**REGULATORY BINDER CHECKLIST**

|  |  |
| --- | --- |
| STUDY TITLE |  |
| NAME OF RESEARCH INSTITUTE |  |
| NAME OF PRINCIPLE INVESTIGATOR |  |
| NAME OF SPONSOR |  |
| COMPLETED BY |  | DATE |  |

*Collect and file the following documents in the regulatory binder, if applicable.*

*Check if the document is present in the Regulatory Binder.*

# PROTOCOL AND AMENDMENT DOCUMENTS

[ ]  Protocol Changes Log

[ ]  IRB-approved Protocol, signed by PI

[ ]  IRB-approved Advertisements

[ ]  IRB-approved Participant Information Sheets

[ ]  IRB-approved Protocol Amendments

[ ]  Protocol Deviation Forms or Memo

# INFORMED CONSENT DOCUMENTS

[ ]  Log of Informed Consent versions

[ ]  IRB-approved Informed Consent

# IRB DOCUMENTS

[ ]  IRB Federal Assurance Number

[ ]  IRB Roster, updated

[ ]  IRB Registration

# IRB APPROVAL AND CORRESPONDENCE DOCUMENTS

[ ]  IRB letters of approval

[ ]  IRB submission/application (original)

[ ]  IRB correspondence

[ ]  IRB annual renewal(s)

[ ]  IRB progress reports

# INVESTIGATOR DOCUMENTS

[ ]  Current Principal Investigator and Co-Investigator(s) Curriculum Vitae (CV)

[ ]  Medical/Dental License(s) for the Principal Investigator and Co-Investigator(s), if necessary

# INVESTIGATOR BROCHURE

[ ]  Clinical brochure

[ ]  Package Insert, including the labeling for approved uses

# FDA DOCUMENTS

[ ]  FDA Forms 1571 and 1572

[ ]  Sample of labels attached to investigational product containers

[ ]  Regulatory Approval/Authorization

[ ]  FDA Correspondence

# FINANCIAL DOCUMENTS

[ ]  Financial Disclosure Forms of Principal Investigator and Co-Investigator(s), signed

# STUDY COMMUNICATION DOCUMENTS

[ ]  Letter of Understanding/Confidentiality Agreement

[ ]  Data Sharing Agreement(s) (DSAs)

[ ]  Any signed agreements

[ ]  Material Transfer Agreement

[ ]  Notes relevant to study, List:

# DELEGATION OF AUTHORITY DOCUMENTS

[ ]  Delegation of Authority Log

# TRAINING DOCUMENTS

[ ]  Staff documentation of GCP and HSP training

[ ]  Dangerous Goods Training

# SCREENING AND ENROLLMENT DOCUMENTS

[ ]  Screening/Enrollment Log – without identifying information

[ ]  Subject Identification Code List

# CONSENT DOCUMENTS

[ ]  Study Product Records- disposition and accountability information

# SCREENING / ENROLLMENT DOCUMENTS

[ ]  Screening and Enrollment Log, without identifying information

[ ]  Subject Identification Code List

# PRODUCT RECORD DOCUMENTS (may be stored elsewhere for blind studies)

[ ]  Study Product disposition and accountability

# LABORATORY CERTIFICATION

[ ]  Normal-range Values for each Reference Lab

[ ]  Certification or Accreditation documentation

[ ]  Specimen Tracking Log

# ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS DOCUMENTS

[ ]  Adverse Event Report Forms

[ ]  Serious Adverse Event Report Forms

[ ]  Investigational New Drug Safety Reports

[ ]  Unanticipated Problems Forms

# CLINICAL SITE MONITORING VISIT DOCUMENTS

[ ]  Site Visit Log

[ ]  Site Visit Report(s)

[ ]  Site Visit Correspondence

# DATA AND SAFETY MONITORING DOCUMENTS

[ ]  Data and Safety Monitoring Plan

[ ]  Independent Safety Monitor Reports

[ ]  Independent Safety Monitor Meeting Minutes

[ ]  Independent Safety Monitor Correspondence

# OTHER DOCUMENTS

[ ]  Procedures for Blind Study

[ ]  Confidentiality Certificates

[ ]  Other, List:

|  |
| --- |
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