**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:///%5C%5CMTCCBMHFP%5CPUBLIC%24%5CClinical%5CBCRI%5CIRB%5CIRB%5CIRB%20Administrative%20Operations%5CCurrent%20Forms%5CLatest%20IRB%20Forms%202018%5CIRB%20Applications%5CRevised%20Applications%206-1-18%5CBaptist.IRB%40bmhcc.org%20) (Baptist IRB)

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| Part I. General Information  |

**Date of Submission**:

**Physician:**

**Name of Device:**

**Device Manufacturer:**

**Hospital:**

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| Part II. Personnel |
| PhysicianThe 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 interestDoes 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 deviceDoes 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 |       |
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| PART III. Use of the Device |
| Anticipated use of the deviceHow 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 patientsPlease summarize how you intend to use the device. Include screening procedures and any patient follow-up visits, tests or procedures.       |
| Informed consentDoes 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 |
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| Part IV. Accompanying Documents **Note: NA = Not Applicable** |
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|  | 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 |

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| Part IV. Acknowledgements |
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| PhysicianAs 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.
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| 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.

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