KCMC
KILIMANJARO CHRISTIAN MEDICAL CENTER
STANDARD OPERATING PROCEDURES

Title: ACTG Query Resolution	Policy #: 1.10

PURPOSE: To establish the process for resolution of AACTG Queries received via email from the Data Managers at the DMC.

POLICY: The data manager and all study personnel will be educated and trained to understand the proper methods of resolving queries 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 resolve queries in accordance with the following requirements.
   a) Check email daily for posted queries.
   b) All queries must be resolved within 2 weeks unless a specific date of resolution is requested.
   c) If the query is unclear or if more information is required, the appropriate protocol specific Data Manager at the DMC should be contacted.

2) Queries present unique problems that will require the data manager/study personnel to utilize various methods of research. The following list is a sample representation of research methods used by the data manager but is not meant to be comprehensive in nature:
   a) Verification of data through the Online Correct function of eData.
   b) Verification of data on the CRFs, and/or source documentation.
   c) Consulting with the appropriate study personnel or clinicians.
   d) Verification of data with internal and external laboratories.

3) Once the data manager/study personnel has determined the resolution of the query, various methods of correction will be employed.
   a) Incorrect database information will be changed in the Online Correct function of eData.
   b) Incorrect data on CRFs will be changed according to SOP 1.02 CRF Completion and Correction, and also corrected in the database through eData's Online Correction function.
   c) Missing CRFs will be completed and keyed.
   d) Other communications will be made as directed by the query instructions.

4) Following corrective actions the data manager/study personnel will respond to the query via email using the Reply All command, and removing the "RE:" in the subject line. Specific information about how the query was resolved should be included in the response.

5) Once weekly, the data manager/study personnel will reference the Unanswered Query List function on the FSTRF DMC website for any outstanding queries, and resolve them promptly.

6) The data manager and study personnel will read and understand the pertinent definitions listed in this policy and procedure.

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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

FSTRF: Frontier Science Foundation

DMC: Data Management Center