

## **REGULATORY BINDER CHECKLIST FOR CLINICAL RESEARCHERS**

A binder should be set up with the following tabs and information filed behind each tab:

### **1. PROTOCOL**

- The most recent version of the protocol should be filed first, with all previously approved protocol versions filed behind the current version
- Any amendments or administrative updates that have yet to be incorporated into the protocol should be filed with the current version of the protocol

### **2. SUPPLEMENTAL PROTOCOL INSTRUCTIONS**

- Operations Manual (procedure manual)
- Other supplemental information provided by the Sponsor

### **3. INFORMED CONSENT FORM**

- The current IRB-approved informed consent form, with all previously approved informed consent form versions defaced and filed behind the current form
- The current IRB-approved HIPAA Authorization form, with all previously approved authorization forms filed behind the current form or HIPAA Authorization Waiver signed by the IRB Chair

### **4. SITE RESPONSIBILITY LOG**

- The log should include the following, if applicable:

Name of the Principal Investigator  
Name and location of the Study Site  
Protocol Number and/or Title  
Name of the Sponsor

A table listing the names of all study site staff, their title or position, their significant trial-related duties, the date they started their trial-related duties, the date they terminated their trial-related duties, a box for their signature, and a box for their initials

Suggested trial-related duties: Make eligibility/termination decisions; obtain informed consent; direct medical care of subjects (treatment decisions); make data entries and corrections on Case Report Forms (CRFs); evaluate adverse events (cause/severity); prescribe study drugs/devices; label and dispense study drug; maintain drug accountability records; other

### **5. SCREENING/ENROLLMENT LOG**

- The log should include the following:

Name of the Principal Investigator  
Name and location of the Study Site  
Protocol Number and/or Title  
Name of the Sponsor

A table listing the subject's name, medical record number, date of birth, date of signed informed consent, date of enrollment, date of termination, and, if applicable, reason not enrolled

- Copy of all signed informed consent forms, whether the subject eventually participated in the study or not

#### **6. FDA FORM 1572**

- The most recent FDA Form 1572 signed by the Principal Investigator, with all previous versions filed behind the current form

#### **7. FDA FORM 1571**

- FDA Form 1571 and all other applicable correspondence with the FDA regarding the IND

#### **8. CURRICULUM VITAE (CV) AND MEDICAL LICENSES**

- CVs and medical licenses of the Principal Investigator and all investigators listed on the FDA Form 1572; in the absence of an FDA Form 1572, CVs and licenses of the Principal Investigator and all study site staff listed on the Site Responsibility Log
- CVs must be signed and dated by the investigator/study site staff member
- CVs must be updated, signed and dated annually
- Copies of study-specific and IRB training certificates for the Principal Investigator and all study site staff listed on the Site Responsibility Log

#### **9. FINANCIAL DISCLOSURE FORMS**

- The Sponsor's Financial Disclosure forms signed and dated by all investigators listed on the FDA Form 1572
- Copies of completed "Financial Conflict of Interest Disclosure Form" for the Principal Investigator and all study site staff listed on the Site Responsibility Log

#### **10. LABORATORY DOCUMENTS**

- Copy of current The College of American Pathologists (CAP) certificate for the Stratton VA Medical Center and for all other laboratories affiliated with the

study (as listed on the FDA Form 1572, if applicable), with all previous versions filed behind the current certificate

- Copy of the current Stratton VA Medical Center Laboratory Test List Reference Ranges, and laboratory test list reference ranges for all other laboratories affiliated with the study (as listed on the FDA Form 1572, if applicable), with all previous versions filed behind the current certificate

#### **11. INVESTIGATOR CONFIDENTIALITY AGREEMENT**

- Copy of the Confidentiality Agreement signed by the Investigator and Sponsor

#### **12. INVESTIGATOR BROCHURE**

- The current IRB-approved Investigator Brochure, with all previously approved versions filed behind the current version
- Package inserts for FDA-approved drugs administered for research purposes
- Device manual/brochure, if applicable

#### **13. IND SAFETY REPORTS**

- Copy of all off-site safety reports sent to the site by the sponsor of the study with documentation of the Principal Investigator's review and assessment of their potential impact on the study

#### **14. SERIOUS ADVERSE EVENT (SAE) REPORTS**

- Copy of all on-site SAE reports completed and sent to the IRB

#### **15. IRB CORRESPONDENCE**

- IRB membership/Federal Wide Assurance lists from the time of initial IRB submission of the protocol, and all subsequent/updated lists until study termination
- For every investigational drug used in the study: VA Form 10-9012 signed by the IRB and R&D Committee Chairs
- VA Form 10-1223, signed by the IRB Chair
- Documents, **filed in chronological order**, indicating IRB, R&D Committee, and all other relevant committees (i.e., Radiation Safety Committee, Subcommittee on Research Safety and Biosafety) submission and approval of the following:

Protocol, amendments, informed consent forms, subject information sheets, recruitment tools, annual progress reports and other reports required by the IRB, annual approval of continuation of the trial and related documents, notification to IRB of off-site IND

Safety Reports received from the sponsor, notification to IRB of on-site SAEs and other unanticipated problems at the site such as protocol violations and deviations, investigator notification to IRB of study closure, and all other investigator-IRB, R&D Committee correspondence

#### **16. IRB APPROVED ADVERTISEMENTS/INFORMATION TO BE GIVEN TO SUBJECTS**

- Copies of all IRB approved advertisements and information to be given to subjects along with a copy of the IRB correspondence granting specific approval of the information

#### **17. CORRESPONDENCE**

- Correspondence between the Investigator and Sponsor
- All other, non-IRB, R&D Committee and other relevant committee correspondence

#### **18. NOTES TO FILE**

- Documentation of unusual events or communications (e.g., sponsor authorization for eligibility waiver)

#### **19. INVESTIGATIONAL PRODUCT ACCOUNTABILITY**

- Documentation that the Investigator is delegating responsibility to the Research Pharmacy for accountability of investigational drugs or devices, if applicable
- Copy of drug shipment invoices
- Copy of dispensing records (pharmacy and/or clinic)
- Copy of drug disposition records (destruction or return to Sponsor)
- Instruction for storing and dispensing investigational product (Drug Treatment and Handling Protocol)
- Treatment decoding information for emergencies, if applicable

#### **20. RESEARCH STAFF MEETING MINUTES**

- Copies of all research staff meeting minutes with Principal Investigator

#### **21. TELEPHONE/COMMUNICATIONS LOG**

- Log of telephone communications with subjects
- Log of telephone communications with Sponsor

#### **22. PROTOCOL COMPLIANCE/MONITOR VISITS/AUDITS**

- Copies of all compliance correspondence, monitor visits, and audit reports

**23. CALENDAR OF DEADLINES FOR COMMITTEES AND SPONSOR**

- Calendar listing all deadline dates for committee correspondence and sponsor submissions

**24. CONTACT LIST OF RESEARCH TEAM NAMES, PHONE NUMBERS, EMAILS, PAGERS**

**25. SCOPE OF WORK, INCLUDING COMPETENCIES AND TRAINING**

- Copies of scope of work, competencies, and training for each member of the research team

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