KCMC Clinical Trials Unit	STANDARD OPERATING PROCEDURE	Effective Date	SOP-Number CTU 009-01
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Title: SUBJECT LOG AND RESEARCH IDENTIFYING CODES

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

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

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PURPOSE: To standardize study-specific subject logs and fulfill regulatory requirements allowing for the identification of research subjects. Study-specific research logs serve to link the identity of research subjects to assigned patient and study identification (PID & SID) codes used on research forms. PID & SID codes serve to maintain research subject's confidentiality but need to be verifiable. All subjects screened for any research study will be documented on the study-specific participant log.

POLICY: The Principal Investigator and research team will maintain research subject's confidentiality by using coded identifiers on protocol-required information that is reported to the sponsor or leaves the designated research team in any form unless otherwise allowed by the subject through written consent. In order to maintain confidentiality and safety of the human subject, the Principal Investigator and research team will assure that a documented verifiable link exists to identify study subjects throughout the course of the research, including, maintaining the study-specific subject log in a secure location with other regulatory documents at the end of the research study.

RESPONSIBILITY: The Principal Investigator, Clinical Research Coordinator, Research Nurse, and Data Manager are responsible for verifying and maintaining an accurate study participant log and linking PID/SID to subject identity for correct reporting, treatment, filing, auditing, or healthcare management.

A. DEFINITIONS:

Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor or entered into the research database for each clinical trial participant.

Confidentiality: The duty to protect private information. As applied to the medical profession, confidentiality is the act of maintaining personal information of patients and research subjects in confidence, preventing disclosure to others outside the immediate healthcare team unless authorized by the patient/research subject, or as required by Local or Federal law. Confidentiality also applies to accessing only what one is authorized to access and maintaining proprietary information belonging to an individual, organization or sponsor in confidence.

Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular 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. (See Informed Consent Process SOP.)

Medical (Personal) Identifiable Information: Any information collected by health care provider or health plan that identifies the person, such as: name; phone number(s); address; dates, such as: birth date and dates of appointments; contact information; hospital record number; and, photographs.

Original Medical Record/Source Documents: Original documents, data, and records, including: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or questionnaires, evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, laboratories, and at medico-technical departments involved in the conducting the clinical trial.

Patient Identification (PID) Code: A unique identifier code that is assigned by the investigator (or designee) to each research subject (participant) participating in a Network (or grouping) of projects by one Sponsor, such as AIDS Clinical Trials Group (ACTG), ISAAC (International Studies of AIDS Associated Co-infections), etc. A PID is used to protect the subject's identity and confidentiality in the research file. PID is used in lieu of the subject's name when the investigator reports adverse events and/or other trial-related data, and on all research documents that go to the sponsor, or outside of the Institution where the research is being conducted. A participant will only have one PID within the Network, but may participate in a number of research studies within that

Network. SID is a study specific unique identifier, used together with PID to link the participant's status within the network. (See SID below.)

Subject Identification (SID) Code: A unique identifier code that is assigned by the investigator (or designee) to each research subject (participant) to protect the subject's identity and confidentiality in the research file. SID is used in lieu of the subject's name when the investigator reports adverse events and/or other trial-related data, and on all research documents that go to the sponsor, or outside of the Institution where the research is being conducted. A SID code is subject specific for a specific study, whereas a patient identification (PID) code is subject specific to a Network specific but not study specific.

B. PROCEDURE:

Only one central log per study should be maintained by the site. The use of PID, SID or screen numbers will not occur until after consent of the subject is received. Immediately following consent, the screen log fields will be entered on the log to avoid code(s) being assigned to two different participants by two different members of the research team. The research team will assure that no forms or study kits are labeled prior to documented assignment of these codes. The clinical research coordinator (or designee) will use the code assignment together with personal identity on all source clinic documents, except questionnaires which are considered there own source document and do not require additional identification. (See Source Document SOP.)

1. PID and SID assignments: The Clinical Research Coordinator (or designee) will coordinate with the Data Manager in receiving, assigning, and documenting Network PID and study-specific SID. If study drug is supplied, the Clinical Research Coordinator (or designee) will communicate assignments of PID/SID with the research subjects' identity to the Research Pharmacist in order to assure correct drug assignment and dispensation.

2. Screen log fields: After the research subject has signed an informed consent, the Clinical Research Coordinator (or designee) will collect and record the following information on the study-specific subject log:

Subject's legal first and last name
Subject's date of birth
Date of informed consent
Screening number (if applicable – enter as soon as assigned)
Study Identification (SID) number (enter as soon as assigned)
Patient Identification (PID) number (enter as soon as assigned)
Whether subject enrolled, and if not reason (e.g screen failure, withdrew consent, etc)
Date of entry (if applicable)

Certain fields, such as: date of entry and whether enrolled or not, will not be filled until that inclusion criteria is confirmed. The site will fill delayed fields as the information becomes known.

3. <u>Process for sub-sites</u>:

a. For studies enrolling at a sub-sites but with follow up at the main site: The sub-site will be provided with one central screen log for the sub-site and a group of assigned codes to be given sequentially. After receiving participant informed consent, the research coordinator (or designee) will enter all information as noted above in the subject log fields. The sub-site will assure that coordinate with the main site weekly for central collection of forms.

b. **For studies enrolling consecutively at sub-sites**: One screen log will be maintained at each sub-site with a group of site assigned codes. The sub-site will coordinate with the main site weekly for central collection of forms.

This SOP has been read and understood by:

Name	Date
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