| **Protocol Number/Name:** | **Investigator Name:** |
|---|---|

| TIMEFRAME | TASK | Done | Notes |
|---|---|---|---|
| **1. General Preparation** | | | |
| Immediately on learning of the review/audit | **A. Notify parties involved in study**<br>• Sponsor (if FDA audit)<br>• IRB<br>• Co-Investigators<br>• Pharmacy<br>• Laboratories<br>• Medical records<br>• Administration<br>• Legal Counsel | | • Assign tasks and review progress each day<br>• If needed, reserve work space for reviewer/auditor (arrange for a large table, phone and copier).<br>• Prepare schedules for everyone participating in the opening meeting |
| 3-2 weeks prior | **B. Respond appropriately and timely if necessary** | | |
| | **C. Prepare a general study summary** | | • Request necessary medical records |
| | **D. List staff and responsibilities (if not done already)** | | |
| **2. Organize Regulatory Files** | | | |
| 2-1 weeks prior | **A. Protocol**<br>• Protocol (all versions)<br>• Investigator's Brochure (all versions)<br>• Protocol Amendments<br>• Form FDA 1572 (all versions)<br>• CVs for PI and staff | | • Organize by general headings and in reverse chronological order<br>• Use flags to indicate important documents |
| | **B. IRB Files**<br>• Approval letter (initial) for initial protocol with original consent form | | |

| | | | |
|---|---|---|---|
| | • Amendment approval(s) with approved consent documents (if applicable) | | |
| | • Consent documents for screened and enrolled subjects | | |
| | • Re-approval letters and original updated consent forms | | |
| | • Status reports for: | | |
| | ○ IRB approval renewal(s) | | |
| | ○ Adverse events | | |
| | ○ Deaths | | |
| | ○ Study termination | | |
| | ○ Final summary | | |
| | **C. Correspondence and phone logs** | | |
| | • Sponsor correspondence | | |
| | • CRO correspondence | | |
| | • FDA Correspondence | | |
| | • IRB correspondence | | |
| | • Monitoring and auditing logs | | |
| | **D. Laboratory** | | |
| | • Laboratory certification and normal ranges | | |
| | **E. Research article accountability** | | |
| | • Receipt log | | |
| | • Dispensing log | | |
| | • Return and destruction log | | |
| | **F. Subject documents** | | |
| | • Complete CRFs for each subject enrolled | | |
| | • Complete source documents for each subject enrolled | | |
| **3. Review** | | | |

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|---|---|---|---|---|---|
| 2-5 hours / subject depending on complexity of the study | **A. Review for each subject enrolled or chosen for review** | | | | |
| | • CRFs completed for each subject | | | | |
| | • Data collection forms for CRFs | | | | |
| | • Source Documentation for each subject enrolled that document the following: | | | | |
| | ○ Condition of subject at time of entry (inclusion exclusion criteria met) | | | | |
| | ○ Exposure to research article | | | | |
| | ○ Concomitant medications | | | | |
| | ○ Clinical assessments of the subject during the study | | | | |
| | ○ Laboratory reports | | | | |
| | ○ Diagnostic tests | | | | |
| | ○ Dose modifications | | | | |
| | ○ Adverse events/deaths | | | | |
| | ○ Protocol exemptions | | | | |
| | ○ Early termination | | | | |