

## **Record Review Audit Documentation Checklist**

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THE FOLLOWING INFORMATION (**Paper or Electronic Version**) MAY BE REQUESTED FOR REVIEW AT THE TIME OF YOUR COMPLIANCE AUDIT. **THIS DOCUMENT IS TO BE USED AS A GUIDE ONLY.**

- **Regulatory Binder / Sponsor Documentation:**
  - The approved protocol and all approved protocol forms (surveys, questionnaires, and/or all other data collection tools associated with the study).
  - IRB applications (Initial Review, Claim of Exemption, Continuing Review, Request for Change, Adverse Event Reports, HIPAA Waiver, etc.) and the resulting IRB approval letter or letter of acknowledgement. (Proof of IDEATE access)
  - Copies of IRB correspondence related to the study. This includes request for revisions or additional information that resulted from an IRB review.
  - Copies of past and present approved informed consent documents.
  - Sponsor and/or Internal Audit/Reviews results.
  - Data Safety Monitoring Plan
  - Publications/Presentations/Results Reporting, etc.
  
- **Participant Study Files/Information:**
  - A complete list of participants, with study ID numbers, enrolled in the study with the participant's consent date.
  - Informed consent documents
  - Collected research data and/or Case Report Forms
  - Participant Reimbursement Payment Forms and / or logs.
  
- **Collected Data:**
  - All information that has been collected for the purpose of the study, including all spread sheets, data collection forms, biological specimens, surveys and questionnaires, regardless of the form.
  - Source of Requested Data (For retrospective record review studies, database/registry studies, or any applicable study, the auditor may need to verify the original request for information received and/or the "raw" data received.) Examples: Data Requested from EDW (Enterprise Data Warehouse), RedCap, EPIC, department database/registry, etc.
  
- **Drugs and Devices Studies:**
  - Record maintenance and storage information
  
- **Clinical Trial Studies:**
  - Registration and Reporting is updated
  
- **Research Clinical Billing**
  - Maintenance of billing documentation

**NOTE:** If the above documents are available electronically, the Principal Investigator or another assigned study team member must be able to retrieve the above documents electronically for the auditor. Additional information may be requested based on the nature of the study.