**CONTINUATION 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](mailto:Baptist.IRB@bmhcc.org) (Baptist IRB)

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

**Submission Date**:

**Date of Last Approval:**

**Name of Device:**

**Device Manufacturer:**

**Participating Hospital/Facility:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Part II. Personnel | | | | |
| Physician(s) - The physician must have a formal affiliation and appropriate privileges with the facility where the HUD will be used. | | | | |
| Name, Degree |  | | | |
| E-mail | @ | | | |
| Phone |  | | | |
| Financial Interest Since this device was last approved for use, has there been any change in any financial relationship between the physician and the manufacturer of the device? If you answered **Yes**, please provide details about financial relationship and what might be disclosed to patients. | | Yes | No |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Service line director of Baptist entity or entities 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 | | | | | | | | | |
| How many patients were treated with this device since its use was last approved?  How many patients have been treated with this device since IRB approval?  Please summarize any problems or difficulties encountered when using this device. | | | | | | | | | |
| Have there been any complaints by patients or others about use of the device that were not resolved by the physician or the hospital administration?  If **Yes**, please provide details. | | | | | Yes | | | No | |
| Have there been any changes in the approved indications for use of the device? If yes, please provide details? | | | | | Yes | | | No | |
| Part IV. Accompanying Documents | | | | | | | | | | | |
|  | | | | | | | | | | | |
|  | | MDR (Medical Device Reporting) report submitted by manufacturer | | | | | |  | | | |
|  | | Any amended documents or changes in approved indications for use. | | | | | |  | | NA | |
|  | | Most recent version of the consent document (if any) | | | | | |  | | NA | |
|  | | Most recently signed consent document (if any) | | | | | |  | | NA | |
|  | | Miscellaneous. Any other material to be submitted for consideration by IRB. | | | | | |  | | NA | |
| Part V. Physician’s Statement | | | | | | | | | | | |
|  | | | | | | | | | | | |
| As the physician, I am 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 of Physician | | | | |  | | Date | | | | |
| Print Name | | | | |  | |  | | | | |