African Research Group for Oncology

Standard Operating Procedure-Study Start-Up for NIH funded ARGO Studies

Version Date: 23/05/2024

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 MSKCC clinical research manager, Cristina Olcese: OlceseC@mskcc.org

PROCEDURE:

1. Protocol Development (excluding Biospecimen and Retrospective Research Protocols)
    a. There will be one protocol document and each participating site will utilize that document.
        i. If site policy is to use their own IRB protocol template this must be shared at the initiation of the study.
    b. Use of an electronic data capture (EDC) system for remote data entry at the participating sites on all new MSK-coordinated multicenter protocols is required. For ARGO studies, we will use REDCap databases.
2. Site Coordination
    a. The MSK PI is ultimately responsible for ensuring regulatory and protocol compliance for the study overall, including the participating sites. MSK staff must complete any required site training before interacting directly with site participants and/or using a site's systems.

   b. Clinical Research Manager will work with PI to share Site Information Form with new sites to complete prior to drafting a new MSK protocol.
   c. Protocol and study documents such as questionnaire to be reviewed by PIs, Managers, RAs/Community Workers (as needed) and Biostatisticians prior to submission for IRB approval.

3. Site Requirements
   a. The participating site PI is responsible for ensuring regulatory and protocol compliance at their site.
   b. All participating site staff must have completed training in Human Subjects Protection (HSP) and Good Clinical Practice (GCP). Site investigators must be in good standing with the FDA and other regulatory agencies.
   c. All participating sites that enroll participants should have a current Federal Wide Assurance (FWA) number throughout the life of the study.
      i. If site does not have a FWA-this should be discussed at the initiation of the study.
4. Required standard language describing multicenter processes must be included in the protocol (in the form of a GCDI addendum). The Multicenter Office (MCT) must review all protocols prior to IRB review. MSK-initiated amendments must be approved by the MSK IRB prior to submission for site IRB review and approval. Protocol amendments affecting MSK only (e.g. change in MSK Co-investigator, etc.) do not require IRB review at the participating site(s).
5. Documentation needed from each site to be submitted to MSK:
   a. Ethical clearance
   b. Consenting Professional list (CPL)
   c. Institution stamped Informed consent form (ICF)
   d. Federal Wide Assurance (FWA) number
   e. Site IRB Membership Lists

f. CVs and medical licenses for each investigator and consenting professional
    i. If delays in issuance of the annual practicing license receipt, copies of receipt documenting payment of renewal fee should be filed until new license is received
g. Staff certifications (CITI-HSP, GCP)
h. Delegation of Authority Log (DOA)
i. Documentation of SIV attendance and individual training for those who did not attend SIV
j. Participating site lab certifications and normal ranges
k. Lab director CV

The above documents must all be submitted to the MSKCC Research Project Manager (RPM) and Clinical Research Coordinator (CRC).

6. Complete ARGO REDCap Study Initiation Form and attach all required documents and indicate the QA variables.
7. REDCap database built by MSKCC REDCap team.
8. Study Team to review and test the REDCap.
9. Once approved by the study team, the REDCap team will move the study to production.
10. Confirm that any needed Data Transfer agreement (DTA)/ Materials Transfer Agreement (MTA) is executed.
11. File repository in the REDCap is completed. The file repository must contain the following documents, which have been signed off on by the MSKCC program manager:
    a. Study Manual
    b. Study Materials including Consent forms, Eligibility checklist, questionnaires.
    c. Specimen collection workflow SOP
    d. Consenting Professional List for each site
12. Review site Equipment needs. Ensure all required equipment is on site prior to accruing patients to the study.

13. 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.
14. Register Protocol to clinicaltrials.gov
15. 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.
16. Clinical Research Manager to ensure completed New Study_New Site Checklist Form
17. MSKCC submits the Participating Submission Form (PSSF) packet to the Multicenter Office (MCT). Once approved, the MCT office will open the site to accrual in the Protocol Information Management System (PIMS). MSKCC RPM will let the new site know they are approved to consent patients via an Activation memo. ***It is imperative that no patients are consented to a study prior to receiving this study activation memo.***

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Revision History

Revision #	Effective Date	Changes
1	30-April-2024	Added Procedure #1.a.i , #2.b, #2.c, #3.c.i and #15 Updated Procedure #5 to include more required documentation to align with GCDI Addendum