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| **VAPORHCS PI Name:       Date:**  **Study/Project ID#:** |  |  |  |



**Instructions (OHSU/VA Joint IRB Studies ONLY):**

* Complete this form using information for HUD activities conducted at VAPORHCS (e.g., do not include enrollment numbers for OHSU patients, reportable events that occurred at OHSU and/or related to OHSU patients only, etc.). If a question does not apply to the HUD activities conducted at VAPORHCS, provide an explanation.
* **Conflict of Interest (COI) in Research Form**

*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.*

COIs for all applicable staff included with submission.

* Submit this form along with any additional documents prompted by the individual questions in the HUD CRQ, and the required additional documents listed below via eIRB by the due date indicated in the Continuing Review Reminder email. ***Unless otherwise noted, all forms/boilerplate referenced in this document can be found at:***<https://www.va.gov/PORTLANDRESEARCH/piservices/rd_forms.asp> **OR** <https://www.va.gov/PORTLANDRESEARCH/hrpp/index.asp>



1. Name of the Device (generic and trade names if applicable):
2. Name of Manufacturer of Device:
3. Date of HUD Designation:
4. HUD number (supplied by manufacturer):
5. How many patients received the device at VAPORHCS since the last review?
6. Have any unanticipated serious adverse events occurred in patients who received this device since the last IRB review?

YES

NO *If* ***NO****, go to Q.7.*

* 1. If **YES to Q.6.**, were the event(s) previously reported to the IRB? YES NO
  2. If **NO** to **6.1.**, please explain why the event(s) were not reported:

1. Have there been any new contraindications, warnings, or precautions for the use of the device issued by the manufacturer since the last review?

YES *If* ***YES****, please include a copy with this form’s submission to eIRB.*

NO

1. Have there been any changes in the HDE documentation since the last review?

YES *If* ***YES****, please include a copy with this form’s submission to eIRB.*

NO

1. 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

