**Instructions:**

* **Use this template for Humanitarian Use Devices (HUDs) only**
* **Update the version date in the header each time you make a change.**
* **Blue highlighting: This is for your reference only. Delete before submitting to the IRB.**
* **Yellow highlighting: Insert the requested information, or choose the appropriate response and delete the other options.**
* **Delete all << >> marks in the document as you go.**

Patient name: Patient date of birth:

# Aurora Health Care, Inc.<<or other institution name>>

# Consent for a Humanitarian Use Device (HUD)

|  |  |
| --- | --- |
| **Title** | <<title or name of device and HDE>> |
| **Doctor** | <<name>><<phone number (daytime)>> <<phone number (24-hour contact number)>> |

Background/Introduction

The <<insert name of HUD>> has been approved by the Food and Drug Administration (FDA) for use as a Humanitarian Use Device (HUD). A humanitarian use device is one which is used for conditions or diseases which typically affect fewer than 4,000 people in the United States per year, and when there is no comparable device marketed to treat/diagnose those conditions or diseases. The ability of this device to treat your condition has not been proven, but it is thought to be safe and may improve your condition. It has not been tested like other FDA-approved articles.

<<Insert background information about the specific HUD.>>

What are the risks of the <<name of HUD>>?

<<In this section, list the physical risks in language that is understandable to the patient. The explanation of risks should be reasonable and should not minimize reported adverse effects.

Risks should be divided into categories of: (i) very likely, (ii) less likely, but serious. Provide the likelihood of the risk as a percentage or absolute numbers (x out of xx people) whenever possible. State whether side effects are temporary or permanent.>>

What are the benefits of the <<name of HUD>>?

<<Insert a description of the anticipated benefits.>>

What are your options if you don’t get treated with the <<name of HUD>>?

<<To enable a rational choice about whether to receive an unproven HUD, patients should be aware of the full range of options available to them. Consent documents should briefly explain any pertinent alternatives to the HUD. While this should be more than just a list of alternatives, a full risk/benefit explanation of alternatives may not be appropriate to include in the written document. The person(s) obtaining the patient's consent, however, must be able to discuss available alternatives and answer questions that the patient may raise about them.>>

What about confidentiality?

Your record of this procedure will be kept private, or will be disclosed only with your permission unless required by law. The use of the <<name of HUD>>in your treatment is not connected to any research study to determine the safety and effectiveness of the HUD. No individually identifiable information will be released to the manufacturer of the device or to the Food and Drug Administration.

Information about your receiving the <<name of HUD>> may be reviewed by an Aurora Health Care billing representative as part of normal hospital operations.

The FDA requires that a yearly report about the use of the HUD be submitted to the Aurora Institutional Review Boards (IRBs), the human subject protection committees that oversee research done at Aurora Health Care. Any reports of problems associated with the use of this HUD will also be reported to the Aurora IRBs, and this report could identify you.

Any information related to your receiving the HUD will be treated confidentially to the extent required by the applicable laws and regulations. Unfortunately, we cannot promise complete confidentiality.

What are the costs of this HUD?

All charges, procedures, physician and hospital costs that you will incur are considered standard procedures and care for your condition. The cost of the HUD will be billed to you or your insurance company. Your health insurance company may or may not pay for the cost of the implant. We don’t ask your health insurance company if they will pay, so it is recommended that you contact the company to see what they will and will not pay for on your behalf. Your investigator or research team can provide you with information about how to do this.

What are your rights if you decide to receive this HUD?

Your decision to allow your doctor to use this <<name of HUD>> is entirely voluntary. You may withdraw your approval to use the HUD at any time prior to its use. If you decide that you do not want to receive the HUD, your decision will in no way affect the care or the quality of care that is available to you.

**Patient name:**

* I have read this form and the HUD has been explained to me.
* I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
* I agree to the use of the HUD described above.
* I will receive a copy of this consent form after I sign it. A copy will be put in my medical record.

Patient signature Date

**DOCUMENTATION OF INFORMED CONSENT**:

🞏 The HUD use and all information contained in this document were discussed with the patient.

🞏 The patient had the opportunity to ask questions, all questions were answered, and the patient expressed understanding.

🞏 The patient gave written informed consent before the device was implanted.

🞏 The patient received a copy of the signed and dated consent form.

Signature Date

**FILE A SIGNED COPY OF THIS FORM IN THE PATIENT’S MEDICAL RECORD (if applicable).**

**Keep the original in the investigator’s research records.**

***Form IC 1001C v. 5-2-13***