KCMC
KILIMANJARO CHRISTIAN MEDICAL CENTER
STANDARD OPERATING PROCEDURES

Title: CRF Data Entry	Policy #: 1.04

PURPOSE: To establish the process for data entry of KCMC Case Report Forms (CRF).

POLICY: The data manager will be educated and trained to understand the proper methods of data entry of KCMC CRFs in accordance with all applicable protocol, federal and sponsor regulations and guidelines.

RESPONSIBILITY: Data Manager

PROCEDURE:
1. The data manager will receive complete, quality assured, and corrected CRFs as defined by the KCMC CRF Quality Assurance SOP #1.03.

2. All CRFs will be scanned and/or data entered by the data manager within 2 weeks of the study visit utilizing the Informa Teleform Software supplied by KCMC. Complete operating procedures for the Teleform program are located on the instructional CD included with the software.

3. All data entry will be proofed for accuracy by the data manager using the following methods:
    (a) Visual proofing of the CRF with the computer screen post scanning/data entry.
    (b) Cross-referencing with source documents as appropriate.

4. All CRFs scanned or data entered via the Teleform program will be initialed and dated in the appropriate location on the CRF.

5. Scanned and keyed data will be saved to the local database once every 4 hours, and backed up onto a disk/CD. All data will be uploaded to the Duke Sharepoints Website daily.

6. Data will be stored on a local database, on disk/CD, and uploaded to the Duke Sharepoints Site.

7. All completed and verified CRFs will be filed in its appropriate CRF folder.

8. The data manager will read and understand the pertinent definitions listed in this policy and procedure.

DEFINITIONS:

Confidentiality: Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

KCMC: Kilimanjaro Christian Medical Center

CRF: Case Report Form

20/05/2005