**INFORMED CONSENT FORM FOR INVESTIGATIONAL TREATMENT**

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| --- | --- |
| **INVESTIGATIONAL TREATMENT** |  |
| **Protocol No.:** |  |
| **drug supplier:** |  |
| **Investigator/TREATING PHYSICIAN:** | [Investigator's name and professional title]  [Investigator's department]  Miami, Florida 33136  United States |
| **RELATED PHONE NUMBER:** | [Investigator's name and professional title]  305-243-XXXX (Office)  305-243-XXXX (24-Hour) |

# KEY INFORMATION ABOUT THIS EXPANDED ACCESS PROGRAM TREATMENT

In this document, "you" refers to the patient. If you are someone who will provide consent on behalf of the patient, remember that "you" refers to the patient.

The purpose of this paper is to obtain your consent to receive an experimental treatment for your (disease/condition). Please read this document and ask any questions you may have about continuing the treatment.

## Voluntary Participation

You do not have to receive this experimental treatment. You may choose not to receive this treatment, and you may decide to stop the treatment at any time without penalty or loss of any benefits. Your decision will not affect your relationship with the hospital staff or your doctor.

## Background *(Include if IRB approval will not be obtained prior to treatment)*

The U.S. Food and Drug Administration (FDA) provides pathways for patients to gain **access** to investigational medical products used to diagnose, monitor, or treat patients with serious diseases or conditions when there are no equal or acceptable treatment options available outside of a clinical trial. One pathway is called emergency use, and the other path is called compassionate use. The difference between these pathways is that a group of people have reviewed and approved the use of the medical product. This group of people is called an Institutional Review Board (IRB). Patients who receive experimental treatment without IRB review receive the treatment under emergency use. You are receiving this treatment under emergency use because there was no time for the IRB to review and decide whether the potential benefit of receiving this treatment is greater than the potential risk.

We ask you to consent to receive this experimental treatment because you have [insert indication], and there are no other options for you that are at least equal to the experimental treatment. There is evidence that you may benefit from treatment with the investigational product called [insert drug]. Investigational means that the FDA has not approved this [insert drug] for your condition. This treatment may work by [insert mechanism of action in lay terms].

## Reasons for Participation

Here are some reasons you may want to receive this experimental treatment:

* The treatment may [insert how treatment may help patient]

Here are some reasons you may not want to receive this treatment:

* The possible side effects you may experience, which are described in greater detail later in this document.

# WHAT IF I HAVE QUESTIONS?

If you have questions, concerns, or complaints, or think the investigational treatment has hurt you, talk to your doctor at 305-243-XXXX (Office) or 305-243-1000 (24-Hour).

The Human Subject Research Office (HSRO)provides administrative support to the University of Miami's IRBs.

Please call the HSRO at 305-243-3195 if:

* The treatment team has not answered your questions, concerns, or complaints.
* You cannot reach the treatment team.
* You want to talk to someone besides the treatment team.
* You have questions about your rights as a patient
* You want to get information or provide input about this experimental treatment.

# WHAT WILL I HAVE TO DO?

## Screening Assessments

Before you begin the treatment, you will need to complete the following tests or procedures to find out if there is a reason you should not receive the experimental treatment. Here is a list of the tests and procedures: [describe procedures and timeframe]

## Description of Treatment

If the tests show that you can receive the treatment, your doctor and treatment team will: [describe procedures and timeframe]

When you stop receiving the treatment, the doctor and treatment team will: [describe procedures and timeframe]

# CAN I STOP THE TREATMENT?

Yes, you can stop receiving the treatment at any time. Tell your doctor if you are thinking about stopping or decide to quit. Your doctor will tell you how to stop safely.

# COULD THIS TREATMENT BE STOPPED UNEXPECTEDLY?

Your doctor may stop this treatment at any time, even if you want to continue, for reasons that include but are not limited to the following:

* Your safety would be at risk if you continued in the program
* You failed to follow instructions or procedures adequately
* The treatment has been canceled for any reason.

The company providing the investigational product and your treating physician are not obligated to provide you with the investigational treatment after your treatment has ended or has been stopped.

# WHAT ARE THE ALTERNATIVES TO THIS TREATMENT?

You do not have to receive this treatment. Your other choices may include getting comfort care. This type of care helps reduce pain, tiredness, appetite problems, and other problems caused by your condition. It does not treat the condition directly.

Your doctor believes that there is no other existing treatment or clinical trial, or you are not eligible for a clinical trial that might help.

# WHAT ARE THE POSSIBLE BENEFITS OF RECEIVING THIS TREATMENT?

We cannot promise that this treatment will benefit you. The goal of this treatment is to treat your [insert indication, treatment and how it may benefit patient]

# WHAT ARE THE POSSIBLE RISKS TO ME IF I CHOOSE TO RECEIVE THIS TREATMENT?

Your treating physician shall share all known possible side effects of treatment and from potential tests done during the expanded access treatment with you.

The list below summarizes the side effects:

[Insert side effects as provided by the pharmaceutical company]

# POTENTIAL SIDE EFFECTS OF OTHER PROCEDURES (delete the procedures that are not applicable)

**Allergic reaction:** As with any drug, you could experience an allergic reaction to *[drug]*. Such allergic reactions include itching, skin rash, a sudden drop in blood pressure, loss of consciousness and/or associated with seizures, including the possibility of death.

**Blood draw risks:** Drawing blood may cause temporary pain from the needle stick, bruising or swelling at the site, and rarely, infection or fainting.

**Bone marrow aspirate:** The risks of a bone marrow aspirate include the following: temporary discomfort and/or bruising at the site of puncture, fainting, and rarely, infection or a small clot or swelling in the area of the puncture.

**Catheter:** Part of this treatment involves having a catheter (thin tube) inserted into one of your blood vessels. There may be slight discomfort during the inserting of the catheters into the vein or artery. Occasionally, a bruise or small lump may form at the point of insertion of the catheter. A small amount of bleeding may occur around the catheter site. Rarely, a local infection may occur around the catheter site. *[Include the following for arterial catherization]* Very rarely, an arterial catheter may cause reduced circulation requiring immediate surgery to re-open the artery. This complication is more likely when the catheter remains in the artery for long periods.

**CT (Computed Tomography) scan risks:** You will have one or more medical imaging studies which use radiation. The tests or treatments include a whole body CT scan. To give you an idea about how much radiation you will get, we will make a comparison with an everyday situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. This treatment gives your body the equivalent of about 3 extra years' worth of this natural radiation. The radiation dose we have discussed is what you will receive from this treatment only and does not include any exposure you may have received, or will receive, from other tests.

In addition, if contrast material (iodine dye) is used, there is a slight risk of developing an allergic reaction, which may cause symptoms ranging from mild itching, or a rash, to severe difficulty breathing, shock, or rarely, death. The contrast material may also cause kidney problems, especially if you are dehydrated or have poor kidney function. The doctors will ask you about any allergies or related conditions before the procedure. If you have any of these problems, you may not be allowed to have a CT scan receive the investigational treatment.

**Drowsiness:** Because the treatment may produce drowsiness in some patients, you should not operate heavy machinery, including driving a car as instructed by your doctor.

**Electrocardiogram (ECG):** This is a painless test that records the heart's electrical activity. The test involves attaching soft, sticky patches to the skin of your chest, arms, and legs. After you complete the test and we remove the sticky patches, you may have some skin irritation from the patches, but this irritation typically goes away on its own

**Exercise testing risks:** The exercise test(s) may cause muscle soreness, dizziness, or shortness of breath. In rare instances, exercise tests may cause chest pain, tightness, or a change in vital signs.

**Fluorescein Angiography:** This procedure injects a fluorescent dye into the bloodstream to highlight the blood vessels in the back of the eye to photograph them. Adverse reactions to the dye are uncommon but may include the following: nausea, headache, upset stomach, vomiting, light-headedness, fainting, hives, or leakage of the dye out of the blood vessel. Very rarely, 1 in 220,000, a sudden life-threatening allergic reaction can occur. Such sudden but rare reactions include breathing difficulties, shock, convulsions, or abrupt heart function loss. These conditions require emergency medical treatment.

**Hypoglycemia:** This medication could lower your blood sugar too much (hypoglycemia). Low blood sugar could make you feel tired, dizzy, sweaty, and/or nauseous. Also, it could cause your heart to feel as if it is racing. There may also be other effects. Untreated hypoglycemia could cause convulsions, loss of consciousness and can lead to death.

**Clinical MRI (Magnetic Resonance Imaging) risks:** The MRI procedure uses a powerful magnetic field to generate detailed body images. The magnet could move objects within your body that contain metal, such as implants, clips, and pacemakers. Tell the doctor if you have or may have any metal items within your body.

MRI scanning is painless, but you might experience discomfort in the machine. In particular, loud beeping and hammering noises occur during the study when the scanner is collecting measurements. You may also be bothered by claustrophobic feelings when placed inside the MRI scanner or lying in one position for a long time. You might also experience stimulation of your body's nerves, which feels like a gentle tap or sensation of mild electric shock. *[If appropriate, also discuss the risks of sedation here.]*

**Injection of Gadolinium during Clinical MRI:** The study team will inject Gadolinium, a substance given during the MRI examination, into a vein in your arm. This injection may cause some minor pain and may cause some bruising near the area of injection. Gadolinium may also cause headaches, nausea, and vomiting. Rarely, it may cause dizziness, rash, itching, or a numb or tingling feeling in the hands or feet, or an allergic reaction. Medical personnel will be available to treat any of these problems if they should occur.

**Nephrogenic Systemic Fibrosis Risk Associated with Gadolinium:** Some people who have had MRIs with gadolinium-based contrast agent gadodiamide have experienced a serious reaction called nephrogenic systemic fibrosis (NSF). NSF is a condition where people develop large areas of hardened skin with lesions called plaques and papules with or without skin discoloration. In some cases, NSF could lead to physical disability and may involve the skin and the liver, lungs, muscles, and heart. The typical patient in whom this has occurred is middle-aged and has end-stage kidney disease.

**Potential Risks of Neuronal Tissue and Bone Deposition of Gadolinium:** Recent studies have shown that small amounts of Gadolinium may be deposited in your neuronal tissue (brain, spinal cord, and nerves) and bones. This deposit appears to accumulate over your lifetime and happens without associated renal (kidney) or hepatobiliary (liver and gallbladder) problems. Neuronal and bone tissue deposits appear to occur in all patients exposed to Gadolinium and can be found in people after as few as four doses. The importance of these findings is not entirely understood. No long-term effects have yet been seen but may be found in the future.

**MUGA (Multiple Gated Acquisition) scan:** You will have one or more medical imaging studies that use radiation. The tests or treatments you will have include a MUGA scan. To give you an idea about how much radiation you will get, we will compare it with an everyday situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space, and some from naturally-occurring radioactive forms of water and minerals. This treatment gives your body the equivalent of about 2 extra years' worth of this natural radiation. The radiation dose we have discussed is what you will receive from this scan only and does not include any exposure you may have received or will receive from other tests.

**PET (Positron Emission Tomography) scan risks:** You will have one or more medical imaging studies that use radiation. The tests or treatments you will have include a PET FDG scan. To give you an idea about how much radiation you will get, we will make a comparison with an everyday situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space, and some from naturally-occurring radioactive forms of water and minerals. Undergoing the PET scan gives your body the equivalent of about 6 extra years' worth of this natural radiation. We have discussed the radiation dose you will receive from this scan , and this discussion does not include any other exposure you may have received or will receive from other tests.

**Psychological risks:** Some of the questions the treatment team ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.

**Radiation Exposure Risks:** You are exposed to radiation on a daily basis, both from natural (sun and earth) and manmade sources. The estimated radiation dose that you will receive as a participant for this type of treatment has been compared to the limits allowed for a radiation worker. This limit is low and is not expected to be harmful. The person obtaining your consent can answer any questions you have, and provide detailed written information about the amount of radiation resulting from this treatment.

**Unknown Risks:** The experimental drug may have side effects that no one knows about yet. You doctor will let you know if they learn anything that might make you change your mind about receiving the experimental treatment.

# PROHIBITED THERAPIES

Talk to your doctor about therapies you should avoid while you are receiving the expanded access treatment.

# WHAT ABOUT BIRTH CONTROL?

[Insert language provided by pharmaceutical company as applicable]

**Contraception Requirements for Women**

The investigational drug may be absorbed into bodily secretions such as vaginal fluids and then passed on to your partner during sex. Your male sexual partner must wear a condom to avoid exposure to the drug.

The drug may harm a fetus or a breastfeeding baby.

If you are pregnant or breastfeeding, you cannot receive the treatment.

If you can become pregnant, you must have a pregnancy test before you begin this treatment.

You must not get pregnant or breastfeed during treatment and for at least [insert time] after stopping the investigational drug.

You must not donate eggs while receiving this treatment and at least [insert time] after the last dose of the investigational product.

If you are a woman who can become pregnant, you must take measures to avoid becoming pregnant while you are receiving this treatment.

The following are acceptable measures to avoid becoming pregnant:

* Abstinence (not having sexual relations with a person of the opposite sex)
* Implantable hormone (e.g. Norplant)
* Intrauterine Device (IUD)
* Male partner has had a vasectomy
* Female sterilization
* Hormonal injection
* Oral contraceptives
* GnRH Agonists (zoladex, triptorelin, leuprolide)-these agents are only effective if they have been in continuous use for at least 3 months [this option is only to be included when applicable, ie hormone-sensitive breast cancer patients]

You must use contraception, at least starting at screening, before starting the expanded access treatment unless you abstain from sexual intercourse. You must use contraception during treatment and at least [insert time] after stopping the investigational drug.

**Contraception Requirements for Men**

The investigational drug may be absorbed into bodily secretions such as semen and then passed on to your partner during sex. To avoid exposure to the drug, you must wear a condom..

There may be risks to the embryo/fetus if your sexual partner is pregnant or becomes pregnant while receiving this treatment. If your partner is a woman of childbearing potential, you and your partner must either practice total abstinence or use effective contraception while receiving the investigational treatment. You or your partner must use one of the following forms of contraception:

* Abstinence (not having sexual relations with a person of the opposite sex)
* Implantable hormone (e.g. Norplant)
* Intrauterine Device (IUD)
* Vasectomy
* Female sterilization
* Hormonal injection
* Oral contraceptives

You must use contraception during treatment and for at least [insert time] after stopping the investigational drug. You should also refrain from donating semen during therapy and for [insert time] after stopping the investigational drug.

There is a theoretical concern that the treatment can result in sperm abnormalities and/or can transmit harmful substances in their semen during sex. Therefore, if you are a male, you must abstain from sex or use a condom, even if you have undergone a vasectomy.

If your partner becomes pregnant or suspects becoming pregnant during treatment and for at least [insert time] after stopping the investigational drug, you must inform your doctor immediately. Your doctor may want to follow the pregnancy and may ask your partner to sign a consent form so they can collect information about the outcome of the pregnancy.

# WHAT IF NEW INFORMATION BECOMES AVAILABLE?

## We will tell you if we have any new information that may affect your willingness to continue the expanded access treatment.

# COMPENSATION FOR INJURY

If you are hurt or get sick as a result of receiving the investigational product, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages, and other damages caused by injury are not available. [Pharmaceutical company] will not pay any money to you or your medical bills. If you sign this consent form, you do not give up any of your rights to seek compensation for injury.

# WILL I BE PAID IF I TAKE PART IN THE EXPANDED ACCESS TREATMENT?

You will not be paid for taking part in this expanded access treatment or pay for any out of pocket expenses related to receiving this treatment, such as travel costs.

# WILL IT COST ME ANYTHING TO BE IN THE EXPANDED ACCESS TREATMENT?

[Pharmaceutical company] will provide [insert investigational drug] free of charge while you are participating in this expanded access treatment. You or your insurance will be responsible for the medical costs of treatments and procedures that would be done as part of your regular medical care. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Your doctor or your doctor's staff can check with your health plan to find out what they will pay for.

# WHAT HAPPENS TO THE INFORMATION COLLECTED FOR THE TREATMENT?

We will do our best to limit the use or disclosure of your personal information, including information from this expanded access treatment and your medical records, to people who need to review this information. Records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you.

The following is a list of individuals who may access your records:

* The IRB.
* Personnel who schedule or perform medical tests or procedures, handle accounting and billing or do other tasks related to this treatment.
* U.S. Office for Human Research Protections
* The U.S. Food and Drug Administration (FDA)
* The drug supplier and its authorized agents

Include if HIV, hepatitis, or STD testing, mental health or substance abuse information: For this treatment, we must access and share information about you that is sensitive. The research team will share this information with the drug supplier and its authorized agents, and the other individuals listed above and below may see the information in your record. This information includes information about your HIV status, hepatitis B and/or C infections.

The study doctor and his/her collaborators will consider your records confidential as permitted by law. However, the following may review your records and the results of your HIV test:

* The drug supplier and its authorized agents
* The Food and Drug Administration (FDA);
* The Florida Department of Health (if you test positive);
* The Department of Health and Human Services (DHHS); and
* The University of Miami employees or other agents.

These individuals are bound by the same provisions of confidentiality.

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Anonymous testing for HIV is available at other locations throughout Dade County.  You can visit the following site, which lists the confidential and anonymous testing sites:

[http://miamidade.floridahealth.gov/programs-and-services/infectious-disease-services/hiv-aids-services/counseling-testing-sites.html](https://nam01.safelinks.protection.outlook.com/?url=http%3A%2F%2Fmiamidade.floridahealth.gov%2Fprograms-and-services%2Finfectious-disease-services%2Fhiv-aids-services%2Fcounseling-testing-sites.html&data=02%7C01%7Ccmg345%40med.miami.edu%7Cf0d56a1bb9cc408bc7e608d7d71c9342%7C2a144b72f23942d48c0e6f0f17c48e33%7C0%7C0%7C637214390034243850&sdata=eTGDgURO44ol45zXbUt1Sa%2FtNtRT0cpGVnuIBKmlYF4%3D&reserved=0)"

If we test you for HIV, hepatitis, and some sexually transmitted diseases, we will need to report positive results to the health department. By signing this consent document, you are agreeing to this use, access, and disclosure of your sensitive information.

**PARTICIPANT STATEMENT AND CONSENT**

I read the information above (or someone read the information above to me). I had the chance to ask questions, and I am comfortable with the answers I received. My signature below means that I understand the information and that I want to receive the investigational treatment.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Participant Signature |  | Date |
| Printed Name of Participant |  |  |

**PERSON OBTAINING CONSENT STATEMENT AND SIGNATURE**

I have personally explained the investigational treatment to the patient and answered all questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

|  |  |  |
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|  |  |  |
| Person Obtaining Consent Signature |  | Date |
|  |  |  |
| Printed Name of Person Obtaining Consent |  |  |

Witness STATEMENT AND Signature

A witness is only required if:

* The subject is unable to read the consent document;
* The subject is unable to sign the document due to physical limitations; and/or
* Consent is obtained using the short form process, and this consent document is the summary.

As an impartial third party, I witnessed the entire consent discussion. I attest that the above‑named participant received a verbal and written description of the investigational treatment. This individual had sufficient time to consider this information, had an opportunity to ask questions, and voluntarily agreed to receive the treatment.

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| Witness Signature |  | Date |
|  |  |  |
| Printed Name of Witness |  |  |

**Legally Authorized Representative or Parent Permission**

I have reviewed the information printed on this form and in any other provided materials. I have been given copies of all of these.

I read the information above (or someone read the information above to me). I had the chance to ask questions, and I am comfortable with the answers I received. My signature below means that I understand the information and that I want (Patient name ) to receive the investigational treatment. I understand that if I have more questions or concerns, I may contact one of the people listed in Section 11 of this document.

Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yyyy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to patient: Parent Spouse Child Sibling Legal guardian

Other

*If “Other,” explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

Reason patient is unable to consent:

Did the person obtaining consent explain the procedures to the patient in an understable manner and did the patient assent to the treatment? Yes No

If No, explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_