**FDA SITE INSPECTION**

**CHECKLIST**

**Study Title:
Principal Investigator:
Sponsor:**

|  |  |  |
| --- | --- | --- |
|  | **Date completed and initials** | **Comments (note if an item is not applicable)** |
| **Prior to Inspection** |
| **Inspection Notification:**[ ] Obtain starting date and any specific requests; ask if inspector will need eEMR access[ ]  Notify all parties of impending inspection including sponsor, Office of Research Integrity and Compliance (ORIC)**, and your Department Chair**[ ]  Reserve audit space (separate area from working space/office)[ ]  Meet with ORIC |  |  |
| **Organization:**[ ]  Prepare general overview of study[ ]  Prepare list of all clinical trials conducted by PI in the past 5 years in which he/she was the PI; note start/stop date, IRB of record, study title, sponsor. [ ]  Designate a person to oversee the inspection. |  |  |
| **File Management**[ ]  Identify & locate records[ ]  Ensure Delegation Log, Subject Screening Log, and Subject Enrollment Log is complete and up to date |  |  |
| **Data Review**[ ]  Review files & subject records[ ]  Review monitoring reports, &/or self-monitoring tool[ ]  Develop & implement a written corrective & preventive action (CAPA) plan to address any identified problems. |  |  |
| **IRB Review**[ ]  Have available current & previous version(s) of protocol [ ]  Have available IRB correspondence (continuing review, amendment approvals, etc.) |  |  |
| **During the Inspection** |
| **PI meet with inspector** [ ]  Receive Form 482 Notice of Inspection[ ]  Provide list of PI’s studies[ ]  Be prepared to discuss the study & PI responsibilities. |  |  |
| **Inspection Coordinator**[ ]  Provide materials as requested[ ]  Coordinate PI availability to talk with inspector daily and answer any questions[ ]  Keep a copy of every record/document that is provided to the Inspector during the inspection.**[ ]** Document inspection progress in daily summary**[ ]** Keep sponsor & ORIC contact up to date on inspection progress |  |  |
| **Exit Interview****[ ]** Coordinate scheduling with PI; notify ORIC & others. |  |  |
| **After Inspection** |
| **Inspection summary** **[ ]** Prepare inspection summary report[ ]  Prepare response to Form 483 if applicable; send to ORIC for review prior to submitting to FDA within 15 business days of exit meeting[ ]  Notify study sponsor & other sponsors as required. |  |  |
| **Printed name of person completing this form:** |  |
| **Signature of person completing this form:**  | **Date** |