VA | U.S. Department of Veterans Affairs
Veterans Health Administration
VA Healthcare – VISN 4
Multi-Site Institutional Review Board

HUMANITARIAN USE DEVICE (HUD) INITIAL APPLICATION

Facility: Select Facility **Date:** _____

Title/Device Name: _____

Manufacturer: _____ **Humanitarian Device Exemption (HDE) #:** _____

Local HUD Holder: _____

Email: _____ **Phone:** _____

NOTE: This HUD is NOT being used in a clinical investigation and/or outside of approved indication/labeling, it is not considered research. Therefore, research personnel credentialing, appointment(s) and training requirements do not apply. Personnel forms such as the Scope of Practice and Conflict of Interest do not need to be included with this application.

REQUIRED ATTACHMENTS:

- Current CV of HUD holder
- Consent form, if applicable
- The device instruction manual, insert or other documents with information about the device
- A copy of the FDA's HDE Approval Order
- Any other documents to be provided to patients

Is the use of the HUD to evaluate its safety and/or effectiveness, or to compare use of the device to another treatment/therapy modality?	☐ Yes	☐ No

If Yes, STOP here. The project is research and a full application must be submitted to the IRB for review and approval. Contact the Research Office for additional information.

1.	Date of HUD Designation:				
2.	Where will the device be stored?	Bldg #		Room #	
3.	Describe any special conditions under which the device will be stored.				
4.	Describe how the device will be controlled (include an approximate number of individuals expected to have access to the device and an explanation of how users will gain access and/or permission to use the device).				

5.	Describe the device, including proposed mechanism of action of the device and any post-manufacturing modifications.
6.	Indication(s) for use of the device *(provided to you by the manufacturer and must be the same information the FDA received in issuing the HDE)*.
7.	Describe the benefits of using the device for the patient population.
8.	Describe any foreseeable risks of using the device.
9.	Summarize how the device will be used at the facility. Describe:
	a. Any screening procedures used to establish eligibility.
	b. The frequency and/or total duration of use of the device in an individual.
	c. Procedures to use the HUD.
	d. Any tests or procedures performed before, during or immediately after use of the HUD.
	e. Any patient follow-up visits or tests to be performed after the device has been used.

10.	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, state so here.)*		
11.	Describe the consent process to be used. If a consent process will not be used, state so here.		
12.	Explain the contraindications, warnings, and (special) precautions for the use of the device *(provided by the manufacturer)*.		
13.	Describe any foreseeable adverse effects of the device *(provided by the manufacturer)*.		
14.	What is the manufacturer's risk designation for the device?		
	☐ Significant ☐ Non-Significant		
	***NOTE**: The IRB does NOT makes this determination.*		
15.	Is the clinician/PI (and, if applicable, the research team) familiar with the FDA regulatory requirements regarding this type of device?	☐Yes	☐No
	If No, contact the Research Office for the FDA regulatory requirements.		
16.	Does the clinician/PI have the appropriate credentials and privileges at the medical center for determining which patients should be eligible for the device and to perform the interventions necessary for use of the device?	☐Yes	☐No
	If No, approval cannot be granted.		
17.	Does the facility 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
	If No, how will the requirements will be met:		

INVESTIGATOR ASSURANCE

1. The use of this HUD will not contribute data to any ongoing research project or clinical investigation.
2. 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.
3. All applicable FDA regulations for use of an HUD will be followed (21 CFR 814).

Local HUD Holder Signature **Date**

I concur that the clinician has the appropriate credentials and privileges at the medical center and will be able to determine which patients are eligible for the HUD and to perform the necessary interventions for its use.

Supervisor/Care Line ACOS Signature **Date**

M-S IRB USE ONLY:

DISPOSITION OF FULL BOARD INITIAL REVIEW:

☐ HUD use meets review criteria in 21 CFR 56 and is approved.

☐ HUD use is disapproved.

Approval Date:

Expiration/Continuing Review Date:

M-S IRB Chairperson or Designee Signature **Date**