African Research Group for Oncology

Standard Operating Procedures for Quality Assurance

Version Date: 06/06/2022

POLICY:

Part of ARGO's mission is to ensure high-quality standards for management of clinical research protocols, processes, and systems and to ensure data quality adheres to relevant institutional and federal regulatory requirements and Good Clinical Practice (GCP) guidelines. All sites are responsible for ensuring adherence to the outlined protocol. If there are any questions, please contact MSKCC Clinical Research Manager: Cristina Olcese at OlceseC@mskcc.org.

PROCEDURE:

- *Patient Eligibility and Consent Procedures:* The use of an Eligibility Checklist (ECL) should be employed before approaching any patient for consent to a study to confirm patient eligibility in real-time. An ECL must be used when protocols have inclusion and/or exclusion criteria.
    - ECLs must align with the final, IRB-approved protocol document, once available.
    - ECLs must be filed in the REDCap file repository
    - ECLs can only be amended by a manager or as delegated by a manager.
- Upon completion of consenting a new patient on protocol, RAs should review the Informed Consent Form (ICF) in real-time for completeness and accuracy. The patient must check the box "yes" they agree to participate on study, and they should sign and print their name. They also need to date the consent form. Real-time QA should be done to confirm that the dates of the participant and the consenting professional match and to ensure that the consenting professional has also appropriately signed the ICF. The Consenting Professional must be listed on the Consenting Professional List (CPL) located in the REDCap File Repository.

- Upon registering the patient into the REDCap database—RAs will again confirm eligibility on the study as they enter eligibility and consent information into the REDCap database.
- *Monitoring:* Each study will be assigned to a member of the MSK GCDI team or ARGO study team to routinely QA the data throughout the lifecycle of a study.
    - ECL and Consent Processes should be QAed every week for the study for which you are assigned to monitor
    - For all new patients consented onto the study that week, a review of the ECL and consent forms should be performed for completeness and accuracy.
    - Missing ICFs and ECLs will be captured in a table to be sent to the appropriate research staff every Friday to reconcile within the week (template table below)
    - REDCap database queries to review blank fields (missing data) or logic checks will be run every 2 weeks and reports will be sent to appropriate research staff every 2 weeks to be reconciled.
    - If applicable: Review the biobank portion of the database every 2 weeks and capture the missing or incorrect data in a table to be sent to the appropriate study staff biweekly
- *Audits of Clinical Research Studies*: Purpose-audits confirm that studies are/were conducted per protocol requirements and applicable regulations and policies. Audits are not done by those who are managing the study.
- The Principal Investigator (PI) is the primary responsible person for the conduct and oversight of the clinical trial. The study team supports the PI to ensure proper preparation and conduct of audits.
- During internal and external audits, the following is reviewed/confirmed:
    - Data: participant data is not fabricated; method used to measure response, if applicable: adherence to inclusion and exclusion criteria; administration of

study medication and accountability; source data verification on baseline data and endpoints with a particular focus on safety and efficacy
    - Reporting of serious adverse events (SAEs)
    - The availability of informed consent for each participant and the procedure to obtain the consent
    - Monitoring of the study by Sponsor
    - Essential Documents maintained in the Regulatory Binder
- *Audit Timeline for NIH funded studies:*
    - MSKCC research team will email PI and research study team to notify them of scope of audit and an overview of expectations/timelines.
    - MSK research team will review the participant cases, regulatory binder and data.
    - If findings are “acceptable” or “acceptable, needs follow up” then MSK GCDI team will forego a meeting and send a final report with audit findings through email. A timeline will be provided to reconcile findings and provide response and Corrective Action and Preventative Action Plan (CAPA) if required.
    - If findings are “unacceptable” in multiple categories, a meeting will be scheduled with the PI and study team to review final report with audit findings.

African Research Group for Oncology

Template of Weekly QA Table for Eligibility and Consent

Site	Error/Issue	Status	Pending Since
	Missing Consenting Professional signature on Consent Form	Uploaded (I did not see the updated form with the signature)	
	Missing Consent and Questionnaire	Yet to be completed	
	Missing Consent and Questionnaire	Yet to be completed	

Key Reminders:

- Baseline data must be entered within 1 week of a protocol participant's consent date. Baseline data is collected on each participant when they begin a clinical research study.
- All data entered must be verifiable by source documentation

Revision History

Revision #	Effective Date	Changes