University Hospitals
Clinical Research Center

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Clinical Research Regulatory Binder Index

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

	Items	Regulation or Guidance
1	Contact Information	Site Staff, Sponsor
2	Protocol and amendments: All versions should be numbered and dated.	ICH GCP Part 8.2.2, 8.3.11, and 8.3.2
3	Informed Consent Document / Assent Document / Information Sheet and all revisions	ICH GCP 8.2.3, 8.3.2, 8.3.12 45 CFR 46 21 CFR 50, 21 CFR 56
4	Investigatory Brochure, Device Manual, Package Inserts	ICH GCP Part 8.2.1, 8.3.1
5	Delegation of Authority, Site Staff Signature Sheet: Documents the study-related procedures delegated by the Principal Investigator to the study staff.	ICH GCP Part 5.7, 4.1.5, 8.3.24
6	Training Documentation: Staff Training Log, Training Signature sheet(s)	
7	CV's / Resume / Biosketch signed and dated every two years to verify that the information is accurate and current.	ICH GCP Part 2.8, 4.1.1, 8.2.10, 8.3.5 21 CFR 312.53
8	Professional Licenses & Certifications Clinical, CREC, GCP, Credentialing, etc	
9	Screening Log: Capture all potential subjects who have been contacted, screened, or pre-screened for the study.	ICH GCP Part 8.3.20
10	Enrollment Log: Captures all subjects who have consented to the study and their Participant IDs / List of participant EMR records assessed	ICH GCP Part 8.3.22
11	Recruitment Materials Pamphlets, Posters, Flyers, Brochures, Phone and Email Scripts, Landing Pages	
12	Safety Reports: Documents adverse events reported to the IRB, sponsor, or regulatory groups, indicating severity and causality AE log, SAEs, Unanticipated Problems, Protocol Deviations, INDSRs.	ICH GCP Part 4.11, 4.11.3, 8.3.16-18
13	*Drug or Device Accountability Records: dispensing log, shipping and receiving records, randomization/blinding plans, return/destruction, temperature monitoring logs/reports. Note: May be maintained by Investigational Drug Services.	21 CFR 312 21 CFR 812 ICH GCP 4.6.3. 8.2.13-18, 8.3.23, 8.3.38-39, 8.4.1-2
14	Laboratory Certification and Documentation: These materials document the competency of all lab facilities being used in the study and support the reliability of test results. CLIA, CAP, normal laboratory and reference values and manuals, lab director's CV, IATA certifications, handling/storage/destruction plans, inventory/shipments, collection logs.	ICH GCP Part 8.2.11, 8.2.12, 8.3.6-7, 8.3.25
15	Case Report Forms, data collection sheets, questionnaires approved by the IRB; source document tools; electronic data capture (EDC) / remote data capture (RDC); operating guidelines	21 CFR 312 ICH GCP Part 8.3.14, 8.3.15, 4.9.3
16	IRB: Correspondence, submissions, approvals, FWA certificate	ICH GCP Part 8.2.7, 8.3.1, 8.3.2, 8.3.3, 8.3.11, 8.3.19
17	IRB Roster or IEC Committee Composition	
18	*FDA Forms: 1571, 1572, Financial Disclosure FDA 3455, Investigator Agreement, annual reports, and correspondence	21 CFR 312.23 and 312.53, 21 CFR 54 ICH GCP Part 4.1
19	Correspondence: Sponsor, NIH, staff, other	ICH GCP Part 8.3.11
20	*NIH grant applications	
21	Monitoring Log, Site Visit Signature Log, Reports, Letters: Documents any study-related activity performed to monitor study progress or the accuracy and completeness of study records	ICH GCP Part 8.2.19-20, 8.3.10, 8.4.5
22	*Data and Safety Monitoring Board / Committee / Plan: Approved charter, reports, minutes, recommendations.	ICH GCP Part 8.3.10, 5.19.3
23	Institutional Approvals	*Study Feasibility, Credentialing, Departmental Approval, PRMC, Investigational Drug Services, Radiology, Electrical Safety
24	*Sample Tracking	*Collection and processing *Storage, shipment, and disposition

*as applicable

In addition, the following should also be maintained:

- Final study report

The following should not 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