

KCMC
KILIMANJARO CHRISTIAN MEDICAL CENTER
STANDARD OPERATING PROCEDURES

Title: CRF Scanning	Policy #: 1.06
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PURPOSE: To establish the process for scanning Case Report Forms (CRFs).

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

RESPONSIBILITY: Data Manager

PROCEDURE:

1. The data manager will receive from the study coordinator complete, quality assured, and corrected CRFs as defined by the KCMC CRF Quality Assurance SOP #1.03.
2. All pertinent CRFs will be scanned by the data manager within 2 weeks of the study visit utilizing the Informa Teleform software supplied by KCMC. Complete operation procedures for the Teleform program are located on the instructional CD included with the software.
3. All CRFs to be scanned by the data manager will be accounted for on the CRF scanning log and cross-referenced once the data is scanned to ensure that all forms placed in the scanner have been processed.
4. The CRF scanning log should be initialed and dated in the appropriate box by the data manager as each batch is scanned and verified.
5. Scanned data will be saved to the local database, on disk/CD, and uploaded to the Duke Sharepoints site twice daily to ensure no data is lost due to power outages or surges.
6. 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