**FDA SITE INSPECTION**

**CHECKLIST**

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

|  |  |  |  |
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|  | **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** | | |