PURPOSE:

This standard operating procedure (SOP) describes the responsibilities and steps in preparation of study-related invoices (grant or industry), as well as the follow-up and reconciliation process.

DEFINITIONS/ABBREVIATIONS:

- **Case Report Form (CRF):** A Case Report Form can be either paper (CRF) or electronic (eCRF). These forms are used to collect data that is then submitted to the sponsor of the clinical trial. The CRF is constructed to collect pertinent information to the clinical trial from the patient's records.
- **Clinical Research Assistant (CRA):** Clinical Trials staff responsible for assisting with assigned research processes such as data management as necessary.
- **Clinical Research Nurse/Coordinator (CRC):** Clinical Trials staff responsible for oversight and coordination of assigned protocols.
- **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 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.
- **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.
- **Epic:** An integrated electronic health record system utilized by St. Luke's University Health Network (SLUHN) to support functions related to patient care.
- **Full Execution (FE):** Completed and formally signed document containing all required signatures from all parties.
- **Institutional Review Board (IRB):** Independent ethics committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects.
- **MediTract:** Online database that houses Saint Luke's University Health Network's clinical trials agreements.
- **Partial Executed (PE):** Partially completed and formally signed document containing some of the required signatures from required parties.

- **Progressive Physician Associates (PPA):** Multispecialty group onsite at SLUHN that provides diagnostic radiology, interventional radiology, and minimally invasive vascular surgery services.
- **Regulatory Coordinator (RC):** Clinical Trials staff responsible for the regulatory functions and oversight of clinical trials.
- **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: 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.
- **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.
- **Saint Luke's Physician Group (SLPG)**
- **St. Luke's University Health Network (SLUHN)**
- **Standard Operating Procedures (SOPs):** Detailed, written instructions to achieve uniformity of the performance of a specific function.

SCOPE:

This SOP applies to all clinical research site personnel involved in the conduct of clinical research at SLUHN.

This SOP describes the invoicing process:

- Starting after contract execution
- Ending after the all final payments have been received and reconciled for the study

This policy is applicable to:

- All clinical trials at SLUHN conducted within the CTO that have funding

PERSONNEL RESPONSIBLE:

This SOP applies to members of the clinical trials and research team as well as other SLUHN financial personnel involved in the post-award financial oversight of a clinical trial.

This includes the following:

- Cash Accounting Supervisor
- Clinical Research Assistant (CRA)

- Director of Clinical Trials & Research
- Network Accounting Department
- Regulatory Coordinator (RC)
- Research Finance Compliance Analyst (RFCA)
- Research Nurse/Coordinator (CRC)

ROLES:

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

Cash Accounting Supervisor: The Cash Accounting Supervisor shall be responsible for forwarding checks that are received in the network lockbox to the RFCA or designee, as well as depositing funds from checks to the appropriate account(s).

Clinical Research Assistant: The Clinical Research Assistant (CRA) shall be responsible for entering the IRB submissions received from the Regulatory Coordinator (RC) into the IRB Submission Log ***(Attachment B)*** saved on to the common drive.

Director of Clinical Trials & Research: The Director of Clinical Trials & Research shall be responsible for sending the RFCA or designee the finalized or FE CTA to build the Payment Tracker ***(Attachment A)***. The Director shall also be responsible for forwarding checks received for clinical trials payments to the RFCA or designee, and ensuring compliance with all aspects of this policy.

Network Accounting Department: The Network Accounting Department shall be responsible for forwarding checks to the RFCA or designee as well as depositing funds from checks to the appropriate account(s).

Regulatory Coordinator: The Regulatory Coordinator shall be responsible for forwarding IRB submissions to the Clinical Research Assistant via DDOTS notifications.

Research Finance Compliance Analyst (RFCA): The Research Finance Compliance Analyst or designee shall be responsible for preparing and sending invoices to the appropriate study contact as outlined in the CTA and Payment Tracker, following up on outstanding invoices, coding received checks with the accurate account information for depositing, updating the Payment Tracker ***(Attachment A)*** as necessary, preparing check requisitions for study related incurred expenses, and keeping record of paid versus outstanding invoices in the applicable tracking spreadsheets.

Research Nurse/Coordinator: The Research Nurse/Coordinator shall be responsible for updating the study Payment Tracker ***(Attachment A)*** as necessary.

PROCEDURES:

PAYMENT TRACKER CREATION

- The Director of Clinical Trials & Research shall forward the RFCA or designee the finalized or FE CTA
- The RFCA or designee shall build the study Payment Tracker ***(Attachment A)***
- The RFCA or designee shall also include the payment contact information (e-mail address preferred) as well as any specific requirements for invoicing per the CTA (i.e. invoice everything studies, payment terms, etc.) in the Payment Tracker ***(Attachment A)***

IRB INVOICING

- The RC shall send IRB submissions to their own outlook email through the DDOTS notification system.
- The RC shall enter each IRB submission into the IRB Submission Log ***(Attachment B)*** in under the appropriate tab (i.e. New Closures, Renewals, AE_UAB, etc.).
- The RFCA or designee shall review the IRB Submission Log to create and submit the invoices as necessary, and update and maintain the IRB Submission Log ***(Attachment B)***.

CTO INVOICING

- The RFCA or designee shall create invoices for invoiceable and pass through fees, as well as completed patient visits (if applicable) as outlined in the FE CTA/Payment Tracker.
- The RFCA or designee shall submit the invoice to the designated study invoice contact listed in the CTA/Payment Tracker.
- The RFCA or designee shall save the invoice under the appropriate folder within common drive, as well as update the Payment Tracker ***(Attachment A).*** and Invoice Tracking Log ***(Attachment D).***

INVOICE FOLLOW-UP

- The RFCA or designee shall review the invoice tracking log ***(Attachment D)*** to determine which invoices require follow-up.
- The RFCA or designee shall reply-all to the original email containing the invoice to follow-up on payment status of the invoice
- The RFCA or designee shall update the Invoice Tracking Log ***(Attachment D)*** with pertinent information as appropriate.

PAID INVOICES & ACCOUNT RECONCILLIATION

- The Network Accounting Department and Director of Clinical Trials & Research shall forward clinical trial checks to the RFCA or designee.

- The RFCA or designee shall code each check received with the appropriate account number, add the date sent to the accounting department, and send a scanned copy of the coded check back to the network accounting department with instructions on where to deposit the check in the body of the e-mail, as well as the original coded check if applicable.
- The RFCA or designee shall enter all necessary payment information for checks received in the Revenue & Expense Tracking Log ***(Attachment E)***.
- The RFCA or designee shall also update the Payment Tracker ***(Attachment A)*** and/or IRB Submission Log with payment information, update and/or move any applicable invoices to the "Paid" folder within the study's invoice folder if payment covers an invoiced fee, make a copy of the coded check for the Revenue and Expense Binders, and remove the invoice from the outstanding tab on the Invoice Tracking Log ***(Attachment D)*** if applicable***.***

CHECK REQUISITIONS: STUDY RELATED EXPENSES

- The RFCA or designee shall review the "Need to Pay" Folder (physical folder, not electronic) and Outstanding Cycle Bill to determine if any of the outstanding charges associated with professional fees and other study related fees (i.e. patient payments, dry ice, etc.), have been paid
- The RFCA or designee shall update the Revenue and Expense Tracking Log with the new expense being paid, and forward the completed check requisition form ***(Attachment F)*** to the Director of Clinical Trials & Research for signature
- The Director of Clinical Trials & Research shall forward the signed check requisition form to the CRA for submission to the network Accounts Payable (AP) department
- The CRA shall make a copy of the approved check requisition form, update any pertinent tracking logs (e.g. Patient Payment Tracker), and provide a copy of the check requisition for filing.
- RFCA or designee shall file the copy of the check requisition in the pertinent financial binder.

CTA EXECUTION & PAYMENT TRACKER CREATION

Role	Step	Activity
Director of Clinical Trials & Research	1.0	Send the finalized or FE CTA to the RFCA or designee and request the creation of the study Payment Tracker ***(Attachment A)***.
RFCA or designee	1.1	Construct the study Payment Tracker ***(Attachment A)*** based on in the FE CTA. **NOTE:** Pass through and Invoiceable fees (CTO and IRB invoiceables) are included under the patient visit grid in the Payment Tracker ***(Attachment A)*** in

		a table called "Invoiceables". **NOTE:** If the contract language states patient visits are to be paid upon the submission of an invoice, enter **"INVOICE EVERYTHING"** at the top of the Payment Tracker ***(Attachment A)*** to indicate that completed visits are to be invoiced and are not paid automatically. **NOTE:** Invoices for patient visits must be submitted after the CRF/eCRF has been submitted.
RFCA or designee	1.2	Include the invoice contact information and Payment Terms for both the patient visit costs and invoiceable fees within the Payment Tracker ***(Attachment A)*** as well as any specific instructions or requirements for invoices (i.e. PO #, site #, additional hard copy submissions, etc.)
RFCA or designee	1.3	Invoice sponsor for all start-up fees after creating the Payment Tracker ***(Attachment A)*** if the language in the CTA states that start-up fees may be invoiced upon execution of the contract and ***not*** after completion of the SIV. Otherwise, start-up fees shall be invoiced upon completion of the SIV.

IRB INVOICING

Role	Step	Activity
RC	2.1	Enter submissions to the appropriate IRB Submission spreadsheet (Med/Surg vs. Oncology) ***(Attachment B).***
RFCA or designee	2.2	Review the IRB Submission spreadsheets ***(Attachment B)*** at least quarterly, and prepare invoices for submissions. **NOTE:** Standard submission types listed on individual tabs within the log that would are invoiceable are as follows: • New study submissions • Amendments • Continuing/Periodic Reviews • Serious Adverse Events (SAEs) • Study closures/final reports

RFCA or designee	2.3	Complete and send the IRB invoice, and add the invoice amount, date the invoice was sent, and invoice number in the IRB Submission Log ***(Attachment B)***. **NOTE:** Highlight the payment received date and check date/check number cells in yellow to display that this invoiceable fee is outstanding.
RFCA or designee	2.4	Save the invoice in the appropriate folder in the Common Drive. Update the Invoice Tracking Log ***(Attachment D)*** with the following: • Study/Trial • PI • Type (Oncology or Med/Surg) • Date Sent to Sponsor • Invoice # • Invoice Amount • Last Date of Follow-Up ***(see step 4.1 below)*** • Comments

CTO INVOICING

Role	Step	Activity
RFCA or designee	3.0	Review the study Payment Trackers at least quarterly to determine if any invoiceable or pass through fees need to be invoiced. **NOTE:** This process is performed from the time a study is activated through close out with the IRB. **NOTE:** Patient related invoice driven study-paid procedures as outlined in the Payment Tracker (i.e. radiology scans, pregnancy tests, labs, etc.) will be identified during the RFCA or designee's review of the EPIC Monthly Research Charges Report provided by the Network Accounting Department (See Billing Compliance SOP), and invoiced as outlined below.
RFCA or designee	3.1	Enter invoiceable services/procedures on each study's Invoice Template ***(Attachment C)*** along with the invoiceable amount.

		NOTE: The date and invoice number listed at the top right of the invoice is to be updated for each invoice. Also, ensure the formula in the total cell captures all fees entered on the invoice to display the total of the invoice. **NOTE:** The electronic file is renamed with the following information: institution, PI, invoice #, date, and a description of the fees associated with the invoice (i.e. Pharmacy Monthly Maintenance & INDSRs). **NOTE:** If the study is an **"INVOICE EVERYTHING"** study, invoice completed visits once the CRC has entered the CRF/eCRF date of submission in the Payment Tracker ***(Attachment A)***. Highlight the visit cell in yellow and include the patient ID, visit/cycle, and date of visit on the invoice.
RFCA or designee	3.2	Enter a description of each invoiceable item along with the date the invoice was sent to the sponsor, and corresponding Invoice number, in the applicable row within the "Invoiceables" table in the Payment Tracker ***(Attachment A)***.
RFCA or designee	3.3	Highlight the applicable invoiceable item in yellow and replace the text of the description with red text to show that it has been invoiced and is outstanding.
RFCA or designee	3.4	Submit the invoice and save the invoice in the appropriate folder of the Common Drive. **NOTE:** For emails, select the high importance option as a tag. Under the options tab in Outlook, select "Request a Read Receipt."
RFCA or designee	3.5	Update the Invoice Tracking Log ***(Attachment D)*** with the following: • Study/Trial • PI • Type (Oncology or Med/Surg) • Date Sent to Sponsor • Invoice # • Invoice Amount

		• Last Date of Follow-Up ***(see step 4.1 below)*** • Comments
RFCA or designee	3.6	Review the Payment Terms section of the CTA to determine when to follow-up, i.e. ***"Site costs will be paid within 45 days of the date of valid invoice as indicated by the date stamp of the email containing the invoice."*** Enter a formula in the Follow-Up column to display the next Follow-up Date (i.e. = Date invoice Submitted + 45).

INVOICE FOLLOW-UP

Role	Step	Activity
RFCA or designee	4.0	Review the Invoice Tracking Log ***(Attachment D)*** to determine which invoices need follow-up, and retrieve the original email containing the invoice and "reply all" requesting payment status on the invoice(s). **NOTE:** Always attach the invoice(s) to follow-up emails, and reference payment trem obligations as set forth in the executed CTA.
RFCA or designee	4.1	Update the Last Date F/U column within the Invoice Tracking Log ***(Attachment D)*** as well as the Comments column with any pertinent information (i.e. check issued date and check number, payment on hold due to missing information, etc.)

PAID INVOICES AND ACCOUNT RECONCILLIATION

Role	Step	Activity
Network Accounting Department	5.0	Send a copy of checks received to the RFCA or designee
Director of Clinical Trials & Research	5.1	Forward checks received via postal mail to the RFCA or designee
RFCA or designee	5.2	Review check(s) along with remittance information, if included, to determine the associated study and/or invoice. **NOTE:** If remittance information is not included either on the check itself or as an additional attachment, follow-up with invoice contact requesting this information.

		NOTE: Checks will **not** be deposited until remittance information is obtained.
RFCA or designee	5.3	Update all applicable spreadsheets/tracking logs with the payment information: **Payment Tracker *(Attachment A)*** • Visits: payment amount and date of payment (check date). Un-highlight the cell associated with the paid visit. • Invoiceables: Enter date of payment and applicable Invoice Number under the "date payment received" column and un-highlight rows and replace red text with black text to indicate that the fee has been paid. **IRB Submission Log *(Attachment B)*** Enter date the payment was received along with the check date, check number, and invoice number in the row associated with this payment and un-highlight all cells.
RFCA or designee	5.4	Write the account number(s) associated with the payment(s) on the actual check, add the date the check is being sent to accounting, scan a copy of the check, and attach it in an email to accounting. **NOTE:** Include the Director of Clinical Trials & Research on this email, and provide deposit instructions in the body of the email**.** **NOTE:** If original check needs to be sent to Accounting, please indicate that the original is in the mail to them, and send via interoffice mail. **NOTE:** If the original check is in the possession of accounting already, ensure that the coded check is sent as a reply email to the original email from Accounting containing the check.
RFCA or designee	5.5	Update the appropriate cost center tab within Revenue & Expense Tracking Log ***(Attachment E)*** with the following information: • Study (Sponsor and Protocol # or Study Name)

		• Charge Code • Check Total • Deductions • Check Date • Check Number • Date Sent to Accounting • Any comments if applicable **NOTE:** If the check covers payments for fees associated with separate accounts (e.g. "split payments"), each separate tab will be updated with this payment information as funds will be deposited to separate charge codes (accounts). **NOTE:** The "Split Check Comments" cell on each tab will also be updated with the additional costs centers with which the funds from the check have been deposited.
RFCA or designee	5.6	File the check under the pertinent study tab within the appropriate financial binder. **NOTE:** Checks are to be filed in descending order of date sent to Accounting. **NOTE:** If the check covers payments for fees associated with separate accounts (e.g. "split payments"), ensure a copy of the check with the appropriate deposit amount highlighted is filed in each financial binder for which the payment covers.
RFCA or designee	5.7	Move the invoice to the "PAID" folder within the pertinent study invoice folder. **NOTE:** If the invoice is partially paid, and items on the invoice remain outstanding, do not move the invoice into the "PAID" folder, but do add a detailed note of which items have been paid with the date of the check covering the payment.
RFCA or designee	5.8	Remove the invoice row from the Invoice Tracking Log ***(Attachment D)***. **NOTE:** If the invoice is partially paid, and items on the invoice remain outstanding, do not remove the

		entry from the Invoice Tracking Log. Instead update the amount outstanding in the "Amount Outstanding Column and add comments as appropriate.

CHECK REQUISITIONS: STUDY RELATED EXPENSES

Role	Step	Activity
RFCA or designee	6.0	Review and code the Outstanding Hospital Cycle Bill(s) with the appropriate floor rate if any of the recently received payments are associated with outstanding invoiced charges. ***(See Billing Compliance – SOP 107 for additional information)***
RFCA or designee	6.1	Review the physical "Need to Pay" folder to determine if any recently deposited checks covered fees associated with outstanding charges owed for professional fees (i.e. radiology reads, office visits, EKG reads, etc.) and any other study related fees (dry ice, patient payments, consent translations, etc.)
RFCA or designee	6.2	Complete a check requisition form ***(Attachment F)*** to pay out monies owed to the appropriate parties (i.e. PPA, SLPG, Airgas, etc.)
RFCA or designee	6.3	Forward completed check requisitions to the Director of Clinical Trials & Research for signature.
Director of Clinical Trials & Research	6.4	Review and sign check requisition, and forward to the CRA for further processing.
CRA	6.5	Update any necessary logs with expense information (e.g. Patient Payment Tracker)
CRA	6.6	Make a copy of the signed check requisition and send a copy to Accounting **NOTE:** A copy must also be made for filing in the Financial Binders
RFCA or designee	6.7	File the copy of the check requisition under the pertinent tab within the appropriate financial binder. **NOTE:** Check requisitions are to be filed in descending order of date sent to AP.
RFCA or designee	6.8	Enter the expense in the appropriate tab within the Revenue & Expense tracking log.

RESOURCES:
N/A

Endorsed by: SOP Committee (6/19/15; 4/8/16)
Approved by: Tracy Butryn, Director of Clinical Trials and Research (7/1/15; 7/12/16)

ATTACHMENT A

PAYMENT TRACKER

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

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

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		

Subject Payments: Insert Terms
Invoice Payments: Insert Terms

ATTACHMENT B

IRB SUBMISSION LOG

St. Luke's University Health Network IRB Meeting: July 12, 2016						
New Studies	Conditionally Approved	Date Approval Letter & Consent Received from IRB	Invoice Amount	Date Invoice Sent	Payment Received Date	Check Date Number

ATTACHMENT C

INVOICE TEMPLATE

RESEARCH SPONSOR INVOICE FORM

801 Ostrum Street
Bethlehem, PA 18015
TIN# 23-1352213

Date: _____
Invoice No.: _____
Page 1 of 1

INVOICE

PI Name:	
Study Name	
Study #	
Site Location	St. Luke's University Health Network
PO #	

Please direct questions regarding this invoice to _____Anthony Collura at 484-526-6398

Qty	Date	Description	Unit Price	TOTAL
				0.00
				0.00
				0.00
				0.00
				0.00
				0.00
				0.00
				0.00
				0.00
				0.00
				0.00
				0.00
				0.00
				0.00
				0.00
				0.00
				0.00
				0.00

Total Services **$0.00**

Please make check payable to:
St. Luke's University Health Network
ATTN: Tracy Butryn, Director of Clinical Trials and Research
801 Ostrum Street, EW2
Bethlehem, PA 18015

Origination Date-April 2009

ATTACHMENT D

INVOICE TRACKING LOG

Study/Trial	PI	Type	Date Sent to Sponsor	Approx. Due Date	Days Outstanding	Invoice #	Invoice Amount	Amount Outstanding	Last Date F/U	Initials	Comments

ATTACHMENT E

REVENUE & EXPENSE TRACKING LOG

Study/Entry	Revenue or Expense	Charge Code	Check Total	Deductions	Split Check Comments	Trial Expense	Revenue (Check Total - Deductions)	Check Date/Check Request Date for Expenses	Check #	Date Sent to AP	Comments

ATTACHMENT F

CHECK REQUISITION FORM

_____ W9 ON FILE _____ NO W9 REQUIRED

_____ NEWLY ENROLLED PATIENT – W9 ATTACHED

REQUISITION FOR CHECK

Date: _____

*Entity, Cost Center & Sub Account #___ ___-___ ___ ___ ___ ___ ___-___ ___ ___ ___ ___ ___ ___
___ ___-___ ___ ___ ___ ___ ___-___ ___ ___ ___ ___ ___ ___
___ ___-___ ___ ___ ___ ___ ___-___ ___ ___ ___ ___ ___ ___

*Is Payee an Employee of SLUHN: Yes_____ No_____ N/A_____

*Check Payable To: _____

*Address: _____

_____

*Amount: _____ Date/Time Check Needed: _____

Purpose: _____

_____

_____

All checks will be mailed from the A/P Department.

Other Instructions or Comments: _____

_____

_____

Authorization:

*Manager's Full Name _____ Phone # _____
(Please print)

*Manager's Signature _____ Date: _____

Director: Tracy Butryn - Director's Signature: _____ Date: _____

*Required fields

3/2016