### logo rgb vert 300.jpg

###  **Institutional Review Board**

 Phone: (404) 785-7555 Fax: (404) 785-9470

 For faster processing, please submit form via email or fax.

Please submit only once, via one method.

 irb@choa.org

<http://www.choa.org/clinicalresearch>

HUMANITARIAN USE DEVICE (HUD) INITIAL SUBMISSION

*As defined in 21 CFR 814.3(n), a HUD is a “medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.”*

*Full Board review is required for initial submission of HUDs.*

|  |
| --- |
| ***Use this form to apply to use a Humanitarian Use Device. IRB approval is required before the HUD can be used at a facility, with the exception of Emergency Use. If you have an Emergency Use situation, contact the IRB as soon as possible at 404-785-7477. This form should not be used for systematic investigations (research), only for clinical use of a HDE.*** |

A. STUDY INFORMATION

|  |  |
| --- | --- |
|  STUDY TITLE |  |
|  PHYSICIAN |  | PHONE |
| EMAIL  |  |
| IS THE STUDY INDUSTRY SPONSORED? | [ ]  YES [ ]  NO |

B. STUDY CONTACT

|  |  |  |
| --- | --- | --- |
| STUDY CONTACT |  | PHONE |
| EMAIL  |  |

C. SPONSOR INFORMATION

|  |  |
| --- | --- |
| SPONSOR NAME |  |
| ADDRESS |  |
| SPONSOR CONTACT |  |
| EMAIL |  | PHONE |

D. DEVICE

|  |  |
| --- | --- |
| 1. Device Name: |  |
| 2. Device Registration (HDE) Number:  |  |
| 3. Device Manufacturer:  |  |
| 4. Provide a brief description of the device: |  |
| 5. Is the HUD being studied for the indication(s) in its approved labeling for clinical care? | [ ]  YES [ ]  NO**If No, STOP. Please submit using the initial submission form, obtain an IDE from the FDA and provide informed consent documents.** |
| 6. What is the disease or condition that the device is intended to treat or diagnose? |  |
| 7. Provide a summary of how the physician will use the device, including screening and follow-up visits, tests or procedures. |  |
| 8. Describe the potential risks associated with the implantation and use of this device. Estimate the probability that a given harm may occur and its potential reversibility, when possible. |  |
| 9. Describe the potential benefits associated with use of the device. |  |
| 10. What alternatives are available to treat or diagnose the patient’s disease or condition? |  |

E. CLINICAL TEAM AND TRAINING

 **In the table below, list names of all members of the clinical team, experience and assigned duties. The clinical team includes all individuals who have contact or interactions with patients or with patient’s PHI. By submitting this protocol, the Treating Physician affirms that each individual named has reviewed the protocol and has consent to his or her inclusion.**

|  |  |  |  |
| --- | --- | --- | --- |
| Name, Degree | Department or non-CHOA Affiliation | Experience (Include project-speficic experience that reflects the ability to perform duties) | Responsibilities administering treatment using HUD |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |
| --- | --- |
| 1. Describe the training required to use the device. |  |
| 2. Is the HDE holder required to provide training on the use of the device prior to use? |  [ ]  **YES** [ ]  **NO** |
| 3. Will clinicians receive a certificate for training? If **Yes**, provide the certificates to the IRB as soon as they are available. |  [ ]  **YES** [ ]  **NO** |

F. PATIENT INFORMATION AND ACCRUAL

|  |  |
| --- | --- |
| 1. Gender: [ ]  Male only [ ]  Female only [ ]  Both | 2. Age of Subjects:        |
| 3. Will specific populations be excluded from the research? If **yes,** then explain:       |  [ ]  **YES** [ ]  **NO** |
| 4. What is the maximum number of patients who will be treated at Children’s? |  |

G. FINANCIAL INTEREST DISCLOSURE

|  |  |
| --- | --- |
| Does any member of the clinical team, or their immediate family members have any financial interest (including royalty, equity interest, consulting salary, stock options, intellectual property rights, compensation related to the project, proprietary interest including, but not limited to, a patent, trademark, copyright, or licensing agreement, or other financial interest related to the project) with the sponsor or other related entities outlined in the Conflict of Interest Related to Research Policies and Procedures? If **yes,** please submit a completed Investigator Conflict of Interest form and any applicable attachments.***FOR PHS-FUNDED studies, financial disclosure related to institutional responsibilities by senior key personnel is also required.*** |  [ ]  **YES** [ ]  **NO** |

H. TREATING PHYSICIAN’S ASSURANCE

|  |
| --- |
| The signature of the Treating Physician and Department Chairperson or advisor indicates that the Treating Physician has the requisite funding, credentials, training and any necessary hospital privileges to carry out all procedures and treatments involved in the protocol. The signatures also affirm that the activities involving patients will not begin without prior review and approval by the IRB and that all activities will be performed in accordance with state and federal regulations. ­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Treating Physician’s Signature Printed Name Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Division or Area Medical Director Printed Name Date**The Treating Physician may not sign as the Division or Area Medical Director. If the Treating Physician is the Director, he/she should seek the signature of his/her supervisor.** |

*Signature page must be received as original, fax to (404) 785-9470, or scanned and sent as a pdf via email to* *irb@choa.org**. Electronic signatures and signature stamps will not be accepted.* ­­­­­­­­­­­­­­­­­­­

CHECKLIST OF DOCUMENTS THAT MUST BE SUBMITTED WITH YOUR INITIAL SUBMISSION

|  |
| --- |
| [ ]  HDE approval order  |
| [ ]  Product labeling/HUD Brochure  |
| [ ]  Patient information packet and/or Consent Form  |