

KCMC
KILIMANJARO CHRISTIAN MEDICAL CENTER
STANDARD OPERATING PROCEDURES

Title: CRF and Questionnaire Completion and Correction	Policy #: 1.02
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PURPOSE: To establish the process for completing and correcting Case Report Forms (CRFs) and questionnaires.

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

RESPONSIBILITY: Data Manager, Study Personnel

PROCEDURE:

- 1) The data manager and study personnel will be trained to complete CRFs and questionnaires in accordance with the following requirements.
 - a) Complete all entries on CRFs and questionnaires in blue or black ink only. No pencil or colored pens.
 - b) All questions should be answered and boxes ticked according to the specific instructions on the form.
- 2) The data manager and study personnel will be trained to correct CRFs and questionnaires in accordance with the following requirements.
 - a) Correct all entries on CRFs and questionnaires in blue or black ink only. No pencil or colored pens. Never use correction fluid ie. "white out."
 - b) To make an error correction, draw a single line through the incorrect information, write the correct information, and then initial and date the change.
 - c) Never erase or obliterate entries that require correction.
- 3) CRF and questionnaire entries that are not done according to procedure will result in incomplete or inaccurate research data, and inadequate source documentation.
- 4) All data corrected CRFs will be scanned or entered in a timely manner using the appropriate program, and initialed and dated by the data manager.
- 5) The data manager and study personnel 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