Ascension Wisconsin IRB

**INFORMED CONSENT FORM GUIDE: INSTRUCTIONS FOR USE**

***Treatment with an Experimental Item***

Template v.10/03/17

This consent template is for protocols that involve the clinical use of an investigational drug, biologic or device through an FDA approved expanded access mechanism. This template is provided as an example, and is not required to be used.

**Instructions for preparing the consent document:**

* Complete the template below by filling in green text with the specific details about this use.
* Leave all black text as is- do not change or delete.
* Once complete, make sure all text is changed to black.
* Delete this instruction section and guide header before using (delete this line, and everything above it)

**Permission for Treatment with an Experimental Item**

Dr. Name of physician is offering to treat select one: you / your child (in which case the word “you” will refer to “your child” throughout this document) / the person you represent (in which case the word “you” will refer to the person you are representing) with name of unapproved drug, device, or biologic because you have a serious condition called name of condition and there are no standard acceptable options.

## What you should know about this experimental treatment

1. This treatment has not been approved by the Food and Drug Administration.
2. This treatment is considered experimental.
3. This treatment is not research and you will not be considered a research subject.
4. Someone will explain this treatment to you.
5. You volunteer to get this treatment.
6. Whether or not you get this treatment is up to you.
7. You can choose not to get this treatment.
8. You can agree to get this treatment now and later change your mind.
9. If you do change your mind, contact your doctor right away.
10. Whatever you decide it will not be held against you.
11. Feel free to ask all the questions you want before you decide.

## How long will this experimental treatment last?

We expect that the experimental treatment will last hours/days/months/weeks/years, until a certain event, etc..

## What happens if I get this experimental treatment?

Describe what the patient can expect using lay language and simple terms.

## Is there any way this experimental treatment could be bad for me?

Describe the risks of the treatment.

This treatment may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

If you are or become pregnant, this treatment may hurt your baby or your pregnancy in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

Getting this treatment may lead to added costs to you. Insurance may not pay for this treatment because it is considered experimental.

## Can this experimental treatment help me?

We cannot promise that this treatment will help you. The goal of this treatment is to describe the potential benefits of the treatment.

## What else do I need to know?

Efforts will be made to limit your personal information, including medical records, to people who have a need to review this information. Organizations that may inspect and copy your information include appropriate representatives of site name and Ascension Wisconsin, and the Food and Drug Administration.

If you are injured or made sick from taking part in this treatment, medical care will be provided. Generally, this care will be billed to you or your insurance. However, it is possible that your insurance will not pay for the care, because the treatment is experimental. Contact your doctor for more information.

## Who can I talk to?

If you have questions, concerns, or complaints, or think the treatment has hurt you, you can talk to your doctor at insert contact information.

This treatment is subject to oversight by the Ascension Wisconsin Institutional Review Board. If you have questions about your rights or any unresolved question, concerns, or complaints, talk to them at (414) 465-3134 or [IRB@ascesnion.org](mailto:IRB@ascesnion.org).

**Consent Statement for Patient**

**Your signature below documents that you agree to take part in this experimental treatment.**

You will be given a copy of this form and you can ask additional questions at any time during the treatment.

Print name of subject

Signature of subject Date Time

Legally Authorized Representative (LAR) name, if applicable

Signature of LAR Date Time

*Staff- Describe use/ authority of LAR:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print name of Authorized Administering Physician obtaining consent

Signature of Authorized Administering Physician obtaining consent Date Time