

# PARENTAL PERMISSION FORM

# CONSENT FORM: Ages 18 and Up

## Emergency Use or Compassionate Use of

**Investigator:**

**Instructions**

**Fill each blank with the requested information and delete all instructional language (green). The form once completed is ready to present to families and does not require prior IRB review and approval.**

| **Name/Degree** | **Title** | **Department** | **Phone Number** |
| --- | --- | --- | --- |
|  |  |  | (206) |
|  |  |  | (206) |
|  |  |  | (206) |

If you have questions about your rights, you can call the Institutional Review Board at (206) 987-7804.

**24-hour telephone number:** (206) 987-2131. Ask for the       on call**.**

The word **“you”** in this form refers to your child/teen.

**What is being offered?**

The purpose of this form is to explain your option for treatment with a product called PRODUCT.

This treatment is considered experimental and research. [delete “and research” for uses

of devices] This means the Food and Drug Administration (FDA) has not approved PRODUCTfor use in treating your condition. The FDA only approves an investigational product once it has been shown to be safe and effective.

The usual way patients receive an investigational product is to participate in a research study. You either don’t qualify for any research studies involving PRODUCTor we currently don’t offer a research study where you could receive PRODUCT.

Sometimes in these situations the FDA allows doctors a one-time exception to use an investigational product for treatment. This type of use is called an Emergency or Compassionate Use. We are offering you this option because you have a serious condition called CONDITION and there are no standard acceptable options.

**What will happen and how long will this treatment last?**

**Instructions**

Describe all procedures necessary to complete the treatment in chronological order – a list format is recommended. All terms should be tailored to an 8th grade reading level. Your description should include at minimum the route of administration or method of implantation, any other procedures/medications required to complete the emergency/compassionate use, and the resulting clinical procedures, laboratory tests, or other monitoring necessary to evaluate the effects of the emergency/compassionate use and minimize the risks.

PRODUCT will be used to treat you for CONDITION.

The tests or procedures that would need to be done include:



This treatment will take TIME.

Once this treatment is complete, your physician will determine what other evaluations and procedures are necessary to continue to treat your CONDITION.

**What risks or harms can I expect?**

**Instructions**

With consultation from the manufacturer, describe the reasonably foreseeable risks related to this treatment. Risk information should be drawn from all available resources, such as existing IND/IDE protocols or known risks with related products. The reasonably foreseeable risks also include the administration (inflammatory response) or implantation (surgery) of the product.

There are potential risks or harms if you agree to this treatment.

These include:



As with any investigational product there may be risks or harms that we do not expect. If you are or become pregnant, this treatment may hurt your baby or your pregnancy in ways that are unknown.

**How might this treatment help me?**

We hope this treatment will benefit you, but we cannot know for sure if this will be the case. PRODUCTas its being usedis still considered investigational.

**What other options do I have?**

There are no generally acceptable alternative treatments for your CONDITION.

**Instructions**

Adapt the following statement as necessary to fit the situation.

If you do not wish to participate in this treatment, you may continue your current treatment or seek supportive care only.

**What will this cost?**

#### **Instructions**

Describe who will be responsible for the cost of the investigational product by selecting the appropriate statement below. The manufacturer should confirm responsibility for cost before shipping/allowing use of the product. Check with the Investigational Drug Service about the cost of a drug. Also identify who will be responsible for any other associated costs with the treatment. Adjust the template statements as necessary to match the circumstances.

#### You and your insurance company will be responsible for the cost ofPRODUCT(typical for devices).

#### OR

#### PRODUCTwill be made available to you at no cost to you and your insurance company (typical for drugs/biologics).

You and your insurance company will be responsible for the cost of your continuing medical treatment, which includes hospital, laboratory, and doctor fees. Your insurance plan may or may not pay for this treatment. If your insurance plan does not pay for this treatment, you will be billed.

If you were injured as the direct result of receiving PRODUCT, Seattle Children's Hospital would provide you treatment. We would refer you for treatment if needed. No funds have been set aside for this treatment.  You or your insurance company would be billed for the treatment.

**Confidentiality and Privacy**

If you take part, we will make every effort to keep your information confidential and will comply with all laws regarding the privacy of health information.

Because your treatment involves the use of an investigational product we may share information about you, as well as portions of your medical record, with the federal government’s Office of Human Research Protections, the Seattle Children’s Institutional Review Board, the Food and Drug Administration and Manufacturer.

**Contacts for Problems, Questions, or More Information**

| If I have questions or would like to know about … | You can call … | At … |
| --- | --- | --- |
| * Emergencies * General treatment questions * Treatment-related injuries * Any concerns or complaints | **Principal Investigator**   NAME | Phone:  Pager: |
| * Your rights when being treated with an investigational product | **Institutional Review Board**  A group of scientists and community members who ensure investigations meet legal and ethical standards. | Phone:(206) 987-7804 |

**Participation is Always Voluntary**

Taking part in this treatment is your choice. If you agree to this treatment, you can decide to stop at any time without losing any benefit or being penalized. If you decided to stop, you would need to talk with  Dr. PI  , so you can stop in a safe way.

 Dr. PI  could also decide to stop the treatment. If we ask you to stop, we would always explain why.

**What would my signature on this form mean?**

**Instruction**

If the patient is **18 years or older** and is capable of consent, add a signature line for the patient and remove the name and signature lines for the parent/legal guardian.

Your signature on this form would mean:

* The treatment was explained to you.
* You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
* You understand that the persons listed on this form will answer any other questions you may have about the treatment or your rights when being treated with an investigational product.
* By signing this consent form, you do not give up any of your legal rights. The investigator(s) or sponsor(s) are not relieved of any liability they may have.

[Choose appropriate bulleted statement(s) below]

* You agree to the emergency or compassionate use.
* If the person reading this form is a parent/guardian, you agree to have your child take part in this emergency or compassionate use.

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*Printed Name of Emergency/Compassionate Use Recipient*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Printed Name of Parent or Legally Authorized Representative*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature of Parent or Legally Authorized Representative*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Date Time*

**Investigator’s Signature**

I have fully explained the treatment described by this form. I have answered the participant and/or parent/guardian’s questions and will answer any future questions to the best of my ability. I will tell the family and/or the person taking part of any changes in the procedures or in the possible harms/possible benefits that may affect their health or their willingness to stay on the treatment.

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*Printed Name of Researcher Obtaining Parental Permission or Consent*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature of Researcher Obtaining Parental Permission or Consent*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Date Time*

### Copies to: Parent/Legally Authorized Representative

Investigator’s file

Medical Records