**[](http://bit.ly/2YNMkLs)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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