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| **Section I: Instructions** | |
| 1. Per OSF HealthCare (OSF) policy ([Humanitarian Use Device (HUD): Non-Investigational (PDF - 127.2 KB) (osfhealthcare.org)](https://www.osfhealthcare.org/media/filer_public/82/69/8269356a-8b64-4e58-9214-31c13ac560cf/humanitarian_use_device_-hud-_non-investigational_policy.pdf), a prospective physician user must obtain OSF permission through Research Administration PRIOR to obtaining IRB review/approval of a Humanitarian Use Device at a facility. To request permission, complete this form electronically and email it and all required documents to [OSF Research Administration](mailto:osf.clinicalresearch@osfhealthcare.org?subject=HUD%20Application). | |
| **2.** Use this Form for NON-INVESTIGATIONAL use of an HUD. Use the [HUD Decision Tree Guidance](https://www.osfhealthcare.org/filer/canonical/1589212743/11238/) for information about investigational use of an HUD. . If planning investigational use of an HUD, then DO NOT use this form. Instead, complete and submit the [OSF Research Application Form](https://www.osfhealthcare.org/filer/canonical/1496498314/5647/) along with other materials accompanying the clinical investigation. | |
| **3.** Use the following checklist to ensure that all required components of your HUD Application are addressed:  OSF HUD Application Form  Peoria IRB “Project/Protocol Review Form” (NOTE: Contact OSF Research Administration with questions/concerns about IRB review)  OSF Material Resource Utilization / New Product Committee approval - Request review here: <https://app.lumere.com/providers/osf/requests/add/>  FDA Approval Order/Documentation of the HDE - See the [Listing of CDRH Humanitarian use Device Exemptions](https://www.fda.gov/medical-devices/hde-approvals/listing-cdrh-humanitarian-device-exemptions)  FDA Summary of Safety and Probable Benefit (SSPB) of the HDE  Data and Safety Monitoring Plan  Technical Manual  Consumer Information (HUD information packet to be provided to patients)  Ancillary Department Approvals (if applicable) | |
| **Section II: General Information** | |
| **1. Name of Humanitarian Use Device:** | |
| **2. HDE Number:** | **3. HDE Applicant/Holder:** |
| **4. IRB of Record:** | **5. IRB ID#:** |
| **6. Primary Physician User Name:** | |
| **a. Primary Employing Institution:**  **b. Secondary Employing Institution (if applicable):**  **c. Credentialed/Privileged at OSF?** | |
| **d. Email:** | |
| **e. Phone:** | |
| **7. Name of OSF facility where the HUD will be used:** | |
| **8. User Facility Department Signatory**   1. **Name:** 2. **Role (e.g., Cath Lab Supervisor):** 3. **Department:** 4. **Email Address:** 5. **Phone:** | |
| **9. List all Other Physician Users who plan to use the HUD at the facility listed above:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **NAME** | **EMPLOYER** | **PRIMARY EMAIL** | **PRIMARY PHONE** | **CREDENTIALED/PRIVILEGED AT OSF?** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | | |
| **Section III: Background** | |
| **1. Provide a description of the device:** | |
| **2. What disease(s) or condition(s) will the device be used to treat or diagnose?** | |
| **3. What alternatives are available to treat or diagnose the disease(s) or condition(s) described above?** | |
| **Section IV: Procedures** | |
| **1. Describe the patient population who will receive the device, including the age range and criteria for determining patient eligibility (i.e., screening procedures):** | |
| **2. Summarize the procedures for use of the device, including any ancillary procedures associated with use of the HUD, such as placement or implantation. Include any follow-up visits, tests or procedures:** | |
| **3. Is training required from the HDE holder (sponsor) prior to the health care practitioner using the device?** | |
| No | |
| Yes **>** Describe the training and indicate who will receive training: | |
| **4. Describe how the physician and/or supporting department(s) will control the HUD, including the storage location, the procedures for storage, dispensing, and limiting access to the individuals listed as personnel above in Section II: General Information to prevent the inappropriate use of the device or the use by non-approved health care practitioners:** | |
| **5. Outline the schedule for monitoring the clinical use and safety of the HUD, including follow-up patient visits, tests, or procedures:** | |
| **6. What financial obligations will the patient incur as a result of receiving this device?** | |
| **7. Will anyone outside of OSF have access to identifiable data?** | |
| No | |
| Yes **>** Identify and describe details (i.e., who will have access, reasons for access, how access will occur and be monitored/documented, etc.): | |
| **Section V: Patient Identification & Informed Consent** | |
| **1. How will potential patients be identified?** | |
| **2. Who will conduct informed consent discussions with patients?** | |
| **3. Describe the proposed consent process:** | |
| **4. Explain whether there will be a waiting period between informing the prospective subject and obtaining consent (e.g., does the indication for the HUD require consenting of potential patients emergently?):** | |
| **Section VI: Confirmatory Statements** | |
| **As the Primary Physician User responsible for the use of this HUD, AND the User Facility Department**  **Signatory, we attest that the following statements are true:** | |
| Our primary intent is to use this HUD according to its FDA-approved HDE indications.  We will abide by OSF and IRB requirements when I/we use this HUD OUTSIDE of its HDE indications (e.g., “off-label”) OR for investigational purposes; and. | |
| This application is NOT for investigational use of the HUD. | |
| Note: If your intent is to use this HUD as an INVESTIGATIONAL DEVICE, then DO NOT complete this form. Complete and submit the OSF “Research Application Form” and other materials accompanying your clinical trial. | |