**SAINT LOUIS UNIVERSITY**

**Emergency Use Consent Form**

|  |  |  |  |
| --- | --- | --- | --- |
| **Patient:** |  | **IRB#:** |  |
|  | *First Name / Last Name* |  | |
| **Physician** |  | **Physician**  **Contact Phone #** |  |
|  | *First Name / Last Name Credentials* |  | |

Consent for Emergency Treatment

The purpose of this form is to explain your treatment options with a (*medication/medical device*) called *(Drug/Device Name).* This product does not yet have approval from the United States Food and Drug Administration (FDA) for this medical use. Because of this, it is referred to as “investigational”.

This consent document may contain words that you do not understand. Please ask the doctor to explain anything that you do not understand.

1. **PURPOSE AND BACKGROUND:**

Your attending physician has determined that this *medication/medical device* may be of benefit for you. Usually, patients can only receive an *investigational drug/device* by participating in a research study. This option is not available to you. However, in an emergency, the FDA will sometimes allow patients to receive the investigational *drug/device* without having to be in a study. This type of treatment is called Emergency Use. If you sign this consent form, you will be given this *drug/device* to treat your condition.

It is important to know that this *medication/medical device* may not benefit you and could lead to bad results including death.

*(Add information on what the drug/device is used for and how it works.)*

1. **PROCEDURES:**

*Describe how and when drug/device will be given. Include follow up information if relevant.*

1. **RISKS:**

*Describe the risks associated with the drug/device and associated procedures.*

1. **BENEFITS:**

You may not benefit from being treated with *(Drug/Device Name*). Your condition may get better, stay the same, or worsen. It is possible that *(Drug/Device Name)* may reduce the disease in your body and improve any symptoms that you may have from your disease.

1. **ALTERNATIVE TREATMENT:**

You may choose not to accept this treatment. *(Please list any other options, such as continuing standard of care, or palliative care.)* You may discuss other options, if available, with your treating physician.

1. **PATIENT COSTS:**

*Please explain/ any costs and who is charged (e.g., insurance). Specify all costs to the patient.*

1. **CONFIDENTIALITY:**

The Saint Louis University Institutional Review Board (the Board that is responsible for protecting the welfare of persons receiving this emergency treatment) and other University officials may review your records. The FDA or *(Manufacturer)* (the maker of *Drug/Device Name*)may also review your medical record. State laws or court orders may also require that information from your records be released.

By signing this form, you authorize SLUCare and your attending physician to release medical information concerning your care, including copies of medical records and/or billing information pertaining to your medical care to individuals or representatives of agencies or organizations in connection with obtaining payment for medical services rendered to you by SLUCare and /or independent contractors engaged by them.

Saint Louis University (SLU) requires that private information about you be protected. This is especially true for your personal health information. Protected Health Information (PHI) is any health information that identifies you. To take part in this treatment, you must give permission to use and share your PHI. The treatment team will only use and/or share your information as listed below.

The PHI available for this treatment will include *your name, address and birth date with your medical history.*

The PHI will be *state the source(s) from which you are obtaining PHI and how the PHI will be obtained (e.g., recorded from your medical record).*

Your PHI will be maintained by *[list appropriate persons]* (the Saint Louis University treatment team) and they will only share the information as described below.

**SLU may use or share your health information with**:

* The SLU Institutional Review Board and other University personnel in order to provide oversight
* Federal or state government representatives, when required by law to review quality and safety, including: U.S. government agencies, such as the Food and Drug Administration.
* [Hospital or representatives (if applicable)] in order to provide oversight
* [List manufacturer/device provider.]

These organizations and their representatives may see your Personal Health Information. They may not copy or take it from your medical records unless permitted or required by law.

***[INSERT THE FOLLOWING PARAGRAPH IF APPLICABLE.]***

The manufacturer is not covered by HIPAA.  This means that the manufacturer does not have to follow the same rules to protect your privacy. SLU may send information to the manufacturer. This information could contain PHI such as your (list any identifiable information, or state “as listed above”).  In addition, the manufacturer or its agents may review your medical record in order to verify information that is provided to them.

SLU agrees to protect your health information by using and/or disclosing it only as you authorize. However, if your PHI is shared with someone outside of SLU and/or if you choose to share this information with others, your health information may no longer be protected by HIPAA.

Your permission to use and/or share your PHI does not have an expiration date.

**If you choose to sign this form:**

* You can change your mind and not allow SLU to use and/or share your PHI (revoke your authorization).
* If you revoke your authorization, you must send a written letter to: [insert Physician’s name and contact information] to inform him/her of your decision.
* If you revoke your authorization, SLU may only use and/or share your PHI **already** collected for this treatment.
* If you revoke your authorization, your PHI may still be used and/or shared should you have an adverse event (a bad effect).
* If you withdraw your authorization, you may not be allowed to continue in the treatment.

If you have questions or concerns regarding your privacy and the use of your personal health information, please contact the University Privacy Officer at (314) 977-5545.

You will also be given a copy of the [Notice of Privacy Practices](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/slu_notice_of_privacy_practices.pdf) (a separate document).

1. **TREATMENT RELATED INJURY:**

If you believe that you are injured as a result of your participation in this treatment, please contact the doctor and/or the Chairperson of the Institutional Review Board as stated in section 10.

You will receive necessary medical care in the event that an injury results because of your participation in this treatment. The University will have the right to determine whether an injury is related to your participation in this treatment or happened because of your medical condition or other reasons which are not related to this treatment. If the injury is due to participation in the treatment, you will not have to pay for the cost of necessary medical care unless your injury is due to your own failure to follow the doctor’s instructions. There are no plans for Saint Louis University to pay for the costs of any additional care. You have not waived your legal rights by signing this form. If you have questions, please call the Saint Louis University General Counsel's office at [314-977-5767](tel:314-977-5767).

1. **NEW INFORMATION:**

You will be informed if any new information about this *drug/device* becomes available during your treatment which may cause you to change your mind about continuing the treatment.

1. **CONTACTS:**

If you have any questions or concerns or if you have any problems that occur from taking *(Drug/Device Name)* you may call Dr. *(Physician Name)* at *(Phone Number)* or call *(Alternate Contact Number)* and ask to speak with *(Alternate Contact).*

If you have any questions about your rights or in the event you believe you have suffered an injury as a result of the treatment, you may contact the Chairperson of the Saint Louis University Institutional Review Board (314-977-7744), who will discuss your questions with you or will be able to refer you to an individual who will review the matter with you, identify other resources that may be available to you, and provide further information as how to proceed.

1. **VOLUNTARY PARTICIPATION:**

Your participation in this treatment is voluntary and refusal to participate will involve no penalty to you or loss of any benefits to which you are otherwise entitled. You may withdraw at any time without penalty or loss of those benefits.

I have read this consent document and have been able to ask questions and state any concerns. I believe I understand the potential benefits and risks that are involved.

1. **STATEMENT OF CONSENT:**

I give my informed and voluntary consent. I will be given a copy of this consent document for my records.

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

Consent Signature of Patient (18 and over) Date

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

Print Name of Patient

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

## *Signature of Parent/Guardian/Legal Representative Date*

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

## *Description of Relationship to Patient*

**I certify that I have explained to the above individual the possible benefit and risks associated with treatment. I have answered any questions that have been raised and the patient has received a copy of this signed consent document.**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Signature of Person Obtaining Consent** | **Date** |
|  | | |
|  |
| *First Name / Last Name Credentials* |
| **Printed Name of Person Obtaining Consent** |