Sidney Kimmel Cancer Center
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Sidney Kimmel Cancer Center (SKCC)

Site Management and Principal Investigator (PI) Oversight Plan for Multi-site Sponsor Trials

Purpose: The purpose of this plan is to document how the PI provides oversight and supervision over each separate Jefferson Health site location, as well as to document key site management processes.
Overview: There are multiple different clinical sites where cancer care is delivered within the Jefferson Health System and the Sidney Kimmel Cancer Center oversees clinical research at each of these locations. These sites include Thomas Jefferson University located in Center City Philadelphia and surrounding Advanced Care Hubs (ACH). PI oversight and clinical trial operations are managed as outlined in this plan. Every site conducts the same core functions within the Jefferson Health System. At each site, subjects can be consented, evaluated, treated, and followed. Sub-Investigators and study coordinators are located at each site and conduct trial duties under the supervision of the primary site's PI. Original source documents will be maintained at each site. Monitoring of these source documents is required at each separate site. Study supplies, including IP, are required to be shipped directly to each site by sponsor.
Scope: This plan describes practices and standards for conducting industry sponsored studies involving multiple Jefferson Health and Sidney Kimmel Cancer Center locations that are coordinated by the SKCC's Clinical Trials Office (CTO).

Task	Plan	Responsible person (s)
PI Oversight	Overall Responsibility of the Principal Investigator is to oversee the conduct of the protocol at all participating locations. This includes ensuring patient safety, confirming protocol compliance, and maintaining data integrity while complying with Good Clinical Practice (GCP), institutional Standard Operating Procedures (SOPs), federal regulations, and applicable regulatory requirements. Additionally, all sites utilize electronic medical records systems, and the PI will have access to view medical records of all subjects on trial at each study site.	Jefferson Health PI Designee(s) • PI
Regulatory	The Research Support Services (RSS) regulatory coordinator is responsible for maintaining a central electronic file with all essential study documents including delegation of authority logs, documentation of training, staff information (e.g. CVs, medical licenses, financial disclosures, training certifications, etc.), lab information (e.g. CLIA, lab certifications, and normal lab ranges, etc.), regulatory board communications (e.g. IRB submissions and approvals, scientific review board approvals, etc.), and other study related correspondence and documentation.	Jefferson Health PI Designee(s) • PI • RSS Regulatory Coordinator • Project Managers

	The Sidney Kimmel Cancer Center uses the Florence eBinders system to obtain signatures on, and to file and maintain, essential regulatory documents. The Florence eBinders system has restrictions in place to limit staff member access to study files. Sponsor representatives may view and monitor regulatory files for their industry-sponsored studies within Florence eBinders. To obtain access, the regulatory coordinator will request a Florence account for the designated sponsor representative and apply permissions to only that specific study's folder. The regulatory coordinator is responsible for distributing IRB-approved documents including protocols, Informed Consent Documents (ICDs), and study materials to study team members by uploading them to our clinical trial management system, OnCore (internally referred to as JeffTrial). Project managers are responsible for notifying the regulatory coordinator of all changes to key personnel in a timely manner. The regulatory coordinator is responsible for processing and maintaining documentation related to key personnel changes including, but not limited to, IRB submissions, delegation of authority logs, documentation of protocol training, and staff credentials. The regulatory coordinator is responsible for completing IRB and other review board applications and obtaining approvals for the study. The PI, project managers, and other study team members work closely with the regulatory coordinator to provide information and documentation necessary to complete those applications and obtain approvals. For example, study team members may provide adverse event logs, accrual information, or deviation logs to the regulatory coordinator, as needed.	
Communication	The site study team, which may include clinical coordinators, data manager, and lab managers, will conduct the day-to-day communication of clinical coordination under the direction of the study PI, sub-investigators, and Project Manager. All sponsor communication and sponsored shared study information will be disseminated to all study staff members. Study Teams will participate in study meetings. Meetings will occur at minimum monthly between the study teams at all sites to review study details. The PI will review accrual, SAE/AEs, deviations/violations, and study management issues at meetings or via email monthly. Trainings may also occur during these forums, when necessary. The frequency of meetings will be increased or decreased on an as-needed basis.	Jefferson Health PI Designee(s) • PI • Sub-Investigator • Site Staff

	Meeting minutes will be kept and saved in the electronic study-shared drive or study binder.	
Safety	Safety monitoring and reporting should be followed per the protocol including the expedited reporting of clinically significant adverse events. Study personnel will comply with protocol Adverse Event (AE)/Serious Adverse Event (SAE) reporting guidelines as well as the reporting requirements set forth by the IRB of record. All AEs will be documented using standard SKCC AE logs that include grading, attribution and duration of all adverse events. These AE logs will be included in annual submission to the IRB.	Jefferson Health PI Designee(s) • PI • Sub-Investigator • RSS Regulatory Coordinator • Site Staff
Monitoring	Monitoring will be completed at the discretion of the Sponsor. Patient chart monitoring will take place on site at each location or remotely (if requested). Original paper source will be provided at each monitoring visit. The EPIC Carelink agreement will need to be completed for external monitors to be granted view-only access to the site EMR system (EPIC). Monitoring for regulatory can occur onsite or remotely. The sponsor CRAs will be provided remote access to the Florence eBinders system in order to view and monitor regulatory documents. All sites will follow the same SKCC data monitoring plan and comply with all sponsor data requirements as indicated in the clinical trial agreement. All monitoring and auditing reports must be submitted to the Quality Assurance and Education Unit (QAE). The QAE may also select 10% of the patient charts to review on a quarterly basis for externally sponsored interventional trials. The charts selected will be monitored by the QAE, and a formal report will be completed. In the event that there are major findings in a particular chart, additional charts for that study may be requested from the study team to fully assess the extent of the trend that was identified. Any major issues identified will be escalated to Jefferson Leadership as appropriate. All sites involved will comply with study sponsor requirements.	Jefferson Health PI Designee(s) • Quality Assurance and Education Unit (QAE) • Sponsor Monitoring • RSS Regulatory Coordinator • Site Staff
Training	A site initiation visit (SIV) will be conducted before site activation and before patient screening is allowed. SIVs are encouraged to be conducted with all sites at the same time. If this is not feasible, a separate SIV will be	Jefferson Health PI Designee(s) • Sponsor • PI

	scheduled with the additional site(s). Protocol training is required for all key personnel participating on the trial. **Protocol Amendments:** The RSS regulatory coordinator is responsible for distributing the new protocol, tracked protocol and/or summary of changes, and other related documents to all study team members and documenting training on the new protocol. **New Personnel:** New staff may not conduct protocol-related activities until the following trainings are completed: protocol training, human subjects protection training, and GCP training. New staff members will be provided an in-person or remote protocol-specific training by study staff.	• Sub-Investigator • RSS Regulatory Coordinator • Site Staff
Investigational Product ***(To be tailored per study)**	All investigational products will be shipped directly to the Investigational Drug Service (IDS) of each of the participating sites. All sponsor requirements for drug storage, dispensing, accountability and destruction will be strictly adhered to by each site's pharmacy. All dispensing logs, drug receipts, destruction records, temperature logs and SOPs will be maintained at each site under their local policies. Copies of these items will be provided at the request of the Sponsor.	Jefferson Health PI Designee(s) • IDS Pharmacy • Site Staff
Lab Sampling and Shipment ***(To be tailored per study)**	All sample collection and shipping materials will be sent directly to each individual site. Each site will be responsible for processing, maintaining, and shipping all specimens as per the central laboratory manual. Each site has International Air Transport Association (IATA) trained staff to assist in the shipping of all specimens.	Jefferson Health PI Designee(s) • Site Staff
Patient Enrollment	Informed consent process will occur and be documented for each subject prior to the initiation of any study activities at each site. The informed consent process and documentation practice for each institution will be conducted according to standard operating procedure. Additionally, all consented patients will be manually entered into our Clinical Trial Management System, OnCore (aka JeffTrial), allowing study staff across the enterprise real-time access to study patient information. Patients must meet all inclusion and exclusion criteria as outlined in the study protocol. The PI or Sub-investigator at each site will confirm and sign off on all subject eligibility criteria. Signed eligibility documents will be kept onsite in the local research charts.	Jefferson Health PI Designee(s) • PI • Sub-Investigator • Site Staff
Data and Document Management	All documents will be maintained as stated in the protocol or study contract. All CRFs will be completed and submitted to the Sponsor per the protocol guidelines.	Jefferson Health PI Designee(s) • Site Staff

	Once the study is completed, the Sponsor has conducted a close out visit, and the IRB's termination acknowledgement has been received, all research subject charts and essential regulatory documents related to the conduct of the trial from each site will be archived. All archived paper documents are stored at an offsite location. Each site will follow their archiving processes, and documents for each trial may be archived separately.	• RSS Regulatory Coordinator
Budget and Contract	Jefferson Clinical Research Institute (JCRI) will negotiate and execute a single contract with the research study sponsor on behalf of Jefferson and all participating Jefferson affiliated sites. JCRI will complete a single coverage analysis per study to determine compliant clinical research billing which must be reviewed and approved by the Principal Investigator. Incorporating the coverage analysis, fee schedules and study team input, JCRI will revise and negotiate a single study budget on behalf of Jefferson and all participating Jefferson sites. JCRI will establish a financial account for each participating site for the study. JCRI will invoice study sponsors on behalf of Jefferson and all its participating sites. The participating site's study team will be responsible for providing the relevant study information in the site visit payment trackers to facilitate the invoicing process. All study payments will be deposited into the Jefferson site-specific study financial account, as appropriate. Throughout the study, JCRI will ensure the appropriate study expenses are applied to each study account and will transfer funds to support study team effort to the Jefferson site via interdepartmental transfer (IDT).	Jefferson Health PI Designee(s) • Jefferson Clinical Research Institute (JCRI)

Document History

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Approval

CCRO Senior Director Approval	Cynthia Gifford-Hollingsworth Cynthia Gifford-Hollingsworth, DrNP	**Date of Signature**	Feb 27, 2023
CTO Executive Director Approval	Kristin Herman Kristin Herman (Mar 9, 2023 14:24 EST) Kristin Herman, MBA	**Date of Signature**	Mar 9, 2023
SKCC Associate Director of Clinical Research Approval	Wm. Kevin Kelly, DO Wm. Kevin Kelly, DO (Mar 9, 2023 16:59 EST) W. Kevin Kelly, DO	**Date of Signature**	Mar 9, 2023

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