**Children’s Healthcare of Atlanta, Inc. “Children’s”**

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

**Title**:

**Physician:**

**Sponsor:**

**Sponsor-Investigator:**

If you are the legal guardian of a child for whom participation is being made available, the term “you” used in this consent refers to your child. You are being asked, on behalf of yourselves and your minor child, to provide permission for the use of this *drug/device* under the Expanded Access Program of the FDA. You need to review all of the attached information carefully.

## 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 exceptional cases, the FDA may permit a doctor to use a non-FDA approved drug or device to treat a patient for Emergency Use when all standard forms of treatment have failed. This is being made available under a special exception to FDA regulations to provide expanded access to a *drug/device* that has not been approved by the FDA for any use. That means that the FDA has not established, among other things, the safety or efficacy of the *drug/device* or side effects or adverse events associated with use of the *drug/device*. Short and long term adverse effects are not known at this time and may be severe, up to and including death. There is no guarantee that treatment with this *drug/device* will provide any benefit.

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 receive this treatment, 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 your doctor 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. Please carefully consider whether you would like to participate. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you.

## What is the purpose of this treatment?

The purpose of this treatment is to (provide a brief summary of condition, the drug/ device and the purpose of treatment). None of the standard treatments or medications have helped in controlling your condition. Through the special program with the FDA, your doctor has the opportunity to treat your condition with a *drug/device* that has not yet been approved by the FDA for any purpose.

## What will I be asked to do?

Provide a detailed description of all procedures to be performed. *Provide a full explanation of all responsibilities and expectations of the subjects.*

## Who will get information about my treatment?

## If you receive this treatment, information about your treatment will be shared with individuals at Children’s who have a need for access to this information, the manufacturer of the drug/device and/or to the FDA. Your insurance company or health benefits program will also get information about your treatment. 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.

## What are the possible risks and discomforts?

Side effects from treatment with this *drug/device* are not well known at this time. Because the FDA has not approved this *drug/device* for any use, side effects, drug interactions and other short and long term adverse effects (AEs) are unknown and could be severe, up to and including death.

The *drug/device* manufacturer reports that most commonly reported AEs at this time are *(include all foreseeable risks or discomforts).*

Rarer, but more serious, risks reported by the manufacturer at this time include: *(insert appropriate risk information for rarer, more serious risks).*

It is possible that doctors will learn something new during your treatment about the treatment’s risks. If this happens, they will tell you about it. Then you can decide if you want to continue this treatment. You may be asked to sign a new consent form that includes the new information if you decide to keep getting the treatment.

## Will I benefit directly from the treatment?

Your doctor is ordering this treatment because it may improve your condition when other standard treatment options have failed. We do not know with certainty that it will work for your specific condition. You may or not benefit from this treatment, or this treatment could worsen your condition or cause other unforeseen AEs.

##### What are my other options?

At this time none of the standard treatment has worked for you, therefore your doctor is seeking your consent for use of this investigational *drug/device*. If you take this treatment, however, you may not be able to participate in research studies, if they exclude people who have taken certain treatments.

**How will you protect my private information that you collect?**

Children’s and your doctor will keep any records obtained during your treatment private to the extent that it is required to do so by law. Whenever possible, a number will be used to identify you in records that go to the *drug/device* manufacturer or FDA number, rather than your name. Your name and other identifying information will not appear if we present or publish information about the treatment.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

**Medical Record**

Copies of the consent form/HIPAA authorization that you sign will be put in your Children’s medical record, together with records relating to your clinical care. The confidentiality of the information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the information from disclosure.

Tests and procedures done at non-Children’s locations may not become part of your Children’s medical record. Also, if you decide to take this treatment, it is up to you to let your other health providers know.

**In Case of Injury**

If you get ill or injured while being treated with this investigational device, Children’s will help you to get medical treatment. Neither Children’s nor your doctor have 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 a Children’s employee or your doctor in the delivery of care. “Negligence” is the failure to follow the community standard of care for treatment.

If you become ill or injured from being treated with this investigational drug/device, 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 being treated with this investigational drug/device, you should contact Dr. \_\_\_\_ at telephone number \_\_\_\_. You should also let any health care provider who treats you know that you are receiving treatment with a drug/device that has not been approved by the FDA for any purpose.

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.

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, Children’s will submit claims to your insurance for items and services that are part of your treatment. Children’s 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. Children’s, your doctor and the *drug/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 at this time. 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, Children’s 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.

**Stopping Treatment**

You have the right to stop treatment at any time without penalty.

For your safety, however, you should consider the doctor’s advice about how to stop the treatment. If you stop treatment before the treatment is complete, the treating doctor may ask you to complete certain steps.

The treating doctors also have the right to stop your treatment without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the treatment plan.

**Authorization to Use and Disclose Protected Health Information**

The privacy of your health information is important to us. We call your health information that identifies you, your “protected health information” or “PHI.” To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the “Privacy Rules.” Here we let you know how we will use and disclose your PHI.

**PHI that Will be Used/Disclosed:**

The PHI that we will use or share includes:

* Medical information about you including your medical history and present/past medications.
* Results of exams, procedures and tests you have been performed.
* Laboratory test results.

**Purposes for Which Your PHI Will be Used/Disclosed:**

We will use and share your PHI to provide you with treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out your treatment, such as laboratories, data management centers, data monitors, and Institutional Review Boards (IRBs). We will provide your information to the FDA for their oversight of this unapproved treatment and to the manufacturer of this *drug/device*. If you stop treatment we may use your PHI to determine your health, vital status or contact information.

**Use and Disclosure of Your Information That is Required by Law**:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

**Authorization to Use PHI is Required to Participate**:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not receive the unapproved investigational *drug/device* as part of your treatment. You will still receive treatment for your condition.

**People Who will Use/Disclose Your PHI:**

The following people and groups will use and disclose your PHI in connection with your treatment:

* The treating doctor and the staff will use and disclose your PHI to provide and oversee the treatment.
* Children’s may use and disclose your PHI to get payment for your treatment and to run normal business operations.
* Your doctor will share your PHI with other people and groups to help manage your treatment or to provide oversight for the treatment.
* The following people and groups will use your PHI to make sure the treatment is done correctly and safely:
  + Children’s offices that are part of the Human Research Participant Protection Program. These include the Children’s IRB and Research Compliance Offices.
  + The manufacturer of the *drug/device* used for your treatment. The manufacturer may use and disclose your PHI to make sure the treatment is done correctly and to collect and analyze the results of the treatment. The manufacturer may disclose your PHI to other people and groups like monitors to help carry out and provide oversight for your treatment.
  + Government agencies that regulate the use including: Food and Drug Administration; Office for Human Research Protections; Public health agencies, Accreditation agencies.

**Expiration of Your Authorization**

Your PHI may be used until 15 years after your treatment is over.

**Revoking Your Authorization**

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the treatment team at \_\_\_\_\_\_\_\_\_\_\_\_\_\_.

At that point, the treating doctors would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the treatment was done properly and the data is correct. If you revoke your authorization you will not be able to continue to receive treatment.

**Other Items You Should Know about Your Privacy**

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won’t be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The *drug/device* manufacturer, and people and companies working with the manufacturer to make the *drug/device* are not covered by the Privacy Rules. Children’s, where possible, will limit the PHI provided to the manufacturer as set forth above.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides your treatment.

**Contact Information**

Contact \_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_:

* if you have any questions about your treatment,
* if you feel you have had a treatment-related injury or a bad reaction to the treatment, or
* if you have questions, concerns or complaints about your treatment

Contact the Children’s Institutional Review Board at 404-785-7477 or irb@choa.org:

* if you have questions about your rights as a treatment recipient,
* if you have questions, concerns or complaints about your treatment, or
* if you would like to provide feedback

**Permission, Consent and Authorization**

Please print your name and sign below if you voluntarily agree and provide permission, individually and on behalf of yourself and your child, to the terms and conditions of this document, including the Consent for Emergency Treatment with a *drug/device* that has not been approved by the FDA for any use and the HIPAA Authorization.

Name of Patient

Signature of Patient (if over age 18) Date Time

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Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion Date Time

Signature(s) of Legally Authorized Representative(s) Date Time

with authority for treatment decisions

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Authority of Legally Authorized Representative or Relationship to Subject

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Signature(s) of Legally Authorized Representative(s) Date Time

with authority for treatment decisions

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Authority of Legally Authorized Representative or Relationship to Subject