### logo rgb vert 300.jpg **Institutional Review Board**

###  Phone: (404) 785-7477 Fax: (404) 785-947 irb@choa.org <http://www.choa.org/clinicalresearch>

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EMERGENCY USE STATUS RENEWAL/CLOSURE FORM

**Emergency use is FDA-regulated, so data related to this emergency treatment may be reported to a sponsor and the FDA. Data may not be used for the treating physician’s own prospective research. Please note that FDA regulations require that any subsequent use of the test article at CHOA undergo prospective IRB review and approval. Physicians should carefully consider the likelihood of future use of the test article and submit an IRB Application for review and approval if subsequent use is reasonably likely**

**Renewals should be submitted at least annually (as determined by the IRB) until treatment is complete.**

BASIC INFORMATION

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| --- | --- |
| **Submission Type:** |  [ ]  **Renewal (Update)** [ ]  **Closure** |
| **IRB Number:**       |
| **Name of Test Article and Brief Description:**       |
|  |
| **Attending Physician/PI** |       |  |
| **Phone**  |       | **Email** |       |
|  |
| **ALTERNATE CONTACT (Coordinator/Admin Contact)** |       | **Phone** **Email** |            |

EMERGENCY USE INFORMATION

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| Provide a summary of test article uses and outcomes:       |
| Have there been any event reports (i.e., SAEs, UPs, etc.) since the last IRB review?If **yes**, please describe and indicate whether or not those were reported to the FDA:       |  [ ]  **YES** [ ]  **NO** |

ATTENDING PHYSICIAN’S SIGNATURE

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| --- |
| The signature of the attending physician certifies that he/she acknowledges responsibility for (1) the ethical conduct of the treatment while using an emergency use test article in protecting the rights and welfare of human research subjects; (2) the timely reporting of all required information. The attending physician assures that the information in this application is correct and all procedures performed under the Emergency Use guidelines were conducted in strict accordance with all applicable Federal, State and local regulations and laws regarding the protection of human subjects in research.­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Attending Physician’s Signature Printed Name Date  |