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Clinical Research Regulatory Binder Index

In general, the items are required or recommended based on the following regulations and guidelines:

| Contact Information | | Items | Regulation or Guidance |
|--|------|--|---|
| Informed Consent Document / Nasent Document / Information Sheet and all revisions Price Sons | 1 | | |
| ### revisions ### re | 2 | Protocol and amendments: All versions should be numbered and dated. | ICH GCP Part 8.2.2, 8.3.11, and 8.3.2 |
| Delegation of Authority, Site Staff Signature Sheet: Documents the study-related procedures delegated by the Principal Investigator to the study staff. | 3 | | 45 CFR 46 |
| procedures delegated by the Principal Investigator to the study staff. Training Decumentation: Saff Training Log. Training Signature sheet(s) CV's / Resume / Biosketch signed and dated every two years to verify that the information is accurate and current. Professional Log. Capture & Cornifications Clinical, CREC. GCP, Credentialing, etc. Screened, or pre-screened for the study. Screened or pre-screened for the study. Enrollment Log. Capture all potential subjects who have been contacted, screened, or pre-screened for the study. Frictional Log. Capture all potential subjects who have been contacted, screened, or pre-screened for the study. Frictional Log. Capture all potential subjects who have been contacted, screened, or pre-screened for the study. Frictional Log. Capture sall subjects who have consented to the study and their participant Log. Captures all subjects who have been contacted, screened, or pre-screened for the study. Frictional Log. Capture sall subjects who have consented to the study and their participant Log. Captures all subjects who have consented to the study and their participant Log. Captures all subjects who have consented to the study and their participant Log. Capture sall subjects who have consented to the study and their participant Log. Capture sall subjects who have consented to the study and their participant Log. Capture sall subjects who have been contacted, screened, or pre-screened for the study. AE log, SAEs, Uhanticipated Problems, Protocol Deviations, INDSRs. 13 | 4 | Investigatory Brochure, Device Manual, Package Inserts | ICH GCP Part 8.2.1, 8.3.1 |
| Training Decumentation: Staff Training Log, Training Signature sheet(s) OV's / Resume / Biosketch signed and dated every two years to verify that the Information is accurate and current. Professional Licenses & Certifications Clinical, CREC, GCP, Credentialing, etc Screening Log: Capture all potential subjects who have been contacted, screened, or pre-screened for the study. Interpret Log: Captures all subjects who have consented to the study and their Participant Ibs / List of participant EMR records assessed Recruitment Materials Pamphlets, Posters, Plyers, Brochures, Phone and Email Scripts, Landing Pages Safety, Reports: Documents adverse events reported to the IRB, sponsor, or regulatory groups, indicating severity and causality A log, SAEs, Uhanticipated Problems, Protocol Deviations, INDRS. Note: May be maintained by Investigational Drug Services. Laboratory Certification and Documentation: These materials document the competency of all bia facilities being used in the study and support the reliability of test results. CLIA, CAP, normal baboratory and reference values and manuals, lab director's CV, IATA certifications, handling/storage/destruction plans, inventory/shipments, collection logs. CLIA, CAP, normal baboratory and reference values and manuals, lab director's CV, IATA certifications, handling/storage/destruction plans, inventory/shipments, collection logs. In BB. Roster or IEC Committee Compession Fig. correspondence, submissions, approvals, FWA certificate Correspondence, submis | 5 | | ICH GCP Part 5.7, 4.1.5, 8.3.24 |
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*as applicable

In addition, the following should also be maintained:

Final study report

The following should <u>not</u> be included in the regulatory binder, but should be maintained elsewhere and made available upon request:

• Financial Documentation - Agreements, Contracts, budgets, W-9, subject compensation voucher log or gift card accountability logs

Central Binders can be used for storing and organizing essential regulatory documents that apply to multiple studies. Those items can include, but are not limited to:

- CV
- Clinical Licensure
- Lab Certifications and Normal Range (CLIA/CAP)
- IRB Membership Lists
- Training Records
- Documentation of professional certifications
- etc.

FDA Requirements:

| • | 21 CFR Part 50 | Protection of Human Subjects and Informed Consent |
|---|-----------------|--|
| • | 21 CFR Part 54 | Financial Disclosure by Clinical Investigators |
| • | 21 CFR Part 56 | Institutional Review Boards |
| • | 21 CFR Part 312 | Investigational New Drug Application |
| • | 21 CFR Part 314 | Applications for FDA Approval to Market a New Drug |
| • | 21 CFR Part 812 | Investigational Device Exemptions |
| • | 21 CFR Part 814 | Pre-market Approval of Medical Devices |
| • | 21 CFR Part 11 | Electronic Records; Electronic Signatures |