**Regulatory Checklist**

**Retrospective Studies**

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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 |
|  | Protocol | Current IRB approved protocol and all previous versions |
|  | IRB Submission Documents | * Original IRB submission forms * IRB approval letters (initial, continuing, modification/amendments) * All IRB correspondence |
|  | Enrollment Log | Log can be maintained electronically. Should be updated regularly and often. A subject is enrolled once data has been collected. |
|  | Protocol Deviations Log | Any deviation from the IRB approved protocol should be logged and reported appropriately to IRB and/or Sponsor |
|  | Data Collection Docs | All templates used to collect study data (surveys, questionnaires, databases) |
|  | 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 |

**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.