Sample Only (revised 11/14/19)– Cannot be used without IRB Approval

TITLE: [***Name of Humanitarian Use Device***]

PHYSICIAN: [*Name*]
[*Address*]

OTHER PHYSICIAN(S): [*Name(s)*]

1. INTRODUCTION:

[*If the device will be used only in children 7 years old and younger, simply write the consent form addressing the parent/legal guardian (ex: "your child").*] In this consent form, the word "you" means your child.

[*If the device will be used in any children 8 years old and older, or any adults who cannot consent for themselves, edit and include the following:*] Please remember that "you" means the patient who will receive the device and/or the parent/legal guardian and/or the legally authorized representative.

[*In simple language:*

- *Explain why the device is called an HUD*
- *Provide a description of the HUD*
- *Explain how the device works in the body and why it is being used to treat the patient's condition*
- *Describe why current therapies are not satisfactory and explain that no comparable device is available to treat the disease or condition*
- *Include a statement that the FDA has approved the device for humanitarian use because it has been found to be safe, but that "the effectiveness of this device for this use has not been demonstrated."*
- *For example*:]

You are being asked to allow the use of a Humanitarian Use Device (HUD), [*name of device*]. An HUD is a device that is intended to benefit patients in the treatment and diagnosis of diseases

Patient Initials _____
[***OR***]
Patient or Parent/Legal Guardian Initials _____
[***OR***]
Parent/Legal Guardian Initials _____
[***OR***]
Patient/Legally Authorized Representative Initials _____

or conditions that affect not more than 8,000 individuals per year in the United States. 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 any words or information you do not understand. We will explain what treatments you could receive other than the HUD.

The US Food and Drug Administration (FDA) has approved the use of [*name of HUD*] to provide treatment for patients who have problems with [*name of disease/injury*] and who have failed other treatments. You are eligible to use [*name of HUD*] because you have [*name of disease/injury*] and you have not improved with available treatments. However, you should note that the effectiveness of the HUD for this use has not been demonstrated.

This is not a research study.

[*Include specific location(s) and the corresponding addresses at which the procedures will be performed.*]
The procedures will take place at…

[*Describe how long the patient's treatment will be in hours, days, weeks, months, years; and how long he/she will be followed (ex: for life, or provide a range, such as 2-5 years).*]
Your expected treatment time will last … and we will collect information on you for ….

2. PROCEDURES:

[*In simple language using a bullet point format with headers, provide a description of the procedures that will occur chronologically, including all screening procedures, procedures involved in the use of the HUD, and all follow-up visits, tests, and procedures associated with the use of the device.*]

3. RISKS:

[*In simple language and in bullet point format (whenever possible), describe all reasonably foreseeable risks, side effects, or discomforts resulting from the use of the HUD. The most serious and common risks should be addressed first followed by disclosure of uncommon and less serious risks*.

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[***OR***]
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To the extent possible, risks of harm or discomfort should be characterized as to their probabilities of occurrence, potential seriousness, duration and reversibility. The current UTHSC guidelines for risk categories include very rare, < 1%; rare, 1 to 5%; occasional, 6 – 20%; common, 21 – 50%; and very common, 51 to 100%. One of these categories should be used for each potential risk, and the range of percentages should be specifically listed. For example:]
There are certain risks and discomforts that may be associated with the use of this device. They include:

Very Common (51-100%)

-
-

Occasional (6-20%)

-
-

[*Conclude this section with the following statements*:]
It is possible that other rare side effects could occur which are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

4. BENEFITS:

[*Include a description of any benefits to the patient, which may reasonably be expected from the device. The description of potential benefits to the patient should be clear and not overstated. You should caution the patient that the effectiveness of the device has not been established in research studies. For example*:]
We cannot promise that this device will provide you with any benefits, because its effectiveness for this use has not been demonstrated in research studies. However, possible benefits include:

-
-
-

5. ALTERNATIVES:

Patient Initials _____
[***OR***]
Patient or Parent/Legal Guardian Initials _____
[***OR***]
Parent/Legal Guardian Initials _____
[***OR***]
Patient/Legally Authorized Representative Initials _____

[*Describe any alternative procedures or courses of treatment that might be advantageous to the patient. To enable a rational choice about participating, patients should be aware of the full range of options available to them.*]
You may choose not to be treated with the [*name of HUD*]. If you choose not to receive this device, there are other treatment choices, such as:

-
-

6. CONFIDENTIALITY:

[*Describe the procedures used to maintain the confidentiality of the records and data pertaining to the patient, how the patient's privacy will be protected, and that the FDA may inspect records. For example*:]
We will keep all medical records that identify you private to the extent allowed by law. Records about you will be kept locked in filing cabinets or on computers protected with passwords. People outside the University of Tennessee Health Science Center and [*name(s) of appropriate institutions, e.g., Le Bonheur Children's Hospital, Regional One Health, Methodist University Hospital, University Clinical Health, etc.)*] may need to see your information as it relates to the use of the HUD. Examples include the US Food and Drug Administration, safety monitors, other hospitals if involved with this procedure, and the manufacturer of the device, [*name of the manufacturer*], as part of the HUD program. We will do everything we can to keep your records private, but we cannot guarantee this.

7. QUESTIONS:

Contact [*name*] at [*number(s)*] if you have questions about the device.

If you feel you have had a device-related injury, contact [*name of the physician*] at [*24-hour/7-day telephone number(s)*]. [***Note**: explain whether the 24-hour/7-day telephone number is an answering service, office number, pager, etc.*]

Contact Cameron Barclay, MSA, Director of the UTHSC Institutional Review Board (IRB), at 901-448-4824 if you have questions regarding your rights as an HUD recipient. You may also visit the IRB website at http://www.uthsc.edu/research/compliance/irb/ .

8. COSTS:

Patient Initials _____
[***OR***]
Patient or Parent/Legal Guardian Initials _____
[***OR***]
Parent/Legal Guardian Initials _____
[***OR***]
Patient/Legally Authorized Representative Initials _____

[*Explain the costs related to the use of the device that will be charged to the patient. If applicable, state that the patient may want to check whether his/her health insurance will cover certain costs. For example*:]
All costs associated with this HUD will be billed to you or your insurance company. Your insurance company may not pay for the costs associated with this device. Therefore, these costs [*state who will be responsible, e.g., "will be your responsibility" or "will be paid by the sponsor" or "will be paid by the sponsor if you do not have insurance or if your insurance does not cover it" etc*.]

9. VOLUNTARY PARTICIPATION:

[*State that receiving the HUD is voluntary. Indicate that refusal to allow the use of the HUD will involve no penalty or loss of benefits to which the patient is otherwise entitled. Also, indicate that the patient may discontinue use of the device at any time and still receive appropriate alternative care for his or her condition. For example*:]
You do not have to agree to receive this HUD. If you refuse to have the device used or you want to stop using the device, you will not be penalized or lose any benefits to which you are otherwise entitled. You will receive appropriate alternative care for your condition.
If you decide to stop using the device, please contact the physician so that appropriate arrangements can be made.

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[***OR***]
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10. CONSENT:

You have read or have had read to you this consent document. The physician or his/her representative has explained the procedures involved with the HUD treatment to you and has answered all the questions you have at this time. You knowingly and freely choose to receive the HUD treatment. A copy of this consent form will be given to you for your records.

_____ _____ _____

Signature of Patient (18 years +) **Date** **Time**

_____

Printed Name of Patient

[***If you are utilizing a Legally Authorized Representative for an incompetent adult patient, then the following 3 lines must be included here, above the Person Obtaining Consent lines:***]

_____ _____ _____

Signature of Legally Authorized Representative **Date** **Time**

_____

Printed Name of Legally Authorized Representative

_____

Relationship of Legally Authorized Representative

[***If the patient is under 18 years of age, then the following 3 lines must be included here, above the Person Obtaining Consent lines:***]

_____ _____ _____

Signature of Parent/Legal Guardian **Date** **Time**

_____

Printed Name of Parent/Legal Guardian

Check Relationship to Minor:

- ☐ **Parent**
- ☐ **Court-Appointed Legal Guardian**

Signature of Person Obtaining Consent **Date** **Time**

Printed Name of Person Obtaining Consent

In my judgment, the patient [*or parent/legal guardian or the legally authorized representative*] has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to receive treatment with an HUD.

Signature of Physician **Date** **Time**