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| **AUDIT PREPARATION CHECKLIST** |

If notified of an FDA inspection, the investigational site should contact the staff members associated with the particular trial. If notified of an FDA inspection, please refer to *Attachment B- FDA Inspection Notification Form*. Once completed, the site should work to review all trial documents to prepare for the inspection.

**Administrative**:

*Reserve a room, desk, and phone for the inspector(s). Be sure that the room is away from clinical activity and in a private setting.*

Protocol Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Audit Date(s):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Building & Room Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **Regulatory**Locate, organize, and review for accuracy the following items:*Some items may not be applicable to all studies* | **Comments** |
| □ Delegation of Authority Log |  |
| * All IRB approvals filed
 |  |
| * Annual Reports/Continuing Reviews
 |  |
| * Financial Disclosures
 |  |
| * Investigator Statements or 1572s
 |  |
| * All protocol versions filed
 |  |
| * All ICF versions filed
 |  |
| * Master subject log
 |  |
| * List of PI’s active protocols
 |  |
| * Screening & Enrollment logs
 |  |
| * IND Safety reports
 |  |
| * Correspondence (IRB, Sponsor, and Monitor, Study team)
 |  |
| * Training Documents
	+ CVs
	+ GCP/CITI
	+ Protocol
	+ Additional training/certifications
 |  |
| * AE Reporting as applicable
 |  |
| **Review of Subjects**Locate, organize, and review for accuracy the following items:*Some items may not be applicable to all studies* | **Comments** |
| * ICFs complete, along with ICF process documentation
	+ Correct version used
	+ Re-consents, if applicable
	+ Both subject and person obtaining consent signed correctly
 |  |
| * Thorough documentation of subject eligibility for trial, with sign-off by the investigator
 |  |
| * Data in subject binders match the data entered in EDC
 |  |
| * Consistency among subject shadow charts
 |  |
| * All information filed
 |  |
| * PI oversight, including sign-off on AEs, labs, etc., as appropriate
 |  |
| * AE/SAEs appropriately reported and documented
 |  |
| * Protocol deviations appropriately reported and documented
 |  |
| *If your inspector does not request EMR or EDC access, it may be necessary to file information in subject binders related, but not limited to:** *Missed visits or procedures*
* *Protocol deviations*
* *Visits out of window*
* *Missed re-consents*
 |
| **Drug/Device Accountability & Ancillary Departments**Locate, organize, and review for accuracy the following items:*Some items may not be applicable to all studies* | **Comments** |
| * Most recent version of Investigator Brochure (IB) or Instructions for Use (IFU)
 |  |
| * Trainings, as applicable, for Pharmacists/lab managers
 |  |
| * Temperature Logs
 |  |
| * Most recent Pharmacy or Device Manual
 |  |
| * Accountability logs
 |  |
| * Shipping/ordering records and receipts
 |  |
| * Dispense records for study product
 |  |
| * Lab certifications
 |  |
| * Lab normal ranges
 |  |
| * Specimen logs
 |  |
| * Calibration and maintenance records of equipment
 |  |