**VA Portland Health Care System (VAPORHCS) Institutional Review Board (IRB3)**

**HUMANITARIAN USE DEVICE INITIAL REVIEW QUESTIONNAIRE (HUD IRQ)**

VAPORHCS PI Name:       Date:

***NOTE:*** *PI listed must be eligible to serve as VAPORHCS PI, or responsible clinician, as defined in the* ***VAPORHCS IRB P&P/SOP*** *located at:* [*https://www.va.gov/PORTLANDRESEARCH/documents/irb/irb-sop.doc*](https://www.va.gov/PORTLANDRESEARCH/documents/irb/irb-sop.doc)

Study/Project ID#:

**Checklist for Submission:**

[ ]  This completed and signed **HUD IRQ**

[ ]  **[ATTACHMENT(S) REQUIRED]** Attach the HUD and Humanitarian Device Exemption (HDE) documentation provided by the manufacturer, including the HDE approval order and any labeling and package insert information.

[ ]  An **Enterprise Research Data Security Plan (ERDSP)** located by navigating to Forms and Templates; selecting VHA ORPP&E, Washington, DC - Documents for Human Subjects Researchers, and then selecting **ERDSP Template**. ***NOTE:*** *This form is required for the Information System Security Officer (ISSO) review and is not an IRB regulated form or review. Please direct questions regarding completing the ERDSP to the VAPORHCS ISSO, Scott Griffin.*

[ ]  COIs for all applicable staff included with submission. *Submit a Conflict of Interest in Research Form for the PI and each Co-PI, study Chair and/or co-investigator/sub-investigator working on this research at the VAPORHCS or on VAPORHCS time.*

[ ]  [IRQ Appendix L, Scope of Work (SOW)](https://www.va.gov/PORTLANDRESEARCH/documents/irb/irq-appendix-l.docx) for each person involved with this HUD at VAPORHCS.

1. Name of the device (generic and trade names, if applicable):
2. Manufacturer of the device:
3. Date of HUD Designation:
4. HUD number (supplied by manufacturer):
5. The HUD will be used:

[ ]  According to its approved labeling and indication(s) to treat or diagnose patients; ***OR***

[ ]  In a clinical investigation/research study to collect safety and effectiveness data *[in which case the use is subject to the same requirements that apply to all FDA-regulated clinical studies, including the IDE regulations if the HUD is being studied for a use other than its approved indication(s)]*.

1. Indication(s) for use of the device (this information should be provided to you by the manufacturer and must be the same information that the FDA received in issuing the HDE):
2. Describe the device itself, the proposed mechanism of action of the device and any post-manufacturing modifications to the device.
3. Provide a summary of how the device will be used at the VAPORHCS. If this application is not being submitted as part of a clinical investigation/research study, include here a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures. (If an attachment is used to provide this information, please state so here.)
4. Explain any alternative practices and procedures (i.e., other clinical/standard care, besides the device), indicating how their risks and benefits compare to those of the HUD. (If there are no alternatives, indicate so.)
5. If the HUD is being used according to its approved labeling and indication(s) to treat or diagnose patients, attach a sample clinical consent form for the use of the HUD.

Attached [ ]  N/A – used for a clinical investigation/research study [ ]

1. Explain the frequency and/or total duration of use of the device in an individual.
2. What are the contraindications, warnings, and (special) precautions for the use of the device? (This information should be provided to you by the manufacturer.)
3. Describe any foreseeable adverse effects of the device (provided by the manufacturer.)
4. What is the manufacturer’s risk designation for the device?

Non-significant [ ]  Significant [ ]

[ ]  N/A – only required if the HUD is being used in a clinical investigation and/or outside of approved indication/labeling

1. Is the clinician/PI (and, if applicable, research team) familiar with the FDA regulatory requirements regarding this type of device? Yes [ ]  No [ ]
2. Does the clinician/PI have the appropriate credentials and privileges at VAPORHCS for determining which patients should be eligible for the device and to perform the interventions necessary for use of the device?

 [ ]  Yes: Clinician’s/PI’s CV is attached to this application

 [ ]  No:Approval will not be granted **[STOP APPLICATION AND DO NOT SUBMIT]**

1. Does the VAPORHCS have appropriate laboratory and other facilities for any tests needed in determining patient eligibility and qualified physicians for interpreting results of laboratory data?

 [ ]  Yes [ ]  No, the requirements will be met by (provide explanation):

**Investigator Assurances:**

1. The use of this HUD, as described in this application, will not contribute data to any /clinical investigation/research study [ ]  True [ ]  False

***OR***

1. *For a clinical investigation/research study involving the HUD*, all regularly required IRB paperwork is being submitted simultaneously with this application [ ]  True [ ]  False

***AND***

1. Any serious adverse events that occur in participants receiving this device will be promptly reported to the IRB, as well as the device manufacturer and the FDA; ***AND***
2. All applicable FDA regulations for use of an HUD will be followed (see 21 CFR 814).

­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature of Clinician/Principal Investigator Date