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| **HUMANITARIAN USE DEVICE INFORMATION FORM**  **(Non-Emergency: Full Board Review)** |
| **INSTRUCTIONS AND INFORMATION**  A Humanitarian Use Device (HUD) is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or are manifested in fewer than 8000 individuals in the United States per year. The sponsor must obtain a Humanitarian Device Exemption (HDE) designation from the FDA's Office of Orphan Products Development.  Even though the device is not considered investigational, IRB review is required.  The initial review must by performed by the full board, although continuations may be done by expedited review.  Submission for the use of a HDE does not require the submission of a protocol, consent form, Investigator’s Agreement and Human Subject Protection Training are NOT required. **Do not use CRCONNECT or Protocol Builder**  **NOTE: DO NOT use this form for an EMERGENCY USE HUD. Refer to “**[**Request for IRB Concurrence of Single Patient Emergency Treatment with an Investigational Medical Device”**](https://research.virginia.edu/sites/vpr/files/2020-04/Request%20for%20IRB%20Concurrence-Emergency%20Device.docx) |

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| **Manufacturer Name:**  **Generic and Trade name of the Device:**  **FDA assigned HDE#:**  **Projected Date of HUD administration:** | |
| **1.** | Indication for use of the device: |
| **2.** | Provide description of the device: |
| **3.** | List any contraindications, warnings, and precautions for use of the device: |
| **4.** | List adverse effects of the device on health: |
| **5.** | List any alternative procedures: |
| **6.** | Does this study involve the use of radiation for research purposes?  Yes  No  ***If Yes****, Radiation Safety Board approval is required unless standard wording from the IRB-HSR Website is used.* |
| **7.** | To avoid any conflict of interest are any IRB-HSR members/alternates listed on the protocol or 1572 form?  Yes  No  **If Yes**, list names: |
| **8.** | What steps will be taken to minimize risk in this patient population? |
| **9.** | **UVA Treating Physician Confirmation:**  As the healthcare provider using this HUD, do you confirm the following:   * You are responsible for submitting reports to the FDA, the IRB, and the manufacturer/HDE Holder whenever a HUD may have caused or contributed to a death, and * You must submit reports to the manufacturer (or to FDA and the IRB-HSR if the manufacturer is unknown) whenever a HUD may have caused or contributed to a death or \*serious injury, or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur [21 CFR 803.30 and 814.126(a)] and. * Is responsible for submitting continuing review materials to the IRB sufficiently in advance of the expiration date to ensure IRB review and re-approval prior to expiration?   \*Serious injury means an injury or illness that (1) is life-threatening, (2) results in permanent impairment of a bodily function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a bodily function or permanent damage to a body structure (21 CFR 803.3).  Yes  No |

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| **Study Personnel**   * All individuals involved in the use of this HUD must be listed below as study personnel. * All e-mails from the IRB-HSR regarding the use of this HUD will be sent to the PI, Study Coordinator, Department Contact and IRB Departmental Coordinator (if applicable) * Only 1 person may be listed as the PI by the IRB-HSR. If the PI is NOT a faculty member a faculty member must be listed as a sub-investigator. Students are not allowed to be the Principal Investigator. | | | | | |
| **Principal Investigator** | | | | | |
| First name: | | Last name: | | | Email: |
| **Department Contact** | | | | | |
| First name: | Last name: | | Email: | | |
| **IRB/Study Coordinator** | | | | | |
| First name: | Last name: | | | Email: | |
| **Sub-Investigator** | | | | | |
| First name: | Last name: | | | Email: | |
| **Sub-Investigator** | | | | | |
| First name: | Last name: | | | Email: | |

**Submit the following documents to** [**sirb@virginia.edu**](mailto:sirb@virginia.edu) **:**

1. Completed *HUD Information Form*
2. [HUD Consent](https://research.virginia.edu/sites/vpr/files/2020-04/Humanitarian%20Use%20Device%20HUD%20Consent%204-23-20.docx)
3. Device Information Manual/Document
4. New Medical Device application if device is new to UVA (This form must now be completed on line at <https://www.healthsystem.virginia.edu/newmedicaldevice/index.cfm?requestid=new>
5. FDA approval letter /assigned HUD#
6. Any additional documentation from the manufacturer

NAME OF UVA TREATING PHYSICIAN*:*

**SIGNATURE OF UVA TREATING PHYSICIAN**:  **DATE:**

For assistance contact: contact either Eileen Sembrowich (x36542/ [ecs3b@virginia.edu](mailto:ecs3b@virginia.edu)) or Susie Hoffman x49634 /[srh@virginia.edu](mailto:srh@virginia.edu))