**Project Title:**

**Manufacturer:**

**Principal Investigator:**

**Introduction/Purpose**

You are being asked to allow the use of a Humanitarian Use Device (HUD) called [Insert name of the device] to [treat/diagnose (choose)] your condition, [Insert name of condition]. Use of the HUD is under the direction of [Insert treating physician’s name and credentials here] who has determined that there is no comparable device available to [treat/diagnose (choose)] your condition. This consent form explains how the device will be used. Please read it carefully and take as much time as you need. Please ask questions at any time about anything you do not understand. We will explain what other treatment could be given other than the HUD.

**What is a Humanitarian Use device (HUD)?**

A HUD is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 8,000 individuals in the United States per year. The U.S. Food and Drug Administration (FDA) approves the use of Humanitarian Use Devices based primarily on evidence that it does not pose a significant risk of injury to the patient and that the potential benefit of the device to the health of the patient outweighs the risks of its use.

According to FDA regulations, use of the [insert device name] is not considered to be research, but its use must be reviewed by an Institutional Review Board (IRB). Although use of the HUD is authorized by the FDA, the effectiveness of the device to [treat/diagnose] [Insert name of patient’s condition] has not been fully proven.

**What will be involved with the use of this device?**

[Insert a description, in lay language, of the procedures to be conducted with enough detail to allow the subject to know exactly what is going to happen, what is expected of him/her and the time period for the use of the device. Include any ancillary procedures associated with use of the device.

Also, provide an explanation of the postulated mechanism of action of the HUD in relation to the disease or condition.

Do not include risks, benefits, inclusion/exclusion criteria or other non-procedural information in this section.]

**What are the possible risks associated with the use of this HUD?**

With use of the [insert device name], you are at risk for some side effects. Most of them are listed in this form, but they will vary from person to person. The potential risks from use of the device include [Insert a description of potential physical, psychological or other risks that may arise from use of the HUD.]

There may be other side effects that cannot be predicted.

**How many patients have already received the HUD?**

So far, there have been [Insert total number of patients] patients who have received the [Insert name of HUD]. Note: This could be worded to describe usage nationally and/or locally since FDA approval and might be useful information for the patient.

**What are the intended benefits to me if receive the device?**

The intended benefit(s) to you may is/are [Insert the intended benefits]. However, it is possible that you may not receive any benefit from use of the HUD.

**What alternative treatments or procedures are available?**

[Insert a description, in lay language, of any alternative procedures/treatments that could be used in lieu of the HUD. If there is no alternative procedure/treatment, then it should be stated as such.]

**Will it cost you anything to receive this device?**

Since the FDA has approved the [Insert name of device] for use in patients, the manufacturer of the [Insert name of device] is allowed to charge for its use. Therefore, you or your insurance company will be expected to pay for the [Insert name of device] and any expenses surrounding use of [Insert name of device].

*Note: Be as specific as possible in describing the costs. Unless FDA determines that the HUD qualifies for an exception, HUDs cannot be sold for a price that exceeds the costs of research and development, fabrication, and distribution of the device.*

**Who will know if I receive this device?**

As is the case with all medical records, records and information about the use of [Insert name of device] will be kept confidential to the extent of the law. Federal privacy regulations provided under the Health Insurance Portability and Accountability Act (HIPAA) provide safeguards for privacy, security, and authorized access of your records.

It may be required that results of the use of [Insert name of device] be reported to the device manufacturer and/or the FDA.

Your records may also be reviewed in order to meet federal or state regulations. Reviewers may include, for example, representatives of [Insert device manufacturer name], the Food and Drug Administration and the [Insert organization’s name]’s IRB.

**What is I have questions?**

If you have any questions or concerns prior to or after receipt of [Insert name of device] or if you need to report what you believe is a side effect from the device, you should immediately contact Dr. [Insert name] at [telephone number] or [name of additional contact person] at [telephone number].

**Does my doctor have a conflict of interest?**

**Note:** If you or anyone associated with use of the HUD has disclosed a significant financial conflict of interest and/or have received a Conflict of Interest management plan, add language describing the conflict here. If there are no conflicts, make that statement.

You will be given a copy of the consent form you have signed.

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Date Signature of Patient

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Description of Authorized Representative’s Authority to Act for Patient (if applicable)

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Using language that is understandable and appropriate, I have discussed use of this HUD with the patient and/or his/her authorized representatives.

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Date Signature of Person Obtaining Consent