**Regulatory Binder Checklist**

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| **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.
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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  |
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**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).

**I. Study Personnel**

# Investigator Qualification Documentation

☐ Log of Study Personnel

☐ 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

**Financial Disclosure Forms**

☐ Signed Financial Disclosure Forms for the PI and co-investigators

**Delegation of Authority Log**  Delegation of Authority Log



# Research and Study Training

 Documentation of human subject protection training (for all staff members)

 Documentation of Protocol training

 Documentation of Occupational Health Program Enrollment (if applicable)

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|  <Add other training required by study, i.e. blood pathogen training> |

**II. Institutional Review Board**

# IRB Documentation

☐ IRB of Record

 ☐ IRB Reliance Agreement (if applicable)

☐ TAMU-CC IRB Federal Assurance Number: FWA00011281

☐ [Updated IRB Roster](https://irb.tamucc.edu/contact-us.html)

# 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

# Serious Adverse Events (SAE)/Unanticipated Problem Documents

☐ Reportable Event Forms

☐ Corrective Action Plans

☐ Correspondence

**III. Study Documents**

# Protocol and Amendments

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

☐ IRB-approved protocol amendments

# 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

# Recruitment Documents and Screening/Enrollment Log

☐ IRB-approved advertisements

 ☐ Recruitment Flyers

 ☐ Recruitment Emails

☐ Screening/Enrollment Log

 ☐ A log without identifying information that lists all screened subjects

 ☐ Subject Identification Code list (aka Master List, which should be kept separately)

# Informed Consent Documents

☐ Log of Informed Consent versions

☐ IRB-approved Informed Consents (blank)

☐ Signed Consent Forms (may be kept in a separate binder)

**Study Monitoring Documents**

☐ Monitoring Form: Training and Credentialing

# Other Documents

☐ Certificate(s) of Confidentiality

☐ Other study documents