

# Tool Summary Sheet

| Tool: | Regulatory Binder Checklist |
| --- | --- |
| 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. |
| 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. |
| 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

Checkbox. Log of protocol changes

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

Checkbox. IRB-approved blank Case Report Forms

Checkbox. IRB-approved advertisements

Checkbox. IRB-approved Participant Information Sheets

Checkbox. IRB-approved protocol amendments

## Informed Consent Documents

Checkbox. Log of Informed Consent versions

Checkbox. IRB-approved Informed Consents

## IRB Documentation

Checkbox. IRB Federal Assurance Number

Checkbox. Updated IRB Roster

Checkbox. IRB registration (optional)

## IRB Approvals and Correspondence

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

Checkbox. Original IRB application/submission

Checkbox. Correspondence related to contingent approvals or stipulations

Checkbox. IRB correspondence

Checkbox. IRB annual renewals

Checkbox. Interim/annual progress reports to the IRB

## Investigator Qualification Documentation

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

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

## Clinical Investigator’s Brochure

Checkbox. Clinical investigator’s brochure or

Checkbox. Package insert; include labeling for approved medications

## FDA Documents (if applicable)

Checkbox. FDA Forms 1571 and 1572

Checkbox. Sample of labels attached to investigational product containers

Checkbox. Regulatory approval or authorization

Checkbox. FDA Correspondence Log

## Financial Disclosure Forms

Checkbox. Signed Financial Disclosure Forms for the PI and co-investigators

## Study Communication

Checkbox. Letter of Understanding/Confidentiality Agreement

Checkbox. Data Sharing Agreement

Checkbox. Material Transfer Agreement

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

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

Checkbox. Notes to File

## Delegation of Authority Log

Checkbox. Delegation of Authority Log

## Clinical Research and Study Training

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

Checkbox. Documentation of Dangerous Goods Training (if applicable)

## Screening/Enrollment Log

Checkbox. Screening/Enrollment Log

Checkbox. A log without identifying information that lists all screened subjects

Checkbox. Subject Identification Code list (which should be kept separately)

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

Checkbox. 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)

Checkbox. 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.)

Checkbox. Updated normal-range values for each reference laboratory

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

## Specimen Tracking Log

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

Checkbox. SAE Report Forms

Checkbox. Unanticipated Problem Forms

Checkbox. IND Safety Reports

## Protocol Deviation Form or Memo

## Clinical Site Monitoring Visits

Checkbox. Site visit log

Checkbox. Site visit reports

Checkbox. Site visit correspondence

## Sponsor Correspondence

## Data and Safety Monitoring Documents

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

Checkbox. Study reports generated for Independent Safety Monitor(s)

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

Checkbox. Recommendations and correspondence from the independent safety monitor(s)

## Other Documents

Checkbox. Unmasking procedures for blinded trials

Checkbox. Certificate(s) of Confidentiality

Checkbox. Other study documents