National Center for Complementary and Integrative Health

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

- ☐ 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