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| **IRB Study Number:**  **Title:** |

**Humanitarian Use Device**

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| NAME OF HUMANITARIAN USE DEVICE | |
| HDE NUMBER | HDE HOLDER |

**Confirmatory Statements:**

I confirm that the following statements are true:

* This application of the humanitarian use device (HUD) is limited to the indication(s) approved by the FDA in the HDE.
* This HUD is **NOT** being used to collect safety or probable effectiveness data.

**NOTE: *If both statements are not true, you must complete the full IRB application. A HUD used in a clinical investigation (i.e., to collect safety and probable effectiveness data) is considered to be used for “investigational use”, whether or not the device is used for the HDE-approved indication. Such investigational use is subject to the IDE regulations at 21 CFR Part 812 in addition to complying with the requirements for IRB approval (21 CFR Part 56) and protection of human subjects (21 CFR Part 50).***

**Background**

1. Provide a description of the device:
2. What disease(s) or condition(s) will the device be used to treat or diagnose?
3. What alternatives are available to treat or diagnose the disease(s) or condition(s) described above?
4. Describe the patient population who will receive the device, including criteria for determining patient eligibility (i.e., screening procedures).

**Subject Population**

Requested number of patients:

Notes:

* This is a specific number and you must not exceed this number. To increase the number of approved patients, a modification must be submitted to the IRB and approved prior to using the HUD in additional patients.

Age Range (check all that apply):

Newborn to 17 years of age\*

18 or older

**Procedures**

# Summarize the procedures for use of the device, including any ancillary procedures associated with use of the HUD such placement or implantation. Include any follow-up visits, tests or procedures.

1. Is any training required from the HDE holder (sponsor) prior to the health care practioner using the device?

No

Yes.

**If Yes**, Describe the training and indicate who will receive training.

1. Describe how the HUD will be controlled, including the storage location, the procedures for storage, dispensing, and limiting access to the individuals listed as personnel on this application to prevent the inappropriate use of the device or the use by non-approved health care practitioners.

# Outline the schedule for monitoring the clinical use and safety of the HUD, including follow-up patient visits, tests, or procedures.

# What financial obligations will the patient incur as a result of receiving this device?

**Risks and Benefits**

1. List the **possible risks** and/or adverse events associated with the clinical use of the HUD (include risks associated with ancillary procedures required for use of the HUD, such as placement or implantation) and how will risks be minimized:

2. List the **potential benefits** to the patient associated with the clinical use of the HUD:

3. Is there a data and safety monitoring plan?  No  Yes

**If YES**, please describe the data safety monitoring plan in detail:

**If NO**, please describe the methods to be used in this study to monitor the ongoing safety of the subjects (for example: sponsor medical monitor, AE reporting, protocol specific safety features like stopping rules, etc.).

1. Will anyone outside of UNC have access to identifiable data?  No  Yes

**If YES**, please describe who the data will be shared with and for what purpose:

**Patient Identification and Informed Consent**

1. How will potential patients be initially identified?
2. Please describe the proposed consent process.
3. Please discuss whether there will be any waiting period between informing the prospective subject and obtaining consent, (e.g., does the indication for the HUD require consenting of potential patients emergently?).

**Notes:**

* *If the PI plans to delegate the responsibility for obtaining informed consent, please ensure that all individuals are listed on the study personnel list in IRBIS.*
* *If applicable, please upload the consent document(s) that you intend to use. If you plan to use standard UNC Consent for Healthcare, state this above.*
* *The IRB may require informed consent that is consistent with the approved labeling*

**Required Attachments** [**(see Listing of CDRH Humanitarian Use Device Exemptions)**](http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/hdeapprovals/ucm161827.htm)

1. FDA Approval Order/Documentation of the HDE
2. Summary of Safety and Probable Benefit
3. Product Labeling
4. Consumer Information (HUD information packet to be provided to patients)
5. Hospital-approved procedure consent form OR HUD-specific consent form that will be used to obtain consent.