**Regulatory Checklist**

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|  | Item | Description |
|  | Table of Contents | A complete table of contents allows documents to be found quickly |
|  | CITI, CVs, and Licenses | CITI should be Biomedical or Social Behavioral Research and Good Clinical Practice (GCP); CVs should be updated every 2 years, signed and dated; Valid Licenses/certificates include medical, nursing, psychology, IATA –confirms staff eligibility to conduct study/perform delegated tasks |
|  | COI Disclosure Forms | Documentation of Conflict of Interest (COI) disclosure and training. |
|  | Institutional Compliance Documents | IRB FWA number and Membership Letters |
|  | Training Records | Study specific training to document that all people involved with the study are adequately informed about the protocol |
|  | DOA | Delegation of Authority log should be for all current and previous IRB-approved study staff; DOA log should include a signature/initial log for each staff member as well as beginning and end dates. |
|  | Protocol | Current IRB approved protocol and all previous versions |
|  | Consents | Current IRB approved consent and all previous versions |
|  | Recruitment | Current IRB approved recruitment materials and previous versions. Materials include flyers, websites, letters, brochures, pamphlets, etc. |
|  | IRB Submission Documents | * Original IRB submission forms * IRB approval letters (initial, continuing, modification/amendments) * All IRB correspondence * Investigator's Brochure/Device Manual |
|  | Ancillary approvals | Include documentation of required additional reviews (i.e., radiation safety, biosafety, COI, etc.) |
|  | Decoding Procedures | Documentation of how to unblind investigational products in case of an emergency without breaking the blind for remaining subjects |
|  | Investigational Product | Instructions for handling the IP and trial related materials, IP shipping records, storage conditions, dispensation and return to/from the subjects and investigational pharmacy, IP destruction |
|  | Clinical Trials Website | If applicable, study listed on clinicaltrials.gov |
|  | FDA Documentation  (if applicable) | Investigator Agreements, Form 1572 signed by PI with current listing of all sub-investigators and facilities, FDA Financial Disclosure Certification Forms. Make sure to update when changes in staff occur |
|  | Sponsor-Investigator | If the PI is the IND/IDE Holder, include form 3674, FDA approval letters, amendment letters, annual reports, safety reports, communications with the FDA, |
|  | Enrollment Log | Log can be maintained electronically. Should be updated regularly. |
|  | Protocol Deviations Log | Any deviation from the IRB approved protocol should be logged and reported appropriately to IRB and/or Sponsor |
|  | Adverse Events Log | Log can be maintained in the regulatory binder or with the subject files. Should include documentation of PI review |

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|  | Item | Description |
|  | Additional Logs | Tissue Log, Monitoring Logs, Unanticipated Events Log, Monitoring Log, etc. |
|  | Blank Case Report Forms | Including all CRF versions |
|  | Data Collection Docs | All templates used to collect study data (surveys, questionnaires, databases) |
|  | Sample/Specimen | Include instruction manuals on how to obtain and process samples, CRFs/source documentation that samples were obtained according to protocol |
|  | Lab (If applicable) | Lab Certification, Accreditation, Licenses, Lab Director's CV, Normal Lab/Reference Values |
|  | Correspondence/  Communications | All pertinent communications should be maintained including meeting minutes, discussions with IRB, Sponsor or CRO, annual reports from Sponsor/CRO |
|  | DSMP/B | All Data Safety and Monitoring Plan/Board information and documentations plan was observed. |

**Note:** Documents such as CV’s, Licenses, CITI training documents or IRB membership may be kept in a central location. In addition, older protocols, consent forms, etc., may be kept electronically. The location of these documents should be noted using a Note to File in the regulatory binder.

**Subject Files Checklist**

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|  | Eligibility Checklist (inclusion/exclusion checklist) |
|  | Completed informed consent, assent and HIPAA authorization forms |
|  | Documentation of Informed Consent (Consent Note) |
|  | Complete data collection sheets and/or case report forms(CRFs) |
|  | Progress notes or Lab reports |
|  | Study specific logs (con meds, diaries, etc.) |
|  | Checklists (consent, visit, etc.) |
|  | Subject Contact Log (date, time, and route (phone/email) subject was contact) |
|  | Notes to file |
|  | Notation of location of any subject data stored electronically or elsewhere (additional binders or offices) |