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| **AUDIT PREPARATION CHECKLIST** |

Once notified of an audit, the clinical site should contact the staff members associated with the particular trial as noted in the Audit 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: | **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: | **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 PI |  |
| * 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 a particular study* | **Comments** |
| * Most recent version of Investigator Brochure (IB) or Instructions for Use (IFU) |  |
| * Trainings, as applicable, for Pharmacists/lab managers |  |
| * Temperature Logs |  |
| * Most recent Manual of Operations |  |
| * 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 |  |