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###  **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) CONTINUING REVIEW

*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.”*

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| ***Use this form for continuing review of a Humanitarian Use Device study. IRB approval is required for continued use of the HUD. HUD activities conducted without IRB approval is a violation of regulations and Children’s policies.***  |

A. STUDY INFORMATION

|  |  |
| --- | --- |
| IRB NUMBER |  |
|  STUDY TITLE |  |
|  PHYSICIAN |  | PHONE |
| EMAIL  |  |

B. STUDY CONTACT

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

C. SPONSOR INFORMATION

|  |  |
| --- | --- |
| 1. Has the funding or sponsor changed since the last review?If **no,** skip to section D. | [ ]  **YES** [ ]  **NO** |
| 2. Please explain change and provide any new documents. |

D. ENROLLMENT STATUS

|  |  |
| --- | --- |
| 1. Has the HUD been used on any patients at this site?If **no,** explain: | **[ ]  YES [ ]  NO** |
| 2. If patients have been enrolled, indicate the status below:[ ]  No patients were ever enrolled and the HUD will not be used [ ]  Enrollment is in progress or still planned[ ]  HUD is permanently closed to enrollment[ ]  HUD is permanently closed to enrollment AND all patients have completed all interventions |
| 3. Number of patients enrolled in the last IRB approval period |   |
| 4. Total number of patients enrolled to date at Children’s |  |
| 5. Total number of patients enrolled study-wide (if available) |  |
| 6. Have any patients voluntarily withdrawn from the research since the last IRB review? If **yes**, list and describe each withdrawal and any revisions made to the study (consent form, protocol, etc.) in response to the withdrawal(s). | [ ]  **YES** [ ]  **NO** |
| 7. Have any patients been withdrawn (non-voluntarily) from the study?If **yes,** list and describe each withdrawal and any revisions made to the study (consent form, protocol, etc.) in response to the withdrawal(s). | [ ]  **YES** [ ]  **NO** |

E. STUDY STATUS

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| 1. Provide a brief summary on the progress to date, including patient outcomes, interim findings, etc. Do not include identifiers. |
| 2. Have there been any significant new findings (either good or bad) since the last IRB approval that should be disclosed to patients?If **yes**, please describe:  | [ ]  **YES** [ ]  **NO** |
| 3. Since the last IRB review, have patients experienced any harm? If **yes**, please describe and state whether the harm was expected or unexpected. | [ ]  **YES** [ ]  **NO** |
| 4. Since the last IRB review, have there been any reportable events?If **yes,** were those reported to the FDA, sponsor and IRB? | [ ]  **YES** [ ]  **NO** |
| 5. Since the last IRB review, has a medical device report (MDR) been submitted to the FDA? If **yes**, include a copy with this submission. If **no**, provide an explanation. | [ ]  **YES** [ ]  **NO** |
| 6. Have the risks or benefits changed since the last IRB review?  | [ ]  **YES** [ ]  **NO** |
| 7. Since the last IRB review, has the status of the HUD changed? If **yes**, please explain | [ ]  **YES** [ ]  **NO** |
| 8. Since the last IRB review, has the HUD been used for a purpose outside its approved indication (i.e., off-label for emergency or compassionate use)?If **yes**, provide a summary of the use.  | [ ]  **YES** [ ]  **NO** |

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. |  [ ]  **YES** [ ]  **NO** |

H. TREATING PHYSICIAN’S ASSURANCE

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| --- |
| 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 SUBMISSION

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| [ ]  Medical Device Report (MDR) to the FDA  |
| [ ]  Any revised documents (funding, consent, etc.)  |