

**Will My Information Be Used for Research in the Future?**

Information collected from you may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. *If you are uploading data to a data sharing site (databrary, data verse project, or Open Science Framework, etc*.: Data, without identifying information, will be made publically available in [state which database],an online database for analysis by other researchers. Results of this study may be presented at conferences, or published in journals, books, and the popular media.

**Who Should I Call with Questions?**

If you have questions about the research study itself, please contact the Principal Investigator at [phone number and e-mail address]. If you have questions about your rights as a research volunteer or would simply like to speak with someone other than the research team about concerns regarding this study, please contact the Wright State IRB Office at (937) 775-4462 or irb-rsp@wright.edu. All reports or correspondence will be kept confidential.

***You will be given a copy of this information to keep for your records.***

**What Are My Rights/Responsibilities As A Research Subject?**

As a subject, your responsibilities include:

*Choose applicable points; refer to your protocol to ensure subjects know what is expected of them:*

* Follow the instructions of the research study staff.
* Take the study drug as instructed *(if device, explain what is required for study compliance).*
* Keep your study appointments. If it is necessary to miss an appointment, please contact the research study staff to reschedule as soon as you know you will miss the appointment.
* Tell the research study staff about any side effects, doctor visits, or hospitalizations that you may have.
* Tell the research staff if you believe you might be pregnant or have gotten your partner pregnant.
* Keep the study drug in a safe place, away from children and for your use only.
* Keep your diaries as instructed.
* Complete your questionnaires as instructed.
* Ask questions as you think of them.
* Tell the research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from the research staff of each study.

**Statement of Consent**

I have read (or someone has read to me) the above information provided in this form. I have had the opportunity to ask questions and have my questions answered. In consideration of all information provided in this form, I give my consent to participate in this research study and authorize the use and disclosure of my protected health information for this study. I will be provided with a copy of this form to keep for my records.

*Include the following if applicable. Add statements as needed.*

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

| **I agree** | **I disagree** |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team. |
| \_\_\_\_\_\_\_ | \_\_\_\_\_\_\_ | The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification. |
| \_\_\_\_\_\_\_ | \_\_\_\_\_\_\_ | The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study. |
| \_\_\_\_\_\_\_ | \_\_\_\_\_\_\_ | The researcher may retain any leftover blood or tissue samples taken during the study. These samples may be used for other research not related to this study. These samples will be retained in non-identifiable form, meaning that there will be no information associated with the blood or samples that will allow anyone to readily ascertain my identity.  |

**Signature of Subject**

*There are three sets of signature options listed below. Use the signature block appropriate for your study. Delete those that do not apply.*

*Signature Block for Capable Adult:*

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

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Signature of Participant Date

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Printed Name of Participant

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Signature of Person Obtaining Consent Date

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Printed Name of Person Obtaining Consent

*Add the following if a witness will observe the consent process. e.g., participant is illiterate, participant physically unable to sign. A witness signature is required for studies using mental health information or if “all information in a medical record” is included. Otherwise delete.*

My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

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

Signature of Witness to Consent Process Date

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Printed Name of Person Witnessing Consent Process

*Signature Block for Adult Unable to Consent:*

Your signature documents your permission for the named participant to take part in this research.

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Printed Name of Participant

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Signature of Legally Authorized Representative Date

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Printed Name of Legally Authorized Representative Date

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Signature of Person Obtaining Consent Date

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Printed Name of Person Obtaining Consent Date

*Signature Block for Parent Permission and Child Assent:*

Your signature documents your permission for the named child to take part in this research.

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Signature of Child Date

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Printed Name of Child

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Signature of Parent or Individual Legally Authorized Date

to consent for the child to participate

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Printed Name of Parent or Individual Legally Authorized Date

to consent for the child to participate

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s participation in the research. Contact legal counsel if any questions arise.

If signature of second parent not obtained, indicate why: (select one)

[ ] The IRB determined that the permission of one parent is sufficient.

[ ] Second parent is: [ ] deceased [ ] unknown [ ] incompetent [ ] not reasonably available

[ ] Only one parent has legal responsibility for the care and custody of the child

*Add the following block if you will document assent of children*

Assent:

[ ] Obtained verbally without a signature

[ ] Not obtained because the capability of the child is so limited that the participant cannot reasonably be consulted.

*Add the following if a witness will observe the consent process. e.g., participant is illiterate, participant physically unable to sign. A witness signature is required for studies using mental health information or if “all information in a medical record” is included. Otherwise delete.*

My signature below documents that the information in the consent document and assent process and any other written and verbal information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

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

Signature of Witness to Consent/Assent Process Date

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Printed Name of Person Witnessing Consent/Assent Process

*OR*

*If you have applied for a Waiver of Documentation of Consent (No Signature Line) Use the following instead:*

**If you agree to participate in this research, please** [description]. *(Describe what the participant must do to indicate agreement to participate. Example: “complete the attached survey”, or “click I Agree to continue”).*