Multi-Site Trial Guidelines

The purpose of this document is to provide guidance on the issues that are involved in the planning, performance, monitoring, recording, reporting and archiving as the Lead Principal Investigator (PI) of a multi-site trial.

Prompt communication from its inception provides clear allocation of responsibilities and effective communication among all parties involved in the conduct of the study and can prevent any potential roadblocks to trial success. This will include the Lead PI, the participating sites' Principal Investigators, the funding source (if applicable), the participating site personnel, Clinical Research Organization (CRO) and Jefferson Clinical Research Institute (JCRI).

Please be mindful that the SKCC restricts any multi-site trial to the continental US (no foreign sites).

Below are considerations to address as the Lead PI when planning for the execution of the multisite trial and the office/unit to aid in its development.

Responsibility	Considerations	Office/Unit
Budget and Contract	✓ Identification of funds (grant, industrial sponsor or SKCC?), even correlative studies ✓ Budget needed upfront to cover realistic costs ✓ Financial discussions with JCRI and internal department ✓ Subcontract with participating sites including payment and terms ✓ Data agreement needed? ✓ Resources/time and effort covered?	Jefferson Clinical Research Institute (JCRI)
Regulatory Oversight	✓ Does this study require an IND/IDE? If so, who will be submitting to the FDA? ✓ Who will be the IRB of record? ✓ Who is maintaining the original regulatory documents? ✓ Where will the documents be kept (electronic JeffTrial, binders)? ✓ How is regulatory communication handled and by whom? ✓ How best to version control the protocol and documents?	Protocol Support Unit (PSU)
Communication	✓ Who are the participating sites? Study site contact information (PI and study team personnel) ✓ Who receives the information primarily and how is it disseminated to the sites? ✓ How are changes to site personnel handled? ✓ Study specific meetings (frequency, method)—consider agenda and minutes	PSU, Clinical Trials Office (CTO) or Early Drug Development Office (EDDO) Project Manager

Responsibility	Considerations	Office/Unit
Safety Oversight	✓ TJU OHR policy, GA 120 is followed ✓ How are AEs/SAEs documented, reported and communicated among the sites? ✓ What is the SAE review and sign off process? ✓ Is a DSMC or DSMB needed?	Quality Assurance & Process Improvement Unit (QIU)
Monitoring	✓ Who monitors and how frequent? ✓ Resources to complete monitoring (regulatory and clinical source documentation), travel ✓ Monitor reporting expectations (responses from sites) and turnaround times ✓ Handling of major issues identified	QIU
Training	✓ Site Initiation Visits ✓ New staff, protocol amendments ✓ Training documentation	CTO/EDDO, QIU, PSU
Investigational Product	✓ Logistics and operations of IP location and shipment to sub sites ✓ Policy on site storage, dispensing, accounting and destruction adherence ✓ Documentation/logs/SOPs	CTO/EDDO, QIU
Data Management	✓ CRF creation, EDC system, use of JeffTrial? ✓ Subject registration in JeffTrial ✓ Creation and maintenance of research charts ✓ Workflow between sites (remote data entry v. Jefferson personnel entering data)	CTO/EDDO
Laboratory Sample Management	✓ Laboratory Manual development ✓ Sample management requirements – supplies (tubes, labels, kits, etc), equipment, source documentation, roles & responsibilities, training records ✓ Sample storage & shipments ✓ Use of any laboratory study-specific tools & systems	CTO/EDDO

SKCC Clinical Research Organization: 215-955-1661

When considering a multi-site trial please consider utilizing the Sidney Kimmel Cancer Network for partnering institutions. The Regional Network Office has an established mechanism for multi-site operational needs within the network. The SKCN consists of 24 members and access to over 15,000 patients across the region. For more information please contact Joshua Schoppe, MPH, CCRP (5-0448).