### 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>

NON-COMPLIANCE REPORTING FORM

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| --- |
| *This form should be used to report potential non-compliance. Non-compliance is defined as any action (or inaction) of the study team associated with the conduct or oversight of the study that fails to comply with federal or state regulations or institutional policies.**Examples of non-compliance include, but are not limited to, failure to obtain IRB approval, study expiration, using expired documents, non-study staff consenting subjects, failure to obtain informed consent, assent, etc. If you are unsure of which form to complete, contact the IRB at 404-785-7477.* |

Please complete in blue or black type. Do not handwrite or staple documents.

1. STUDY INFORMATION

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| --- | --- |
| **1. IRB NUMBER** |  |
| **2. STUDY TITLE** |  | | | |
| **3. PRINCIPAL INVESTIGATOR** |  |
| **4. PI PHONE** |  | **5. PI EMAIL** |  | |
| **6. RESEARCH COORDINATOR** |  |
| **7. COORDINATOR PHONE** |  | **8. COORDINATOR EMAIL** | |  |
| **9. SPONSOR EMAIL** |  | | | |

1. DETAILS OF EVENT

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| 1. Date of event (may be a date range) |  |
| 2. Provide a summary of the events, including a timeline of occurrence of non-compliance and discovery: | |
| 3. Provide an assessment of the increased risk (if any) to subjects resulting from the non-compliance: | |
| 4. Explain the corrective actions taken in response to the non-compliance and explain any preventative actions that will be taken to prevent the non-compliance from occurring in the future: | |
| \*Attach any supporting documentation, such as audit reports, correspondence with the sponsor, etc. | |

1. INVESTIGATOR ACTION

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| Please indicate any actions that are requested as a result of this report: |
| 1.  The informed consent process/document will be revised.  *Please submit an amendment requesting the revisions. If the amendment cannot be submitted at this time (i.e., requires sponsor approval first), please explain:* |
| 2.  The protocol will be revised. *Please submit an amendment requesting the revisions. If the amendment cannot be submitted at this time (i.e., requires sponsor approval first), please explain:* |
| 3.  Currently enrolled subjects will be notified. *Please attach a copy of the proposed notification.* |
| 4.  The event compromised the validity of the data. *Please explain.* |
| 5.  Other corrective and/or preventative action will be taken. *Please explain and attach any relevant documentation.* |

Statement of Principal Investigator: I have personally reviewed this report and agree with the above assessment.

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Principal Investigator’s Signature Printed Name Date

*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 will not be accepted.*