



U.S. Department of Veterans Affairs  
 Veterans Health Administration  
 VA Healthcare – VISN 4

**Multi-Site Institutional Review Board**

**HUMANITARIAN USE DEVICE (HUD)  
 CONTINUING REVIEW**

**Facility:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Title/Device Name:** \_\_\_\_\_

**Manufacturer:** \_\_\_\_\_ **Humanitarian Device Exemption (HDE) #:** \_\_\_\_\_

**Local HUD Holder:** \_\_\_\_\_

**Email:** \_\_\_\_\_ **Phone:** \_\_\_\_\_

- |    |   |                              |                             |
|----|---|------------------------------|-----------------------------|
| 1. | Date of HUD Designation:  |                              |                             |
| 2. | How many patients received the device since the last review?  |                              |                             |
| 3. | Have any unanticipated serious adverse events occurred in patients who received this device since the last review? <i>If No, continue to 5.</i> | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
|    | <i>If Yes, was/were the event(s) previously reported to the IRB?</i>  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 4. | Have there been any new contraindications, warnings, or precautions for the use of the device issued by the manufacturer since the last review? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
|    | <i>If Yes, attach a copy.</i>   |                              |                             |
| 5. | Have there been any changes in the Humanitarian Device Exemption (HDE) documentation since the last review? <i>If Yes, please explain.</i>      | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

**INVESTIGATOR ASSURANCE**

The use of the HUD as described above will not contribute data to any ongoing research project or clinical investigation

**Local HUD Holder Signature**

**Date**

**M-S IRB USE ONLY:**

**DISPOSITION OF CONTINUING REVIEW:**

- HUD use may continue; continues to meet review criteria in 21 CFR 56.
- HUD use must be suspended.
- HUD use must be terminated/closed

**Next Continuing Review Date:**

- Full Board
- Expedited

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

**Date**