

Main Consent Form

---

**Sample Only (revised 02/23/21)– Cannot be used  
without IRB Approval**

**TITLE:** *[The study title must match the title in your application and on your master protocol. Also, include the protocol/grant number if applicable.]*

**PRINCIPAL INVESTIGATOR:** *[PI Name]*  
*[PI Address]*

**CO-INVESTIGATOR(S):** *[Name(s)]*

**TAKE NOTE:**

- *The consent form should be written to conform to the UTHSC IRB template in regard to headings, format, and content. Additional content from the sponsor is allowable for review in the event that it is not repetitive of template content, and this content should be placed at the end of each applicable section.*
- *Lay terms or explanations must be used for all medical terms (consult our lay term glossary at <http://www.uthsc.edu/research/compliance/irb/researchers/consent-forms.php> ). Sentence structure should be simple. Do not use abbreviations such as “e.g.” and “i.e.”, difficult-to-understand prepositions such as “via”, or symbols such as “+”.*
- *You may not combine a repository consent form with the main consent form. A repository is being established when identifiable private information and/or identifiable biospecimens that will be, or have already been, collected will be stored for future research studies (in addition to, or separate from, any current objectives of any other study). ]*

**1. KEY INFORMATION:**

*[If your study includes ONLY children 7 years old and younger, simply write the consent form addressing the parent/legal guardian (ex: “your child”).] A person who takes part in a research study is called a research or study subject. In this consent form “your child” always refers to the research subject.*

**[OR]**

---

*[Insert Preparation Date]*

Page 1 of 34

Subject Initials \_\_\_\_\_  
**[OR]**

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

*[If your study includes any children 8 years old and older, **OR** any adults who cannot consent for themselves, edit and include the following:]* A person who takes part in a research study is called a research or study subject. In this consent form “you” refers to the research subject **[and/or]** **[choose:** the parent/legal guardian **and/or** the legally authorized representative].

**[OR]**

*[If your study does not include either of the above populations, no statement is needed as the consent form should be written in the second person addressing the adult subject as “you”.]*

*[All studies should include the following:]*

You are being given the opportunity to participate in this research study. The purpose of this consent form is to help you decide if you want to be in the research study.

*[In simple language, explain why the research is being done and what the experimental components are.]*

The purpose of this study is to...

*[If applicable – Explain what a Pilot, Phase I, II, III, or IV study is. For example:]*

This is a Phase II study. A Phase II study is the second step of testing a new drug in humans, primarily to obtain initial information about the effectiveness and safety at the chosen dose.

*[If you are using an investigational drug, drug combination and/or device, indicate what is FDA approved and what is investigational, and define the term “investigational”. If a drug is FDA approved but you are using it off-label, explain this as well.]*

[X] is an investigational [drug, device, vaccine]. An investigational [drug, device, vaccine] is one that has not been approved by the US Food and Drug Administration (FDA) as treatment for your condition.

*[In addition, include a brief description of any comparative (e.g., standard or control) agents or devices, if any, to be used in the project.]*

### **Procedures:**

*[Provide in lay terms a basic description of the design of your study.]*

In this study, we will be collecting data from your medical record as you complete visits for your clinical care. We will also be asking you to complete some additional questionnaires about your quality of life.

**[OR]**

---

*[Insert Preparation Date]*

Page 2 of 34

Subject Initials \_\_\_\_\_  
**[OR]**

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

In this study, we will be collecting blood specimens and conducting lab tests to see how you process the medications that you are receiving for your condition. We will also be swabbing the inside of your mouth for a DNA specimen to determine how your genetic makeup alters the way your medications work in treating your medical condition.

**[OR]**

In this study, we will randomize subjects between different treatments to compare their efficacy and safety.

*[If the study involves randomization choose from one of the following statements. If the study does not involve randomization, delete the following three paragraphs.]*

*[If subjects will be randomized in a 2-arm trial where only 1 arm is experimental, explain the following:]*

You will be randomly assigned (like the flip of a coin) to receive [placebo, or name the standard drug] or [name the study drug]. You have a \_\_\_ in \_\_\_ chance of receiving [name the study drug], the experimental treatment. The investigator will not be the person who decides which you receive. A computer program that gives random numbers will be used to decide which you receive. *[Include and edit this sentence only if there is no placebo in your study:]* It is not known whether the experimental treatment is as good as, better than, or worse than the standard treatment.

**[OR]**

*[For randomized studies that include more than 2 arms where at least 1 arm is experimental, explain the following:]*

You will be randomly assigned (like drawing numbers from a hat) to receive [placebo, or name the standard drugs, or name the study drugs] \_\_\_\_\_, \_\_\_\_\_, or \_\_\_\_\_. You have a \_\_\_ in \_\_\_ chance of receiving [name the study drug], the experimental treatment. The investigator will not be the person who decides which you receive. A computer program that gives random numbers will be used to decide which you receive. *[Include and edit this sentence only if there is no placebo in your study:]* It is not known whether the experimental treatment/s is/are as good as, better than, or worse than the standard treatment/s.

**[OR]**

*[If subjects will be randomized in a 2-arm trial where both arms are standard treatment, explain*

---

*[Insert Preparation Date]*

Page 3 of 34

Subject Initials \_\_\_\_\_  
**[OR]**

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

*the following:]*

You will be randomly assigned (like the flip of a coin) to receive [name standard drug A] or [name standard drug B]. You have a \_\_\_ in \_\_\_ chance of receiving [name standard drug A or B]. The investigator will not be the person who decides which you receive. A computer program that gives random numbers will be used to decide which you receive. It is not known whether [name standard drug A] is as good as, better than, or worse than [name standard drug B].

*[If your study will use a placebo, provide a definition. For example (when completing sentences, delete all blanks from this template):]*

You may receive placebo during this study. The placebo looks like \_\_\_\_\_ but has no medication in it.

*[If applicable, provide a definition regarding the blind in your study. For example, if your study is double-blinded:]*

Neither you, the study doctor, nor any study personnel will know which treatment you will receive or have received. This is important for the research design so that neither you nor the investigators will know about the developing trends in the research information being gathered.

*[Indicate how long the subject's participation in the research study will be in hours, days, weeks, months, or years.]*

Your participation in this study will last \_\_\_\_\_.

*[Indicate also (if applicable) whether you intend to collect follow-up information and how long this will be done, e.g., until 6 months after the last study drug dose, for the rest of the subject's life, etc.]*

*[Indicate how many total visits there are, how often the visits are, and whether the visits are in-person, online, via telephone, etc.]*

### **The following procedures are being performed for research purposes only:**

*[List all procedures that would NOT performed if the subject were NOT participating in the study, including how many ADDITIONAL blood draws, clinic visits, etc., are being performed for research purposes only. For example:]*

- Copying information such as your medical history, [etc.] from your medical record;
- An X-ray;
- 2 blood draws;

---

*[Insert Preparation Date]*

Page 4 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

- An electrocardiogram (ECG); and
- 3 questionnaires.

*[The total amount of blood to be drawn solely for research purposes during the entire study (in teaspoons/tablespoons) should be provided.]*

You will have a total of 10 tablespoons of blood drawn for research purposes.

*[All studies should include the following:]*

For a detailed explanation of the procedures, refer to the section of this consent form entitled, DETAILED PROCEDURES TO BE FOLLOWED.

### **Risks:**

*[Describe in lay terms the most common (highest in frequency) physical risks of the research procedures (including drug/device administration) and the most serious physical risks (greatest in magnitude), even if the latter rarely occur. For example:]*

Some of the most common side effects from the study drug are dry mouth, hot flashes, itchiness, joint pain, and fatigue. This drug could also cause liver damage and death, but these rarely occur.

*[If applicable, indicate any serious psychological, social, or economic risks. For example:]*

### **HIV/Sexually Transmitted Disease Testing:**

You will be tested for HIV (AIDS virus) *[or hepatitis, etc.]* during this study. If the test results are positive, you will be informed and referred for appropriate counseling. You may experience some psychological distress (become sad, angry, etc.) if you test positive and did not know you had this disease. *[Edit the following sentence according to your current procedure; i.e., indicate whether results will or will not be placed in either record.]* The information about your test result will be placed in your medical record and in your research record. In accord with state law, a positive result for a sexually transmitted disease must be reported to the Tennessee Department of Health.

*[All studies should include the following:]*

For a detailed list of the potential risks, refer to the section of this consent form entitled, RISKS ASSOCIATED WITH PARTICIPATION.

### **Benefits:**

---

*[Insert Preparation Date]*

Page 5 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

*[In simple language, indicate the possible benefit for both the subject and the ways in which the study has the potential to develop medical knowledge important to society. If there are no direct benefits to subjects associated with participation in the study, then this should be clearly stated.]*

Your *[name of condition and/or name specific symptoms]* may improve while you are in this study; however, this cannot be promised.

The results of this study may help people with *[name of condition]* in the future by *[insert ways]*.

**[OR]**

You will not receive any benefits from being in this study. The results of this study may help people with *[name of condition]* in the future by *[insert ways]*.

**[OR]**

*[For placebo controlled trials: The discussion of potential benefits should distinguish between subjects receiving the active (or study) medication and those receiving placebo. For example:]*

Subjects receiving the active (or study) medication may benefit insofar as *[explain physical benefit; e.g., the size of the hemorrhage may be reduced]*, although this cannot be guaranteed, because the study medication is still being tested for the treatment of your condition. Subjects receiving placebo will not benefit from the active (or study) medication.

The results of this study may help people with *[name of condition]* in the future by *[insert ways]*.

**[OR]**

*[For active controlled trials: The discussion of potential benefits should distinguish between subjects receiving standard therapy/medication and those receiving the study medication. For example:]*

If you are randomized to receive standard therapy, it is likely to be as safe and effective in treating *[name of condition and/or name specific symptoms]* as it is when given outside the research setting. If you are randomized to receive *[name of study drug]*, its safety and effectiveness in treating *[name of condition and/or name specific symptoms]* may be the same as, better than, or worse than standard treatment. The benefits of the study drug are less certain because it is still being tested for the treatment of your condition.

The results of this study may help people with *[name of condition]* in the future by *[insert ways]*.

**[Note: Do not list compensation for participation or free services as a benefit.]**

### **Alternatives:**

*[For treatment studies, include the following 3 paragraphs.]*

*State whether subjects may receive the treatment(s) used in the research without participating in the study. For example:]*

You may receive *[study drug, device, procedure]* without participating in this study.

---

*[Insert Preparation Date]*

Page 6 of 34

Subject Initials \_\_\_\_\_  
**[OR]**

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

**[OR]**

You cannot receive [study drug, device, procedure] without participating in this study.

If you decide not to enter this study, there are other choices available. These include: **[list the major ones such as drugs/devices/procedures]**. Ask the study doctor to discuss these alternatives with you. You do not need to be in this study to receive treatment for your condition.

**[Briefly explain whether subjects will receive medical treatment for their condition whether or not they participate in the study. For example:]**

You will receive medical treatment for [the subject's medical condition] whether or not you participate in the study.

**[For non-treatment studies, include the following statement.**

**If subjects have a medical condition being studied (but not treated within the study) by their regular doctor or by the facility at which they receive care, briefly explain whether they will receive medical treatment for their condition whether or not they participate in the study (1<sup>st</sup> example sentence below). If not, include the 2<sup>nd</sup> example sentence below.]**

You will receive medical treatment for [medical condition] whether or not you participate in the study.

**[OR]**

If you do not participate in this study, none of the procedures described in this consent form will be performed.

### **Voluntary Participation:**

**[All studies should include the following:]**

Your participation in this research study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

**[For therapeutic trials, also include the following statement:]**

Deciding to not take part in this research study will not change your regular medical care in any way.

**[If you will be recruiting potential subjects who are students, residents, or fellows (of UT/any school associated with this research) and/or employees (of UT/any institution/agency associated with this research), include the following statement(s):]**

---

**[Insert Preparation Date]**

Page 7 of 34

Subject Initials \_\_\_\_\_  
**[OR]**

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

If you are a student of [school name], participating or not participating in this study will in no way influence your grade in any course. If you are a resident or fellow of [school name], participating or not participating in this study will in no way influence your academic standing. If you are an employee of [name of institution/agency], participating or not participating in this study will not affect your employment status.

### 2. DETAILED PROCEDURES TO BE FOLLOWED:

[Add the following statement only if this is an externally sponsored, multi-center study (when completing sentences, delete all blanks from this template):]

Approximately \_\_\_\_\_ subjects will be participating in this study at approximately \_\_\_\_\_ centers, and \_\_\_\_\_ subjects will be participating locally.

[OR]

[Add the following statement only if this is a local or a one-site study:]

\_\_\_\_\_ subjects will be participating in this study.

[Include specific location(s) and the corresponding addresses at which the research will be performed.]

The study will take place at \_\_\_\_\_.

[In simple language, using a bullet point format with headers or a table, explain the following:

- The tests and procedures that will be done (including medical record abstraction)
- Which procedures/drugs are standard of care and which are for research purposes only
- If research procedures will occur at a standard of care visit, indicate how much additional time will be required to complete the research procedures
- The amount of blood to be drawn for research purposes at each visit (in teaspoons/tablespoons) and the total amount of blood to be drawn during the entire study (in teaspoons/tablespoons)
- Estimate the time required of the subject for each visit

For example:]

Day 1/Visit 1 (this will take an additional 45 min. at your routine doctor visit):

- Electrocardiogram (EKG), a tracing of the electrical activity of your heart
- 2 tablespoons of blood will be drawn from your arm by needle stick for [kind of] blood tests
- Information such as your age, weight, height, and medical history such as [previous heart attacks, etc.] will be copied from your medical record

---

[Insert Preparation Date]

Page 8 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_



## Main Consent Form

---

### Day 2/Visit 2 (2 hours 30 min.):

- Complete a questionnaire
- You will receive [the study drug] intravenously (into your vein) for 2 hours

*[For studies involving biospecimens, when it is possible that genetic analysis may be performed, state whether the research will (if known) or might include analyses of the genetic makeup of subjects. This might include sequencing to determine the differences between subjects in terms of disease severity, likelihood of disease progression, and so forth; sequencing of genes that may indicate a disease susceptibility heretofore unknown to the subjects; sequencing to determine pharmacogenomic phenotypes; and 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 an explanation of what genes are and why they may be of interest to investigators. For example:]*

Your specimen [*choose:* will *or* may] be used for whole genome sequencing. Genes are like blueprints in each of your cells that determine traits that you inherit, like eye color and hair color. Genes may also influence what diseases you get and how you respond to treatment. DNA is the substance that makes up your genes. Whole genome sequencing involves learning about the makeup of all your genes.

*[Indicate whether clinically relevant research results, including individual research results, will be disclosed to subjects, AND if so, by whom (the study doctor, a genetic counselor, etc.) AND how (in the clinic, over the phone, by mail, etc.). For example:]*

Due to the type of research that is conducted with your blood specimen, you will not be informed of any individual results or general research results that may be relevant to your health.

**[OR]**

If results of the studies conducted with your blood specimen may be relevant to your health, the study doctor or the study staff may offer to share this information with you in the clinic. The study doctor and/or the study staff will explain the test results and what they may mean for your health.

*[If subjects will be provided a choice regarding receiving results, add:]*

Please check the appropriate box below indicating whether or not you want to receive such information:

\_\_\_\_\_ Yes, I do want to receive the results of the studies that are performed on my specimen.

\_\_\_\_\_ No, I do not want to receive the results of the studies that are performed on my specimen.

---

*[Insert Preparation Date]*

Page 9 of 34

Subject Initials \_\_\_\_\_  
**[OR]**

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

Your participation in this research study may be stopped by the study doctor [*or the sponsor*] without your consent for any of the following reasons:

*[if the protocol lists specific reasons, insert the specific reasons for discontinuation listed in the protocol]*

- If you do not show up for visits
- If you do not follow the study doctor's instructions

***[For therapeutic trials, add the following paragraph:]***

If you decide to stop taking part in this research study, you should tell your study doctor, and any information that you have already provided will be kept in a confidential manner. *[If applicable, add the following 2 sentences]* In addition, the study doctor will discuss further treatment options with you, and you will be asked to return to the clinic to have all the final clinical evaluations completed and laboratory tests performed. You may ask that your identifiable samples be destroyed.

***[OR]***

***[For non-therapeutic trials, add the following paragraph:]***

If you decide to stop being part of the study, you should tell your study doctor, and any information that you have already provided will be kept in a confidential manner. *[If applicable, add the following]* You may ask that your identifiable samples be destroyed.

### 3. RISKS ASSOCIATED WITH PARTICIPATION:

*[In simple language and in simple bullet format (whenever possible), explain the possible risks and discomforts, including:*

- *Potential risks of investigational agents, devices, procedures, and treatments, as well as known risks of comparative agents, devices, procedures, and treatments used in the study;*
- *If applicable, psychological, social, or economic risks; and*
- *Only include the risks associated with procedures and/or treatments being performed solely because the subject is participating in this research study. Risks of standard of care procedures that would normally be performed even if the subject were not participating in this research study should not be included in the consent form. However, if randomizing to a standard of care treatment when other standard of care treatments/alternatives exist, the*

---

*[Insert Preparation Date]*

Page 10 of 34

Subject Initials \_\_\_\_\_  
***[OR]***

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
***[OR]***

Parent/Legal Guardian Initials \_\_\_\_\_  
***[OR]***

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

*risks of the standard of care treatment should be included because the patient may not incur these particular risks outside of the study.].*

*[Start with the potential side effects of the experimental drugs and devices. To the extent possible, risks of harm or discomfort should be characterized as to their probabilities of occurrence, potential seriousness, duration, and reversibility. You may do this using 1 of the following 2 ways:*

- If you can state the percentage of occurrence for each risk, the use of categories is not necessary. However, you should list the risks in bullet format, and in descending order with the most frequently occurring risks first and so on; OR*
- You may use categories of risk: The current UTHSC guidelines for risk categories include Very Rare, less than 1%; Rare, 1 to 5%; Occasional, 6 – 20%; Common, 21 – 50%; and Very Common, 51 to 100%. One of these categories should be used for each potential risk with the corresponding range of percentages. For example:]*

All drugs can have side effects. Although not all or none of these side effects may occur, if they do occur, they may need medical attention. You must notify your study doctor about all symptoms, side effects, complaints, illnesses, or injuries which you experience during the course of the study regardless of whether or not you think these are related to the study drug. You should discuss these with your study doctor as well as your regular health care provider, if you choose.

As a result of your participation in this study, you are at risk for the following side effects.

**[Study Drug Name]** may cause some, all, or none of the side effects listed below.

Very Common (51-100%)

- 
- 

Occasional (6-20%)

- 
- 

*[Add the following statement only if the study involves an experimental treatment where some subjects are not randomized to the experimental drug/biologic/device:]*

If you are not randomized to the experimental treatment, you will not be exposed to the risks (listed above) associated with the experimental drug, [insert name of study drug/biologic/device].

---

**[Insert Preparation Date]**

Page 11 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

*[If the study includes a placebo, list the potential side effects associated with the placebo immediately following the side effects of the study drugs.]*

***[Include the following 2 paragraphs for all studies:]***

There is a risk that your private identifiable information may be seen by people not involved in the research (such as if a researcher's computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

The research may involve risks to you *[if applicable, add: or to the embryo or fetus, if you are or may become pregnant,]* which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

***[If any of the following procedures will be performed only for research purposes, use the following template language:]***

### **Blood Draw:**

Risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, lightheadedness, and/or fainting are also possible, although unlikely.

### **Intravenous Line (IV):**

There is a slight chance that multiple needle-sticks will be necessary to make sure the IV is placed correctly. You might feel a small amount of pain when the IV is placed but it does not last very long. A bruise or a minor infection might develop where the IV is placed.

### **Computed Tomography (CT) Scan:**

A part of this study requires you to have computed tomography (CT) of your [insert body part]. The CT scan involves low doses of radiation.

*[Indicate the amount of radiation to which subjects may be exposed by comparing it to the level of radiation that people experience on a regular basis, such as daily exposure to the background radiation in nature. For more information about radiation dose assessments go to <http://www.doseinfo-radar.com/RADARDoseRiskCalc.html>. For example:]*

---

*[Insert Preparation Date]*

Page 12 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

The total amount of radiation per scan is 5mSv (millisievert). A millisievert is a unit of measure of radiation dose. This amount is less than the radiation exposure from 2 mammograms.

*[If appropriate, include the potential risks and discomforts of contrast agents and sedation. For example:]*

Before or during the study, you may be given an injection of a contrast liquid in your vein to allow the radiologist to obtain clearer images of your organs. The contrast dye may cause nausea or vomiting, sneezing, itching, or hives.

You may hear a slight buzzing, clicking, and/or whirring sound as the CT scanner moves around your body.

If you wear or have an electronic medical device, such as a pacemaker or a drug pump, please make sure you tell your study doctor and research staff. The Food and Drug Administration (FDA) has reported that CT scans may interfere with electronic medical devices such as pacemakers, defibrillators, neurostimulators, and implanted or externally worn drug infusion pumps. In the reports received by the FDA, CT scans may have caused unintended “shocks” from the neurostimulators, errors in insulin infusion pumps, and brief changes in pacemaker output pulse rate.

### **DEXA:**

This research study involves exposure to radiation from a DEXA whole body scan. This radiation exposure is not necessary for your medical care and is for research purposes only. This use involves minimal risk and is necessary to obtain the research information desired. The radiation dose from the whole body scan that will be performed during the trial is approximately 2 to 10 microsieverts. This scan provides about the same amount of radiation exposure as you would receive from exposure to natural sources of radiation in one day.

### **Drug Screening:**

You will undergo screening for illicit (street) drug(s). If others find out you have tested positive for illegal drugs, it may cause mental stress, unfair treatment from other people, problems with getting insurance or finding a job, legal difficulties, or other unknown problems. It is important to seek medical care if you have a drug abuse problem. *[Edit the following sentence according to your current procedure; i.e., indicate whether results will or will not be placed in either record.]* The information about your test result will be placed in your medical record and in your research record.

---

*[Insert Preparation Date]*

Page 13 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

*[If the subject is a minor and the result of the drug test will be shared with the parent/LAR, include a statement using simple terms regarding the potential psychological distress and familial conflict that may occur as a result of receiving the results of a positive drug test, and if applicable, indicate that referrals for counseling will be provided.]*

### **ECG:**

The pads placed on your chest for the ECG may cause a mild allergic reaction.

### **Fasting:**

The potential discomforts associated with fasting are minor and include dizziness, headache, stomachache, or fainting.

### **HIV/Sexually Transmitted Disease Testing:**

You will be tested for HIV (AIDS virus) *[or Hepatitis, etc.]* during this study. If the test results are positive, you will be informed and referred for appropriate counseling. You may experience some psychological distress (become sad, angry, etc.) if you test positive and did not know you had this disease. *[Edit the following sentence according to your current procedure; i.e., indicate whether results will or will not be placed in either record.]* The information about your test result will be placed in your medical record and in your research record. In accord with state law, a positive result for a sexually transmitted disease must be reported to the Tennessee Department of Health.

***[If the study drug is taken home, insert this or similar language:]***

Only you should take the study drug. It must be kept out of reach of children or anyone else who may not be able to read or understand the label.

### **MRI:**

There are no known major risks with an MRI scan. But it is possible that harmful effects could be found in the future. Even though the tunnel is open, it may bother you to be placed in a tight space (claustrophobia), and to hear the noise made by the magnet during the scan. You will be given earplugs to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan. It may be hard to lie on the table during the scan. You are at risk for injury from the MRI magnet if you have pacemakers or other implanted electrical devices, brain stimulators, dental implants, aneurysm clips (metal clips on the wall of a large artery), metallic prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, implanted delivery pump, or shrapnel fragments. Welders and metal workers are also

---

*[Insert Preparation Date]*

Page 14 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

at risk for injury because of possible small metal fragments in the eye of which they may be unaware. You will be screened for these conditions prior to the study, and if you have any of these conditions, you will not receive an MRI scan. If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs, so you must tell your study doctor before the scan if you have any metal pieces in your body.

**Non-Paternity DNA Testing:** *[When the research includes familial genetic testing the following language should be added:]*

This blood test may show that one or both of your parents are not related to you (adoption).

**Placebo:** *[If the subject's current treatment for his/her condition will be withdrawn and replaced only with placebo, include an explanation of the symptoms subjects may experience if they are assigned to the placebo group. Note: these symptoms should be listed immediately following the potential side effects associated with the study drug(s)]*

If you are assigned to the placebo group, your illness or condition may become worse because you are not receiving [insert name of study drug or active medication] or the treatment you were already taking for your illness or condition.

**Pregnancy Risks for Females:** *[The following paragraphs should be included if there is a risk to either the mother or fetus sufficient to exclude pregnant females from participation or to avoid pregnancy during the course of the study.]*

Females who are pregnant or nursing a child may not take part in this study. If you are a female and are able to become pregnant, you will have a *[insert the appropriate method: blood or urine]* test to make sure that you are not pregnant before you receive treatment in this study.

*[If the subject is a minor and the result of the pregnancy test will be shared with the parent/LAR, include a statement using simple terms regarding the potential psychological distress and familial conflict that may occur as a result of receiving the results of a positive pregnancy test, and if applicable, indicate that referrals for counseling and/or obstetric services will be provided.]*

If you choose to take part in this study, you must use birth control such as:

- sexual abstinence;
- birth control pills, birth control shots, IUD, birth control implants (placed under the skin by a health care provider), or patches (placed on the skin);
- sexual activity with a male partner who has had a vasectomy (surgery to become sterile); OR
- 2 forms of birth control, such as condom/diaphragm AND spermicidal foam or gel.

---

*[Insert Preparation Date]*

Page 15 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

You must also use this birth control for at least \_\_\_ days after your last dose of any study treatment.

You must not donate eggs [*insert timeframe, such as "from your first dose of the study drug and for at least one month after the last dose of the study drug"*]. It is not known whether [*insert name of drug*] has an effect on eggs.

*[The following paragraph should also be included if there is a risk of reducing the effectiveness of hormonal birth control due to a study medication.]*

Taking \_\_\_\_\_ may reduce the effectiveness of your oral hormonal birth control (in other words, birth control pills). If you use oral hormonal birth control, you must use an additional, non-hormonal form of birth control, such as, condom/diaphragm AND spermicidal foam or gel while you are taking \_\_\_\_\_, and for \_\_\_\_\_ days after you stop taking \_\_\_\_\_.

If you think that you have become pregnant during the study, you must tell your study doctor immediately. Pregnant females will be taken out of the study.

**Pregnancy Risks for Males:** *[The following paragraph should be included if there is a risk to either the mother or fetus sufficient to avoid fathering a child during the course of the study.]*

Males who are in this research study should not get a sexual partner pregnant while taking the study drug [*If applicable also add the following:*] and for [specify amount of time] after the last dose of study drug. In addition, you must also avoid sperm donation while enrolled in the study and for at least [specify amount of time] after your last dose of the drug. The effect of the study drug on sperm is not known.

If you take part in this study, you must agree to use birth control such as sexual abstinence, vasectomy, or two methods of birth control (for example, condom or diaphragm AND spermicidal foam or gel) while you are in this study and for at least [\_\_\_\_ days] after your last dose of study treatment. You should tell your partner of the potential for harm to an unborn child. She should know that if pregnancy occurs, you will need to report it to the study doctor, and she should also promptly notify her doctor.

**Questionnaires/Surveys:** *[If your study includes questionnaires/surveys with sensitive questions, then include the following:]*

Completion of the \_\_\_\_\_ may make you feel uncomfortable or cause troublesome feelings or emotions. You may refuse to answer any of the questions and you may take a break at any time during the study.

---

*[Insert Preparation Date]*

Page 16 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_



## Main Consent Form

---

### **Radiological Procedures:**

A part of this study requires you to have [*name of procedure, e.g., a chest x-ray*] performed. [*Indicate the amount of radiation to which subjects may be exposed by comparing it to the level of radiation that people experience on a regular basis, such as daily exposure to the background radiation in nature. For more information about radiation dose assessments go to <http://www.doseinfo-radar.com/RADARDoseRiskCalc.html>. For example:*]

The total amount of radiation you will receive in this study is about the same as you would receive from exposure to about 1 day of natural sources of radiation (about 1 mrem).

### **Videotaping/Photography/Audio Recording:** [*Edit the following sentence according to which procedure(s) you will include in your study:*]

Having your photograph taken, your voice recorded, and being videotaped may make you feel uncomfortable. You may take a break during any time of the study. There is also a potential risk of loss of confidentiality that someone who views your video and photograph or listens to your audio recording might identify you.

### **Washout:** [*Include an explanation of the symptoms subjects may experience during the washout period, for example:*]

During the washout period, your [*name of condition*] may become worse because you are not receiving [*insert name of the subject's current medication or the study drug that is being washed out*].

### **Previously Unknown Medical Conditions or Genetic Risk Susceptibilities:**

[*If results of studies using the specimens are relevant to the health of subjects and may be returned to them, then indicate that disclosure of the results may have adverse psychological and social consequences. For example:*]

If test results show that you are positive for \_\_\_\_\_ and you are made aware of this result, it may cause mental stress, unfair treatment from other people, or other unanticipated problems.

[*OR*]

Genetic testing in this study may reveal that you are at increased risk for [*breast cancer*] compared to the general population.

## 4. CONFIDENTIALITY:

### **Research records/specimens**

---

[*Insert Preparation Date*]

Page 17 of 34

Subject Initials \_\_\_\_\_  
[*OR*]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[*OR*]

Parent/Legal Guardian Initials \_\_\_\_\_  
[*OR*]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

*[Explain how paper research records will be maintained. For example:]*

All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

*[Explain how electronic research records will be maintained. For example:]*

All your electronic research records will be computer password protected and accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

**[OR]**

All your electronic research records will be kept on an encrypted computer where your information is replaced with a code and password only known to the research personnel, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

*[If the study includes specimens that will be maintained at the local site, explain whether or not the specimens will be labeled with a code. For example:]*

Your [tissue, blood, etc.] sample will be labeled with a code.

**[OR]**

Your [tissue, blood, etc.] sample will be labeled with your [name, social security number, etc.].

*[If any individual research records or specimens will be transmitted during the study, explain whether or not the data will contain identifiers, be sent using an encrypted method, and whether specimens will be labeled with a code. For example:]*

Your identifiable research records will be transmitted to [name the investigative site, data center, etc.] using an encrypted method (not regular email), where your information is replaced with a code and password only known to the entities below). **[OR]** Your research records will be transmitted to [name the investigative site, data center, etc.] and will be labeled with a code (will not contain any identifiable information about you).

Your [tissue, blood, etc.] will be transmitted to [name the investigative site, data center, etc.] and will be labeled with a code. **[OR]** Your identifiable [tissue, blood, etc.] will be transmitted to [name the investigative site, data center, etc.].

*[If coded research records or specimens will be sent to an external site(s) during the study, explain whether or not the master key/list that links the subject's name with the code will be maintained at the local investigative site.]*

---

*[Insert Preparation Date]*

Page 18 of 34

Subject Initials \_\_\_\_\_  
**[OR]**

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

A master key/list which links your name with the code on your [research record and/or specimen] will be maintained at [name the local investigative site].

[For any research that involves the collection of identifiable private information and/or identifiable biospecimens, add one of the following statements.]

Identifiers might be removed from your [choose one or leave both, as applicable: private information or biospecimens], and 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 you.

[OR]

Your [choose one or leave both, as applicable: private information or biospecimens] collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

### Medical Records

[Explain whether documentation of the participation of the subject in the research study, such as a copy of the consent form or other notation, will be placed in the subject's medical record.]

**Note:** If the research study will take place at Regional One Health, University Clinical Health, or Methodist/Le Bonheur facilities, these institutions require that a copy of the consent form be filed in the subject's medical record. For example:]

Information about your participation in this study or the results of procedures performed in this study will be placed in your medical record. As such, it may be available to your insurer.

However, it will not be available to your employer, except with your explicit authorization and/or as permitted by law.

[OR]

Information about your participation in this study or the results of procedures performed in this study will not be placed in your medical record.

### GINA

[For studies involving genetic analysis that may reveal the genetic susceptibility of subjects or others to health problems of which they are currently unaware or from which they do not presently suffer, add the following paragraph.]

A federal law called the Genetic Information Nondiscrimination Act (GINA), provides additional protections for the genetic information about you that may result from this research. GINA makes it illegal for a health insurer to request or use any genetic information about you to make decisions about your eligibility for coverage or your premiums. The law also prevents

---

[Insert Preparation Date]

Page 19 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

employers with 15 or more employees from using genetic information to make decisions about hiring, promoting, or firing you. The protections of the law do not apply to insurers providing life, disability, or long-term care insurance.

### Presentations/Publications

*[Explain whether or not individual subjects will be identified in any presentations or publications based on the research. For example:]*

While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.

*[For all government-sponsored, industry-sponsored, and investigator-sponsored clinical trials of drugs, biologics, or devices, include the following:]*

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by US 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.

### Limits to Confidentiality

*[Explain any limits to confidentiality. For example:]*

Information obtained during the course of the study, which in the opinion of the investigator(s) suggests that you may be at significant risk of harm to yourself or others, may be reported to a third party to protect the rights and welfare of those at potential risk.

### Authorization to Use and Disclose Protected Health Information for Research Purposes

*[NOTE: This must **not** be altered with sponsor language, as sponsors are not covered under the HIPAA regulations.]*

Under federal privacy regulations, you have the right to decide who can review and copy your identifiable health information (called “protected health information” or PHI). PHI collected in this study may include information such as:

- Past and present medical records
- Records about your study visits
- Records about phone calls made as part of this research
- Research records

---

*[Insert Preparation Date]*

Page 20 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

By signing this consent form, you are giving your permission for the study doctor and the study staff to get your PHI from your doctor and/or facilities where you have received health care.

They may also share your PHI with:

*[Edit this list as it applies to this study:]*

- The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
- *[if a multi-institutional study, add]* Researchers at *[name of institutions]*
- *[if a cooperative study, add]* *[the name of the cooperative group]*
- *[if the research involves an FDA-regulated drug/device/biologic, add]* The US Food and Drug Administration (FDA)
- *[if applicable, add]* Department of Health and Human Services (DHHS) or other government agencies
- *[if applicable, add]* Governmental agencies in other countries
- *[if research procedures will be billed to the subject's insurance, add]* Your medical insurance provider
- *[if research procedures are taking place at both Methodist and Le Bonheur, add]* Methodist Le Bonheur Healthcare
- *[if research procedures are taking place at Le Bonheur Children's Hospital add]* Le Bonheur Children's Hospital
- *[if research procedures are taking place at Methodist Hospitals, add]* Methodist Healthcare-Memphis Hospitals
- *[if research procedures are taking place at Regional One Health, add]* Regional One Health
- *[if research procedures are taking place at University Clinical Health, add]* University Clinical Health
- *[if research procedures are taking place at a UT Le Bonheur Pediatric Specialists facility, add]* UT Le Bonheur Pediatric Specialists, Inc.
- *[if your study has a sponsor, add]* *[name of sponsor]*, which sponsors and provides funds for this research
- *[if applicable, add]* *[name of CRO]*, which has been hired by the sponsor to coordinate the study
- *[if applicable, add]* A Data and Safety Monitoring Board (DSMB)

*[If you included a sponsor, CRO, DSMB, or similar unaffiliated organization in the above bullet point list, you must add:]* However, some of these organizations or institutions above do not have the same obligations to protect your PHI.

---

*[Insert Preparation Date]*

Page 21 of 34

Subject Initials \_\_\_\_\_  
**[OR]**

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

Your PHI will only be used and/or given to others:

- To do the research
- To study the results
- To see if the research was done correctly

*[Provide an expiration date for the authorization by choosing one of the following 3 statements:]*

Your PHI will be used until the study is completed.

**[OR]**

*[if the research is FDA-regulated, state]* Your PHI will be used for as long as the sponsor reports study information to the FDA.

**[OR]**

*[if the research is without a foreseeable end point, such as a repository or a registry, state]* Your PHI will be used indefinitely.

You may withdraw or take away your permission to use and disclose your PHI at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you may not be able to stay in the study.

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used and given to others. The federal regulations allow you to review or copy your PHI that is used in this study.

*[If the research study includes treatment of subjects, add the following sentences.]* However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. Once the study is over, your right to review and copy your PHI will be reinstated.

**Certificate of Confidentiality** *[If your study includes a federal Certificate of Confidentiality, add the following 4 paragraphs:]*

This research is covered by a Certificate of Confidentiality from *[name the federal agency granting the CoC, such as the National Institutes of Health]*. The researchers with this Certificate may not disclose or use information, documents, *[if using or collecting them in this study, add: or biospecimens]* that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, *[if using or collecting them in this study, add: or biospecimens]* protected by this

---

*[Insert Preparation Date]*

Page 22 of 34

Subject Initials \_\_\_\_\_  
**[OR]**

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

Certificate cannot be disclosed to anyone else who is not connected with the research except when: (1) there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases); (2) you have consented to the disclosure, including for your medical treatment; or (3) the materials are used for other scientific research, as allowed by federal regulations protecting research subjects.

*[Use the following language if this study is sponsored by a federal or state government agency, or is FDA-regulated:]* The Certificate cannot be used to refuse a request *[add the following if sponsored by a federal or state government agency:]* for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by *[name the federal or state government agency]* which is funding this project *[add the following if FDA-regulated:]* or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

*[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws:]* The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of *[list what will be reported, such as child abuse and neglect, or harm to self or others]*.

*[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants:]* The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document *[restate what will be disclosed, such as including research data in the medical record]*.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

### 5. COMPENSATION AND TREATMENT FOR INJURY:

*[All studies utilizing a main consent form MUST include the statements in this section, even if you believe there is no potential for a physical or non-physical injury. If sponsors have different liability or reimbursement language, this can be added after all of UTHSC's required liability language and can be separated by subheaders if preferable (e.g., "UTHSC's statements"; "Sponsor X's statements").]*

---

*[Insert Preparation Date]*

Page 23 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

*[All consent forms must include 1 of the 2 following paragraphs. If you are conducting your research at any of the additional sites/organizations in the list below, you must name all of them in each of the 3 sentences of the template paragraph, using only one paragraph. This language should NOT be edited otherwise.]*

- *when both Methodist & Le Bonheur are involved, also include:* Methodist Le Bonheur Healthcare
- *when only Methodist hospitals are involved, also include:* Methodist Healthcare-Memphis Hospitals
- *when only Le Bonheur Children's hospital is involved, also include:* Le Bonheur Children's Hospital
- Regional One Health
- University Clinical Health
- UT Regional One Physicians
- UT Le Bonheur Pediatric Specialists, Inc.
- UT Methodist Physicians Group
- Methodist Medical Group

*[Use when NONE of the additional institutions in the above list is involved:]*

You are not waiving any legal rights or releasing the University of Tennessee or its agents from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee does not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee does not provide for treatment or reimbursement for such injuries.

**OR**

*[Use when ONE or MORE institutions in the above list is involved]*

You are not waiving any legal rights or releasing the University of Tennessee, [*name each additional institution*], or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and [*name each additional institution again*] do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and [*name each additional institution again*] do not provide for treatment or reimbursement for such injuries.

*[Edit the 2<sup>nd</sup> statement below to indicate whether the study doctor will provide the medical treatment to subjects in case of a research related injury, provide acute treatment and refer, or just provide a referral. For example:]*

---

*[Insert Preparation Date]*

Page 24 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_



## Main Consent Form

---

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide acute medical treatment, and will provide you with a subsequent referral to appropriate health care facilities.

*[For all studies, include the following sentence. This language should NOT be edited.]*

If you are injured or get sick as a result of being in this study, you and/or your insurance will be billed for the costs associated with this medical treatment.

*[For all studies, include the following sentence. This language should NOT be edited.]*

No compensation will be available to you for any extra expenses that you may have as the result of research-related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc.

*[For all studies, include the following sentence. This language should NOT be edited.]*

No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

*[In addition to the UTHSC statements above, if the sponsor may reimburse part or all of these costs associated with the treatment of a research related injury, indicate this and any exceptions/limitations. (You may use a separate subheader above the sponsor statements if preferable.) For example:]*

If you have followed the instructions of the study doctor, [name of the sponsor] will reimburse you, your insurance company, and/or the hospital for any costs related to a research injury.

### 6. QUESTIONS:

Contact [name] at [number(s)] if you have questions about your participation in this study, or if you have questions, concerns, or complaints about the research.

If you feel you have had a research-related injury [*or a reaction to the study drug*], contact [name of the principal or co-investigator] at [must be a 24-hour/7-day telephone number(s)]. **Note:** *explain whether the 24-hour/7-day telephone number is an answering service, office number, pager, etc.*

---

*[Insert Preparation Date]*

Page 25 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

You may contact Cameron Barclay, MSA, UTHSC IRB Director, at 901-448-4824, or visit the IRB website at <http://www.uthsc.edu/research/compliance/irb/> if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.

### 7. PAYMENT FOR PARTICIPATION:

*[If applicable, explain that participants will not be paid for participating in this study. For example:]*

You will not be paid for participation in this research study.

*[If payment will be made, explain the following:]*

- *the amount of each payment*
- *the total possible payment*
- *in what form payments will be made, e.g., cash, check, or type of gift card*
- *when payments will be made*
- *whether payments will be made to the subjects OR their parent/legal guardian OR their legally authorized representative*
- *whether subjects will receive a bonus payment if they complete the entire study*

*For example:]*

You will receive a check for \$\_\_\_\_, mailed to you after each completed study visit. If you complete all the study visits, you will receive a maximum payment of \$\_\_\_\_. If you do not complete the study, you will be paid for the visits you have completed.

**[OR]**

You will receive a \$\_\_\_\_ gift card to [name of store or entity] at the completion of each study visit. If you complete all the study visits, you will receive a total of \_\_\_\_ gift cards worth \$\_\_\_\_. If you are 12 and older, the gift card will be given to you; however, if you are under 12 years old, the gift card will be given to your parents for your use.

*[If applicable, if your study might include subjects who are employees of UT and you are paying subjects using a check or cash, include the following sentence:]*

However, if you are an employee of the University of Tennessee, you will not receive a check or cash; your payment for participation will be added to your paycheck and will be subject to the standard taxes.

---

*[Insert Preparation Date]*

Page 26 of 34

Subject Initials \_\_\_\_\_  
**[OR]**

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

*[Indicate whether profit-making activities might result from commercialization of the information and/or specimens collected during the research study (e.g., the development of a marketable diagnostic test), and whether subjects will share in any profits deriving from these activities. For example:]*

Successful research using information about your health and your specimen (even if identifiers are removed) could result in commercial products, such as a drug to treat your disease. You will not share in any financial rewards associated with the development of these products.

### 8. COSTS OF PARTICIPATION:

*[Explain whether there are any costs to the subject or his/her parent/legal guardian or his/her legally authorized representative. If there are, explain whether insurance will be billed and who will pay if insurance does not.]*

There are no costs to you for participating in this study. *[If applicable, include the following statements:]* [Sponsor Name] will provide the study [drug/device] free of charge during this study. Tests and procedures that are done only for research purposes will not be billed to you or your insurance company.

**[OR]**

You or your insurance company may be billed for:

- [list costs as necessary]

*[If some or all of the costs associated with procedures being performed for research purposes only will be billed to insurance, add:]*

You may want to talk with your insurance company about its payment policy for medical care or procedures performed as part of a research study. If your insurance company does not pay, you may be billed for those charges.

### 9. CONFLICT OF INTEREST:

*[Include this section in the consent form only if, with respect to the sponsor of the research, one of the individuals among the key study personnel (including their spouses, parents, or children) has:]*

- *Received remuneration from a publicly traded entity in the previous 12 months preceding the disclosure, and/or possesses any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000; or*

---

*[Insert Preparation Date]*

Subject Initials \_\_\_\_\_  
**[OR]**

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Parent/Legal Guardian Initials \_\_\_\_\_  
**[OR]**

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

- Received remuneration from a non-publicly traded entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when any individual among the key study personnel holds any equity interest in that entity; or
- Held intellectual property rights and interests (patents, trademarks, or copyrights) in the drug, device, or other article being tested, and income related to such rights and interest has been received.

**If no conflict of interest exists, do not include this section in your consent form.**

*If a conflict of interest exists, insert the following statement:*

Some subjects want to know whether the investigators or other persons involved in conducting the research study have a financial interest in the product being tested or the company sponsoring the research. You should know that *[name(s) of key study personnel with conflict of interest]* *[insert a brief description of the financial interest; e.g., receives consulting fees from or holds the patent on the product being tested, or owns stock in (insert name of company), which provides funds for this research project]*.

### 10. FUTURE CONTACT: **[Change this section to “9.” if you have no Conflict of Interest section]**

*[Include and edit the following paragraph if you wish to attempt to find subjects lost to follow up.]*

If we lose contact with you during the study for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued participation; etc.), we will attempt to find you or make contact with you in the following ways:

- The phone number(s) you provided to us will be called, but if you are not the person who answers, we will not say the title of the study or the fact that you are/were participating in a study.
- Certified mail will be sent to you requesting that you call us.
- A letter will be sent to the address(es) you provided to us, but neither the return address nor any markings on the envelope will identify the title of the study or the fact that you are/were participating in a study.
- *[list any other ways that you stated in your application]*

Put your initials on one of the lines below:

---

*[Insert Preparation Date]*

Page 28 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

\_\_\_\_\_ We CAN attempt to find/contact you in the above ways.

\_\_\_\_\_ We MAY NOT attempt to find/contact you in the above ways.

*[Include and edit the following paragraph if applicable to your study, such as with investigational drug and device studies.]*

Please note that if we lose contact with you and there is new information about your participation in the study that could affect your safety, we will attempt to find you or make contact with you in any way possible.

*[Include and edit the following paragraph if you wish to retain subjects' contact information and PHI, including screening results, in order to contact them in the future regarding participation in other studies.]*

Sometimes we wish to keep your contact information, medical diagnosis, and other health information in order to contact you in the future and tell you about other studies in which you might be eligible to participate.

Put your initials on one of the lines below:

\_\_\_\_\_ We CAN keep your contact information and health information to ask you about participating in future studies.

\_\_\_\_\_ We MAY NOT keep your contact information and health information to ask you about participating in future studies.

---

*[Insert Preparation Date]*

Page 29 of 34

Subject Initials \_\_\_\_\_  
[OR]

Subject or Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Parent/Legal Guardian Initials \_\_\_\_\_  
[OR]

Subject/Legally Authorized Representative Initials \_\_\_\_\_

## Main Consent Form

---

**11. CONSENT OF SUBJECT:** [*Change this section to “10.” if you have no Conflict of Interest section*]

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

\_\_\_\_\_  
Signature of Research Subject (18 years +)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Printed Name of Adult Research Subject

*[If you are utilizing a Legally Authorized Representative for an incompetent adult subject, then the following 3 lines must be included here, above the Person Obtaining Consent lines:]*

\_\_\_\_\_  
Signature of Legally Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Printed Name of Legally Authorized Representative

\_\_\_\_\_  
Relationship of Legally Authorized Representative

*[If the research study involves adolescents as research subjects between the ages of 14-17, then the 5 following lines must be included here, above the Person Obtaining Consent lines:]*

\_\_\_\_\_  
Assent of Minor (Ages 14-17)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Printed Name of Minor Research Subject (Ages 14-17)

\_\_\_\_\_  
Printed Name of Minor Research Subject (Ages 0-7)

---

*[Insert Preparation Date]*

## Main Consent Form

---

\_\_\_\_\_  
Signature of Parent/Legal Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Printed Name of Parent/Legal Guardian

Check Relationship to Minor:

Parent

Court-Appointed Legal Guardian

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

In my judgment, the subject [*or parent/legal guardian or the legally authorized representative*] has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

---

[*Insert Preparation Date*]

**Assent Discussion for  
Subjects 8-13 Years of Age**

**[Note: If the research study involves children as research subjects between the ages of 8-13, include the following Assent Discussion page as the last page of the consent form. You MUST retain the Assent header on that page which identifies its use with children ages 8-13. If your lower age limit for subjects is greater than 8 and less than 13, please change both instances of “8-13” on the assent discussion page to your lower limit; for instance, “11-13.”**

**If the study involves adults who do not have the ability to consent but may be able to provide assent, include the Adult Assent Discussion page as the last page of the consent form.**

**Delete the following pages if your study does not involve children as research subjects between the ages of 8-13 or adults who do not have the ability to consent but may be able to provide assent.]**

**A. Assent Obtained:**

The assent discussion was initiated on \_\_\_\_\_ (date) at \_\_\_\_\_ (time).  
The information was presented in age-appropriate terms.

\_\_\_\_\_  
**Minor Subject’s Printed Name (8-13 years)**

\_\_\_\_\_  
**Minor Subject’s Date of Birth**

\_\_\_\_\_  
**Minor Subject’s Signature (8-13 years)**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Time**

**\* Please note that the parent/legal guardian must sign the consent signature page above.**

I hereby certify that I have discussed the research project with the minor subject and/or his/her parent/legal guardian. I have explained all the information contained in the informed consent document, including any risks that may be reasonably expected to occur. I further certify that the research subject was encouraged to ask questions and that all questions were answered.

\_\_\_\_\_  
**Printed Name of Person Obtaining Assent**

\_\_\_\_\_  
**Signature of Person Obtaining Assent**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Time**

**B. Assent Not Obtained, but Minor Subject was Enrolled:**

Assent of the minor subject was NOT obtained for the following reason:

\_\_\_\_\_  
**[Insert Preparation Date]**



## Assent Discussion for Subjects 8-13 Years of Age

---

- Minor is cognitively or emotionally unable to participate in an assent discussion (e.g., minor has either a psychiatric or developmental disorder; minor received narcotics within the last 4 hours; minor is sedated; etc.). *[delete if option does not apply to your study]*
- Minor refused to provide assent; however, the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the minor and is available only in the context of the research [45 CFR 46.408(a)]. *[delete if option does not apply to your study]*

### **C. Assent Was Obtained, but Minor Subject was Unable to Sign:**

- The minor assented to participation, but has an incapacity that prevents applying a signature (e.g., the subject's dominant hand is incapacitated, the subject is illiterate, etc.). The assenting subject's inability to sign the assent document has been duly noted in the research record.

## Assent Discussion for Adult Subjects

### A. Assent Obtained

The assent discussion was initiated on \_\_\_\_\_ (date) at \_\_\_\_\_ (time).

\_\_\_\_\_  
Adult Subject's Printed Name

\_\_\_\_\_  
Adult Subject's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

**\* Please note that the legally authorized representative(s) must sign the consent signature page above.**

I hereby certify that I have discussed the research project with the adult subject and/or his/her legally authorized representative(s). I have explained all the information contained in the informed consent document, including any risks that may be reasonably expected to occur. I further certify that the research subject was encouraged to ask questions and that all questions were answered.

\_\_\_\_\_  
Printed Name of Person Obtaining Assent

\_\_\_\_\_  
Signature of Person Obtaining Assent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

### B. Assent Not Obtained, but Adult Subject was Enrolled

Assent of the adult subject was NOT obtained for the following reason(s):

- Adult subject is cognitively or emotionally unable to participate in an assent discussion (e.g., subject has a psychiatric, medical, or developmental disorder; subject received narcotics within the last 4 hours; subject is sedated; etc.). *[delete if option does not apply to your study]*
- Adult subject refused to provide assent; however, the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the adult subject and is available only in the context of the research. *[delete if option does not apply to your study]*

### C. Assent Was Obtained, but Adult Subject was Unable to Sign:

- The subject assented to participation, but has an incapacity that prevents applying a signature (e.g., the subject's dominant hand is incapacitated, the subject is illiterate, etc.). The assenting subject's inability to sign the assent document has been duly noted in the research record.

\_\_\_\_\_  
*[Insert Preparation Date]*