KCMC Clinical Trials Unit	STANDARD OPERATING PROCEDURE	Effective Date	SOP-Number CTU 004-02
		Page 1 of 6	04 OCT 2006

Title: CLINICAL TRIAL'S OFFICE CHART

SOP References: Informed Consent Process, Source Documentation, Study Visits
Supersedes: NA

Author/Date: Julieta Giner, RN

Approvals/Date:

_____

John Crump, MB, ChB, DTM&H
KCMC-Duke Collaboration, Site Manager

_____

John A. Bartlett, MD
KCMC-Duke Collaboration, Site Principal Investigator

Annual Review:	Review Date	Revision Date	Signature

Document History:

Version Number	Reason for Changes	Date
N/A	Initial	23 DEC 2005
004-02	Standardize format	04 OCT 2006

Title: CLINICAL TRIAL'S OFFICE CHART

SOP References: Informed Consent Process, Source Documentation, Study Visits
Supersedes: NA

Distributed to:	Name/Location	# of Copies	Name/Location	# of Copies

PURPOSE: To establish procedures for filing and maintenance of human subject's clinical trial's office chart.

POLICY: The Principal Investigator and designees are responsible for the integrity of the clinical trial's office chart for every subject screened or entered into clinical research at KCMC. The Principal Investigator and designees are required to provide the clinical trial's office charts for on site review to the study Sponsor, or designee, and any regulatory authority. The clinical trial's office chart will remain at KCMC for a minimum of three years at the completion of a study and will not be destroyed without the permission of the study Sponsor. The original clinical trial's office chart or parts of the original office chart will not be removed from KCMC for any reason, unless superceded by local law, and then only with a documented order and Sponsor notification prior to removal. In such an event, a certified copy of the entire clinical trial's office chart will be obtained prior to releasing the chart.

RESPONSIBILITY:

Principal Investigator, Clinical Research Coordinator, and Clinical Research Nurse designee: Educated and trained to apply the Code of Federal Regulations governing clinical research in humans and International Conference on Harmonization (ICH) Guidelines Good Clinical Practice (GCP) & Clinical Safety Data Management.

A. DEFINITIONS:

Certified Copy: Certified copies may be used to substitute for an original copy when it is unpractical to present the original copy. A certified copy is initialed or stamped with a dated statement on the copy that indicates it is an exact copy of the original information. This is to be done by the

person who is making the copy or the person verifying that the copy is the same as the original. Medical records received from an outside facility and used to provide continuity of care will be filed in the clinical trial's office chart, but will not be certified unless they are verified against the original. (Refer to the KCMC clinical trials unit source documentation standard operating procedure for additional requirements.)

Clinical Trial's Office Record/File: The clinical trial's office record, or file, serves to substantiate the clinical trial's record, including case report forms, and the manner in which the clinical research is being conducted. The clinical trial's office record exists in paper-based and electronic format. The paper-based format is the legal record at KCMC.

Essential Documents: Documents that serve to demonstrate compliance of the Investigator, sponsor, and monitor with standards of Good Clinical Practice (GCP) and applicable regulatory requirements.

Flow Sheet: A worksheet used to document a sequence of operations or process of care. Flow sheets are used in clinical research to capture required components of study visits and serves as a source document.

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected.

Human Subject: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or patient.

Informed Consent: A process by which a subject voluntarily confirms his/her willingness to participate in a particular research trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a signed and dated regulatory authority approved written informed consent form (ICF).

Source Documentation: Source documentation is the original document where data is collected. Source documents include: flow sheets, eligibility checklists, clinic notes and other medical records, laboratory

and radiological results, death certificate and autopsy report, and more. Source documentation serves to reconstruct, evaluate and validate findings and activities during a clinical research trial. ***Source documentation must be attributable (signed), legible, contemporary (dated), original, and accurate.*** (Refer to the KCMC clinical trial's unit source documentation standard operating procedures for additional requirements.)

Clinical Trial's Office Records Storage Location: Designated, secure area where clinical trial's office records are stored.

B. PROCEDURES:

1. Filing:

a. Review/Discussion: In order to provide immediate clinical care, and to maintain integrity of the clinical trial's record, each study participant will have a clinical trial's office chart maintained by the KCMC clinical trial's unit site research coordinator, or designee. The clinical trial's office chart will serve to substantiate the clinical trials record. Clinical trial's office charts will be housed in the clinical research office in alphabetical order. All documents in the clinical trial's office chart will be securely fastened with binder clips in a pressboard folder. Clinical trial's office charts will be labeled in dark ink on the front cover with the person's legal name: surname (family name), full first name, and middle initial, whose records are inside.

Limited study-related source documents will be kept in a separate locations in the KCMC clinical research office, including: 1) informed consents, which will be filed in ascending order in large, hard, study-specific, labeled notebooks, with the subject log as the cover sheet, 2) other essential documents, i.e., IRB/IEC correspondence, that will be maintained in floating files in file cabinets located in the KCMC administrative research office, 3) study-related laboratory requisitions and results, which may be filed separately, as long as results are available for clinical decision making and for monitoring of toxicities, and 4) questionnaires.

b. Filing: Source documents will be filed in descending order in a pressboard folder, with binder clips securing all documents inside. Study-specific events (e.g., flow sheets) will be maintained on one side of the folder, while original, or certified copies of other healthcare visits will be maintained on the opposing side.

Study-related laboratory requisitions and results may be filed with the study-specific visit in the case report form binder as long as a laboratory flow sheet

documents results, and is maintained in the clinical trial's office chart. Laboratory flow sheets should be filed in descending order and maintained as the top sheet, filed on top of the study-specific visit notes.

Questionnaires will be filed by study visit in the subject's case report form binder.

c. Copies: Copies of clinical trial's research visits, treatments and laboratory results will be sent to KCMC medical records for continuity of care. A copy of the signed informed consent form will be sent to KCMC medical records, with the exception of informed consents authorizing individual genetic testing for clinical research studies. Original signed informed consent authorizing individual genetic testing will be maintained in a separate section from the main study consent form, in ascending order. No copy or documentation of this authorization will be sent to KCMC medical records.

This SOP has been read and understood by:

Name	Date
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	

Title: CLINICAL TRIAL'S OFFICE CHART

SOP References: Informed Consent Process, Source Documentation, Study Visits
Supersedes: NA