OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Study Management
	SUBJECT	Management of Regulatory Files
	SOP #	2.2
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	September 13, 2019

OBJECTIVE

Describe the responsibilities entailed in maintaining the regulatory files for clinical research trials. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin Healthcare System campus.

APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46	Protection of Human Subjects
21 CFR 50	Protection of Human Subjects
21 CFR 54	Financial Disclosure by Clinical Investigators
21 CFR 56	Institutional Review Boards
21 CFR 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemptions

HHRI Sponsored Project Administration: Guidance and Procedures

REFERENCES TO RELATED SOPs

SOP 2.1
SOP 3.1

ATTACHMENTS

Regulatory Files Content

1) Devise a regulatory binder for each study.
   a) Paper or electronic binders are acceptable.
      i) Electronic regulatory files must be organized, accessible and kept current.
      ii) Some paper original regulatory documents must be filed in order to satisfy sponsor and federal regulations, for example a FDA form 1572, protocol signature page(s), delegation of authority forms, signed informed consent forms.
   b) Use sponsor binder if applicable.
   c) Add new or updated documents as appropriate.
   d) Identify required regulatory and sponsor mandated documents.
   e) Determine which documents must be original and which may be copied or scanned.
   f) Retain copies of all original and revised documents.
   g) Retain copies of all submissions and correspondence associated with the study.

2) Keep regulatory binder in a confidential and secure location.

REGULATORY FILES CONTENT

1. Curriculum Vitae – principal investigator and sub-investigators
2. Research training documentation for all study personnel; If training documentation is stored in another place for ease of reference, a note to file with training documentation location is required
3. Delegation of Duties/Authority
4. Financial Disclosure Forms
5. Form FDA 1572 or Investigator Agreement
6. HSRC Approved Advertising/Recruitment Materials
7. HSRC Approved Informed Consent Form
8. HSRC Correspondence – all correspondence between HSRC and investigative staff
    a. E-mail
    b. Fax
    c. Phone Contact
9. HSRC Protocol Initial Approval
10. HSRC Protocol Continuing Approval
11. HSRC Member List and/or FWA #
12. Investigational Product Accountability
    a. Product shipping inventory
    b. Dispensing log
    c. Product return or destruction documentation
13. Investigator's Brochure, Product Insert, Device Instruction for Use
14. Laboratory Certifications
15. Laboratory Normal Values – for all laboratories utilized in the protocol
16. Licenses as appropriate i.e., MD state license, RN state license
17. Monitoring Logs
18. Protocol
19. Protocol Amendments
20. Protocol Correspondence – all communication between investigative staff and sponsor
    a. E-mail
    b. Fax
    c. Phone Contact
21. Required Regulatory Approvals (i.e., Radiation Committee)
22. Screening Logs
23. Serious Adverse Event Reports and IND Safety Reports
24. Sponsor Correspondence – all correspondence between Sponsor and investigative staff
25. Subject Enrollment Logs
26. Signature Pages
27. Telephone Log

There may be required updates or renewals for long-term studies, such as CVs, training documentation, protocol amendments, laboratory certification(s), or laboratory values. Ensure that a copy of outdated information is kept.

***There may be different or additional files required by the Sponsor ***