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| **HUMANITARIAN USE DEVICE INFORMATION FORM**  **(Non-Emergency: Full Board Review-For Clinical Use Only)** |
| **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 not more than 8,000 individuals in the United States per year. HUD designations are issued by the FDA. 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.  Once IRB approval is granted, use of the HUD within the approved indication(s), as well as other clinical uses that are intended solely to address the specific needs of an individual patient(s) is allowed. All uses of the HUD for clinical treatment and diagnosis at an institution are to be reported to the IRB at the time of continuing review.  Submission for the use of a HUD does not require the submission of a protocol, consent form, Investigator’s Agreement or Human Subject Protection Training \*\* **Do not use CRCONNECT or Protocol Builder\*\***  **NOTE: DO NOT use this form for a Single 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#:**  **Is this off-label use of the HUD?**  Yes  No  *If applicable, provide documentation from the HDE holder allowing off-label use or attestation that use does not violate existing restrictions or limitations.* | |
| **1.** | **Briefly describe the device:** |
| **2.** | **Age range of patient(s):**    **Number of patient(s) for whom clinical use of the HUD is requested:** |
| **3.** | **What disease(s) of condition(s) do you plan to treat or diagnose with the use of the device?** |
| **4.** | **Describe available alternatives to treat or diagnose the disease(s) or condition(s) described above, indicating how the risks and benefits compare to those of the HUD. If there are not available alternatives, state this.** |
| **4.** | **Describe the potential risk to patients vs. potential benefit from use of the HUD, including related ancillary procedures such as device placement or implantation.** |
| **5.** | **List any contraindications, warnings, and precautions for use of the device:** |
| **6.** | **List potential risks of the HUD:** |
| **7.** | **What steps will be taken to minimize risk in this patient population; outline the plan of care for the patient(s) including follow up visits, tests or procedures?** |
| **8.** | **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. * You are 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 NAME OF UVA TREATING PHYSICIAN*:* |

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| **HUD Personnel**   * All individuals involved in the use of this HUD must be listed below as personnel. | | | | | |
| **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** [**irbhsr@virginia.edu**](mailto:irbhsr@virginia.edu) **:**

1. Completed *HUD Information Form (this form)*
2. HUD Patient Information Document (May submit document from manufacturer or one developed from [HUD Patient Information Document Template.](https://research.virginia.edu/sites/vpr/files/2021-05/Humanitarian%20Use%20Device%20HUD%20Patient%20Information%20Template-05-18-21.docx)
3. Device Information Manual/Document
4. New Medical Device application if device is new to UVA (This form must now be completed online at <https://www.healthsystem.virginia.edu/newmedicaldevice/index.cfm?requestid=new>
5. The FDA HDE (Humanitarian Device Exemption) number and approval order (obtainable from the HDE-holder or the [FDA’s website](https://www.fda.gov/medical-devices/hde-approvals/listing-cdrh-humanitarian-device-exemptions))
6. Any additional documentation from the manufacturer and/or information materials to be provided to the patient(s).