KCMC Clinical Trials Unit	STANDARD OPERATING PROCEDURE	Effective Date	SOP-Number REG 001-01
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Title: **Regulatory Affairs**

SOP References: Essential Documents and Source Documentation
Supersedes: N/A

Version Number	Reason for Changes	Date
	Initial release	dd MON 2006

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PURPOSE: The purpose of this standard operating procedure (SOP) is to provide consistent processes/procedures to be followed for regulatory management/maintenance. Regulatory documents are those documents that individually and/or collectively permit the conduct of a clinical trial. These documents are generated throughout the various stages of a clinical trial, including, before the trial begins, during the conduct of the trial, and after completion or termination of the trial.

Regulatory documents serve to ensure the compliance of the investigator with the standards of good clinical practice (GCP) and with all applicable regulatory requirements. These documents ensure the rights and welfare of prospective subjects are protected, that pertinent laws, regulations, and institution procedures and guidelines are observed, that all research involving human subjects receives IRB review and approval before commencement of the research, compliance with all IRB decisions, conditions, and requirements, that protocols receive timely continuing IRB review and approval, reporting unexpected or serious adverse events to the IRB, and IRB review and approval is obtained before changes are made to approved protocols or consent forms

SCOPE: This SOP is based upon: 1) the Code of Federal Regulations (CFR), 2) guidances that apply to the involvement of human subjects in clinical research, 3) standards for GCP, and (4) references to procedures/processes/policies to be followed. This SOP is applicable to Clinical Research Sites conducting therapeutic, vaccine, or prevention studies on human subjects, both domestic and internationally.

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, Duke University Health System (DUHS), KCMC Ethics Committee and National Institute for Medical Research (NIMR).

RESPONSIBILITY:

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

INSTRUCTIONS:

- Regulatory documents in this SOP include 1) a description of the purpose and/or requirements of each document, 2) the location where the document should be filed (central file or protocol file) 3) a reference to the pertinent instructions/forms/SOPs
- It is acceptable to consolidate some of the documents centrally (Central files): CV, Medical License, Laboratory certificates, Lab normal ranges, IND safety letter/memos, IB, Package Inserts, Key Personnel Signature Log, Ethics training, old protocol version filed by protocol.
- Separate regulatory files must be maintained for each clinical trial protocol (Protocol file). Individual elements must be readily identifiable and filed in date order:

FOLDER TABS, ORDER OF TABS AND CONTENTS WITHIN FOLDERS:

Protocol

- current protocol version

- clarification memos
- administrative letters
- Letters of amendments

Site Registration(Essential documents)

- Site Registration/Site Approvals
- 1572
- Financial disclosure
- Site monitor log
- Delegation of Responsibilities Log/ Signature Log
- IRB board roster that approved protocol and memo of abstention of PI if sits on board that voted
- Sponsor correspondence: Any written or electronic correspondence related to the protocol (For Industry sponsored studies may want separate file due to large volumes of correspondence)

New Submission

- Copies of documents sent to KCMC, NIMR, DUHS IRB, NIH
- New Submission approval
- Amendments/Approvals related to the protocol during the first year

Renewal 1

- copies of all documents associated with the renewal submission
- any amendment submission to the protocol during that renewal year
- associated approvals

Add renewal years as appropriate i.e. Renewal 2 etc.

Consent Forms

- all approved consent forms with consent form stamp

KCMC SAEs

- submission and approval

IB and package Insert

- submission/acknowledgement

Protocol Violation/Deviations

- submission/acknowledgement

- (It is acceptable for Duke University Health System (DUHS) to maintain regulatory files for KCMC as necessary on Sharepoint.
- DUHS will provide oversight, coordination and applicable administrative support for KCMC.
- All of the documents addressed in this SOP must be available for audit/inspection by the sponsor and regulatory authorities.
- All local, institution, and/or institutional review board (IRB)/independent ethics committee (IEC) policies/regulations will be followed including any procedures that are more stringent than NIH SOPs.
- Destruction or retention of Informed consents and regulatory documents will be in accordance with Federal regulations and local institution/IRB/IEC policies and procedures.

This SOP has been read and understood by:

Name	Date
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