PURPOSE:

To provide a general outline of the key steps in creating and finalizing a Clinical Trial Agreement (CTA) and budget. Developing a CTA and budget for a clinical trial involves Legal and Network Reimbursement review to ensure SLUHN is protected legally, and that all costs are covered for participating shared services and collaborators, clinical procedures that are performed specifically for research purposes, and research staff effort required to conduct the study.

When creating a budget for a clinical trial, all pertinent SLUHN policies and Medicare rules (please refer to Billing Compliance SOP) must be followed. Standard budget guidelines such as Research Floor Rates for clinical procedures/tests, standard invoiceables, and other non-patient costs shall be strictly adhered to for sponsored studies unless otherwise approved.

DEFINITIONS:

- **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 Trial Agreement (CTA):** The legally binding agreements between a sponsor and an institution (site) as to how certain business and property rights will be handled between the parties. These agreements are separate from Investigator Agreements and Confidentiality Agreements and are not regulated by or disclosable to FDA. CTAs allocate risk, responsibility, financial support, and obligations of the parties; and they protect the rights of the parties.
- **Clinical Trials Office (CTO):** Centralized clinical trials staff, responsible for the conduct and support of SLUHN clinical trial functions
- **Closeout Visit (COV):** Final monitoring visit performed at the investigative site to complete a final review and reconciliation of all regulatory files, all data and source documentation, reconcile all unused study drug, and discuss requirements for document storage.
- **Contract 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.
- **Current Procedural Terminology (CPT):** a coding system, defined in the publication *Current Procedural Terminology,* for medical procedures that allows for comparability in pricing, billing, and utilization review
- **Data Doctor Office Technology Systems, Inc. (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
- **Epic:** An integrated electronic health record system utilized by St. Luke's University Health Network (SLUHN) to support functions related to patient care, including registration and scheduling; clinical systems for doctors, nurses, emergency personnel, and other care providers; systems for lab technologists, pharmacists, and radiologists; and billing systems.

- **Full Execution (FE):** Completed and formally signed document containing all required signatures from all parties
- **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.
- **Investigational New Drug (IND):** the means by which a pharmaceutical company obtains permission to ship an experimental drug across state lines (usually to clinical investigators) before a marketing application for the drug has been approved.
- **Note to File (NTF):** Regulatory document used to confirm and document aspects of a clinical trial
- **Partial Execution (PE):** Partially completed and formally signed document containing some of the required signatures from required parties
- **Principal Investigator (PI):** Lead investigator, responsible for the sound conduct of the project in accordance with the protocol and regulations.
- **Research Finance 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.

- **Serious Adverse Event (SAE):** Any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, and or congenital anomaly/birth defect.
- **St. Luke's University Health Network (SLUHN)**
- **Standard Operating Procedures (SOP):** Detailed, written instructions to achieve uniformity of the performance of a specific function.

SCOPE:

This SOP applies to all site personnel who conduct or are involved in clinical research within the CTO.

This policy describes the process:

- Starting from receipt of the study start-up package, including CTA and Budget templates
- Ending when the CTA is fully executed

This policy is applicable to the following studies:

- All industry and Government-sponsored clinical trials conducted at SLUHN and run through the SLUHN CTO

*****NOTE:* Protocol review ,BCA development, EPIC protocol builds, and budget/CTA amendments will not be addressed in this SOP. Please refer to SOP 107*****

PERSONNEL RESPONSIBLE:

This SOP applies to those members of the clinical research team involved in clinical trials, facilitating the start-up process of a new clinical trial. This includes the following:

- Principal Investigator (PI)
- Clinical Trials Management
- Study Start-up Project Coordinator
- Research Finance Compliance Analyst (RFCA)
- SLUHN Legal and Network Reimbursement

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 oversight of this policy, and budget development and negotiation.

Research Finance Compliance Analyst (RFCA): The Research Finance Compliance Analyst shall be responsible for the understanding and compliance with rules for billing Medicare, Medicaid, and third party payers for services, drugs, devices, tests and procedures rendered in the clinical research context. He/she shall be responsible for constructing the BCA for each awarded study.

Clinical Trials Manager: The Clinical Trials Manager shall be responsible for the review of each clinical trial protocol and ongoing protocol amendments, in conjunction with the RFCA and PI, to assist in the development and/or revision of the BCA, and communicate any protocol requirements that may affect the budget.

Principal Investigator or designee: The principal investigator shall be responsible for thoroughly reviewing the completed BCA with the RFCA or designee. During this review, the PI will provide feedback based on their clinical knowledge and standard practice experience.

Study Start-up Project Coordinator: The Study Start-up Project Coordinator shall be responsible for facilitating the CTA review and negotiation process, and shall serve as the primary liaison between the study sponsor and/or CRO, SLUHN Legal, CTO staff, and the Director of Clinical Trials and Research.

SLUHN Legal: The SLUHN Legal designee shall be responsible for the thorough and timely review of all CTAs to ensure compliance with local, state, and federal laws, and overall protection of SLUHN from a legal standpoint.

SLUHN Network Reimbursement: SLUHN Network Reimbursement shall be responsible for establishing standard Research Floor Rates, and the final review of all sponsored budgets to ensure coverage of costs.

PROCEDURES:

CTA Process:

- Obtain CTA template from study sponsor and send to SLUHN legal and Director of Clinical Trials and Research for review
- Redline any changes and comment as necessary until CTA language is finalized
- Ensure any changes to payment terms and/or Exhibits such as the budget are incorporated
- Obtain execution copies of finalized CTA and routing instructions from sponsor
- Route PE CTA to sponsor and obtain FE CTA
- Send FE CTA to legal to upload to MediTract and save FE copy on Common Drive

Budget Process:

- Obtain budget template from study sponsor and send to Director of Clinical Trials and Research or designee for review
- Develop Budget Spreadsheet ***(see Attachment A)*** using the BCA for determination of what shall be paid by the sponsor using established Research Floor Rates
- Incorporate costs into the sponsor-provided budget template or use internal budget template ***(see Attachment B)***
- Negotiate fees with sponsor, providing rationale for fees as needed
- Update payment terms as necessary
- Incorporate finalized budget and payment terms in CTA prior to PE
- Complete Finance Approval Form and obtain SLUHN Network Reimbursement approval
- Develop Payment Tracker
- Send W-9 to Sponsor and obtain new Sub-Account

CTA REVIEW AND NEGOTIATION

Role	Step	Activity
Study Start-up Project Coordinator	1.0	Obtain CTA template from Sponsor or CRO
Study Start-up Project Coordinator	1.1	Send CTA template along with Sponsor's ICF template to legal for review and approval. Also include the following information:

		• Sponsor • Protocol number • Research Locations • PI name **NOTE:** This information can be obtained from the New Study Feasibility Form completed by the Clinical Trials Manager and PI
SLUHN Legal	1.2	Review CTA template and revise/comment as necessary
SLUHN Legal	1.3	Send redline CTA to Study Start-up Project Manager to address any outstanding questions
Study Start-up Project Coordinator	1.4	Review and address any comments from SLUHN Legal as necessary and send redlined CTA to sponsor for review **NOTE:** Data entry language should reflect at least a 10 day window for visits, and at least a 5 day window for queries **NOTE:** Notices should be sent via secure mail to the Director of Clinical Trials and Research with a copy to Legal **NOTE:** SLUHN termination language should be included, and that a COV be conducted at the site within 30 days of completion of the study at SLUHN. **NOTE:** Monitoring visits must be during normal business hours at mutually agreeable times. **NOTE:** Standard record storage timeframe is 15 years after the study is completed and closed at SLUHN. If different terms are used, SLUHN Legal shall inform the Director of Clinical Trials and Research of the change .
Study Start-up Project Coordinator	1.5	Obtain Sponsor/CRO revisions and comments to the CTA and send back to SLUHN Legal for review **NOTE:** Repeat Steps 1.2 through 1.5 until CTA language is finalized

		NOTE: During one of the review rounds, the CTA shall be sent to the Director of Clinical Trials and Research or designee to review and revise the Compensation section and Payment Terms (usually Exhibit A) if not being negotiated separately along with the budget. These sections shall be negotiated and revised throughout the process for Steps 1.2 through 1.5
Study Start-up Project Coordinator	1.6	Obtain routing instructions and execution copies of finalized CTA and send to SLUHN Legal and Director of Clinical Trials and Research or designee for final review prior to PE
Director of Clinical Trials and Research or designee	1.7	Ensure finalized payment terms and Exhibits (e.g. Budget) are incorporated into the finalized CTA ***(see Step 2.1 below)***
Study Start-up Project Coordinator	1.8	Send CTA to SLUHN Legal to obtain institutional signatures
Study Start-up Project Coordinator	1.9	Obtain PI signature in accordance with the routing instructions provided by sponsor/CRO
Study Start-up Project Coordinator	1.10	Send PE CTA to sponsor/CRO per routing instructions
Study Start-up Project Coordinator	1.11	Obtain FE CTA and send to SLUHN Legal to upload to MediTract

BUDGET DEVELOPMENT AND NEGOTIATION

Role	Step	Activity
Study Start-up Project Coordinator	2.0	Obtain Budget template from Sponsor or CRO
Study Start-up Project Coordinator	2.1	Send Budget template, protocol, and CTA to Director of Clinical Trials and Research or designee **NOTE:** Specific steps for BCA development will not be outlined in this SOP. *Please refer to SOP 107.*
Director of Clinical Trials and Research or designee	2.2	Develop Budget Spreadsheet ***(see Attachment A)*** from BCA, allocating fees for all sponsor paid items/services, as well as time and effort. **NOTE:** Fees for services associated with CPT codes shall be derived from the current Research Floor Rate spreadsheet developed by SLUHN Network Reimbursement.

		NOTE: Fees for time and effort shall be calculated based on the party responsible for completing the task, as well as the amount of time involved using the Time and Effort Back-up Documentation ***(see Attachment F)***. **NOTE:** An attempt shall be made to mark-up all minimum fees by 30% as the Research Floor Rates are at "cost", but at no time shall fall below the established Research Floor Rate unless otherwise approved.
Director of Clinical Trials and Research or designee	2.3	Include a Data Entry/Management Fee (current fee is $50.00 - $100.00 per visit minimum dependent on the amount of data required) and CTO Fee using the CTO Back-up Documentation ***(see Attachment G)***., and apply overhead to each visit sub-total (current rate is 35%).
Director of Clinical Trials and Research or designee	2.4	Transfer budget numbers into the sponsor budget template, or utilize SLUHN budget template ***(see Attachment B).***
Director of Clinical Trials and Research or designee	2.5	Ensure the following standard invoiceable items are included/added (if applicable): <u>IRB Fees:</u> • Initial Review = $3,500.00 • Each Amendment = $1,000.00 • Each Periodic Review = $1,200.00 • Each SAE/UAP = $350.00 • Final Report = $950.00 <u>Start-up Fees:</u> • Administrative Start-up = $6,500.00 (therapeutic) or $4,500.00 (Observational) • Lab Start-up = $2,000.00 • Pharmacy Start-up = $2,000.00 • Radiology Start-up = $1,500.00 <u>Other Invoiceable Items:</u> • Pharmacy Monthly Maintenance Fee = $250.00 per month while drug is onsite • IND Safety Report Fee = $25.00 per report • Closeout Fee = $1,500.00

		• Storage and Archive Fee = $1,000.00 • Advertising Fee = $1,000.00 • Contract/Budget Amendment Fee = $200.00 per revision • Monitoring Visit Fee = $100.00 per visit • Monitor/CRA Change Fee = $500.00 each • Pre-screening/Chart Review Fee = $2,500.00 • Dry Ice = $1000.00 • Unscheduled Visits = $350.00 per visit • IRB Prep Fee = $200.00 per submission • Incidental Supplies = $500.00 • Reconsenting Fee = $200.00 each • Audit/Inspection Fee (Not-For-Cause ONLY) = $800.00 pre day • First Site Activation/Accelerated Start-up Fee = $1000.00 • Screen Fails = cost of Screening Visit **NOTE:** These fees are non-negotiable unless otherwise approved. **NOTE:** There may be additional invoiceable items listed based on protocol and BCA (e.g. CT/MRI Scans, Office Visits, ECHO/MUGA, Tumor Biopsy, central radiology reads, etc.).
Director of Clinical Trials and Research or designee	2.6	Review the CTA for sections regarding the compensation section, payment schedule and/or budget (see Step 1.5), and make changes as necessary. **NOTE:** Efforts shall be made to make visit payments automatic based on completed visits as indicated by submitted CRFs by SLUHN, and to be paid on a monthly basis. **NOTE:** Invoiceable items must be paid within 30-45 days of the date of invoice. Language referencing the sponsor's "receipt" of the invoice may not be used.

		NOTE: Language must be included that the Final Report will not be submitted to the IRB until all final payments have been received, and that all final payments are due within 30 days of the completion of the COV. **NOTE:** Language must be included that invoices shall not be required less than 90 days after the date of services rendered. **NOTE:** Language must be included that the final invoice for any outstanding payments shall not be required less than 90 days after the Closeout Visit. **NOTE:** Language must be included that payments are to be sent to the Director of Clinical Trials and Research. **NOTE:** A valid email address to where invoices are to be sent must be included.
Director of Clinical Trials and Research or designee	2.7	Send the budget proposal to the sponsor/CRO for review.
Director of Clinical Trials and Research or designee	2.8	Obtain Sponsor/CRO revisions and comments to the Budget and make additional changes as necessary. **NOTE:** If back-up documentation for any fees is requested, please provide the appropriate NTF. **NOTE:** Repeat Steps 2.7 through 2.8 until the budget is finalized.
Study Start-up Project Coordinator	2.9	Ensure the finalized budget and payment terms are incorporated into the finalized CTA ***(see Step 1.6 above)*** **NOTE:** Director of Clinical Trials and Research or designee shall review execution copy for final approval that all payment and budget terms are accurate.
Study Start-up Project Coordinator	2.10	Request and complete all Sponsor required Payment Forms, and send appropriate W-9 to sponsor.
Study Start-up Project Coordinator	2.11	Email appropriate contact in Accounts Payable that a W-9 was sent, indicating which W-9 was sent (e.g. Network, Bethlehem, or Anderson) and the study

		sponsor/protocol number.

NETWORK REIMBURSEMENT APPROVAL

Role	Step	Activity
Director of Clinical Trials and Research or designee	3.0	Complete the Finance Approval Form ***(see Attachment C).***
Director of Clinical Trials and Research or designee	3.1	Send completed Finance Approval Form ***(see Attachment C)***, Budget Spreadsheet***(see Attachment A)***, and/or final budget to Network Reimbursement designee for review and approval via email.
Director of Clinical Trials and Research or designee	3.2	Obtain signed Finance Approval Form and upload onto the Common Drive.

PAYMENT TRACKER DEVELOPMENT

Role	Step	Activity
Director of Clinical Trials and Research	4.0	Email the finalized CTA and Budget to the RFCA or designee to develop the Payment Tracker.
RFCA or designee	4.1	Develop the Payment Tracker ***(see Attachment D)***. **NOTE:** Ensure the following items are included: • PI and Study name • IRB Number • Account Number • Drugs for INDSR log (when applicable) • Payment Terms for both per patient visit costs and invoiceables • Email address where invoices are to be sent
RFCA	4.2	Save the Payment Tracker ***(see Attachment D)*** on the Common Drive.
Director of Clinical Trials and Research or designee	4.3	Update the SIV/Activation Checklist ***(see Attachment E)*** as applicable

RESOURCES:
N/A

Endorsed by: SOP Committee (8/15/14; 2/20/15)
Approved by: Tracy Butryn, Director of Clinical Trials and Research (8/27/14; 2/20/15)

Effective Date:	Revision Date(s):
9/27/14	2/20/15; 4/8/16

ATTACHMENT A

Budget Spreadsheet

PI:
Sponsor:
Short Title:

Procedures and tests	CPT Code	Floor Rate	Visit X	Visit X	Visit X	Visit X	Visit X	Visit X	Visit X	Visit X	Visit X	Visit X
Sub-Total												
CTO Fee												
Data Entry Fee												
TOTAL with 35% OH												

ATTACHMENT B

SLUHN Budget Template

PI:
Sponsor:
Short Title:
Site:

All payments must include an itemized detail of what the payment covers, and must indicate the sponsor and study on the payment*

All payments shall be mailed to:

The below per patient visit costs will be automatically paid on a monthly basis based on completed CRFs as indicated in the Payment schedule*

VISIT	Vist X	Vist X	Vist X	Vist X	Vist X	Vist X	Vist X	Vist X	Vist X	Vist X	Vist X	Vist X
VISIT PAYMENT (with 35% OH)												

INVOICEABLES:

Shall be paid within 30 days of the date of invoice submitted by site*

Administrative Start-up = $6500.00
Lab Start-up = $2000.00
Pharmacy Start-up = $2000.00
Radiology Start-up = $1500.00
Pharmacy Monthly Maintenance Fee = $250.00 per month drug is onsite
Closeout Fee = $1500.00
Storage/Archive Fee = $1000.00
IND Safety Reports = $25.00 each
Advertising Fee = $1000.00
Contract/Budget Amendment Fee = $200.00 per revision
Monitoring Visit Fee = $100.00 per visit
IRB Prep Fee = $200.00 per submission
Pre-Screening Chart Review Fee = $2500.00
Unscheduled Visits = $350.00
Screen Fails = $XXX
Dry Ice = $1000.00
Incidental Supplies = $500.00
Reconsenting Fee = $200.00 each
Audit/Inspection fee (Not-for-Cause ONLY) = $800.00 per day
First Site Activation Fee (Accelerated Start-up) = $1000.00
Monitor/CRA Change Fee = $500.00 per change

IRB Fees as Follows:
Initial Review = $3500.00
Periodic Review = $1200.00 each
Amendments = $1000.00 each
SAEs and UAPs = $350.00 each
Final Report = $950.00

ATTACHMENT C

St Luke's UNIVERSITY HEALTH NETWORK

801 Ostrum Street
Bethlehem, PA 18015
484-526-4000

Clinical Research Contract Proposal – Technical Facility Side Only

Finance Approval Form for Negotiated Reimbursement Rates

Instruction – The Clinical Trials Office (CTO) will complete this form after conducting a Billing Coverage Analysis (BCA) that lists the item(s) and services that are billable to insurance as "Routine Care" or are to be covered by the study as research. Items not covered by Medicare or another payer must be reimbursed by the study sponsor/company. The intent of this form is to summarize from the BCA those items that will not be paid for by Medicare and /or another payer. The study sponsor/company will need to reimburse St. Luke's University Health Network for such procedures/services. Negotiated contract terms and rates will be reflected in an executed contract between both parties.

After the CTO completes this form, it is to be forwarded to the Finance Department for approval. After Finance approves the negotiated rates, the approved form will be sent back to the CTO for filing.

Research Company Name: _____

Account # of Clinical Trial: _____

Clinical Trial Name: _____

Principal Investigator: _____

Contact Person Name and Extension: _____

Devices:

- Are devices utilized in this clinical trial? _____
- If yes, is the device a Category B device? _____

****If the device is a Category B device, approval from the Fiscal Intermediary (Medicare) must be obtained. These approvals will be obtained by the sponsor for the study and a listing of covered clinical trials and devices can be found on Medicare's website. Confirmation of approval from the Fiscal Intermediary should be printed and maintained with CTO files prior to commencement of the trial****

My Health. My Hospital.™

Will this trial include outpatient or inpatient services or both? _____

Outpatient Research Procedures

CPT/ Code/ Name	Floor Rate	Negotiated Contract Rate (incl. overhead)

Inpatient Research Procedures

Work with Finance for Inpatient Rate Development. Implants and/or devices not covered by Medicare will be provided or paid for by the Sponsor/ Company.

Time and Effort Non-Billable Items:

Service Description	Included Yes/ No	Amount
Informed Consent/ Medical RX		
Principal Investigator's Time		
AE/SAE Assessment		
Study Coordinator's Time (separate line item or included in study activities such as VS, AE assessment, con meds, PS, QOL, etc.)		
Pharmacy - Protocol Start Up Fee		
Pharmacist Dose fee/Drug Maintenance Fee		
Lab Start-up Fee		
Administrative Start-up fee		
Radiology Start-up Fee		
IND Safety Report processing		

IRB initial review fee		
IRB annual reapproval or amendments		
IRB Final Report		
Inclusion/Exclusion (Eligibility)		
SAE submission/IRB review		
Study specific activities (i.e. photography, advertisements, Dry Ice, Misc. supplies)		
Central lab submission (safety labs)		
Special lab submission (biomarkers, PK samples, etc)		
Patient stipends or travel reimbursements		
Overhead rate		
Education travel time Monitoring Visit Fee Close-out fee Storage/Archive Fee		

Finance Approval Signature: _____

Date Approved By Finance: _____

Finance Department Comments:

ATTACHMENT D

Payment Tracker

PI:
Sponsor:
Protocol Title:
IRB#:
Account#:
Drugs:

Study Activities	Visit X	Visit X	Visit X	Visit X	Visit X	Visit X	Visit X	Visit X	Visit X
Patient #									
DOV									
Date CRF Submitted									
Expected Payment									
Actual Payment									
DOP									
Patient #									
DOV									
Date CRF Submitted									
Expected Payment									
Actual Payment									
DOP									

DOV: Date Of Visit
DOP: Date Of Payment

ENTER EMAIL ADDRESS TO SEND INVOICES

Subject Payments: Insert Terms
Invoice Payments: Insert Terms

CTO Invoiceables	Date Invoice Sent	Date Payment Received
Administrative Start-up = $6500.00		
Lab Start-up = $2000.00		
Pharmacy Start-up = $2000.00		
Radiology Start-up = $1500.00		
Pharmacy Monthly Maintenance Fee = $250.00 per month drug is onsite		
Closeout Fee = $1500.00		
Storage/Archive Fee = $1000.00		
IND Safety Reports = $25.00 each		
IRB Prep Fee = $200.00 per submission		
Advertising Fee = $1000.00		
Contract/Budget Amendment Fee = $200.00 per revision		
Monitoring Visit Fee = $100.00 per visit		
Inspection/Audit Fee (Not for cause ONLY) = $800.00 per day		
Pre-Screening Chart Review Fee = $2500.00		
Reconsenting Fee = $200.00 each		
Unscheduled Visits = $350.00		
Screen Fails = $		
Dry Ice = $1000.00		
Incidental Supplies = $500.00		
IRB Invoiceables	**Date Invoice Sent**	**Date Payment Received**
Initial Review = $3500.00		
Periodic Review = $1200.00 each		
Amendments = $1000.00 each		
SAEs and UAPs = $350.00 each		
Final Report = $950.00		

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		CV's 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, CV's, 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, CV's, 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		Verify PI has signed the EMR Certification of Verification of Copies
		Research Nurse		Sponsor activaton letter received
		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.

Manager Signature: _____ **Date:** _____

ATTACHMENT F

St. Luke's University Health Network
Clinical Trials & Research
Time & Effort Backup Documentation

Title	Avg. Hourly Rate (Includes 36% Fringe Benefits)
Principal Investigator (PI)	$250
Clinical Research Nurse/Coordinator	$50
Clinical Research Associate	$30
Pathology Staff	$50
Radiologist	$230
Investigational Pharmacist	$100

Principal Investigator (PI)	Estimated Time (Minutes)	Cost
Informed Consent	30	$125
Additional Informed Consent (each)	15	$63
Inclusion/Exclusion Criteria	15	$63
Medical History & Demographics (When not bundled with Physical Examination)	15	$62
ECOG Performance Status (When not bundled with Physical Examination)	5	$21
Concomitant Medications	10	$42
Adverse Event Assessment	15	$62
Photography	30	$125
Adverse Event Reporting (Inclusive of follow-up)	60	$250

Clinical Research Nurse/Coordinator	Estimated Time (Minutes)	Cost
Informed Consent	90	$75
Additional Informed Consent (each)	60	$50
Inclusion/Exclusion Criteria	60	$50
Randomization (Phone/Internet)	60	$50
Additional Vitals	10	$8
Medical History (When not bundled with Physical Examination)	15	$12
ECOG Performance Status (When not bundled with Physical Examination)	10	$8
Height (When not bundled with Physical Examination)	15	$12
Weight (When not bundled with Physical Examination)	15	$12
Blood Pressure (When not bundled with Physical Examination)	15	$12
Heart Rate (When not bundled with Physical Examination)	15	$12
Pulse Oximetry (When not Bundled with Physical Examination)	15	$12
Urine Pregnancy Tests (Dipsticks provided by Sponsor)	20	$17
Cockcroft-Gault (GFR) Equation (Manual Calculation)	15	$17
Pharmacokinetics (PKs)/Biomarkers - Initial Draw	90	$75
Pharmacokinetics (PKs)/Biomarkers - 2nd Draw	45 (in addition to initial 90 minute draw)	$38
Pharmacokinetics (PKs)/Biomarkers - 3rd+ Draw	30 (in addition to initial 90 minute and 45 minute draw)	$25
Study-Provided EKG Machine - Single (Includes Calibration)	30	$25
Study-Provided EKG Machine - Triplicate (Includes Calibration	60	$50
Photography	90	$75
Archival Tumor Tissue Request and Retrieval	120	$100
Survival Status	30	$25
Subject Identification Card	15	$12
Subcutaneous Injection	30	$25
Drug Accountability/Medication Diary	45	$38
Concomitant Medications	30	$25
Adverse Event Assessment	15	$12
Adverse Event Reporting (Inclusive of follow-up until resolution)	60	$50
Comprehensive Assessment of Progression Status	60	$50
Observation for Post-Treatment Adverse Events	60	$50
Questionnaires/Assessments	30	$25

Clinical Research Associate	Estimated Time (Minutes)	Cost
Central Lab Draw	90	$45

Pathology Staff	Estimated Time (Minutes)	Cost
Archival Tumor Tissue Prep	120	$100

Radiologist	Estimated Time (Minutes)	Cost
RECIST Read	30	$115

Investigational Pharmacist	Estimated Time (Minutes)	Cost
Drug Preparation/Dispensing	60	$100

ATTACHMENT G

St. Luke's University Health Network
Clinical Trials & Research
CTO Fee Backup Documentation

Title	Avg. Hourly Rate (Includes 35% Fringe Benefits)
Director of Clinical Trials and Research	$100
Principal Investigator (PI)	$250
Financial Research Analyst (FRA)	$40
Clinical Research Nurse/Coordinator	$50
Clinical Research Manager	$58
Clinical Research Associate	$30

PI	Estimated Time (Minutes)	Cost
General Trial Oversight	30	$125
Review/Sign Off on Lab Results (Central & Local)	20	$83
Review/Sign off on Radiology Results	20	$83
Sign off on Orders	15	$63
CRF Verification and Sign-off	30	$125
Total	**115**	**$479**

Clinical Research Nurse/Coordinator	Estimated Time (Minutes)	Cost
Completion of Orders	20	$17
Billing Compliance	20	$17
Scheduling - Multiple Depts.	30	$25
CTMS Maintenance	15	$12
Misc. Patient Communications	20	$17
Patient Retention Efforts	15	$12
Total	**120**	**$100**

Clinical Research Associate	Estimated Time (Minutes)	Cost
Coordination and Processing of Central Labs and/or Pathology	90	$45
Preparing Lab Requisition Form(s), Packing and Shipping to Central Lab	30	$15
Ordering Dry Ice	15	$7
Total	**135**	**$67**

Clinical Research Manager	Estimated Time (Minutes)	Cost
General Trial Oversight and Operational Management	30	$29
Total	**30**	**$29**

Financial Research Analyst	Estimated Time (Minutes)	Cost
Billing Compliance/Charge Review	30	$20
Invoicing (Prep and Follow-up)	30	$20
Total	**60**	**$40**

Director of Clinical Trials & Research	Estimated Time (Minutes)	Cost
Oversight of Clinical Trials and Reserach Office Staff	30	$50
Total	**30**	**$50**

CTO Fee Grand Total	$766