**Please ensure that all applicable materials listed below are submitted to the IRB office. The IRB will not put the HUD on an IRB agenda until all applicable materials listed below are received.**

\_\_\_\_\_\_\_\_\_\_\_\_ Humanitarian Use Device Application

\_\_\_\_\_\_\_\_\_\_\_\_ Generic and trade name of the device (may be included in the HUD application)

\_\_\_\_\_\_\_\_\_\_\_\_ A description of the device (may be included in the HUD application)

\_\_\_\_\_\_\_\_\_\_\_\_ Contraindications, warnings, and precautions for use of the device (may be included in the HUD application)

\_\_\_\_\_\_\_\_\_\_\_ Adverse effects of the device on health (may be included in the HUD application)

\_\_\_\_\_\_\_\_\_\_\_ Alternative practices and procedures (may be included in the HUD application)

\_\_\_\_\_\_\_\_\_\_\_\_ A summary (or protocol) 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

\_\_\_\_\_\_\_\_\_\_\_\_ HDE letter from the FDA

\_\_\_\_\_\_\_\_\_\_\_\_ FDA HDE number (may be included in the FDA letter)

\_\_\_\_\_\_\_\_\_\_\_ Date of HUD designation (may be included in the FDA letter)

\_\_\_\_\_\_\_\_\_\_\_ Indication(s) for use of the device (may be included in the FDA letter)

\_\_\_\_\_\_\_\_\_\_\_\_ Informed consent document or patient information sheet (if any)

\_\_\_\_\_\_\_\_\_\_\_\_ Copy of the HUD manufacturer’s product labeling, clinical brochure, patient information and all other pertinent material

\_\_\_\_\_\_\_\_\_\_\_\_ Principal Investigator Agreement

SAINT LUKE’S HOSPITAL INSTITUTIONAL REVIEW BOARD

HUMANITARIAN USE DEVICE APPLICATION

1. **Administrative**

|  |  |
| --- | --- |
| Physician responsible for HUD use: |  |
| Email address: |  |
| Phone Number: |  |

|  |  |
| --- | --- |
| Other physician using device: |  |
| Email address: |  |
| Other physician using device: |  |
| Email address: |  |
| Study Coordinator: |  |
| Email Address: |  |
| Phone Number: |  |

1. Device Information
2. Name of HUD:
3. Humanitarian Device Exemption (HDE) Number:
4. Manufacturer of Device:
5. Please provide a description of the device and its use.
6. What is the disease or condition the device is intended to treat or diagnose?
7. Describe the instances in which the device will be used.
8. Describe the contraindications, warnings and precautions for the use of this device.

1. Describe the potential adverse effects of the device on the health of the patient.
2. Describe the alternatives that are available to treat or diagnose the patient’s disease or condition.
3. Describe the potential benefits to the patient associated with the use of the device.
4. Describe the plan for monitoring patient safety after use of this device.
5. What safety and effectiveness data will be collected, if any?
6. Describe the process for informing subjects of the use of the HUD.
7. Describe the process for obtaining informed consent (if consent is obtained). (include who will obtain consent from subjects and where/when consent will be obtained).

Please provide a consent form specific to the use of the device utilizing the HUD consent template available.

By signing this form, the Principal Investigator assures the IRB that the following are true:

* The HUD is only being used within its approved clinical indications.
* Any serious and unexpected adverse event possibly related to the use of the device will be promptly reported to the IRB.
* He/she is trained or experienced in the use of the device.
* He/she will report the progress of the use of the HUD to the IRB no less than once per year and will obtain IRB approval for use no less than once per year.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Physician Responsible for HUD Use Date