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

IRB Initial & Continuing Review of Humanitarian Use Device (HUD)



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| **VAPORHCS PI Name:** |  |
| **Study/Project ID#:** |  |
| **Type of Review:** | [ ]  Initial [ ]  Amendment [ ]  Continuing Review |

**IRB Reviewer:**

*Reviewer attestation: by entering my name above, I am confirming that I completed this review and did not have a conflict of interest with this protocol.* ***NOTE:***If you have a conflict of interest in reviewing this protocol, please contact an IRB Analyst via pvamc-irb@va.gov immediately, so that this review may be reassigned.

***NOTE:*** *A list of approved HDEs is available via the following link. Click on the number of the appropriate HDE to view the approval order, labeling, and patient information.* <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm>



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| --- | --- | --- | --- |
|  |  | **Yes** | **No** |
|  | Has the FDA granted a Humanitarian Device Exemption (HDE)? | [ ]  | [ ]  |
|  | Based on review of the HDE information and the information received from the PVAMC clinician, are the risks to patients (physical, social, psychological, economic, and legal risks) minimized by using procedures consistent with product labeling and that do not unnecessarily expose the patients to risk? | [ ]  |  [ ]  |
|  | Are all appropriate measures of disease progression used in determining eligibility of the patient for use of the HUD? | [ ]  |  [ ]  |
|  | Is there assurance that all other possible treatment modalities will have been tried and determined to have failed before using the HUD?  | [ ]  |  [ ]  |
|  | When considering the patient’s need for the HUD, is the likelihood that the device is appropriate for the patient’s condition or disease state determined appropriately? | [ ]  |  [ ]  |
|  | Does the physician have the appropriate training and qualifications for safe and effective use of the HUD?  | [ ]  |  [ ]  |
|  | Will all appropriate histories, physical exams, and lab tests be conducted in determining a patient’s need for the HUD, and are there qualified physicians in place to interpret any necessary laboratory/ data?  | [ ]  |  [ ]  |
|  | Are the risks reasonable in relation to anticipated benefits? | [ ]  | [ ]  |
|  | All items on the HUD Application/CRQ have been completely and satisfactorily answered. | [ ]  | [ ]  |
|  | Should any limitations be specified on the use of the device other than those listed on the application? If YES, please describe:       | [ ]  | [ ]  |

**Go to “Recommendation” Section if this is not a continuing review.**

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| **Answer the following if this is a Continuing Review:** | **Yes** | **No** |
| 1. Have there been any changes in the HDE documentation, any SAEs, or any new information from the manufacturer since the last review?
 | [ ]  | [ ]   |
| 1. If **YES to 1**, does this change the risks to patients receiving the device?

[ ]  N/A – no patients enrolled | [ ]  | [ ]  |
| 1. If **YES to 1**, does this change the risks to patients receiving the device?

[ ]  N/A – no patients enrolled | [ ]  | [ ]  |
| 1. Does this HUD meet criteria for expedited continuing review per 21 CFR 814.124(a) and 21 CFR 56.110?

**NOTE: IRBs may use the expedited review procedures, if:** *The HUD is being used according to its approved labeling and indication(s) to treat or diagnose patients.* | [ ]  | [ ]  |
| **RECOMMENDATION** |

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| --- | --- |
| [ ]  | **Approval:** as is, no changes needed. |
| [ ]  | **Contingent Approval:**  |
| [ ]  | **Defer:** delay approval because **substantive** issues must be resolved. *Only permitted if review by convened IRB.* |
| [ ]  | **Disapprove:** *Only permitted if review by convened IRB.* |

**Comments:**