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| **Study Title:** | |
| **Investigator:** | **IRB#:** |

**Instructions:** Confirm that the following documentation is present before trial is open to subject screening or accrual. See [IND/IDE Regulatory Documentation Checklist Item Descriptions](http://compliance.emory.edu/documents/SI_INDIDE_RDCID.docx) for additional information.

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| **Document** | **Comments:** Note if an item is Not Applicable (N/A).  If maintained in a location other than the regulatory binder, note and confirm documentation of the location in the regulatory binder. |
| **FDA Submissions:** original application, or IND or IDE amendment/supplement, adding protocol; correspondence with FDA including FDA’s no objection/may proceed letter. |  |
| **Protocol/ Protocol Amendment** Signed Signature Page(s) |  |
| **Case report forms** (CRFs) |  |
| **ICF, HIPAA Authorization Form and if applicable Revocation letter** (currently approved version) |  |
| **IRB Approval** documentation (initial study approval and any protocol amendments, ICFs, any information given to subjects, advertisement, and other) |  |
| **IRB** **composition** (download [**Compliance Letter**](http://www.irb.emory.edu/documents/IRBcomplianceletter.pdf) on IRB website) |  |
| **Investigator Agreement or Form FDA 1572** signed by Site PI listing all sub-investigators |  |
| **CV, Licenses** and/or other relevant documents evidencing qualifications of investigator and sub investigatorslisted on Form 1572 or Investigator Agreement |  |
| **FDA** [financial disclosure certification form](http://compliance.emory.edu/documents/fda_financial_disclosure_certification.docx) of each individual listed on Form 1572 or Investigator Agreement |  |
| [**Delegation of Authority Log**](http://www.ctac.emory.edu/clinical_trial_resources/delegation_of_authority_log.doc)**:** may include Site Signature log(s) |  |
| **Records of Study Specific training** of each individual listed on Delegation of Duties Log |  |
| **Data Safety Monitoring Plan** | *Note if included in protocol* |
| **Site Monitoring Plan** | *Note if included in protocol* |
| **Registration with clinicaltrials.gov**: Must be completed within 21 days of enrolling first subject | Date registered: |
| **Investigational Product:** IB/PI/Device Manual Signature Page(s); Copy of Label(s) Attached to IP | *Note if IB not required* |
| **Laboratory** Certifications/Accreditations; Normal Laboratory Values |  |
| **Miscellaneous:** Advertisement for recruitment; Signed agreement between involved parties, e.g.: CRO |  |
| **Signature** of person completing this form | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: |