

# Tool Summary Sheet

| Tool: | Regulatory Binder Checklist |
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| Purpose: | To provide an organizational framework for filing paper versions of essential study documents (or referencing location of an electronically stored file) |
| Audience/User: | Study coordinators or individuals responsible for establishing the Essential Document Binder (synonyms: Investigator Binder, Regulatory Binder, Investigational Site File (ISF), or Study Binder) |
| Details: | * This document clarifies the standard content of the Binder.
* It is the responsibility of the investigator to ensure compliance with Good Clinical Practice (GCP), institutional review board (IRB), and applicable regulatory requirements.
* This document serves as a template and may be modified for study-specific needs/requirements.
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| Best Practice Recommendations: | * Store items in reverse chronological order, with the newest items within a section placed at the front of the section.
* Multi-site studies: The lead site may choose to customize the checklist for the study and provide to all participating sites.
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| References: | Good Clinical Practice (E6) Section 8.1, 8.2, 8.3, 8.4 |

## **Tool Revision History:**

| ****Version**** |  |
| --- | --- |
| Number | Date | Summary of Revisions Made: |
| 1.0 | 11May2012 | First published version |
| 2.0 | 24Apr2013 | Cover sheet added, checklist updated |
| 3.0 | 12May2014 | Fix of typographical errors |

# Regulatory Binder Checklist

The following documents (all versions) should be collected and filed in the regulatory binder, if applicable to the clinical study (ref: ICH/GCP).

## Protocol and Amendments

 Log of protocol changes

 Institutional Review Board (IRB)-approved protocol, with signed principal investigator (PI) signature page

 IRB-approved blank Case Report Forms

 IRB-approved advertisements

 IRB-approved Participant Information Sheets

 IRB-approved protocol amendments

## Informed Consent Documents

 Log of Informed Consent versions

 IRB-approved Informed Consents

## IRB Documentation

 IRB Federal Assurance Number

 Updated IRB Roster

 IRB registration (optional)

## IRB Approvals and Correspondence

 IRB approval letters (e.g., protocol, protocol amendments, consent/assent documents, continuing review, advertisement or recruitment materials, investigator’s brochure, package insert)

 Original IRB application/submission

 Correspondence related to contingent approvals or stipulations

 IRB correspondence

 IRB annual renewals

 Interim/annual progress reports to the IRB

## Investigator Qualification Documentation

 Updated investigator and sub-investigator CVs (signed/dated within 2 years)

 A clinical (dental, medical, etc.) license for the PI and co-investigators, if licensed

## Clinical Investigator’s Brochure

 Clinical investigator’s brochure or

 Package insert; include labeling for approved medications

## FDA Documents (if applicable)

 FDA Forms 1571 and 1572

 Sample of labels attached to investigational product containers

 Regulatory approval or authorization

 FDA Correspondence Log

## Financial Disclosure Forms

 Signed Financial Disclosure Forms for the PI and co-investigators

## Study Communication

 Letter of Understanding/Confidentiality Agreement

 Data Sharing Agreement

 Material Transfer Agreement

 Signed agreements between parties (i.e., sponsors/investigators)

 Important decisions regarding study conduct, such as notes to the Study File

 Notes to File

## Delegation of Authority Log

 Delegation of Authority Log

## Clinical Research and Study Training

 Documentation of human subject protection training and Good Clinical Practice training (for all staff members)

 Documentation of Dangerous Goods Training (if applicable)

## Screening/Enrollment Log

 Screening/Enrollment Log

 A log without identifying information that lists all screened subjects

 Subject Identification Code list (which should be kept separately)

## Signed Consent Documents (may be kept in a separate binder)

 Study Product Records (documentation of study product and accountability forms/logs)

## Study Product Records (may be kept in the research pharmacy to protect the blind)

 Documentation of study product (e.g., botanicals, probiotics, or other natural products) disposition and accountability, or memo as to where records are located (e.g., research pharmacy) and who is maintaining accountability logs

## Laboratory Certification (Clinical Laboratory Improvement Amendments [CLIA], College of American Pathologists [CAP], etc.)

 Updated normal-range values for each reference laboratory

 A copy of certifications or accreditations (CAP, CLIA, or state certificate)

## Specimen Tracking Log

## Serious Adverse Events (SAE)/Unanticipated Problem Documents

 SAE Report Forms

 Unanticipated Problem Forms

 IND Safety Reports

## Protocol Deviation Form or Memo

## Clinical Site Monitoring Visits

 Site visit log

 Site visit reports

 Site visit correspondence

## Sponsor Correspondence

## Data and Safety Monitoring Documents

 Data and Safety Monitoring Plan (if not included as part of the study protocol)

 Study reports generated for Independent Safety Monitor(s)

 Minutes from independent safety monitor(s) meeting(s)

 Recommendations and correspondence from the independent safety monitor(s)

## Other Documents

 Unmasking procedures for blinded trials

 Certificate(s) of Confidentiality

 Other study documents