African Research Group for Oncology

MEMORIAL SLOAN KETTERING CANCER CENTER

Title: Clinical Research Protocols **Standard Operating Procedure #2**

Section: 100 – Study Start-Up for Non-NIH funded ARGO Studies

Version Date: 17/07/2025

POLICY:

The protocol for initiating a new study is outlined below. These steps are critical for the successful launch of each new study. All sites are responsible for ensuring adherence to the outlined protocol. If there are any questions, please reach out to the ARGO Program Manager: Nafisat Lawal email: LawalN@argo-research.org or MSK Clinical Research Manager: Cristina Olcese email: OlceseC@mskcc.org

PROCEDURE:

1. Request to open a new study is communicated with ARGO-OAUTHC and ARGO-MSKCC. This is done via email to Professor Isaac Alatise, Dr. Nafisat Lawal, Dr. Peter Kingham, Vicky Baudin, Cristina Olcese, and Rivka Kahn. In this email request, include the completed Site Information form for each site if applicable.

Once approval granted—please proceed with following steps:

2. Draft protocol and questionnaire to be reviewed by all key stakeholders: PI, Research Managers, Biostatisticians, RAs and Community Healthcare Workers (as needed) prior to submission to IRB.
    a. If study is funded by MSK or data will be analyzed at MSK-protocol and questionnaire must be reviewed by MSK PI, Clinical Research Manager and Research Project Manager as well as MSK Biostatistician prior to submission to IRB.

Once ethical approval obtained for the study, the following documents must be submitted to the ARGO Research Manager at OAUTHC:

1. Institutional Review Board (IRB) documentation needed from each site:
    a. Ethical clearance
    b. Consenting Professional list (CPL)
    c. Institution stamped Informed consent form (ICF)
    d. Federal Wide Assurance (FWA) number
    e. Staff certifications (CITI, HSP)
2. Complete ARGO REDCap Study Initiation Form and attach all required documents and include any QA variables.
3. REDCap database built by ARGO REDCap team.
4. Study Team to review and test the REDCap.
5. Once approved by the Study team, the REDCap team will move the study to production.
6. Confirm that any needed Data Transfer agreement (DTA)/ Materials Transfer Agreement (MTA) is executed.
7. File repository in the REDCap is completed. The file repository must contain the following documents, which have been signed off on by the OAU program manager:
    a. Study Manual
    b. Ethical clearance for each site.
    c. Study Materials including Consent forms, Eligibility checklist, questionnaires.
    d. Specimen collection workflow SOP.
    e. Delegation of Authority Log (DOA)
    f. Consenting Professionals List for each site
    g. SIV attendance documentation
8. Review site Equipment needs. Ensure all required equipment is on site prior to accruing patients to the study.
9. All research studies must have a Protocol Start Up Meeting, commonly referred to as the Site Initiation Visit (SIV), to prepare the research study team for conducting the study and to ensure the team is familiar with the

study documentation, administrative procedures, investigator responsibilities, etc. The SIV should occur before any participants are enrolled. (In-person training HIGHLY preferred). Attendance must be documented. SIV should include:

a. Detailed explanations of Study Goals and Objectives, Study workflows, Eligibility, and all Study materials.
b. Detailed explanation of access to REDCap file repository for Study materials.
c. Confirmation that all equipment required to conduct the study is present on site.
d. Question and Answer session for the recruiting RA's, in which all questions raised by the RA's are answered.
e. Site discussion of accrual goals and methods/plan of reaching these goals.

10. Register Protocol to clinicaltrials.gov
11. RedCap training occurs. Access is granted to the RA's. RA's must confirm their REDCap access is functional.
    a. REDCap access will only be given to RA after presenting certificate of completion of CITI training.
    b. Detailed REDCap training, including practice REDCap entry to be signed off on by Manager.
12. Manager to complete New Study_New Site Checklist Form.
3. Once checklist is reviewed by ARGO Program Manager a study activation letter will be sent to study team (PI, Manager, RA), copying the directors and all key stakeholders so everyone is aware. ***It is imperative that no patients are consented to a study prior to receiving this study activation letter.***

Revision History

Revision #	Effective Date	Changes
1	30-April-2024	Added Procedure #11-completion of

		New Study_New Site Checklist Added Procedure #12-Study activation letter
2	17-July-2025	Updated ARGO Program Manager and contact info.
3	18-March-2026	Updated GCRT Program Manager and contact info.