### 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](mailto:irb@choa.org)

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

DEVICE EXPANDED ACCESS/COMPASSIONATE USE INITIAL SUBMISSION

*The compassionate use provision provides a path to accessing investigational devices that have not received FDA approval or clearance for patients for whom the treating physician believes the device may provide a benefit in treating and/or diagnosing their disease or condition. Compassionate use can be for devices that are being studied in a clinical trial under an IDE for patients who do not meet the requirements for inclusion in the clinical investigation but for whom the treating physician believes the device may provide a benefit in treating and/or diagnosing their disease or condition. It can also be used for devices that are not being studied in a clinical investigation (i.e., an IDE for the device does not exist). This provision is typically approved for individual patients but may be approved to treat a small group.*

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| ***FDA approval and concurrence from the IRB Chair is required before the device 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) or Emergency Use.*** |

A. BASIC INFORMATION

|  |  |  |
| --- | --- | --- |
| NAME OF DEVICE |  | |
| PHYSICIAN |  | PHONE |
| EMAIL |  | |
| ADMINISTRATIVE CONTACT |  | PHONE |
| EMAIL |  | |

B. DEVICE

|  |  |  |
| --- | --- | --- |
| 1. IDE Number: |  | |
| 2. Device Manufacturer: |  | |
| 3.. Provide a brief description of the device: | |  |
| 4. Provide a brief description of circumstances necessitating the use: | |  |
| 5. 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? | |  |

C. DEVICE MANUFACTURER/SPONSOR INFORMATION

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

D. FINANCIAL INTEREST DISCLOSURE

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| 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** |

E. 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 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*](mailto:irb@choa.org)*. Electronic signatures and signature stamps will not be accepted.* ­­­­­­­­­­­­­­­­­­­

CHECKLIST OF DOCUMENTS THAT MUST BE SUBMITTED WITH YOUR INITIAL SUBMISSION

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| Consent Form—Please use our Expanded Access Consent Template at: <https://www.choa.org/research/institutional-review-board/forms> |
| Copy of uninvolved physician’s assessment of use |
| Copy of authorization from IDE holder/device manufacturer |
| Copy of FDA communication/approval (In some cases the FDA may request IRB concurrence prior to issuing approval) |

E. IRB Chair/Vice Chair Concurrence

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| The signature of IRB Chair/Vice Chair indicates that the required documents have been reviewed and are sufficient to allow Expanded Access use of the device.  ­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  IRB Chair/Vice Chair Signature Printed Name Date |