RealTime
eClinical Solutions

FDA Audit Preparation Checklist for Clinical Research Sites

Pre-Audit Preparation

- ☐ **Notify Key Stakeholders**
  - ☐ Inform Principal Investigator (PI), study coordinators, and site staff about the audit.
  - ☐ Alert the sponsor or CRO, if applicable.

- ☐ **Review Study Protocol and Documentation**
  - ☐ Ensure the protocol is up-to-date and approved by the IRB.
  - ☐ Verify all protocol amendments are documented and implemented.

- ☐ **Organize Regulatory Files**

  Confirm the Regulatory Binder or eReg platform is complete and includes:
  - ☐ IRB approvals and correspondence.
  - ☐ Delegation of Authority Logs.
  - ☐ Training records for study staff.
  - ☐ Investigator's Brochure and updates.
  - ☐ Financial disclosures.

- ☐ **Check Informed Consent Documents**
  - ☐ Ensure all signed consent forms are complete, accurate, and stored securely.
  - ☐ Confirm compliance with the most recent IRB-approved version.

- ☐ **Audit Source Documents**
  - ☐ Review patient charts, lab reports, and source data for completeness and consistency with case report forms (CRFs).
  - ☐ Address any discrepancies or missing data.

Questions?
Email us at info@realtime-eclinical.com or call (210) 852-4310.

- ☐ **Verify Drug/Device Accountability**
  - ☐ Check Investigational Product (IP) storage and records.
  - ☐ Confirm documentation of receipt, dispensing, and return/destruction.

- ☐ **Conduct a Mock Audit**
  - ☐ Simulate an FDA inspection to identify and address potential issues.

Facility Preparation

- ☐ **Prepare the Study Workspace**
  - ☐ Designate a clean, quiet space for the auditor.
  - ☐ Ensure access to essential records and study materials.

- ☐ **Confirm Equipment Calibration**
  - ☐ Verify all equipment used in the trial (e.g., ECG, scales, etc.) is calibrated and records are available.

- ☐ **Review Laboratory and Testing Records**
  - ☐ Ensure lab certifications (e.g., CLIA) are current.
  - ☐ Verify that lab data aligns with study documentation.

Staff Readiness

- ☐ **Train and Brief Study Staff**
  - ☐ Ensure staff understands their roles and responsibilities during the audit.
  - ☐ Rehearse potential questions and document retrieval procedures.

- ☐ **Designate a Point of Contact**
  - ☐ Assign a knowledgeable staff member to accompany the auditor and provide requested information.

During the Audit

- ☐ **Be Courteous and Transparent**
  - ☐ Greet the FDA inspector and provide requested documents promptly.

- ☐ Answer questions truthfully and concisely.

- ☐ **Document the Audit**
  - ☐ Keep a log of all auditor requests and responses.
  - ☐ Note any findings or concerns raised during the inspection.

- ☐ **Provide Requested Records**
  - ☐ Ensure only the requested documents are provided, maintaining patient confidentiality. Provide only the documents specifically requested by the auditor.

Post-Audit Actions

- ☐ **Review Preliminary Findings**
  - ☐ Address any issues noted in the Form 483 or verbally communicated by the auditor.

- ☐ **Implement Corrective Actions**
  - ☐ Work with the sponsor or CRO to resolve findings.
  - ☐ Submit a formal response to the FDA, if required.

- ☐ **Conduct a Post-Audit Debrief**
  - ☐ Meet with the team to review lessons learned.
  - ☐ Update SOPs and training based on audit findings.

Ongoing Preparedness

- ☐ **Maintain Documentation Standards**
  - ☐ Regularly update regulatory binders or eReg systems.
  - ☐ Ensure consistent data entry and source documentation.

- ☐ **Conduct Regular Internal Audits**
  - ☐ Identify and resolve compliance gaps before an FDA inspection.