Title: CRF ACTG Data Entry	Policy #: 1.05

PURPOSE: To establish the process for data entry of KCMC Clincal Trials Unit Case Report Forms (CRF) for ACTG studies.

POLICY: The data manager will be educated and trained to understand the proper methods of data entry 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 for ACTG studies will be keyed by the data manager within 2 weeks of the study visit utilizing the eData program supplied by FSTRF. Complete operating procedures for the ACTG eData program are located on the FSTRF website.

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 data entry.
   (b) Cross-referencing with source documents as appropriate.

4. All CRFs entered via the eData program will be initialed and dated in the appropriate location on the CRF.

5. Keyed data for ACTG studies will be exported to FSTRF via website twice daily to ensure no data is lost due to power outages or surges.

6. All completed and verified CRFs will be filed in its appropriate CRF folder. Secure cabinets are located in the data management office for storage.

7. 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