**APPLICATION TO EMPLOY A HUMANITARIAN USE DEVICE FOR APPROVED INDICATIONS**

**THIS IS NOT AN APPLICATION TO CONDUCT RESEARCH WITH THE DEVICE**

Return this form to: Baptist IRB [Baptist.IRB@bmhcc.org](file:///\\MTCCBMHFP\PUBLIC$\Clinical\BCRI\IRB\IRB\IRB%20Administrative%20Operations\Current%20Forms\Latest%20IRB%20Forms%202018\IRB%20Applications\Revised%20Applications%206-1-18\Baptist.IRB@bmhcc.org%20) (Baptist IRB)

|  |
| --- |
| Part I. General Information |

**Date of Submission**:

**Physician:**

**Name of Device:**

**Device Manufacturer:**

**Hospital:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Part II. Personnel | | | | | | | |
| Physician The physician must have a formal affiliation and appropriate privileges with the facility where the HUD will be used. | | | | | | | |
| Name, Degree | |  | | | | | |
| Affiliation | |  | | | | | |
| E-mail | | @ | | | | | |
| Phone | |  | | | | | |
| Financial interest Does this device involve intellectual property created, invented or owned by the physician who will use the device? | | | Yes | | | No |
| Does the physician who will use this device have a financial relationship in the company that manufactures or distributes the device? | | | Yes | | | No |
| If you answered **Yes** to either question, please provide details about the intellectual property or financial relationship and what might be disclosed to patients. | | | | | | |
| Training in use of device Does the HDE approval letter from FDA require or specify that the physician receive training in use of the device? | | | Yes | | | No |
| If Yes, please provide documentation that the applicant has received the required training | | | | | | | |
| Use additional pages to submit the information requeste d above if more than one physician will use the device at he same location. | | | | | | | |
| Service line director of Baptist entity where device will be employed | | | | | | | |
| Name |  | | | | | | |
| Affiliation |  | | | | | | |
| E-mail | @ | | | | | | |
| Phone |  | | | | | | |
| Administrative contact for use of this device | | | | | | | |
| Name | |  | | | | | |
| Affiliation | |  | | | | | |
| E-mail | | @ | | | | | |
| Phone | |  | | | | | |
|  | |  | | | | | |
| PART III. Use of the Device | | | | | | | |
| Anticipated use of the device How many patients do you think will be treated with this device in 1 year?  Use of the device is anticipated in  Adult patients  Pediatric patients  Adult and pediatric patients  Please summarize how you intend to use the device. Include screening procedures and any patient follow-up visits, tests or procedures. | | | | | | | |
| Informed consent Does the manufacturer of the device require or allow informed consent by patients for use of the device?  Yes. Manufacturer requires a separate consent by patient.  Allowed. Manufacturer leaves decision to physician.  Please indicate whether you will use a consent document.  Not required by manufacturer. Decision left to local IRB | | | | | | | |
| Inventory control of the device Either the physician or the entity must agree to be responsible for inventory control of the device and have an appropriate standard operating procedure. | | | | | | | | Yes |
| Physician will be responsible for inventory control of the device | | | | Yes | No | | |
|  | | | |  |  | | |

|  |  |  |  |
| --- | --- | --- | --- |
| Part IV. Accompanying Documents **Note: NA = Not Applicable** | | | |
|  | | | |
|  | FDA letter authorizing marketing of the Humanitarian Use Device |  | |
|  | Manufacturer’s description of device: |  | |
|  | Product labeling |  | |
|  | Patient information packet |  | |
|  | Prior annual reports of the manufacturer regarding the use of the device |  | NA |
|  | Documentation of physician’s training in use of device |  | NA |
|  | Proposed Informed Consent Document(s)  Version/Date |  | NA |
|  | Recruitment materials including advertisements intended to be seen or heard by potential patients  Description |  | NA |
|  | Miscellaneous. Any other material to be submitted for consideration by IRB. |  | NA |

|  |  |
| --- | --- |
| Part IV. Acknowledgements | |
|  | |
| Physician As physician responsible for use of this Humanitarian Use Device, I accept responsibility for:   * Maintaining privileges to use the device at the entity indicated on the first page of this application. * Using the according to the clinical indications listed in the FDA-approved product labeling * Submitting annual reports to the Baptist IRB, including any changes in the device description or informed consent. | |
| Signature | Date |
| Print Name |  |

## Entity administrator/Service line leader

I approve the use of this device in the Baptist facility for which I am responsible.

|  |  |
| --- | --- |
| Signature | Date |
| Print Name |  |