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

**Instructions:** Complete the Sponsor/Sponsor-Investigator IDE Regulatory Documentation Checklist periodically to document that regulatory documentation has been reviewed and is current. For trials with non-Emory sites, also complete monitoring checklist multi-site trials. 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 |
| **FDA submissions**  Original application**;** FDA correspondence; Supplements; Reports of Unanticipated adverse effects; Progress reports & current investigator lists |  | IDE Anniversary Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Current IDE Progress Report ­­­\_\_\_\_\_\_\_\_\_\_\_\_  Date submitted to FDA\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date submitted to IRB\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date Current Investigator list submitted to FDA\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Device Manual(s)/Instructions for Use with Signature Pages, if applicable** |  | Current version/date­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date submitted to IRB \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Protocol/ Protocol Amendment(s) with Signature Page(s), if applicable** |  | Current version/date­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date approved by IRB \_\_\_\_\_\_\_\_\_\_\_\_\_  Current study approval period: \_\_\_\_\_\_\_\_\_\_\_ |
| **ICF, HIPAA Authorization Form and, if applicable, Revocation letter** |  | Current ICF version/date­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date approved by IRB \_\_\_\_\_\_\_\_\_\_\_\_\_  Current Authorization version/date­­­­\_\_\_\_\_\_\_  Date approved by IRB \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Institutional Review Board reviews**  Documentation of IRB Approval: protocol and amendments, continuing review, ICFs, trial information for subjects, advertisement, and other |  | Current study approval period: \_\_\_\_\_\_\_\_\_\_\_ |
| **Investigator Agreement** signed by Site PI and all participating investigators |  |  |
| **CV, Licenses** and/or other relevant documents evidencing qualifications of investigators |  |  |
| **FDA** [**Financial Disclosure Certification Forms**](http://www.or.emory.edu/research-compliance/oric/documents1/fda_financial_disclosure_certification.docx) (FDF) completed by each investigator |  |  |
| [**Delegation of Authority (DOA) 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** including updates for each individual listed on Delegation Log |  |  |
| **Reportable Events: UADEs, UPs or non-compliance** includingReports of Unanticipated adverse effects, internal & external with documentation of review by the S-I |  | Required Reports to IRB, date:\_\_\_\_\_\_ |
| **Data and Safety Monitoring Committee Reports** |  | Required Reports to IRB, date:\_\_\_\_\_\_ |
| **Site Monitoring Log & Reports** |  | Site monitoring completed, date:\_\_\_\_\_\_\_\_  Required Reports to CTAC, date:\_\_\_\_\_\_ |
| **clinicaltrials.gov information updated within past 6 months** |  | Updated:**\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Investigational Device** documentation:  Records of shipping, receipt, use, and disposition of device |  |  |
| **Screening and Enrollment Log(s)** |  |  |
| **Laboratory**  Certifications/Accreditations; Normal Lab Values |  |  |
| **Ancillary Committee Approval(s), if applicable** |  |  |
| **Miscellaneous** |  |  |
| Signature of person completing this form |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: |