KCMC Clinical Trials Unit	Appendix 1	Effective Date	SOP-Number CTU
		Page 1 of 5	27DEC2006

Title: **Patient and Study Identification Number**

Supersedes: N/A

Author/Date:	**Travis Reeves**

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**
	Initial release	17/10/2006

Title: **Patient and Study Identification Number**

Supersedes: N/A

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

PURPOSE:

To establish a system of generating patient ID (PID) and study ID (SID) numbers for networks not providing their own PID/SID

POLICY:

The staff and administration of the KCMC-Duke Collaboration will be trained with respect to the correct procedure of generating the PID and SID for subjects enrolled in all studies

RESPONSIBILITY:

Administrators, study coordinators, data manager and staff

PROCEDURE:

The following steps explain how to generate a PID and SID.

PID:

    1) The PID should be generated according to this format: __ __ __ - __ __ __ __ - __.

        a. The first three spaces represent the site number. The next 4 spaces are for the sequential enrollment number of each patient. The final space is an alpha character and is representative of the location where this number was generated (see abbreviation guide below).

SID:

    1) The SID should be generated according to this format: __ __ __ __ __ - __ __ __ __ - __.

        a. The first spaces are alphanumeric and represent the study identifier that records the study in which the patient is enrolling. The next 4 spaces are for the sequential enrollment number of each patient. Lastly, the final space is an alpha character and is representative of the location where this number was generated (see abbreviation guide below).

Title: Patient and Study Identification Number

Supersedes: N/A

ABBREVIATION GUIDE:
Study Identifiers (SID):
ISAAC Protocol Studies: I001A, I001B, I002A, I002B, I003, I004, I005
Mobile VCT: MVCTP

Sites of Enrollment:
KCMC: K
KIWAKKUKI: W
Mawenzi Hospital: M

The following steps outline the process of assigning a PID/SID.

PID Instructions:
1) First, all patients should be asked if they have been previously enrolled in a KCMC-Duke Research Collaboration project. If the answer is 'yes,' then the following steps should be followed:
    a. The enroller should use the patient's study identification card to find the previously assigned PID.
    b. If the identification card is not available, the individual enrolling the patient in the research project should call Evaline Ndosi or Catherine Nderingo in the Data Office at KCMC (using the numbers listed below) and provide the patient's name, date of birth, sex, district, village, and date of enrollment in the previous study. Only call the mobile phone numbers for Evaline and Catherine if it is before 3:30 PM. Otherwise, you must contact the study coordinator.
    c. Data Office landline: 2754086
    d. Evaline Ndosi mobile: 0784590610
    e. Catherine Nderingo mobile: 0787067799
    f. The data office staff (or study coordinator) will use the patient information database to look up the patient's PID that was previously generated and provide this to the individual enrolling the patient.
    g. In the event that the data management staff are not available, the interviewer should defer generating a PID and inform the study coordinator who will follow-up the issue as soon as possible.
2) If the answer to question 1 is 'no,' then the following step should be followed.
    a. The enrolling officer should assign the PID using the logbook provided at each site and indicate that the PID is no longer available for use by filling in ALL the spaces and signing their name next to the chosen PID.

SID Instructions:
1) The enrolling individual should use the SID logbook available at each enrollment site to assign a SID number and indicate that the SID is no longer available for use by filling in

Title: Patient and Study Identification Number

Supersedes: N/A

ALL the spaces and signing their name next to the chosen SID. The SID logbook should correspond to the study in which the patient is being enrolled.

2) If a patient is being enrolled in more than one study, then it is necessary to assign multiple SID numbers. The numbers should be generated from the logbooks which correspond to the studies in which the patient is entering.

Neither the PID nor SID should be entered onto a study form until it has been entered into the logbook to prevent duplicate numbers. In addition, the logbook which will track the generation of PID/SID numbers for each site should be maintained in a central location during work hours and securely locked away after the enrollment process has ended.

After assigning a PID or SID, the individual enrolling the patient should complete the "Regulatory Logbook" located at each enrollment site.

This SOP has been read and understood by:

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

KCMC Clinical Trials Unit	Appendix 1	Effective Date	SOP-Number CTU
		Page 5 of 5	27DEC2006

Title: Patient and Study Identification Number

Supersedes: N/A

12.	
13.	
14.	
15.	