INFORMED CONSENT DOCUMENT FOR TREATMENT WITH AN

INVESTIGATIONAL DEVICE

TITLE:

**The purpose of this form is to explain your options for treatment with an investigational device. Investigational means that the U.S. Food and Drug Administration (FDA) has not yet approved the device.**

**Although clinical studies to determine if the device is safe and effective may be happening, you will be given this device to treat your condition and will not be part of a clinical study. This type of use of an investigational device is known as a Compassionate Use.**

**[Include the following language if consent with an LAR is required]**

If you are the legally authorized representative providing consent the word “you” in this document refers to the person you represent.

This consent form describes the treatment and helps you decide if you want to receive the treatment. It provides important information about what you will be asked to do during the treatment, about the risks and benefits of the treatment, and about your rights.

### **WHAT IS THE PURPOSE OF THIS TREATMENT?**

The purpose of this treatment is **[insert the purpose].**

### **WHAT WILL HAPPEN DURING THIS TREATMENT?**

**[Describe what will happen during the treatment to include the treatment component, any necessary procedures and a description of the device.]**

### **HOW LONG WILL THE TREATMENT LAST?**

If you agree to take part in this treatment, your involvement will last for **[insert expected length of treatment].**

### **WHAT ARE THE RISKS OF THIS TREATMENT?**

You may experience one or more of the risks indicated below from this treatment. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with this treatment.

**[If death is a foreseeable outcome to the risks of the treatment, include this statement]**

Some risks described in this consent document, if severe, may cause death.

**[Format the risks either as a bulleted list or in table format as provided on the following pages. REMOVE any section where there are no risks in that category.]**

### **[Bulleted list format for physical risks:**

### **Describe the condition/disease/indication in which these risks were experienced if different from the condition/disease/indication of this treatment.]**

### **Likely / Common**

Life Threatening

* Risk 1
* Risk 2

Serious

* Risk 1
* Risk 2

Mild

* Risk 1
* Risk 2

**Less Likely / Less Common**

Life Threatening

* Risk 1
* Risk 2

Serious

* Risk 1
* Risk 2

Mild

* Risk 1
* Risk 2

**Rare**

Life Threatening

* Risk 1
* Risk 2

Serious

* Risk 1
* Risk 2

Mild

* Risk 1
* Risk 2

### **[Table format for physical risks:**

### **Describe the condition/disease/indication in which these risks were experienced if different from the condition/disease/indication of this treatment.]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Frequency of Risks** |  | **Mild**  | **Serious**  | **Life-Threatening** |
| **Likely\Common** | * Risk 1
* Risk 2
 | * Risk 1
* Risk 2
 | * Risk 1
* Risk 2
 |
| **Less Likely\Less Common** | * Risk 1
* Risk 2
 | * Risk 1
* Risk 2
 | * Risk 1
* Risk 2
 |
| **RARE** | * Risk 1
* Risk 2
 | * Risk 1
* Risk 2
 | * Risk 1
* Risk 2
 |

**[If the treatment or procedure may involve risks to the individual (or to the embryo or fetus, if the individual is or may become pregnant) which are currently unforeseeable, insert the following language]**

**[Women Capable of Becoming Pregnant]**

If you become pregnant, there may be unknown risks to your unborn child, or risks to your unborn child that we did not anticipate. There may be long-term effects of the treatment that could increase the risk of harm to an unborn child. You must tell the doctor if your birth control method fails while you are receiving the treatment. If you believe or know you have become pregnant while receiving the treatment, please contact the clinician identified at the top of this document as soon as possible. Please discuss with the treatment team how long you need to wait before becoming pregnant after completing the treatment or procedures.

**[Sexually Active Male]**

If you are a sexually active male it is important that you not impregnate anyone or donate sperm during your treatment. There may be unknown risks to the unborn child or risks we did not anticipate. If pregnancy is a possibility, you must agree to use birth control during your treatment. If you believe or know that you have impregnated anyone, donated sperm or otherwise fathered a child, please contact the clinician identified at the top of the document as soon as possible.

### **WHAT ARE THE BENEFITS OF THIS TREATMENT?**

This treatment may benefit you because [insert reason].

### **WHAT OTHER TREATMENT OPTIONS ARE THERE?**

Before you decide whether or not to participate in this treatment, your doctor will discuss the other options that are available to you. Instead of participating in this treatment, you could **[insert other alternatives, if any]**

**[If there are no alternatives state:]**

There are no other treatment options.

### **WILL IT COST ME ANYTHING TO PARTICIPATE IN THIS TREATMENT?**

Your insurance plan may or may not pay for treatment with this **[insert device name]**. You should check with your specific insurance plan in advance to find out what costs it will pay. If your insurance plan does not pay for this treatment, you will be billed for the cost of the **[insert device name**] and all related doctor and hospital costs.

### **WHAT IF I AM INJURED AS A RESULT OF THIS TREATMENT?**

Washington University investigators and staff will try to reduce, control, and treat any complications from this treatment. If you feel you are injured because of the treatment, please contact the doctor **[insert doctor contact number]** and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your treatment will be made by Washington University and **[insert Industry Sponsor’s name if applicable].** If you need to seek medical care for an injury, please notify your doctor as soon as possible.

### **HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?**

Other people such as those indicated below may become aware of your participation in this treatment and may inspect and copy records pertaining to this treatment. Some of these records could contain information that personally identifies you. We will keep your participation in this treatment confidential to the extent permitted by law.

* Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
* The U.S. Food and Drug Administration
* **[If the treatment is sponsored add the sponsor (give company name) or funding source]**
* **[If applicable add: The sponsor (give company name) may also inspect any part of your medical record for the purposes of auditing the conduct of the treatment.]**
* **[If applicable add: Your primary care physician if a medical condition that needs urgent attention is discovered]**
* **[If applicable add: Public health agencies to complete public health reporting requirements]**
* Hospital or University representatives, to complete Hospital or University responsibilities
* Information about your participation in this treatment may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
* The last four digits of your social security number may be used in hospital or University systems to track billing information for treatment procedures.
* Washington University’s Institutional Review Board (a committee that oversees the conduct of research involving human participants and the use of investigational drugs or devices for treatment purposes.)
* **[indicate other entities with whom PHI may be shared and the purpose of sharing,]**

**[If the consent form will go in the medical record include the following:]**

This consent form or similar documentation that you are receiving this treatment will be included in your medical record. Anyone with access to your medical record, including your health insurance company will be able to see that you are receiving this treatment.

### **IS RECEIVING THIS TREATMENT VOLUNTARY?**

Your decision to receive this treatment is completely voluntary. You may choose not to receive this treatment. If you decide to receive this treatment, you may stop treatment at any time. If you decide not to take part in this treatment, or if you want to stop treatment at any time, you won’t be penalized or lose any benefits for which you otherwise qualify.

You may withdraw by telling the treatment team you are no longer interested in receiving in this treatment. Ending the treatment early may cause you to experience the following harms or discomforts: **[Describe any adverse consequences of a patient’s decision to withdraw from treatment]**

**[Include the following if there are procedures for orderly termination of treatment by the patient:]**

If you decide to end the treatment early, we will ask you to **[describe procedures for withdrawing, such as coming to a final visit, and what that visit involves.]**

Under certain circumstances, the doctors might decide to end your treatment earlier than planned. This might happen because **[describe why the treatment might be ended e.g., because in our judgment it would not be safe for you to continue, because your condition has become worse, because you are or became pregnant, etc.]**.

### **Will I receive new information about the treatment while participating?**

If we obtain any new information during this treatment that might affect your willingness to continue receiving the treatment, we’ll promptly provide you with that information.

### **WHAT IF I HAVE QUESTIONS?**

We encourage you to ask questions. If you have any questions about the treatment itself, please contact: **[name(s), phone number(s)].** If you experience a treatment-related injury, please contact: **[name(s), phone number(s)]**.

If you have questions, concerns, or complaints about your treatment with the investigational drug please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu.

This consent form is not a contract. It is a written explanation of what will happen during the treatment if you decide to participate. You are not waiving any legal rights by agreeing to participate in this treatment. As a participant you have rights and responsibilities as described in this document and including:

* To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the treatment team or others.
* To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
* To follow the procedures described in this document and the instructions of the treatment team to the best of your ability unless you choose to stop your treatment.
* To give the treatment team accurate and complete information.
* To tell the treatment team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop treatment.

Your signature indicates that this treatment has been explained to you, that your questions have been answered, and that you agree to take part in this treatment. You will receive a signed and dated copy of this form.

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

(Signature of Patient) (Date)

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

(Patient’s name – printed)

**[Include when needed]**

Legally Authorized Representative’s Name and Relationship to Patient:

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

(Patient’s name printed)

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

(Signature of Legally Authorized Representative) (Date)

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

(Name of Legally Authorized Representative - printed) (Relationship to Patient– printed)

**Who should sign as the Legally Authorized Representative (LAR)?**

If the patient has a legal guardian or attorney-in-fact this individual must sign as the LAR.

If there is no legal guardian or attorney-in-fact the individuals listed below may sign in order of priority.

(1) Spouse unless the patient has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;

(2) Adult child;

(3) Parent;

(4) Brother or sister;

(5) Relative by blood or marriage.

### **Statement of Person Who Obtained Consent**

The information in this document has been discussed with the patient or, where appropriate, with the patient’s legally authorized representative. The patient has indicated that he or she understands the risks, benefits, and procedures involved with this treatment.

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

(Signature of Person who Obtained Consent) (Date)

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

(Name of Person who Obtained Consent - printed)