KCMC
KILIMANJARO CHRISTIAN MEDICAL CENTER
STANDARD OPERATING PROCEDURES

Title: CRF Quality Assurance	Policy #: 1.03

PURPOSE: To establish the process for quality assurance of Case Report Forms (CRF) prior to data scanning or data entry.

POLICY: The data manager will be educated and trained to understand the proper methods of completing CRFs and proofing all CRFs submitted by the study coordinator for quality assurance in accordance with all applicable protocol, federal and sponsor regulations and guidelines.

RESPONSIBILITY: Data Manager

PROCEDURE:
1. The data manager will receive completed CRFs from study personnel along with copies of applicable source documentation when required:
    (a) Laboratory results
    (b) HIV RNA results
    (c) Flow cytometry results

2. The data manager will proof all completed CRFs as follows:
    (a) All information transferred from provided source documentation to CRFs will be proofed for accuracy.
    (b) All toxicity grading will be verified for accuracy.
    (c) All CRFs will be proofed for accuracy, completeness, logic, and conformance to CRF completion instructions.

3. Errors found on CRFs will be returned to the appropriate study personnel and corrected as follows:
    (a) All errors will be corrected on the CRFs by drawing a line through the incorrect data, writing the correct information, and initialing and dating the change.
    (b) The appropriate study personnel will be notified of any errors that also require correction of the source documentation.
    (c) If an error or suspected error is found which requires clinical judgement, the appropriate study personnel will be consulted for correction.

4. 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