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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