CONSENT FOR EMERGENCY USE OF AN INVESTIGATIONAL PRODUCT

Information about this template: *This template is provided as a sample to assist care providers in the development of a compliant consent form for emergency uses of investigational or unapproved products. This template must be reviewed carefully and customized so that it is appropriate for the situation. Highlighted and bracketed text is used to indicate where information should be added. All highlights, brackets, and instructions (such as this) should be deleted prior to use. The footer information should be modified to reflect the correct date and document title. A redacted copy (no identifying information) of the executed consent should be provided with the Emergency Use Report to the Allina Health IRB. For more information on Emergency Uses, please call the IRB office (612-262-4920).*

Title of the Emergency Use Project: [TITLE]

1. INFORMATION ABOUT EMERGENCY USE TREATMENTS AND THIS DOCUMENT

We have determined that you have [Condition], which is a life-threatening or severely debilitating condition. We believe that [DRUG/DEVICE] may help you. There is currently no other available treatment that we believe would be as helpful for you.

[DRUG/DEVICE] is an investigational or unapproved product. An investigational product 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 [DRUG/DEVICE] works and to give you an opportunity to decide whether you want us to use it to treat you.

Please read this information carefully. It tells you important things about the use of [DRUG/DEVICE]. A member of our team will review the information with you. If you have questions at any time, please ask us.

To help you decide if you want to take part, you should know:

- Consent for use of investigational or unapproved products is completely voluntary.
- You can choose to say no.
- You are free to change your mind at any time if you say yes now.
- Your decision won't cause any penalties or loss of benefits to which you are otherwise entitled.
- Your decision won't change the access to medical care you get now or in the future if you decide no now or decide yes but change your mind later.

If you agree to use of [DRUG/DEVICE], you will need to sign this consent form to show that you do want to take part. We will give you a signed copy of this form to keep. A copy of this form will be put in your medical record.

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

2. SPECIFIC INFORMATION ABOUT THE TREATMENT

Dr. [Name] would like to treat your [condition] using the [drug/device] [if device, include a description of the device]. However, [drug/device] is not approved by the FDA for use in treating [condition] [if applicable, insert "and is limited by United States law to investigational use"]. Dr. [Name] is recommending the use of [drug/device] because he believes this is the best option to treat your [condition].

[Add information regarding the condition]

[Add information about the drug/device]

What will happen to you?

[Add information – in lay terms – of any procedures, blood tests, etc. that the patient will undergo as part of the emergency treatment. Include an estimation of how long the treatment and any related follow up will last (e.g., duration of participation).]

3. RISKS, BENEFITS AND ALTERNATIVES

What are the risks of being treated with [DRUG/DEVICE]?

[Describe reasonably foreseeable risks (including any risks to fetuses, if applicable). Include a statement that some risks may be unforeseeable. Include a statement about who to notify/what to do if side effects occur.]

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

[Describe anticipated benefits (e.g., cure of condition, minimizing severity/effects of condition). Include disclosure that it is possible that patient will not benefit]

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

Standard treatments for [CONDITION] include [LIST AND DESCRIBE STANDARD TREATMENTS]. We will be glad to talk to you about your other treatment options.

[Modify the following as appropriate for implanted devices.] 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 persons listed in Section 6 "Contact Information" (below).

4. POSSIBLE COSTS ASSOCIATED WITH THIS TREATMENT

[*Select one of the following then delete the other option as well as all bracketed instructions*:]

[*For investigational drug or device if manufacturer 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. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company.

[For investigational drug or device if patient will be responsible for ALL costs (charging the patient requires prior FDA approval):]

You or your insurance will be responsible for the cost of all care associated with the procedure[*s*] and the [DRUG/DEVICE] itself. This includes the cost of treatment if [DRUG/DEVICE] makes you sick or causes you injury. It is possible that your insurance will not pay for the cost of the [*include as applicable: drug, device, procedure to implant the device*] because the [DRUG/DEVICE] is considered investigational. If that occurs, you will be responsible for all costs, and these costs may be substantial.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of receiving this treatment.

Will you be paid to take part in this procedure?

You will not be paid for taking part in this procedure.

Billing Error Information

If you believe you have received a bill in error, contact Dr. [Name] or his/her staff at the phone number listed in Section 6 of this form.

5. HOW INFORMATION ABOUT YOU WILL BE SHARED

If you give us permission to use [DRUG/DEVICE], we will need to provide information about you, your condition, and your treatment to [COMPANY NAME], which is the manufacturer or supplier of the [DRUG/DEVICE] and to the Food and Drug Administration (FDA). [COMPANY NAME] and the FDA need this information as part of the approval process for treatment use of [DRUG/DEVICE] and to monitor safety. We also need to provide similar information to the Allina Health Institutional Review Board (IRB), the internal board responsible for reviewing uses of investigational products such as this.

Allina Health, the Food and Drug Administration (FDA), and/or other government officials may also need to review your medical records 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 Allina Health Notice of Privacy Practices. You should already have received a copy.

6. CONTACT INFORMATION

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 Emergency Use: [NAME]
Mailing Address: [ADDRESS]
Telephone: [PHONE]

You may also express a concern or ask questions about emergency uses of investigational products and your rights by contacting the IRB listed below:

Allina Health IRB
2925 Chicago Avenue
Route 10811
Minneapolis, MN 55407

Telephone: 612-262-4920
e-mail: irb@allina.com

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], the title (at the top of this form), and details about the problem. This will help us look into your concern. When reporting a concern, you do not have to give your name unless you want to.

7. SIGNATURE

Consent

I have read and understand the information in this consent document. I have had an opportunity to ask questions and all of my questions thus far have been answered to my satisfaction. If I have more questions or concerns, I may contact one of the people listed in Section 6 of this consent document. I voluntarily agree to the use of [DRUG/DEVICE] for my treatment and understand that I can change my mind at a later time. I do not give up any of my legal rights by signing this consent document.

Printed Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

If the patient is not able to consent for themselves to the use of this investigational/unapproved product, use the following signature block to obtain permission from a legally authorized representative or a parent.

Legally Authorized Representative or Parent Permission

I have read and understand the information in this consent document. I have had an opportunity to ask questions and all of my questions thus far have been answered to my satisfaction. If I have more questions or concerns, I may contact one of the people listed in Section 6 of this consent document. By signing this form I am voluntarily providing permission for the use of [DRUG/DEVICE] to treat [PATIENT NAME] and understand that I can change my mind at a later time. I do not give up any legal rights by signing this consent document.

Printed Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Relationship to patient: ☐ Parent ☐ Spouse ☐ Child ☐ Sibling ☐ Legal guardian ☐ Other

If "Other," explain: _____

Reason patient is unable to consent: _____

Physician or Designee

I have provided this patient and/or his/her legally authorized representative(s) with information about this emergency use that I believe to be accurate and complete. The patient and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the treatment, including risks and benefits of its use.

Printed Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____