**Project Title:**

**Sponsor:**

**Principal Investigator:**

**Information about Expanded Access Treatments**

We have determined that you have [Name of Disease/Condition], which is a [life-threatening /severely debilitating] [Disease/Condition]. We believe that [Name of Drug/Device] may help you. There is currently no other approved and common treatment that we believe would be as helpful. The approved and commonly used treatments are unlikely to [prolong your life/prevent severe debilitation].

[Drug/Device] is an investigational agent. An investigational agent is one that researchers are still studying to find out whether it’s safe and effective. Because this [Drug/Device] is investigational, the Food and Drug Administration (FDA) has not yet approved it for general use.

The purpose of this form is to help you understand how [Name of Drug/Device] works and to give you an opportunity to decide whether you want us to use it to treat you. We may also give you information from the company that supplies the [Drug/Device].

**If applicable, insert:** “The principal investigator (and/or members of the research team) has a conflict of interest involving [describe the conflict].

**If applicable** **insert**: [Saint Luke’s Health System] has an institutional conflict involving [describe the conflict, e.g., owns shares in the company that makes [Name of Drug/Device] and may profit from its use.]

Before you sign this form, be sure you understand how [Name of Drug/Device] relates to your condition, as well as the risks and possible benefits of using it.

**Information about treatment**

Name of Doctor Providing Treatment with the investigational product:[Name of Treating Physician]

Name of the investigational product:

[The drug/device must be clearly identified so that it cannot be confused with another drug/device, either FDA-approved or still under investigation.]

**Why is this** [Drug/Device] **being recommended?**

[Name of Drug/Device] works by [Describe what the drug/device does and why it is thought that it will work for this patient].

**What is usually done for patients who have this type of disease or condition?**

Currently approved products used in treating [Name of condition] include [List and give a brief description of standard products/treatments]. We will be glad to talk to you about your other treatment options.

**Costs associated with this treatment**

[For an investigational product where the patient will be responsible for all costs. **Note:** Charging the patient requires prior FDA approval.]

You or your insurance company will be responsible for the cost of all care associated with the procedures and the [Drug/Device] itself. This includes the cost of treatment if the [Drug/Device] makes you sick or causes you injury. It is possible that your insurance company will not pay for the cost of the [Insert as applicable: drug, device, procedure associated with use of the drug/device, implantation of the device, etc.] because the [Drug/Device] is considered investigational. If that occurs, you will be responsible for all cost, some of which could be substantial.

**Or**

[For an investigational drug or device if the sponsor is providing free drug/device]

The [Drug/Device] will be provided to you at no cost. You or your insurance company will be responsible for the remaining costs related to this treatment, including the cost of treatment if the [Drug/Device] makes you sick or causes you injury. You will be responsible for any costs your insurance does not cover. Please note that your insurance is not obligated to pay for any care or treatments consequent to the use of [Drug/Device], unless it is specifically required to do so by law or contract. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company.

**Or**

***Note:*** The following option will apply only in rare cases. For an investigational drug or device when the sponsor will cover costs of both the drug/device and the treatment of drug/device-related injury or illness; such instances are uncommon and involve additional agreements between the sponsor and the grants and contracts office

If you become ill or are physically injured as a result of participation in this study, you should seek prompt medical attention. You may seek treatment at any medical facility. You should also contact the Study Doctor or the Research Nurses at (phone number)*.*

If any injury or illness happens to you as a direct result of being in this study, the sponsor of this study will provide medical treatment at no cost to you. Treatment may include hospitalization, first aid, emergency care and follow-up care, as needed. Payments will not be offered for other expenses (such as time off work, lost wages, childcare, etc.)

In no way does signing this consent form waive your legal rights nor does it relieve the Study personnel, Sponsor or involved institutions from their legal and professional responsibilities.

Use this for Greenphire payment cards

You will receive ($$$$) per visit for being in the study. The money is to help with the cost of transportation and other expenses due to participation.

You will be given a ClinCard, which works like a debit care. After a study visit, payment will be added onto your card by computer. The money will be available within one business day. You can use this ClinCard at an ATM or at a store. No one at Saint Luke’s Health System will know where you spent the money.

You will be given one card during the study. If your care is lost or stolen, please call the study team for information on how to obtain a new care.

The Office of Research Services (ORS) will be given your name, address, social security number, and the titles of this study to allow them to set you in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are &600 or more in a calendar year.

Your personnel information will be kept one a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

*Optional Text Messaging Service: This message service is provided by Greenphire. Not required, this would be up to the study team to decide if they wish to offer such to their subjects.*

You can choose to sign up for emails or text messages about the study. The messages will remind you about your study appointments and give you other information that might be helpful during the study. (You will pay your standard texting rate.) This message service is optional. You are not required to give your cell phone or email address in order to be in the study. If you decide to receive messages when the study starts, you can still change your mind later.

CLINCARD   
I want to receive visit reminders by (check one):

Email\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (your email)

Text message\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (your cell phone number)

Not at all

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

(Clinic ID Number)

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

(Date / Time)

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(Printed Name of Individual Obtaining Consent)

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(Signature of Individual Obtaining Consent)

**How information about you will be shared**

If you give us permission to use [Drug/Device], we will give the following information about you to [Company name], which is the manufacturer or supplier of the [Drug/Device]:

[Specify what information will be given to the company]

We may also supply the [Saint Luke’s Health System]’s Institutional Review Board with the following information:

* Any problems that occur when you are treated with this [Drug/Device].
* [Any other information that applies]

Organizational, Food and Drug Administration (FDA), and/or other government officials may also need the information to make sure that the [Drug/Device] is used in a safe and proper manner.

For more information about our use and disclosure of protected health information, please refer to the [Saint Luke’s Health System]’s Notice of Privacy Practices. This notice should already have been made available to you and you may also find this notice online, at [Web address]

**Risks and Benefits**

**What are the risks of being treated with this [Drug/Device]?**

[This section must include the potential and known side effects of the treatment.]

It is also possible that new, unanticipated, different or worse symptoms will result from using this [Drug/Device]. Use of [Drug/Device] can also hasten death.

**What are the possible benefits of being treated with this [DRUG/DEVICE]?**

[This section must include the potential best outcome of the treatment]

**What is the most likely outcome of being treated with this [DRUG/DEVICE]?**

[This his description should be based on the physician’s knowledge of the proposed treatment, in conjunction with an awareness of the patient’s condition.]

Add if applicable**:** If you begin curative treatment with this [Drug/Device], you may no longer be eligible for hospice care. You may be able to receive hospice care again after you have ended the treatment with [Drug/Device] and meet hospice eligibility requirements.

You are free to stop the using this [Drug/Device] at any time, and your treatment with it is voluntary. Before stopping, you should discuss your choice with your doctor, as stopping its use may pose additional risks to you that your doctor may need to manage. If you stop treatment before it is finished, there will be no penalty or loss of benefits to which you may otherwise be entitled. If you decide to stop treatment before it is finished, please tell one of the doctor persons listed below.

**Who can I contact about this treatment?**

Please contact the doctor listed below to:

* Obtain more information about the [Drug/Device]
* Ask a question about the [Drug/Device]
* Talk about treatment-related costs to you or your health plan
* Report an illness, injury, or other problem (you may also need to tell your other doctors)
* Stop the treatment before it is finished
* Express a concern

Doctor Overseeing Treatment: [Treating physician’s name]  
Mailing Address: [Treating physician’s address]  
Telephone: [Treating physician’s telephone number]

You may also express a concern about this use of the investigational [Drug/Device] or a violation of your privacy by contacting the Institutional Review Board listed below:

Saint Luke’s Health System Institutional Review Board

4401 Wornall Road, Kansas City, MO 64111

816-932-5019

[IRB@saint-lukes.org](mailto:IRB@saint-lukes.org)

When you call or write about a concern, please provide as much information as possible, including the name of the doctor providing treatment with the [Drug/Device] and details about the problem. This will help officials at Saint Luke’s Health System look into your concern.

**What documents will I receive?**

You will receive a copy of this consent form (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential file and may be entered into your regular Saint Luke’s Health System medical record.)*

If applicable, add the name of additional documents the patient will receive.

**Consent to Treatment**

* You have discussed used of this [Drug/Device] with your doctor.
* You have been told about the risks and potential benefits of [taking this drug/having this device implanted] and my alternatives to use of [Drug/Device].
* You have been told that approved and commonly used treatments for your [Name of condition] are unlikely to be as helpful as [Drug/Device] are unlikely to prolong your life.
* You have been told that the [Drug/Device] is not yet approved by the FDA.
* You have been told who to contact if you have any questions or if the [Drug/Device] makes you sick or causes you injury.
* You have been told that you, your insurance company or your estate will be responsible for the costs of treatment unless [Company/Manufacturer] agree by contract to cover the costs.

I agree to treatment with [Drug/Device].

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Name of Patient (and LAR, if applicable) Date

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Signature of Patient or LAR

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Name of Physician or designee Date

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Signature pf physician or designee