**Instructions:** Use the item descriptions below to determine if regulatory documentation is complete for IND/IDE trials with an Emory Sponsor/Sponsor-Investigator; document review on appropriate Monitoring checklist(s).

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| **Item** | **Description** |
| **FDA submissions** | Confirm that file is complete and that IND or IDE reports have been submitted to the IRB at continuing review (CR).  **IND:** All FDA submissions regarding an IND must be accompanied by a Form 1571 sequentially numbered starting with serial # 0000 for the initial submission; IND annual reports are required to be submitted to FDA within 60 days of the IND anniversary date (date the IND became effective);  **IDE**: progress reports are required at regular intervals and at least yearly; a current investigator list is required to be submitted at 6 month intervals. |
| **Investigator Brochure/Package Insert /Device Manual** | Confirm both current & previous product information versions are on file & that current version has been reviewed by the IRB. |
| **Protocol/ Protocol Amendment**(s) | Confirm current & previous protocol versions are on file; that current version has been reviewed/approved by the IRB, and also submitted to FDA as IND amendment/IDE supplement for significant changes. |
| **ICF, HIPAA Authorization Form and, if applicable, Revocation letter** | Confirm that current & previous IRB approved versions are on file. |
| **Institutional Review Board** (IRB) **approvals** | Confirm documentation of current & previous IRB approvals (i.e., approval letters) is on file. This includes approval of protocol amendments, ICF revisions, advertisements, continuing reviews, and any other correspondence documenting approval. |
| **Form FDA 1572 or Investigator agreement** | Verify current list of all sub-investigators, clinical laboratories & research facilities on Form FDA 1572 for IND studies; verify Investigator agreement from each investigator for IDE studies. |
| **CV, Licenses** and/or other relevant documents evidencing qualifications | Verify documentation of qualifications (CV/resume) is present & licenses are current for all investigators and sub investigatorslisted on Form 1572 or Investigator Agreement. |
| **FDA** [**Financial Disclosure Certification Form**](http://www.or.emory.edu/research-compliance/oric/documents1/fda_financial_disclosure_certification.docx) (FDF) | Confirm FDF on file for each individual listed on Form 1572 or Investigator Agreement. Sponsor must obtain FDF from each individual prior to allowing participation in trial. |
| [**Delegation of Authority (DOA) Log**](http://www.ctac.emory.edu/clinical_trial_resources/delegation_of_authority_log.doc) | Confirm current listing of all who are performing study activities with appropriate delegation of responsibilities and accurate listing of start date; may include Site Signature log to identify entries on source documents. |
| **Records of** [**Study-Specific Training**](http://www.ctac.emory.edu/clinical_trial_resources/study_specific_training_log.doc) | Confirm documentation of study-specific training of each individual listed on DOA log prior to performing study activities & with any protocol amendments. Study-specific training documentation must specify document versions of protocol, consent, IB, etc. |
| **Reportable Events: SAEs, UPs, or Non-compliance** | Confirm documentation of safety report reviews of internal and external events by Emory sponsor/S-I, and of required reports to IRB & FDA. Confirm protocol or other non-compliance meeting reporting criteria has been reported within required time frame. |
| **Data Safety Monitoring Committee (DSMC) reports** | Confirm documentation that DSMC is meeting according to DSMP & all reports have been submitted to the IRB at CR or promptly if required |
| **Site Monitoring log & Reports** | Confirm documentation that study is monitored for protocol compliance & data quality as specified in DSMP; site monitoring reports have been reviewed by Emory sponsor/S-I with corrective and preventive action (CAPA) plan if appropriate and submitted to Clinical Trial Audit & Compliance (CTAC) within 10 days |
| [**clinicaltrials.gov**](http://prsinfo.clinicaltrials.gov/) | Confirm registration & updates (every 6 months) for applicable clinical trials; results should be posted no later than 12 months after trial completion |
| **Investigational Product** | Confirm documentation of receipt, labeling, disposition and return of investigational devices and/or investigational drug not managed by IDS. |
| **Subject Screening and Enrollment Log** | Confirm log is being maintained and enrollment did not exceed IRB approved enrollment number. |
| **Laboratory** | For IND trials, confirm documentation is on file for each clinical lab facility listed on the Form FDA 1572: clinical lab norm reference ranges; lab certification or accreditation (i.e., CLIA & CAP) and any updates; the Lab Director’s CV and Medical License. |
| **Ancillary Committee Approval** | Confirm documentation of any required ancillary committee approval (e.g., Grady ROC, VAMC R & D, RSC etc.); confirm documentation of ongoing approval as required and documentation of approval(s) prior to implementing protocol amendment or ICF change |