

|  |  |
| --- | --- |
| **Office of Research Compliance** Jelke Building, 6th Floor  1653 W. Congress Pkwy.  Chicago, IL 60612 | Tel: 312.942.1296 Fax: 312.942.6875  [www.rush.edu](http://www.rush.edu) |
|  |  |

**List of items to be included in study files**

This document clarifies the standard content of the master regulatory file checklist:

* It is the responsibility of the Principal Investigator (PI) to ensure compliance with Good Clinical Practice (GCP), Institutional Review Board (IRB), and other regulatory requirements.
* This document serves as a template and may be modified for study specific needs /requirements.
* Store items in a consistent chronological order, whether paper or electronic.
  + For paper regulatory records, the newest items within a section should be placed at the front of the section.
* Numbered, bolded items below indicate probable tab designations.

1. **File Cover Page**

* Protocol Name
* Protocol Number
* IRB/ ORA Number
* PI Name

1. **Study Contact Information**

* Name, address, telephone /fax/ cell numbers; 24-hour contact person; emergency contact information
* PI, research coordinator and other study personnel
* Monitoring contact and organization, Contract Research Organization (CRO) (if applicable)

1. **Protocol / Amendments/ Administrative Changes**

* IRB approved protocol, with signed PI Signature Page
* Log of Protocol Changes, Date of submission to the IRB
* All versions of Protocol with version date/ and or version number, with signed PI Signature Page
* Site Initiation Statement/ Letter of approval from sponsor
* Dates of modification approval relative to implementation
* Lapse of approval
* Progress reports
* Signature Page between Sponsor and PI
* Protocol training and/or Device training record for the study staff by the sponsor
* Study Newsletter

1. **Study Agreements --** these may be kept in a separate file

* Letter of Understanding/ Confidentiality Agreement
* Data sharing agreement
* Material Transfer Agreement
* Signed agreements/ contracts between sponsor and PI

1. **Investigator Brochure (IB) / Device Manual or FDA approved package insert**

* All versions stored with the most current version on the front
* Copies of signature page indicating PIs receipt and review of the IB/ Device Manual

1. **Informed Consent Forms and HIPAA Authorizations**

* Log of informed consent form versions
* All IRB approved, IRB stamped versions of any consent and or assent form used in the study (including translations, short forms, tissue banking, etc.)
* All approved, IRB stamped versions of the HIPAA Authorization (if a separate HIPAA form is used)

1. **IRB Approvals and Correspondence**

* All IRB submissions, correspondence, and approval letters (*e.g.,* initial study approval, protocol/ consent amendments, annual continuing reviews, final study report, reportable protocol violations/ deviations, unanticipated and/or serious adverse events, etc.)
* All IRB approved documents (*e.g.,* protocols, consent/ assent documents, advertisement materials, recruitment materials, investigator’s brochure, package insert, etc.)
* Original IRB application/submission
* Correspondence related to contingent approvals or stipulations.
* IRB correspondence
* IRB annual renewal approvals
* Interim/ annual progress reports to the IRB
* Clinical research unit (departmental and /or interdepartmental) correspondence

1. **Other IRB Approved Documents**

* IRB approved participant information sheets.
* IRB approved study questionnaires, diaries, quality of life (QoL) surveys, other surveys, phone script for screening / other assessments, etc.
* All approved study participant recruitment and/ or education materials including flyers, brochures, etc.

1. **IRB Documentation**

* Federal Wide Assurance (FWA) and IRB Registration Information
* IRB membership roster

1. **Sponsor Correspondence**
2. **FDA Documentation**

* FDA forms 1571 or 1572 – signed/ dated copies all submitted to the FDA
* Initial application, acknowledgement of receipt, comments, and Letter to Proceed.
* Amendments to the application
* Adverse Event Reports
* Annual Progress Reports
* Form 3674, Certification of Registration to ClinicalTrials.gov
* Sample of labels attached to the Investigational product containers
* FDA Correspondence Log (if applicable)
* Signed/ dated copies of Form FDA 3545/ 3455 ( Disclosure of Financial Interests) for all staff on FDA 1572/1571
* Closeout/ withdrawal application

1. **Data Safety Monitoring Board (DSMB)**

* Copy of all DSMB Minutes
* Study reports generated for independent Safety Monitor(s)
* Recommendations and correspondence from DSMB or Independent Safety Monitor(s).
* External Audit Reports

1. **Logs**

* Subject Screening / enrollment log/ screen failure log
* Specimen tracking log
* Interactive Voice Response System (IVRS)/ Interactive Web Response System (IWRS) Training
* Electronic Data Capture (EDC) Training
* Site Signature/Delegation of Authority (DOA) log- outlining the responsibilities that the PI may assign to other qualified members of the study team and their dates of involvement in the study.

1. **Study Site Monitoring Visits**

* Site visit log – to provide documentation at the site that the study was monitored and the frequency of site monitoring
* Site visit reports
* Site visit correspondence (including queries and query responses)

1. **Investigator and Study Staff Qualification Documentation**

* Updated Principal Investigator, Sub-Investigator, and all study Staff listed on FDA 1571/1572/DOA – Curriculum Vitaes (CV) –signed /dated every 2 years.
* Clinical (Physician/Nursing, etc.,) License for all study staff listed on the delegation log and 1572/1571, etc.
* CITI /HIPAA Training Log for all study staff listed on delegation log and 1572/1571, etc.
* Shipping Biologicals (IATA) training if applicable

1. **Adverse Events (AE), Serious Adverse Events (SAE) / Unanticipated Problem (UP) Documents**

* Internal AE and UP tracking log updated in a timely manner
* SAE reports submitted to the Sponsor/IRB in a timely manner
* Investigational New Drug (IND)/Investigational Device Exemption (IDE) tracking log, signed/dated by the PI / updated in a timely manner.

1. **Protocol Deviation Form(s)**

* Protocol violations/ deviations/ exemptions including the Corrective Action and Preventative Action (CAPA) plans and responses.

1. **Laboratory Documentation for Rush Lab as well as Sponsor Lab**

* Normal Lab/ Reference Ranges which are to be current and up-to-date.
* Laboratory Certifications – Laboratory site/ certification and quality of performance: a. Certificate of Accreditation- Clinical Laboratory Improvement Amendments (CLIA); b. Certificate from the College of American Pathologists (CAP)
* Laboratory Director CV (Signed/dated every 2 years); Medical License
* Laboratory Correspondence
* Lab Manual
* Records of retained Laboratory samples
* Disposal of radioactive and biohazardous waste

**19. Investigational Product (IP) Records**- may be kept in the research pharmacy or pharmacy file to protect the blind or blinded study staff member.

* Documentation of the study product (e.g., study drug or device) disposition / accountability, or memo as to where records are located (e.g., pharmacy) and who is maintaining accountability logs.
* Proper Storage of IP
* IP Accountability/Shipment logs
* Proof of Receipts (PORs)
* IP Return Form/log
* IP Destruction Form/log
* IP Transfer Documentation
* IP Temperature log / relabeling instructions/ Site Randomization code/ Unassigned/Assigned Blind- breaker inventory document/ handling instructions

**20. Non-Drug Study Supplies**

**21. Unmasking Procedures**

**22. Certificate of Confidentiality**

**23. Blank Case Report Forms (CRF) and Guidelines**