The Christ Hospital

IRB Application for Humanitarian Use Device (HUD)

IRB Number:

HDE Number:

**Name of Humanitarian Use Device**

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**SECTION 1: CONTACT INFORMATION**

**Contact Person:**

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| **Name:**      **Phone:**      **Email:**       |

**Physician Responsible for HUD Use**

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| **Name:**      **Department:**      **Address:**      **Phone/Fax/Email:**      **Qualifications to use device:**      **Do you maintain active TCH Credentials and Privileges?** [ ]  **Yes -** [ ]  **No** |

**Other Physician Authorized to Use the Device**

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| **Name:**      **Department:**      **Address:**      **Phone/Fax/Email:**      **Qualifications to use device:**      **Do you maintain active TCH Credentials and Privileges?** [ ]  **Yes -** [ ]  **No** |

**Other Physician Authorized to Use the Device**

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| **Name:**      **Department:**      **Address:**      **Phone/Fax/Email:**      **Qualifications to use device:**      **Do you maintain active TCH Credentials and Privileges?** [ ]  **Yes -** [ ]  **No** |

**SECTION 2: DEVICE INFORMATION**

1. **Generic and Trade Name of HUD**

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1. **Date of HUD Designation**

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1. **Manufacturer of Device**

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1. **Provide a description of the device and its use.**

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1. **What is the disease or condition the device is intended to treat or diagnose?**

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1. **Describe the instances in which the device will be used.**

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1. **Provide a summary of how the physician proposes to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.**

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1. **Describe the contraindications, warnings and precautions for the use of this device.**

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1. **Describe the potential adverse effects of the device on the health of the patient.**

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1. **Describe the alternatives that are available to treat or diagnose the patient’s disease or condition.**

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1. **Describe the potential benefits to the patient associated with the use of the device.**

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1. **What safety and effectiveness data will be collected, if any?**

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1. **Describe the process for informing subjects of the use of the HUD.**

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**SECTION 3: PHYSICIAN RESPONSIBILITIES AND ASSURANCES**

**Please refer to TCH IRB *SOP 3.21 Humanitarian Use Device***

**The physician responsible for HUD use agrees/adheres to the following:**

1. The HUD is only being used within its approved clinical indications.
2. Comply with requirements for continuing review at the intervals determined by the IRB.
3. He/she is trained or experienced in the use of the device.
4. Submit the applicable forms to the FDA, TCH IRB, and whenever a HUD may have

caused or contributed to a serious injury (21 CFR 803.30 and 814.126(a)). Serious injury means an injury or illness that (1) is life-threatening, (2) results in permanent impairment of a body function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure (21 CFR 803.3). TCH IRB requires the submission of a Reportable Event form. (For more information on Reportable Events, refer to IRB *SOP 2.05* *Reporting Serious Adverse Events and Unanticipated Problems*)

1. Promptly report any FDA action(s) regarding the HUD to the IRB.
2. Promptly report any modifications to the HUD or the clinical use of the HUD, in accordance with the IRB procedures.
3. Notify the FDA of any withdrawal of approval for the use of a HUD by the IRB within 5 working days after being notified of the withdrawal of approval.
4. Obtain and document clinical informed consent (if applicable as required by the institution). (When the use of a HUD is for clinical diagnosis or treatment, i.e. not associated with human subject research activity, research informed consent and HIPAA regulations do not apply).
5. Provide patient information packets (when available) to patients prior to their receiving the HUD. If no packet is available, the patient should be provided with the following information:
	* + An explanation that the HUD is designed to diagnose or treat the disease or condition described in the HDE labeling and that no comparable device is available to treat the disease or condition.
		+ A description of any ancillary procedures associated with the use of the HUD.
		+ A description of the use of the HUD.
		+ All known risks and discomforts.
		+ Information reflecting the HUD status of the device including a statement indicating that the effectiveness of the device for this use has not been demonstrated.

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| **Physician Responsible for HUD Use Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:**       |

**SECTION 4: SUBMISSION CHECKLIST**

Please ensure that all applicable materials listed below are submitted to the IRB office:

[ ]  TCH IRB Application for Humanitarian Use Device

[ ]  The FDA HDE (Humanitarian Device Exemption) number and approval letter

[ ]  The product labeling

[ ]  Clinical brochure

[ ]  Patient information packet that may accompany the HUD