**Emory University**

**Consent and HIPAA authorization to Receive Treatment in an Expanded Access Program for Use of an Unapproved Drug/Device**

**Title**:

**IRB #:**

**Program Doctor:**

**Sponsor:**

**Investigator-Sponsor:**

If you are the legal guardian of a child who is being asked to participate, the term “you” refers to the child.

## Introduction

In the United States, the federal Food and Drug Administration (FDA) must approve drugs or devices that are sold to treat illnesses and conditions. In some cases, the FDA may permit a doctor to use a non-FDA approved drug or device to treat a patient.

You are being offered treatment with a drug/device that has not been approved by the FDA. This form is designed to tell you things you need to think about before you decide if you want to receive this treatment. **It is entirely your choice. If you decide to receive this treatment, you can change your mind later on and stop treatment.**  The decision to receive this treatment will not cause you to lose any medical benefits you have. If you decide not to take part in this program, your doctor will continue to treat you. Insurance or health benefits programs may or may not pay for this treatment. You should check with your insurance or health benefits provider to see if this treatment will be covered.

Before making your decision:

* Please carefully read this form or have it read to you
* Please listen to the program doctor or program staff explain the treatment to you
* Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

## What is the purpose of this treatment?

Your doctor will treat your illness or condition with a drug/device that has not been approved by the FDA for use in humans. The drug/device …

## What will I be asked to do?

*Insert information about treatment procedures*

**How will your study drug be provided**?

The study drug that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member.  The principal investigator or health care providers on his/her research team will provide the study drug to you.  If you have questions about the study drug, you should ask the principal investigator or study nurse.  You may also call the pharmacy if you have questions about the study drug. The number for the pharmacy is included on your study drug package, if given one.

Note: The research team for this study includes non-licensed team members who may obtain your consent, or help guide you through the study. There are some kinds of questions only licensed clinicians can answer. For example, detailed questions about drug interactions. If you have questions like these, the non-licensed coordinator will ask a licensed study team member to answer your questions.

## Who will get information about my treatment?

## If you receive this treatment, information about your treatment will be given to your doctors, the manufacturer of the drug or device and/or to the United States Food and Drug Administration. Your insurance company or health benefits program will get information about your treatment too. You will not receive any compensation if your information is used to make a new product. If you stop treatment, information that was already collected may be still be used for this program.

## What are the possible risks and discomforts?

There may be side effects from the study drug or procedures that are not known at this time.

The most common risks and discomforts expected in this study are:

The less common risks and discomforts expected in this study are:

Rare but possible risks include:

**If it is biologically possible for you to become pregnant**: to protect against possible side effects of the study drug, people who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a person of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant people will be taken out of the study.

**If it is biologically possible for you to make someone pregnant:** the effect of the study drug on sperm is not known. To protect against possible side effects, you should not get a sexual partner pregnant while taking the study drug and for \_\_\_\_\_\_\_\_\_\_ days/weeks/months after the last dose. You and the study doctor should agree on a method of birth control to use throughout the study.

If you will take the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

## Will I benefit directly from the treatment?

This drug/device is not FDA approved because there is not enough information to make sure the drug/device is safe or works for your condition. There may be early information that shows this could be a good treatment option, but it is not known for sure. You may or not benefit from this treatment, or this treatment could worsen your condition. Make sure to discuss any benefit questions with the program doctor, to make sure this is the right treatment for you.

##### Will you be paid for your time and effort?

You will not be offered compensation for getting this treatment.

##### What are your other options?

If you choose not to join this study, you can get care outside of this study. [List the major standard care options and/or possibility of other studies; if the study compares two standard care treatments, state which one the subject would be most likely to get outside of the study, if applicable.] The study doctor will discuss these with you. You do not have to be in this study to be treated for your condition.

If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

**How will your private information be protected?**

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

# Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

* Giving state public health officials information about certain infectious diseases,
* Giving law officials information about abuse of a child, elderly person or disabled person.
* Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

**Storing and Sharing your Information**

We will store all the data [and specimens] that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data [and specimens] may be useful for other research being done by investigators at Emory or elsewhere. We may share the data [or specimens], linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

OR

Your data [and specimens] from this study will not be shared with anyone outside this study, even if we take out all the information that can identify you.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

We will use your [specimens and] data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

**Returning Results to Participants/Incidental Findings**

**[INSERT OTHER SECTIONS FROM MODULAR CONSENT FORM HERE]**

**Medical Record**

If you have been an Emory patient before, then you already have an Emory medical record. If you have never been an Emory patient, you do not have one. An Emory medical record will be made for you if an Emory Atlanta provider or facility gives you any services or procedures for this study.

OPTION 1 FOR NON-SENSITIVE Copies of the consent form/HIPAA authorization that you sign will be put in any Emory medical record you have now or any time during the study.

OPTION 2 FOR SENSITIVE: We will take reasonable steps to keep copies of this form out of Emory’s medical records system. If we aren’t successful in keeping these forms out, despite our efforts, we will take steps to remove them. If they cannot be removed, we will take steps to limit access to them.

Emory may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include:

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

## In Case of Injury

## If you get ill or injured from being in the program, Emory will help you to get medical treatment. Emory, however, has not set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. “Negligence” is the failure to follow a standard duty of care.

If you become ill or injured from being in this program, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this treatment, you should contact Dr. \_\_ at telephone number \_\_\_. You should also let any health care provider who treats you know that you are receiving an unapproved drug/device treatment.

If you have Medicare or Medicaid, the government agencies that run these programs may need information about your identity and your treatment. Your insurance will be billed for any costs of medical treatment for your injury or illness. Your insurer may be told that you are receiving this treatment and that is not approved by the FDA. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

## Costs

You will have to pay for the items or services that are part of your treatment. [Option -- The only exception is that you may receive the drug or device for free from the manufacturer.] If you have insurance, Emory will submit claims to your insurance for items and services that are part of your treatment. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay and that are not paid by anyone else.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any treatment costs. Some insurance companies will not pay for unapproved treatment, regular medical treatment or treatment for complications. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and the drug or device manufacturer will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to receive this treatment and that the treatment is not approved by the FDA. Ask them what they will pay for and what they will not pay for. You can also ask the treatment team for help in figuring out what you will have to pay.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for your treatment and what those costs will be.

## Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor’s advice about how to go off the study treatment. If you leave the study before the last planned study visit, the researchers may ask you to complete some of the final steps such as lab work or imaging as applicable.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

These are some reasons why the researchers may take you out of the study:

**INSERT APPROPRIATE HIPAA OR CONFIDENTIALITY LANGUAGE HERE**

**Contact Information**

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact [study contact person(s)] at [telephone number(s)]:

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or [irb@emory.edu](mailto:irb@emory.edu).

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at [**https://tinyurl.com/ycewgkke**](https://tinyurl.com/ycewgkke)**.** 

## Consent and Authorization

***TO BE FILLED OUT BY SUBJECT ONLY***

**Print** your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

**Name of Subject**

**Signature of Subject (18 or older and able to consent) Date Time**

**Signature of Legally Authorized Representative Date Time**

**Authority of Legally Authorized Representative or Relationship to Subject**

***TO BE FILLED OUT BY STUDY TEAM ONLY***

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**Name of Person Conducting Informed Consent Discussion**

**Signature of Person Conducting Informed Consent Discussion Date Time**