STUDY INFORMATION

Complete this form if you need IRB approval for the use of a humanitarian use device (HUD).

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| **1** | Industry/Private Sponsor |
|  | List the sponsor in the space below.To input text, click in the light grey area below.  |
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| **2** | UT Funding Account Number |
|  | If industry sponsored, provide the applicable UT account number.To input text, click in the light grey area below.  |
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| **3** | Name of the Device |
|  | To input text, click in the light grey area below.  |
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| **4** | Description of Device |
|  | If a device description is provided through FDA reviewed instructions, please state so below and upload those documents as “files related to the device.” Alternatively, provide a description of the device below.To input text, click in the light grey area below.  |
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| **5** | Description of Condition/Disease |
|  | Describe the condition or disease for which this use of a HUD is intended.To input text, click in the light grey area below.  |
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| **6** | FDA Approved Indication |
|  | If an FDA approved intended indication for this device is provided through FDA reviewed documents, please state so below and upload those documents as “files related to the device.” Alternatively, provide a description of the device’s FDA approved indication or use.To input text, click in the light grey area below.  |
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| **7** | Device Provenance  |
|  | Describe the process of receipt, inventory, storage, and disposition of for unused devices. To input text, click in the light grey area below.  |
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| **8** | Eligibility Criteria |
|  | If eligibility criteria for the humanitarian use of this device is provided through FDA reviewed documents, please state so below and upload those documents as “files related to the device.” Alternatively, provide a description of eligibility criteria below.To input text, click in the light grey area below.  |
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| **9** | Risks |
|  | Describe possible risks to patients and why these risks are acceptable in light of potential benefits.To input text, click in the light grey area below.  |
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| **10** | Procedures |
|  | Summarize the proposed use of the device including 1) a description of any screening procedures, 2) the HUD procedure, and 3) any patient follow-up visits, tests, or procedures.To input text, click in the light grey area below.  |
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| **11** | Consent |
|  | Describe the process for consenting patients.To input text, click in the light grey area below.  |
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| **12** | Training - Recommendations |
|  | If training materials for the humanitarian use of this device is provided through FDA reviewed documents, please state so below and upload those documents as “files related to the device.” Alternatively, provide a description of edibility criteria below.To input text, click in the light grey area below.  |
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| **13** | Training – Received  |
|  | Describe the training of all physicians have received for the use of the HUD.Please note: The training should match or exceed what is required by the FDA/Sponsor.To input text, click in the light grey area below.  |
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| **14** | Training – Ancillary  |
|  | If other ancillary clinical personnel are required by the HUD holder to receive training on the device, provide each individual’s name, role, and a description of the training they have received.To input text, click in the light grey area below.  |
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| **15** | Supporting Documents |
|  | Upload additional supporting documents as “files related to the device” as needed |
|  | * HUD Labeling Information
* Proof of FDA Humanitarian Device Exemption (HDE)
* Manufacturer’s Clinical Protocol/Directions for Use
* Patient Information Packet
* A clinical protocol (if available)
* Informed Consent (this may be the manufacturer’s information packet)
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