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RUSH UNIVERSITY MEDICAL CENTER

Research Compliance's "Frequently Asked Question" (FAQ) is a series of awareness tips sent to those involved in research activities. They are developed to enhance and build awareness around safeguards to protect the integrity of research and inform Rush's research community.

List of items to be included in Study Master Regulatory File

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, and other regulatory requirements.
- This document serves as a template and may be modified for study specific needs /requirements.
- Store items in reverse chronological order, with the newest items within a section 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
2. **Study Contact Information**
   - **Name, address, telephone /fax/ cell numbers; 24 hour contact person; emergency contact information:**
     - **Sponsor**
     - **PI**
     - **Research Coordinator and other study personnel**
     - **Monitoring contact and organization, Contract Research Organization (CRO).**
3. **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 News Letter

4. **Study Agreements:** These are generally kept in a separate file and are not shared with the study sponsor
   - Letter of Understanding/Confidentiality Agreement
   - Data Sharing Agreement
   - Material Transfer Agreement
   - Signed agreements/contracts between sponsor and PI
5. Investigator Brochure(IB)/Device Manual or FDA approves 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
6. 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
7. IRB Approvals and Correspondence
   - All IRB approval letters (e.g., protocol, protocol amendments, consent/assent documents, continuing review, advertisement, 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
8. Other IRB Approved Documents
   - IRB approved blank Case Report Forms (CRF) and Guidelines{where applicable}
   - 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.
- All other IRB approvals including termination of the study.

9. IRB Documentation
   - List of IRB Board Members
   - Federal Wide Assurance (FWA) and IRB Registration Information
   - All IRB Correspondence (all submissions, i.e., requests for initial approval, for protocol/consent amendments, annual continuation review, final study report, reportable protocol violations/deviations, etc.)
10. Sponsor Correspondence
11. 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
12. Data Safety Monitoring Board (DSMB)(if applicable)
    - 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
13. 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.

14. 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)**

15. 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 1572/1571/DOA wherever applicable.**
- **CITI /HIPAA Training Log for all study Staff listed on 1572/1571/DOA**
- **Shipping Biologicals (IATA) training if applicable**

16. 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 and dated by the PI and updated in a timely manner.**

17. Protocol Deviation Form(s)

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

18. Laboratory Documentation for Rush Lab as well as Sponsor Lab

- **Lab Normals/Reference Ranges which are to be current and up-to-date.**
- **Laboratory Certifications – Laboratory site/certification and quality of performance:**
  - **Certificate of Accreditation- Clinical Laboratory Improvement Amendments (CLIA)**
  - **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., botanicals,

probiotics, or other natural products) disposition/accountability, or memo as to where records are located (e.g., research 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 /Re-labeling instructions/ Site Randomization code/Unassigned/Assigned Blind- breaker inventory document/ handling instructions**

20. Non-Drug Study Supplies

21. Unmasking Procedures

22. Certificate of Confidentiality