PURPOSE: To outline the activities required to facilitate all study start-up requirements. Streamlined study start-up coordination through a centralized resource is necessary to ensure quick timelines and compliance with all internal and external requirements.

This standard operating procedure (SOP) describes the processes followed at this investigative site for all study start-up activities from initial sponsor contact through activation, including:

- Assessment of feasibility and interest
- Confidentiality Disclosure Agreement (CDA) execution
- Completion of Sponsor Questionnaires
- Conduct of Pre-site Visits (PSV)
- Determination of site selection
- Budget Development and Negotiation
- Clinical Trial Agreement (CTA) negotiation and execution
- Completion of Regulatory Start-up Requirements
- Conduct of Site Initiation Visit (SIV)
- Activation of trial

Note: Some steps will be described in separate corresponding SOPs in greater detail. This SOP outlines the general process. ***Pleaser reference SOPs 102, 104, 106, 109, 201, 202, and 203 for more detail.***

DEFINITIONS/ABBREVIATIONS:

- **Billing Coverage Analysis (BCA):** This analysis is required for all clinical research studies with industry or government funding to define cost coverage and coverage references.
- **Clinical Research Organization (CRO):** An organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.
- **Clinical Trials Office (CTO):** Centralized clinical trials staff, responsible for the conduct and support of SLUHN clinical trial functions.
- **Collaborative Institutional Training Initiative– (CITI):** Web-based Training Program providing ethics and Good Clinical Practice (GCP) education to all members of the research community.
- **Confidentiality Agreement (CDA):** A legal agreement between two or more parties that is used to signify that a confidential relationship exists between the parties.
- **Curriculum Vitae (CV):** A document that overviews one's education, experience, training, and qualifications.

- **Data Doctor Office Technology Systems (DDOTS):** A software program system utilized by the CTO staff to integrate comprehensive functionalities needed throughout the clinical trial process into a single, open web platform.
- **Delegation of Authority Log (DOAL):** Detailed, written form that outlines what individuals are responsible and able to perform study-related tasks and procedures as authorized by the principal investigator.
- **Financial Conflict of Interest (FCOI):** Significant Financial Interest of an Investigator that could directly and significantly affect the design, conduct, or reporting of Research
- **Financial Disclosure Form (FDF):** A form that discloses an absence or presence of financial interest or arrangement that an individual may have that could affect the reliability of data submitted to FDA.
- **Food and Drug Administration (FDA):** Agency of the United States Department of Health and Human Services (DHHS), responsible for the regulation of clinical trials.
- **Informed Consent Form (ICF):** IRB approved form outlining all aspects of a clinical trial in lay language, signed by the subject consenting to participate.
- **Institutional Review Board (IRB):** Independent ethics committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects.
- **Investigator's Brochure (IB):** A comprehensive document summarizing the body of information about an investigational product.
- **National Clinical Trials Network (NCTN):** A National Cancer Institute (NCI) program that gives funds and other support to cancer research organizations to conduct cancer clinical trials. The groups in the NCTN include the Alliance for Clinical Trials in Oncology, ECOG-ACRIN Cancer Research Group, NRG Oncology, SWOG, Children's Oncology Group (COG), and the NCI of Canada-Clinical Trials Group (NCIC-CTG). The NCTN was previously known as the NCI Clinical Trials Cooperative Group Program.
- **Pre-Site Visit (PSV):** A visit to examine a site to determine its suitability to conduct the clinical trial
- **Principal Investigator (PI):** Lead investigator, responsible for the sound conduct of the project in accordance with the protocol and regulations.
- **Research Financial Compliance Analyst (RFCA):** Clinical Trials Office staff member responsible for the overall day to day pre and post-award financial operations of SLUHN industry or grant funded clinical trials.
- **Sitecore:** The SLUHN internet for the public to view. The CTO lists the protocols which are open to accrual, by disease site, along with IRB number, title, physician and coordinator contact information, synopsis, inclusion criteria and exclusion criteria. Research website that lists current, active clinical trials by disease sub-category

- **Site Initiation Visit (SIV):** A visit that occurs prior to site activation for a specific protocol that is used to orient and train staff on the protocol and study related processes; to confirm readiness for study implementation; and to identify additional requirements that must be satisfied prior to site activation and subject recruitment.
- **Standard Operating Procedures (SOPs):** Detailed, written instructions to achieve uniformity of the performance of a specific function.
- **St. Luke's University Health Network (SLUHN)**

SCOPE:

This SOP applies to all clinical research site personnel involved in the conduct of clinical research run through the centralized CTO.

This policy describes the process:

- Starting from the time the CTO is contacted by a Sponsor/CRO/Investigator with a potential research opportunity
- Ending when the trial is activated and ready to enroll

This policy is applicable to:

- Industry Funded clinical trials
- NCTN clinical trials
- Government funded clinical trials

PERSONNEL RESPONSIBLE:

This SOP applies to those members of the clinical research team involved in facilitating any of the study start-up activities necessary to activate a new trial. This includes the following:

- Director of Clinical Trials and Research
- Clinical Trials Manager
- Principal Investigator
- Study Start-Up Project Coordinator
- Research Finance Compliance Analyst
- Clinical Trials Administrative Assistant

ROLES:

The following information describes which areas and associated roles that shall adhere to this policy:

Director of Clinical Trials and Research: The Director or designee shall be responsible for ensuring compliance with all aspects of this policy, specifically that all timelines are met,

final decision whether a trial will move forward, and that all trials in the pipeline are prioritized appropriately.

Clinical Trials Manager: The Clinical Trials Manager or designee shall serve as the primary liaison between the physicians, study staff, and Study Start-up Project Coordinator, and shall be responsible for ensuring timely completion of all clinical study start-up documents, careful evaluation of all new potential protocols for operational and enrollment feasibility, and obtaining required signatures as needed.

Principal Investigator (PI): Lead investigator, responsible for the sound conduct of the project in accordance with the protocol and regulations, and careful assessment of the protocol for enrollment feasibility and institutional need.

Study Start-Up Project Coordinator: The Study Start-Up Project Coordinator shall be responsible for coordinating all study start-up activities and ensuring timely throughput time from initial sponsor contact, through protocol inception to study activation, serving as the primary liaison between the sponsor, PI, and study team, responsible for the timely completion of CDA's, Feasibility Questionnaires, pre-site visits, and site-initiation visits.

Clinical Trials Administrative Assistant: The Clinical Trials Administrative Assistant shall be responsible for the coordination and scheduling of site visits with the clinical trials staff and sponsor representative, and ensuring that all visits are scheduled in a timely manner.

PROCEDURES:

PROTOCOL ACCEPTANCE AND SITE SELECTION

Role	Step	Activity
Study Start-Up Project Coordinator	1.0	Receive information regarding new potential trial, and add the trial to the Protocol Pipeline Log ***(see Attachment A).*** **NOTE:** If initial information is received directly from an interested physician, proceed through start-up process. **NOTE:** If initial information is received from the sponsor/CRO, request as much information as they are willing to provide without a CDA in place, and send to study team and physicians to determine initial interest **Note:** If not interested in pursuing trial, inform

		sponsor/CRO and mark as declined in Protocol Pipeline Log. No further steps in this SOP need to be followed.
Study Start-Up Project Coordinator	1.1	Contact sponsor, or CRO to obtain full protocol, protocol synopsis, and/or any other pertinent trial information to determine definite interest and PI. **NOTE:** If a CDA is required to obtain full protocol, protocol synopsis, and/or any other pertinent trial information request a "Word" version from the Sponsor or CRO.
Study Start-Up Project Coordinator	1.2	Send "Word" version of CDA to the legal department for review and approval, and send any revisions from SLUHN legal to the sponsor for review. **NOTE:** This process shall continue until the terms of the CDA are finalized.
Study Start-Up Project Coordinator	1.3	Send finalized CDA to legal for institutional signatures. **NOTE:** If the sponsor requires the PI to sign in addition to the institutional signatory, send the CDA to the PI to sign, as well
Study Start-Up Project Coordinator	1.4	Send executed CDA to sponsor/CRO, and request full protocol and next steps (e.g. PSV requirement, site selection, etc.) **NOTE:** If we have activated a study with the sponsor/CRO in past 2 years or less, request a waiver of the PSV requirement.
Study Start-Up Project Coordinator, Clinical Trials Manager, and PI	1.5	Save full protocol in Common Drive, and send protocol to the appropriate Clinical Trials Manager for completion of the New Study Feasibility Checklist ***(see Attachment B)*** with the PI. **NOTE:** If the PI has not yet signed a copy of the Accrual Closure Policy, the Clinical Trials Manager shall also obtain a signed copy of the policy. **NOTE:** If the accrual projection listed on the New Study Feasibility Checklist ***(see Attachment B)*** is

		less than 5, a Request for Exemption from the Accrual Closure Policy Form must be completed *****Please refer to the SOP 104: Accrual Closure Policy for references to the policy and accompanying attachments such as the Request for Exemption*****
Clinical Trials Manager or Designee	1.6	Review protocol for operational and enrollment feasibility, and send pertinent components to ancillary departments (e.g. lab, pathology, radiology) for review of requirements, assign a coordinator, and review the list of key personnel and investigators to ensure they meet the CITI & FCOI training requirements. **NOTE:** If issues are identified during the internal feasibility review, the Managers shall be responsible for informing the PI and Director of their concerns and request to stop pursuing the protocol. **NOTE:** If not interested in pursuing trial, obtain rationale from physician/manager, inform sponsor/CRO and mark as declined in Protocol Pipeline Log ***(see Attachment A)***. No further steps in this SOP need to be followed.
Study Start-Up Project Coordinator	1.7	Complete any sponsor specific feasibility questionnaires, site contact sheets, etc. and begin the study start-up process based on next steps identified as part of ***Step 1.4***.
Clinical Trials Administrative Assistant and Clinical Trials Manager	1.8	Schedule and conduct PSV if required **NOTE:** If SLUHN has worked with the study sponsor within the last year, a request should be made for a PSV waiver or, at a minimum, an abbreviated phone PSV. **NOTE:** Clinical Trials Manager is responsible for informing the Administrative Assistant as to who needs to attend the PSV.
Study Start-Up Project Coordinator	1.9	Obtain official documentation that SLUHN has been selected as a site (email will suffice).
Study Start-Up Project Coordinator	1.10	Add the trial to the Trial Portfolio Log ***(see Attachment C)***

BUDGET AND CONTRACT

Role	Step	Activity
Study Start-Up Project Coordinator	2.0	Obtain budget and contract templates from Sponsor or CRO
Study Start-Up Project Coordinator	2.1	Send contract template along with Sponsor's ICF template to legal for review and approval.
Study Start-Up Project Coordinator	2.2	Send budget template and protocol to Director of Clinical Trials and Research for review and approval.
Study Start-Up Project Coordinator	2.3	Send protocol and ICF template to Research Finance Compliance Analyst or designee for BCA completion. **NOTE:** Specific steps to develop and finalize the BCA will not be outlined in this SOP. ***Please refer to SOP 107: Billing Compliance.***
Not Applicable	---	Specific steps carried out to develop, negotiate, and finalize budget and contract will not be outlined in this policy. ***Please refer to the SOP 106: CTA and Budget Negotiation.***

REGULATORY START-UP

Role	Step	Activity
Study Start-Up Project Coordinator	3.0	Obtain regulatory start-up documents (FDA Form 1572, FDF, DOAL, Signatures Pages (IB and Protocol), One Page/Abbreviated CV, etc., and regulatory binder
Study Start-Up Project Coordinator	3.1	Create DDOTS shell
Study Start-Up Project Coordinator	3.2	Create a study-specific folder in the common drive, to include the following folders, and upload all documents in the appropriate folder. • 1572 • Amendment Forms • Consents • CRFs • FDFs • IB • Initial IRB Application

		• Key Personnel • Letters and Memos • Monitoring Visit Letters • New Study Feasibility Form • NTFs • Patient Materials • Periodic Review Forms • PI Acknowledgement of Submission Policy Changes • Protocol • Signed Accrual Closure Policy • Termination Form
Study Start-Up Project Coordinator	3.3	Complete all required regulatory documents, and obtain any necessary signatures.
Study Start-Up Project Coordinator	3.4	Check for accuracy of all completed documents, and ensure that the CV, Medical License, CITI training, and FCOI documents are all current.
Study Start-Up Project Coordinator	3.5	Develop and attach any necessary NTFs such as explanation of business names, locations, and affiliations, and send entire regulatory packet to the sponsor/CRO via email.
Study Start-Up Project Coordinator	3.6	File all original regulatory documents in the regulatory binder for review by the sponsor/CRO during the SIV.
Not Applicable	---	Specific steps carried out to complete the initial regulatory documents will not be outlined in this policy. ***Please refer to the SOP 201: Regulatory Start Up and Initial IRB Submission.***

INITIAL IRB SUBMISSION

Role	Step	Activity
Study Start-Up Project Coordinator	4.0	Obtain documents from sponsor or CRO needed to submit to the IRB (protocol, informed consent form template(s), investigator's brochures, patient materials, user manuals, etc.)
Study Start-Up Project Coordinator	4.1	Update the Trial Portfolio Log ***(see Attachment C)*** with IRB number and create IND Safety Report Log(s) ***(see Attachment D)***
Study Start-Up Project Coordinator	4.2	Obtain the PI's signature on the IRB Approval Letter, send a copy of the approval documents to the sponsor/CRO, upload to the common drive,

		and file in the appropriate section of the Regulatory Binder.
Not Applicable	---	Specific steps carried out to complete the initial IRB submission and obtain IRB approval will not be outlined in this policy. ***Please refer to the SOP 201: Regulatory Start Up and Initial IRB Submission and the SOP 202: IRB Approval Distribution.***

SITE INITIATION AND ACTIVATION

Role	Step	Activity
Study Start-Up Project Coordinator and Clinical Trials Manager	5.0	Create and email SIV/Activation Checklist ***(see Attachments E and F)*** to Clinical Trials Manager to begin working towards completion w/their staff **NOTE:** The SIV/Activation Checklist ***(see Attachments E and F)*** identifies all items that need to be completed prior to activation as well as the party responsible for completion. **NOTE:** All items are expected to be completed prior to the SIV. **NOTE**: Activation is expected 3-5 business days following the SIV.
Clinical Trials Administrative Assistant and Clinical Trials Manager	5.1	Schedule and conduct SIV.
Study Start-Up Project Coordinator or Clinical Trials Manager	5.2	Print, sign and date SIV/Activation Checklist ***(see Attachments E and F)*** and file in Regulatory Binder.
Study Start-Up Project Coordinator	5.3	Calculate study start-up timelines and enter in Timeline Tracking Log **(see Attachment G)**
Study Start-Up Project Coordinator	5.4	Open Study/Arms in DDOTS.
Study Start-Up Project Coordinator	5.5	Move the trial from the pending tab to the open tab in the Trial Portfolio Log ***(see Attachment C),*** and move to the Activated tab in the Protocol Pipeline Log ***(see Attachment A)***.
Study Start-Up Project Coordinator	5.6	Add the trial to Sitecore.

RESOURCES:
N/A

Endorsed by: SOP Committee (10/25/13; 3/21/14; 4/17/15; 4/8/16)
Approved by: Tracy Butryn, Director of Clinical Trials (11/12/13; 5/28/14; 8/12/14; 4/17/15; 7/12/16)

ATTACHMENT A:

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	AA	AB	AC	AD	AE	AF	AG	AH	AI	AJ
1	PI	STUDY	NOTES/COMMENTS	INITIAL CONTACT	DEFINITE INITIAL INTEREST (Y/N)	CDA RECEIVED	CDA EXECUTED	SPONSOR FEASIBILITY SURVEY SENT	SPONSOR FEASIBILITY SURVEY COMP	PROTOCOL RECEIVED	DEFINITE INTEREST	PROTOCOL SENT TO MANAGERS FOR	INTERNAL FEASIBILITY REVIEW COMP	PSV REQUIRED (Y/N)	BARB INFORMED TO SCHEDULE PSV	PSV DATE	SITE SELECTION	START-UP DOCS RECEIVED	BUDGET SENT TO TRACY	MCA SENT TO ANTHONY	BCA COMPLETED	BUDGET SENT TO SPONSOR	BUDGET FINALIZED	Finance Approval Form Signed	CTA SENT TO JANE	CTA FINALIZED	CTA FULLY EXECUTED	ICF SENT TO SPONSOR	ICF FINALIZED	SUBMITTED TO IRB	IRB APPROVAL LETTER RECEIVED	REG DOCS COMPLETE	ACTIVATION CHECKLIST SENT	ACTIVATION CHECKLIST COM	BARB INFORMED TO SCHEDULE SIV	SIV DATE
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Pipeline | On Hold | Declined | Activated

Effective Date(s):	Revision Date(s):
12/12/13	5/28/14; 8/12/14; 4/17/15; 4/8/16

ATTACHMENT B:

St Luke's HOSPITAL & Health Network

New Study Feasibility Checklist

Trial Title:				
Department:				
Sponsor:				
SLHN PI:		IVRS ☐	EDC ☐	Imaging ☐
SLHN Co-I:		IVRS ☐	EDC ☐	Imaging ☐
Lead Research Coordinator:		IVRS ☐	EDC ☐	Imaging ☐
Backup Research Coordinator		IVRS ☐	EDC ☐	Imaging ☐
Pharmacist		IVRS ☐	EDC ☐	Imaging ☐
Data Manager		IVRS ☐	EDC ☐	Imaging ☐
Laboratory Coordinator		IVRS ☐	EDC ☐	Imaging ☐
Key Personnel *everyone listed must have CITI & FCOI training*		IVRS ☐	EDC ☐	Imaging ☐
Treatment locations/campus' (e.g. where IP will be given)				
Additional non-treatment research locations (e.g. imaging, labs, physical exams)				
Location of IP drug storage:				
When will drug be shipped?	Per Patient ☐	Upon First Patient Enrolled ☐	Upon Activation ☐	
Patient Payments?	Yes ☐ No ☐			
	If yes, number of onsite visits:			

Please Note: Trials REQUIRING the use of a central IRB in lieu of the SLHN IRB CANNOT be done at SLHN

Study Summary

Study Objective Short description of the study/protocol intended for the lay public. Include a brief statement of the study hypothesis.	
General Eligibility Criteria Interventional studies: Summary criteria for participant selection. The preferred format includes lists of inclusion and exclusion criteria. Observational studies:	

St Luke's HOSPITAL & Health Network

New Study Feasibility Checklist

Study Population Description: A description of the population from which the groups or cohorts will be selected (e.g., primary care clinic, community sample, residents of a certain town).	

Study Characteristics

Does this trial address an area where we currently have no treatment option or need an additional clinical trial option?	Yes ☐	No ☐
If No, Describe how study differs from current options:		
Does this trial compete with an existing or pending trial?	Yes ☐	No ☐
If Yes, provide priority list including the competing trials and provide justification why this trial should be opened.		
Does the use of the investigational agent(s) in this protocol require an application to and approval by the BRANY Institutional Biosafety Committee (IBC)?	Yes ☐	No ☐
If Yes,		
o Recombinant DNA not exempt by the NIH Guidelines or requiring Biosafety Level or above (this includes transgenic plants and animals)	Yes ☐	No ☐
i. Infectious Agents including:		
• Human blood, body fluids, or unfixed tissue	Yes ☐	No ☐
• Tissues, organs or cell cultures of human origin	Yes ☐	No ☐
• Human Gene Transfer	Yes ☐	No ☐
Does the protocol call for the submission of pathology blocks?	Yes ☐	No ☐
If Yes, please contact Pathology to determine if this is feasible		
Does the protocol require extra radiology tests or procedures?	Yes ☐	No ☐
If Yes, separate arrangements will need to be made with Radiology		
Does the protocol utilize a central or local lab?	Central ☐	Local ☐
Does the protocol require correlative PKs?	Yes ☐	No ☐
Is PI credentialing required?	Yes ☐	No ☐
Is Radiation Safety Committee review/approval required?	Yes ☐	No ☐
Does this trial utilize an Investigational Device?	Yes ☐	No ☐
a) *If Yes, answer the following:*		
i. Will the device be supplied by the sponsor or purchased? _____		
ii. Will the device require storage space?	Yes ☐	No ☐
1. If yes, *Where will the device be stored?* _____		

ATTACHMENT B CONT'D:

St Luke's HOSPITAL & Health Network

New Study Feasibility Checklist

Does the protocol have any "Other" unique requirements that are not listed above?	Yes	☐	No	☐
If Yes, please list_____ & ensure arrangements & contacts are made				

Sponsorship

Is this an Industry Sponsored Trial?	Yes	☐	No	☐
Who is the Contact at the Sponsor?				
Is this a Cooperative Group study (oncology only)?	Yes	☐	No	☐
If Yes, what is the National Target accrual?				
Is this an Investigator Initiated Trial?	Yes	☐	No	☐
If Yes,				
o Who will serve as the lead site (e.g. sponsor) and who is the contact?				
Please note: SLHN-sponsored interventional IITs must be discussed with the Tracy Suzyn (Max), Director of Clinical Trials before moving forward				
o Is there funding for this trial?	Yes	☐	No	☐

Accrual

What is the expected total accrual for SLHN?	Patients
Please note: *It will be expected that you enroll at least 20% of this target accrual per year, or the trial shall be reviewed for closure per Accrual Closure Policy (Attached)	

Is the PI and/or Co-I prepared to review and sign off on all required study documents in a timely manner and on a regularly scheduled basis as required by regulatory authorities, the study protocol, and/or institutional policies?	Yes	☐	No	☐
Signature of Principal Investigator:				

SLHN New Study Feasibility Checklist Page 3 of 3 March 30, 2016

ATTACHMENT C:

Trial Portfolio Log

PI	Disease Site	Charge Code	Protocol Title	IRB Number	Trial Type (Device, Drug, Registry, etc?)	Therapy Type (1st line, 2nd line, 3rd line?)	Sponsor Type	Sponsor	Trial Status	IRB Approval Date	Activation Date	SLHN Target Accrual	SLHN Total Acrual	Date Last Patient Enrolled	Coordinator	Expiration Date	National ID

ATTACHMENT D:

IND Safety Report Log

Per 21CFR312.55 sponsor shall keep participating investigators informed of new observations. Please sign the last page of this summary to verify receipt of the listed off-site **IND Safety Reports for Merck_MK-0653A_Dale_2005-46**

Adverse Event #	Report Date	Description of event	Report Type	Attribution/Assessment

Physician's Signature (Please sign last page only) _____

Date of Signature _____

ATTACHMENT E:

Checklist for Study Start Up (Pharma)

Sponsor:	
Study No:	
Investigator:	

Date completed or N/A	If N/A, provide reason	Responsible Party	Person who completed Task	Task
		Study Start-up PC		Verify approval of ICF from both IRB and Sponsor
		Manager or designee		Upload Study Summary to Clinical Trials Website
		Manager or designee		Upload of Approved Protocol and Consents to website/Common Drive
		Study Start-up PC		FDA 1572 reviewed for completeness and accuracy
		Study Start-up PC		Financial Disclosure forms reviewed for completeness and accuracy
		Study Start-up PC		Protocol Signature Page reviewed for completeness
		Study Start-up PC		IB Signature Page reviewed for completeness
		Study Start-up PC		CVs verified they are current and have signature & date
		Study Start-up PC		Medical Licenses verified they are current
		Study Start-up PC		Verify receipt of Regulatory Binder.
		Study Start-up PC		Originals of the following sent to sponsor: FDA 1572, Financial Disclosure Forms, Protocol and IB Signature Pages, CVs, and Medical Licenses
		Study Start-up PC		Copies of the following filed in Regulatory Binder: FDA 1572, Financial Disclosure Forms, Protocol and IB Signature Pages, CVs, and Medical Licenses
		Study Start-up PC & Research Staff		Completion of Delegation of Authority Log
		Research Nurse		Read protocol cover to cover
		Research Nurse		Obtain Standard of Care Determination from Manager
		Research Nurse		Review Protocol for Special Requirements (ie: special radiology measurements, special equipment, unique labs)
		Research Nurse		Send protocol to pharmacy contacts for chemo order template creation (if weight-based IP). And, provide parameters to pharmacy for administration of protocol treatment.
		Research Nurse		Verify pharmacy template is accurate.
		Research Nurse		Verify Receipt of Lab Manual
		Research Nurse		Verify Receipt of Lab Kits
		Research Nurse		Verify Receipt of Pharmacy Manual
		Research Nurse		Verify Receipt of Study Drug
		Research Nurse		Verify Receipt of Radiology Manual and Supplies
		Research Nurse		Verify Receipt of additional study supplies (ie: EKG machine)
		Research Nurse		Verify all applicable parties have completed eCRF training
		Research Nurse		Verify receipt of username & password for eCRF account
		Research Nurse		Verify receipt username & password for registration system (ie: IVRS)
		Research Nurse		Verify PI has received all necessary training (ie: eCRF)
		Research Nurse		Verify PI/Sub-I, & other necessary staff has received Protocol/Study specific training and this is clearly documented (Email with training slides and PI signed memo)
		Research Nurse		Sponsor activation letter received
		Study Start-up PC		Verify PI has signed the EMR Certification of Verification of Copies
		Study Start-up PC		Verify Contract is fully executed
		Study Start-up PC		Verify Department Cost Center Number has been assigned
		Research Finance Compliance Analyst		BCA/Cover sheet and BCA completed, signed, and saved in Common Drive
		Research Finance Compliance Analyst		Payment Tracker Created
		Research Finance Compliance Analyst		EPIC Protocol Build
		Study Start-up PC		IND Safety Report Log Updated/Created
		Director		Verify MAC Approval on CMS Website
		Research Nurse		Set up and complete SIV
		Manager		Send announcement to activate trial at SLUHN and update database

ATTACHMENT F:

Checklist for Study Start Up (Cooperative Group)

Sponsor:
Study No:
Investigator:

Date completed or N/A	If N/A, provide reason	Responsible Party	Person who completed Task	Task
		Regulatory Coordinator		Verify approval of ICF from IRB and send to CTSU
		Manager or designee		Upload Study Summary to Clinical Trials Website
		Regulatory Coordinator		Upload of Approved Protocol and Consent(s) to Common Drive
		Regulatory Coordinator		IND Safety Report Log Updated/Created
		Regulatory Coordinator		Regulatory Binder Created
		Research Nurse		Read protocol cover to cover
		Research Nurse		Review Protocol for Special Requirements/Credentialing (ie: special radiology measurments, special equipment, unique labs)
		Research Nurse		Send protocol to pharmacy contacts for chemo order template creation (if weight-based IP). And, provide parameters to pharmacy for administration of protocol treatment.
		Research Nurse		Verify pharmacy template is accurate.
		Research Nurse		Verify Ordering of Lab Kits
		Research Nurse		Verify Ordering of Study Drug
		Research Nurse		Verify PI/Sub-I, & other necessary staff has received Protocol/Study specific training and this is clearly documented
		Director		Finance Approval
		Research Finance Compliance Analyst		EPIC Protocol Build
		Research Finance Compliance Analyst		Cost Analysis Developed and added to ongoing spreadsheet
		Research Finance Compliance Analyst		Payment Tracker Created
		Manager		Send announcement to activate trial at SLUHN

ATTACHMENT G:

Timeline Tracking Log

PI	Protocol	Initial Information Received	Receipt of Start-up Docs	IRB Approval	Activation	Initial Contact to Activation	Receipt of Start-up Docs to Activation