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| **Study Title:** | |
| **Investigator:** | **Site:** |

**Instructions:** Complete the Emory Sponsor IND/IDE Multi-site Regulatory Documentation Checklist periodically to document that regulatory documentation has been reviewed and is current for trials with an Emory sponsor conducted at non-Emory sites. See [IND/IDE Regulatory Documentation Checklist Item Descriptions](http://www.or.emory.edu/research-compliance/oric/documents1/SI_INDIDE_RDCID.docx) for additional information.

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| **Document** | **Yes, No or N/A** | **Comments:** Note if an item is maintained in a location other than the regulatory binder and confirm documentation of the location in the regulatory binder |
| **Site Contact Information Sheet** |  |  |
| **Signature Pages:**  Protocol/ Protocol Amendment Signature Page(s)  IB/PI/Device Manual Signature Page(s)  Site Signature log(s) ( to document entries on source documents) |  |  |
| **Agreements:** Signed Site Agreement, Confidential Disclosure Agreement& any other agreement between Involved Parties |  |  |
| **IRB** local IRB Composition; Documentation of IRB Approval (protocol and amendments, ICFs) |  | Current study approval period: \_\_\_\_\_  Current protocol version/date­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_  Date approved by IRB \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **ICF, HIPAA authorization and, if applicable, Revocation letter** |  | Current ICF version/date­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date approved by IRB \_\_\_\_\_\_\_\_\_\_\_\_\_  Current Authorization version/date­­­­\_\_\_\_\_\_\_  Date approved by IRB \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Form FDA 1572 or Investigator Agreement** signed by Site PI listing all sub-investigators |  |  |
| **CV and License of Site PI** |  |  |
| **FDA** [**Financial Disclosure Certification Forms**](http://www.or.emory.edu/research-compliance/oric/documents1/fda_financial_disclosure_certification.docx) (FDF) completed by each investigator listed on Form 1572 or Investigator agreement |  |  |
| **Records of Sponsor provided training** |  |  |
| **Safety Reports**, with documentation of review & [assessment](http://www.or.emory.edu/research-compliance/oric/documents1/SI_DrugAdverseEventAssessmentForm.docx) by the IND/IDE sponsor & communication of safety information to participating investigators |  | Required Reports to  IRB, date:\_\_\_\_\_\_\_\_\_  FDA, date:\_\_\_\_\_\_\_\_\_  Participating investigators, date:\_\_\_\_\_\_\_\_ |
| **Laboratory**  Certifications/Accreditations; Normal Lab Values |  |  |
| **Investigational Product (IP)**  Copy of Label(s) Attached to IP; Shipping Records for IP (note if managed by IDS) |  |  |
| **Site Monitoring Reports & Follow-up documentation** |  | Site monitoring completed, date:\_\_\_\_\_\_\_\_  Required Reports to CTAC, date:\_\_\_\_\_\_ |
| **Correspondence to individual site** (including trial updates, updated product or safety information, teleconference minutes) |  |  |
| **Miscellaneous** |  |  |
| Signature of person completing this form |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: |