PURPOSE: To establish the locations of essential documents within Duke University Health System (DUHS) Division of Infectious Diseases (ID) Protocol Office.

POLICY: The clinical research coordinator assigned to the Protocol Office will maintain essential documents for each protocol within the Protocol Office area and ensure compliance with applicable guidelines and regulations of Good Clinical Practice, Code of Federal Regulations, sponsors and DUMC.

RESPONSIBILITY:

1. Clinical Research Coordinator (CRC) is educated and trained to ensure that essential documents are maintained as stated in this SOP.

PROCEDURE:

A. Hanging File Folders for Protocols

Protocols that existed before pre-hanging folders are in Binders. As new documents were added to protocols in Binders, hanging folder were set up. The following protocols have both systems: ACTG 362, ACTG A5001, ACTG A5015, ACTG A5029, ACTG A5084, ACTG A5095, ACTG A5116, ACTG A5102, ACTG A5115, SILCAAT, M97-720. HIV Pathogenesis, Wl HLA, PBMC, ACTG Blanket Protocol only have Binders.

Each protocol is assigned a group of hanging files folders to store protocol-specific documents. Files are divided into 3 Sections: Regulatory, IRB Approvals/Correction, Reports. Each Section has specific tabs within the Sections as stated below. The files are kept in a File Cabinet in the Protocol Office. The file tabs are prepared with the shortened name or protocol number and type of documents contained in the folder. The following is a list of file folders with tab names that should be prepared for each protocol.

Regulatory Section:Tabs

1. Protocol:

- Only file one copy of each version to include amendments/Letters of Amendment/Clarification memos/Administrative changes that are pertinent to the version number and have not been incorporated into the version .
- If the protocol to be filed is a replacement (a version 1 for version 2), take out the older version and put in the new one. The older version does not get thrown out.

Each version must be saved. Put the older version in the file cabinet with the other saved protocol using alphanumeric filing system.

2. Site Registration (ACTG) or **1572/Site Signature Log/Site Visit log/Delegation of Responsibilities** (Private Studies):

- DAIDS Site Registration faxes, e-mail receipts, Fed-ex receipts
- Copy of Form FDA 1572 or IoR (original signatures are Fed-Ex to sponsor)
- Any documents the sponsor specifically requested for regulatory reasons (such as financial disclosure forms)
- Site Registration Approvals
- All DAIDS Correspondence (Private Studies have separate file for correspondence, see Reports section below).

IRB Approvals/Corrections (Modifications) tabs

1. Submission

- All documents to and from the IRB (filed date order most current in front) for original submission/approval and any submissions/approvals that are under that IRB# (i.e. xxxx-xx-xR0)

2. Renewal 1, Renewal 2, Renewal 3 etc.

- All documents pertaining to the renewal to and from IRB (filed date order most current in front) and all submissions/approvals under that renewal IRB# (i.e. xxxx-xx-xR1, xxxx-xx-xR2, etc.)

3. Consent Forms

- **All IRB approved consent forms with stamp**

- Consent form templates from the sponsor
- Consent forms prepared in the Protocol Office that were never approved by the IRB should remain with the submission documents that went to the IRB.

Reports to the IRB tabs

1. SAEs

- Submissions to the IRB regarding Serious Adverse Event Reports (SAEs) for Duke Subjects.

2. Protocol Deviations:

- Submissions/acknowledgements for Sponsor requests for protocol deviations and violation to be reported to IRB.

3.Investigational Brochures and Package Inserts

- Submissions/acknowledgements for Investigational Brochures and Package Inserts sent to the IRB

4. Sponsor Correspondence

- Any correspondence to and from the sponsor for Private Studies

Grants and Contracts files are maintained the Financial Managers office they are not part of the Regulatory Documents.

B. Other Regulatory Filing cabinet contents

1. IND Safety Letter/Investigational Brochures/Package Inserts:

    - safety reports, package inserts and investigator brochures alphabetized by study medication. Safety reports are filed somewhat chronologically with the newer reports closer to the front and left side of the drawer.

2. Old Protocol Versions:
    - Contains older versions of protocols for opened studies.

C. Departmental Protocols (PI) are not separated under tabs. They just have one file folder and documents are filed in date order with most current date in front.

D. IND Safety Reports from IRB are filed in Binders by Month.

E. ACTG Summary of Safety Notices are filed in Binders by Month.

History

Version	Effective Date	Supersedes	Review Date	Change
S005.1		NA		*Initial Release version S005.1*

Approval

Janet Mueller

Regulatory Coordinator Signature Date

Charles B. Hicks, MD

Principal Investigator Signature Date