# Humanitarian Use Device Informed Consent Form

**[Note, this is a sample document that may not cover all nuances for various devices. You may add, delete and / or edit sections to make them applicable to the device being used.]**

**Principal Physician:**

**Physician’s Phone Number:**

**Additional Physicians Authorized to Use the Device:**

**Title of the Device:**

**IRB Number: [To be filled in by the IRB when approval is given]**

**Name of Recipient:**

**[Instructions]**

* ***[DELETE all items in [ ] from the final document.***
* ***The consent document must be written in lay language.***
* ***Use lay language to explain medical concepts. If a medical term is used follow it by a lay explanation. Resources are available on the HSPO website.***
* ***Keep sentences short.***
* ***The use of bulleted lists and/or tables may be helpful.***
* ***Unless otherwise noted all of the sections listed above and below are required.***
* ***Unless otherwise noted the text within each section may be revised to be appropriate to the specific HUD for which approval is sought.***
* ***Requiring the subject to initial on the bottom of each page is optional.***
* ***Font size must be a minimal of 12 point but may be larger and should be font that is easy to read, e.g. times, arial, garamond.***
* ***Make the final document all one color.***
* ***Inclusion of a version reference in the footer of the consent form is recommended.]***

**What should you know about Humanitarian Use Devices (HUDs)?**

A Humanitarian Use Device (HUD) is a medical deviceintended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.

Because the device is anticipated to benefit only a small group of people, complete information about the safety and effectiveness of the device is not known. The FDA has approved use of the device as an HUD because the device is not expected to expose patients to an unreasonable or significant risk of illness or injury and the probable benefits outweigh the risk of injury or illness from its use.

To use an HUD the physician must also get the approval of the local Institutional Review Board (IRB). The IRB is responsible for protecting participant’s rights. You may contact the IRB if you have questions about your rights or if you think you have not been treated fairly. A staff person in the IRB may be contacted at
860-679-1019, 860-679-4851 or 860-679-4849.

**What is the name of the HUD that will be used?**

You are being asked to allow the use of an HUD called *[insert name of HUD].* The FDA has approved the use of [*insert name of HUD]* to provide treatment for patients who have [*insert name of disease or injury]* and who have failed other treatments.

Through discussion and this document, we will explain to you how the device will be used. Please ask questions at any time about anything you do not understand. Please read this form carefully and take as much time as you need in deciding whether to let the doctors use the HUD.

**What will happen if you agree to the use of the HUD?**

If you agree to the use of [*insert name of HUD]*, you will:

* *[Describe the procedure in detail chronologically using lay language, short sentences, and short paragraphs.*

**What are the risks of using the HUD?**

The HUD has not been proven effective for this use.

*[Identify the risks of using the HUD and of any procedures required for its use. Include in the description of risks warnings listed on the product labeling. In addition to physiological risks/discomforts, if appropriate, describe psychological, social, and legal risks that might result.]*

*[If appropriate to the procedure, end with the statement:]* There may be side effects and discomforts that are not yet known.

**Are there benefits from the use of the HUD?**

*[State the direct or possible benefit from the use of the HUD, if any.]*

**Will it cost you anything to use the HUD?**

If your insurance company will not pay for the procedure or the device, you will be responsible for these costs. If your insurance company will pay for only a portion of the procedure or the device, you will be responsible for the costs that insurance does not cover. You can talk with your physician about the costs.

**Will you be paid for using the HUD?**

You will not be paid for receiving the device.

**Can you decide not to allow the use of the HUD?**

Yes, you can decide not to allow use of the HUD. *[Also explain whether subject may withdraw consent at a later date, and if the device cannot be removed once it has been used include language to that effect, or if it can be removed, provide a brief description of what that would entail. Edit text to make applicable]*  You may also withdraw your consent to have the device used any time *[insert restrictions such as before the procedure to implant the device is performed.* ] For example, if you consent today for a procedure scheduled for tomorrow, you can still change your mind tomorrow. *[Edit as needed]* Once the device is implanted it may/may not be removed.

**What are the options if you do not want to use the HUD?**

*[Describe alternatives other HUDs or investigational devices that are available that should be considered before deciding whether or not to use this HUD. If there are no alternatives, state that an alternative is to not allow the use of the HUD. Avoid suggesting that participation is the only way to obtain medical care.]*

You do not have to agree to the use of [*insert name of HUD].* If you do not agree, you will continue to receive standard care for your condition. Your care at UConn Health will not be adversely affected if you choose not to receive the HUD.

*[Edit to select the appropriate Statement, edit text as necessary, delete non-relevant statements]* There is currently no other approved device available to treat your condition. [OR] There is one other device approved as an HUD for this condition. [OR] There is research being done on another device and you could explore if that clinical trial is appropriate for you] [If applicable, provide a brief description of the other device.]

**Who will pay for treatment if you are injured as a result of the use of the HUD?**

If you are injured as a result of the use of *[insert name of HUD]*, your insurance company will be billed for the costs of treatment. Neither UConn Health, nor the FDA, nor the government has any program that would pay the costs for the use of [*insert name of HUD].*or for the treatment of any complications of the procedures required for the use of[*insert name of HUD].*

**What other things should you know?**

**a. Whom should you call if you have questions about the device?**

Call the principal physician, Dr. \_\_\_\_\_\_\_ at *[insert telephone number.]*

# **b. What should you do if you have a device-related problem?**

 If you have an urgent medical problem related to the use of the HUD, call [*designated physician]* at [*phone or beeper number available 24 hours.]*

If you think you are injured or ill as a result of the use of the HUD, call the principal investigator, Dr. \_\_\_\_\_\_\_\_, at [*insert telephone number.]*

The medical services at UConn Health will be available to you as they are to all sick or injured individuals. UConn Health does not have a program to pay you if you are hurt or have other bad results from receiving this device. You are financially responsible for payment of any treatment or hospitalization. At your request, your insurance provider will be billed for payment of any treatment or hospitalization.

**What does your signature mean?**

By signing this consent form you are not giving up any legal rights. Your signature means 1) that you have had information about the HUD explained to you, 2) that you have been given the opportunity to ask questions and 3) that you accept the provisions in this form, and you agree to receive the HUD.

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Patient’s Printed Name

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Patient’s Signature Date

[Add other signature lines as needed to reflect assent of minors or decisionally impaired individuals, consent from legally authorized representatives, witnesses etc..]

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Printed Name of Individual Obtaining Consent

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Signature of Individual Obtaining Consent Date

**NOTE:** A copy of the signed and dated consent form must be kept by the principal physician, a copy must be given to the patient, and a copy must be placed in the patient’s record.