INFORMED CONSENT DOCUMENT FOR EMERGENCY USE WITH AN INVESTIGATIONAL DRUG OR DEVICE

TITLE:

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

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

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. By signing this form you are agreeing to undergo this treatment.

* If you have any questions about anything in this form, you should ask the doctor for more information.
* You may also wish to talk to your family or friends about this treatment.
* Do not agree to receive this treatment unless the doctor has answered your questions and you decide that you want to receive this treatment.

### **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 drug or 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 fetus, or risks to your fetus 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 **[name and phone number]** as soon as possible. Please discuss with the treatment team appropriate birth controls methods and how long you need to wait before becoming pregnant after completing the treatment.

**[Sexually Active Male]**

If you are a sexually active male it is important that your partner not become pregnant during your treatment. There may be unknown risks to the fetus or risks we did not anticipate. If you believe or know that your partner has become pregnant during your treatment please contact **[name and phone number]** 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?**

**[Choose one of the below options and delete the other option]:**

Your insurance plan may or may not pay for treatment with this **[insert drug or 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 drug or device name**] and all related doctor and hospital costs.

**OR**

You will be provided **[insert drug or device name]** at no cost. Your insurance plan may or may not pay for the other procedures you have performed because of the treatment. 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 the procedures, you will be billed for the cost of the 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 (314) 633-7400 or 1-(800)-438-0445.

Decisions about 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?**

We will keep your participation in this treatment confidential to the extent permitted by law. However, it is possible that 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.

* 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
* 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 ending treatment such as coming in for 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 or device please contact the Human Research Protection Office, 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, (314) 633-7400, or 1-(800)-438-0445 or email hrpo@wusm.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 receive this treatment.

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

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(Signature of Patient) (Date)

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(Patient’s name – printed)

Legally Authorized Representative’s Name and Relationship to Patient:

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

(Patient’s name printed)

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

(Signature of Legally Authorized Representative) (Date)

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(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.

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(Signature of Person who Obtained Consent) (Date)

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(Name of Person who Obtained Consent - printed)