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The process validation approach in the 21st century

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Background/Objective: KEMRI/CDC Research and Public Health Collaboration carried out this capacity building study in Siaya County, Western Kenya, in preparation for future TB vaccine trials. The first step in the study was to administer and appropriately document Informed Consent/Assent to parents and their adolescents respectively.

We report on the role of QC in ensuring that the informed consent/Assent process was administered and documented in compliance with GCP requirements.

Materials and Methods: 5004 participants were enrolled and multiple ERC approved Assent forms and pre-requisite Parental Consent forms were administered in English, Kiswahili or Luo as per the participants' preference. The consenting staff performed self QC checks on the documents for completeness, accuracy, consistency and legibility. Signed copies of consents/assent documents were given to the participants. The QC staff matched all the Assent forms with their prerequisite Parental Consent forms, before 100% verification for completeness, accuracy, consistency and legibility. All the errors were tracked in an error log, followed up and resolved appropriately by the staff responsible.

Results: Quality control checks identified 109 discrepancies broken down as: 39 (35.8%) over writings, 32 (29.4%) alterations without proper documentation, 32 (29.4%) inconsistency in names, 1 (0.92%) blank and 5 (4.9%) signature inconsistencies. Of those 56 (51.4%) and 53(48.6%) errors were in Assent forms and Parental Consent forms respectively. All these errors were appropriately followed up, resolved and relevant documentation done.

Discussion: Informed Consent/Assent is the first critical step in every clinical trial. Ensuring that it is appropriately done in terms of quality therefore sets the pace for all the subsequent study procedures.

Conclusion and Recommendation: The role of Quality Control in overseeing the administration and documentation of the Informed Consent/Assent is vital to ensure that participants of clinical research are appropriately consented to confirm their voluntary willingness to participate after being informed of all the study aspects.

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