PURPOSE:

The purpose of this policy is to describe the process of billing compliance for all clinical research studies conducted within the Clinical Trials Office (CTO) of St. Luke's University Health Network (SLUHN).

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.
- **Billing Coverage Analysis (BCA) Cover Sheet:** Document prepared prior to the creation of the BCA to determine if the study is a qualifying clinical trial. This document is also required to be reviewed and signed by the Principal Investigator and will serve as their approval of the designated billing of procedures and services throughout the life of the study as indicated in the accompanying BCA.
- **Clinical Research Nurse/Coordinator (CRC):** Clinical Trials staff responsible for oversight and coordination of assigned protocols
- **Clinical Trial Agreement (CTA):** A legally binding contract made between two parties (usually the study sponsor and the institution) for clinical trials
- **Clinical Trials Office (CTO):** Centralized clinical trials staff, responsible for the conduct and support of SLUHN clinical trial functions
- **Current Procedure Terminology (CPT) Code:** Codes that represent procedures, products, or services that may be provided to Medicare beneficiaries and to individuals enrolled in private health insurance programs.
- **EPIC:** An integrated electronic health record system utilized by St. Luke's University Health Network (SLUHN) to support functions related to patient care.
- **IDX:** Medical billing software used for billing, scheduling, and patient registration within SLPG
- **Institutional Review Board (IRB):** Independent ethics committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects
- **Informed Consent Form (ICF):** IRB approved form outlining all aspects of a clinical trial in lay language, signed by the subject consenting to participate.
- **Local Coverage Determination (LCD):** A determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts
- **National Coverage Determination (NCD):** United States' nationwide determination of whether Medicare will pay for an item or service
- **National Comprehensive Cancer Network (NCCN):** The National Comprehensive Cancer Network, a not-for-profit alliance of 25 of the world's leading cancer centers devoted to patient care, research, and education.

- **National Clinical Trial (NCT) Number:** A unique identification code given to each clinical study registered on ClinicalTrials.gov.
- **Progressive Physician Associates (PPA):** Multispecialty group onsite at SLUHN that provides diagnostic radiology, interventional radiology, and minimally invasive vascular surgery services.
- **Principal Investigator (PI):** Lead investigator, responsible for the sound conduct of the project in accordance with the protocol and regulations
- **Production (PRD) Environment:** Environment within the EPIC system where research study records are built.
- **Proof of Concept (POC) Environment:** Environment within the EPIC system where research protocols are built, published, and released.
- **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.
- **Saint Luke's Physician Group (SLPG)**
- **Saint Luke's University Health Network (SLUHN)**

SCOPE:

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

This policy describes the process:

- Starting from development of the Billing Coverage Analysis (BCA) Cover Sheet
- Ending when charges are entered onto patient accounts prior to submitting the final study-related medical claim

This policy is applicable to:

- All SLUHN Clinical Trials supported by the centralized CTO that have government or industry funding

PERSONNEL RESPONSIBLE:

This SOP applies to those members of the clinical research team involved in registering, reviewing, conducting, and managing clinical trials at SLUHN. This includes the following:

- Principal Investigator (PI)
- Director of Clinical Trials & Research
- Clinical Trials Managers
- Research Finance Compliance Analyst (RFCA)
- Research Nurse/Coordinator

ROLES:

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

Research Finance Compliance Analyst (RFCA): The RFCA shall be responsible for the understanding and compliance with rules for billing Medicare, Medicaid, and other third party payers for services, drugs, devices, tests and procedures rendered in the clinical research context. He/she shall be responsible for constructing and signing their approval of the BCA Cover Sheet and BCA for each awarded study as well as reconciling daily contract charges associated with patient visits within the EPIC system. Should there be a discrepancy; (i.e. missing charges, duplicate charges, charges entered on the wrong account, etc.); he/she shall be responsible for reversing charges routed to the incorrect account as well as notifying department-designated contacts to correct any issues in a timely manner.

Principal Investigator (PI): The principal investigator shall be responsible for thoroughly reviewing the completed BCA Coversheet and accompanying BCA with the RFCA or designee. During this review, the PI will provide feedback based on their clinical knowledge and standard practice experience, and shall sign and date the BCA Cover Sheet documenting his/her approval.

Director of Clinical Trials & Research: The director shall be responsible for ensuring compliance with all aspects of this policy.

Clinical Research Nurse/Coordinator (CRC): The Clinical Research Nurse/Coordinator shall be responsible for ensuring all patient visits are entered in the designated Outlook calendar. This list shall include the following: patient name, date of birth, study name, study location, and visit (i.e. Cycle 8, Day 1). The CRC shall also be responsible for the adherence to the BCA, and the proper communication to the appropriate ancillary staff (e.g. registration, infusion, schedulers, pharmacy, etc.) to ensure charges are accurately registered.

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. The Manager or designee shall also be responsible for communicating all patient encounter information to the RFCA and Director, and assisting in reconciliation of discrepancies as needed.

PROCEDURES:

PROTOCOL REVIEW AND BCA DEVELOPMENT

- The RFCA or designee shall complete the BCA Cover Sheet ***(Attachment A)*** and review the study protocol and informed consent to determine if the study is a qualifying clinical trial.

- If it is determined that the study is a qualifying clinical trial, the RFCA or designee shall review the protocol and corresponding schedule of events to develop the BCA ***(Attachment B)***.
- The RFCA or designee shall review the draft BCA Cover Sheet as well as the BCA with the Clinical Trials Manager and/or Director of Clinical Trials and Research prior to reviewing with the PI and/or sending to the PI for review and approval.
- The RFCA or designee shall meet with the PI to review the BCA, or email the PI the excel version of the BCA along with the BCA Cover Sheet and include questions in regards to billing in the body of the email (i.e. CT scan frequency for patient population, lab frequency, etc.).

STUDY RECORD & PROTOCOL BUILDS

- The RFCA or designee shall be responsible for creating the RSH Study record and Billing Protocols associated with the study in the EPIC system upon approval and finalization of the study budget and CTA.
- The RFCA or designee shall build the RSH Study record within the Production (PRD) environment utilizing information from the trial portfolio log
- The RFCA or designee shall build the billing protocol in the EPIC Proof of Concept (POC) environment utilizing the BCA.
- The RFCA or designee shall request the publishing and release of the protocol once built in the EPIC POC environment.
- The RFCA or designee shall link the billing protocol to the newly created RSH Study record associated with the study prior to the department's activation of the study.

ASSOCIATING PATIENTS WITH RESEARCH STUDIES & PROTOCOL TIMELINES

- The CRC shall be responsible for associating patients with a research study record (RSH Study Record) and Billing Protocol immediately upon the subject's signing of the informed consent form (ICF).
- The CRC shall be responsible for updating the patient's status from the time the subject signs the ICF through subject completion/discontinuation/withdrawal from the study.

NEW PATIENT, REGISTRATION, & PROFESSIONAL BILLING NOTIFICATIONS

- The CRC shall be responsible for notifying the appropriate parties of any new patients who have signed the ICF and are in the screening phase of a clinical study, as well as patients starting treatment.
- The CRC shall utilize the BCA to determine if research order forms (***Attachment C***) are needed for the patient's encounter, and complete the forms as necessary.

- For radiology services, the CRC shall inform the designated PPA contacts via e-mail of patients that are scheduled to have study paid radiological services (CT scans, MRI's, ultrasounds, x-rays) prior to their scheduled encounter.
- For office visits and services with an associated professional fee, the CRC shall notify the designated SLPG contacts via e-mail of patients that are scheduled to have such services (e.g. EKG's, ECHO's) prior to their scheduled encounter.

DAILY BILLING COMPLIANCE REVIEW

- The RFCA or designee shall review the CRC's Outlook calendars to identify patient visits that have occurred the previous day.
- The RFCA or designee shall utilize the BCA to confirm that the patient's encounter listed on the CRC's calendar was associated with hospital and/or professional charges
- The RFCA or designee shall review the Patients Needing Research Billing Review report in EPIC to verify that all patient encounters documented in the CRC's Outlook calendars populate on this report.
- The RFCA or designee shall place a Stop Bill on any research related patient accounts that do not populate on the Patients Needing Research Billing review report until the account has been verified for billing accuracy
- The RFCA or designee shall utilize the BCA to verify that all services and procedures were charged and routed to the appropriate account(s) in EPIC. If charges have not been routed appropriately, the RFCA shall route charges to the correct accounts (insurance vs. study), and/or notify responsible parties of any billing discrepancies he/she is unable to correct within EPIC.
- The RFCA or designee shall confirm that all discrepancies have been corrected by reviewing the account in EPIC and IDX within 48 hours of identifying the discrepancy.
- The RFCA or designee shall enter each patient's hospital account number along with associated study account charges (if applicable) into the Daily Review spreadsheet (***Attachment F***) along with comments in regards to any discrepancies associated with these charges (i.e. rerouted, missing, incorrect charges, etc.)
- The RFCA or designee shall be responsible for releasing accounts once reviewed and accurate to the CBO for billing.
- The RFCA or designee shall update the appropriate payment tracker(s) with patient encounters dates of service as necessary.
- The RFCA or designee also confirm that any identified discrepancies have been corrected by reviewing the account in EPIC and IDX

MONTHLY RESEARCH CHARGES REPORT AND INVOICING

- The RFCA or designee shall run the Monthly Research Charges report in EPIC each quarter that contains hospital charges that were billed to the corporate study accounts during the prior three months.
- The RFCA or designee will review and identify any discrepancies that were missed during daily reviews (e.g. procedures that should have been billed to the patient's insurance or if any procedures that should have been billed to the corporate study account are not listed), as well as identify tests/procedures that need to be invoiced to the study sponsor per the executed Clinical Trial Agreement (CTA). ***(See SOP 108)***
- The RFCA or designee shall update the Monthly Research Charges report with the correct floor rate for each test/procedure correctly billed to the corporate study accounts
- The RFCA or designee shall notify responsible parties of any billing discrepancies, and request that the appropriate adjustments are made
- The RFCA or designee will send the updated Monthly Research Charges report to the Network Accountant once it has been updated, upload to the common drive, and provide a copy to the Director of Clinical Trials and Research
- The RFCA or designee shall print the Monthly Research Charges Report and provide a table (cover page) listing each corporate research study account and the amount charged to the account during the month under review to the Director of Clinical Trials & Research.

PROTOCOL AMENDMENTS

- The RC shall notify the appropriate manager and RFCA or designee of any amendments, and shall enter them into the Budget Amendment Review Log.
- The RFCA or designee and service line manager will review the amended protocol to determine if the budget will be affected
- The RFCA or designee will update the Budget Amendment Review Log with a note whether the amendment affects the budget, and a summary of any such changes.
- Should the amendment affect the BCA, the RFCA or designee will update the BCA accordingly, and obtain appropriate signatures of approval. The RFCA shall notify the Director of Clinical Trials and Research via email if the amendment will affect the study budget, and will provide the updated BCA as along with a summary of changes.
- The RFCA or designee shall also be responsible for updating the billing protocol in the EPIC system with changes reflecting the amendment
- The RFCA or designee shall request the publishing and release of the updated protocol once revised/built in the EPIC POC environment.

PROTOCOL REVIEW AND BCA DEVELOPMENT

Role	Step	Activity
RFCA or designee	1.0	Complete the BCA Cover Sheet ***(Attachment A)*** while reviewing the study protocol to determine if the study is qualifying clinical trial.
RFCA or designee	1.1	Review protocol study schedule of events and develop the BCA using the BCA Template ***(Attachment B)*** if the study is deemed to be a qualifying clinical trial.
RFCA or designee	1.2	Identify each item, service, or procedure to be performed during the course of the research study as either "M" (billable to Medicare or other third party payer), "S" (billable to the sponsor), "TE" (Billable to sponsor for time and effort only – services and procedures not associated with a CPT/HCPCs code), "NA" (Bundled with another item/service), "NB" (Not Billable), INV (Invoiced), or INV-TE (Invoice sponsor for time and effort only)
RFCA or designee	1.3	Identify and include the correct CPT code and research floor rate for each procedure and service that will generate a hospital or professional charge. **NOTE:** It is the CRC's responsibility to review the BCA and order the CPT codes as listed.
RFCA or designee	1.4	Complete the "Comments" section of the BCA to provide more detail regarding the appropriate billing coding decision (e.g. time and effort only, NCD and LCD citations, NCCN Guideline citations, etc.), and specific footnotes.
RFCA or designee, Clinical Trials Manager, and Director of Clinical Trials and Research	1.5	Review the completed BCA Cover Sheet and accompanying BCA.
RFCA or designee and PI	1.6	Email an electronic copy of the BCA and BCA Cover Sheet to the PI and include questions in regards to billing within the body of the email (i.e. procedure frequency, whether or not the PI would order a certain procedure, etc.). Finalize the BCA upon receiving feedback from the PI. Sign and date the BCA Coversheet as appropriate to indicate approval.

RFCA or designee	1.7	Save a signed copy of the BCA Cover Sheet to the Common Drive within the appropriate study folder. Email a working electronic copy of the BCA to the Director of Clinical Trials and Research.

RSH STUDY RECORD & BILLING PROTOCOL BUILDS IN EPIC

Role	Step	Activity
RFCA or designee	2.0	Create the RSH Study record associated with the research study within the PRD environment upon approval and finalization of the study budget and CTA. The following information shall be listed within each study record: • Study Name • NCT# • Study Status (Active or Inactive) • Study Type (Interventional, Observational, or Expanded Access) • Study Title • Principal Investigator • Study Coordinators • Department • Disease Site • Account Number (free text)
RFCA or designee	2.1	Construct the study billing protocol(s) in the EPIC POC environment utilizing the finalized BCA. **NOTE:** Each visit/treatment day shall be labeled in the study billing protocol as it appears in both the study protocol and BCA.
RFCA or designee	2.2	Send an email request to EPIC liaison to publish and release the billing protocol build. Also provide the study account number and request the EPIC liaison add this to the drop down menu within the RSH record.
RFCA or designee	2.3	Link the study billing protocol to the RSH Study record. **NOTE:** There may be multiple study billing protocols, depending on the study design (i.e.

		multiple arms, treatment groups, phases, etc.). It is the CRC's responsibility to link each patient to the appropriate study billing protocol (***See Step 3.1***).

ASSOCIATING PATIENTS WITH RESARCH STUDIES AND PROTOCOL TIMELINES

Role	Step	Activity
CRC	3.0	Associate research patients with the appropriate RSH Study record in EPIC once the patient has signed the ICF.
CRC	3.1	Link the patient to the appropriate study billing protocol timeline within the RSH Study record. **NOTE:** Once the subject is randomized (if applicable), reassign them to the appropriate study arm or treatment schedule by linking them to a different billing protocol.

NEW PATIENT, REGISTRATION, AND PROFESSIONAL BILLING NOTIFICATIONS

Role	Step	Activity
CRC	4.0	Notify the RFCA, Manager, and Director of Clinical Trials & Research of newly consented patients via email ***(see Attachment H)***.
CRC	4.1	Notify the RFCA or designee, Manager, Director of Clinical Trials & Research, designated pharmacy staff, and all applicable infusion center staff of patients who will be starting treatment via email ***(see Attachment I).*** **Device Stuidies:** Request the department manager to sign the Device Medicare Patient Notification Form and send via email per instructions on the form ***(Attachment E)*** within 48 hours of device implantation. **NOTE:** Carbon Copy (CC) the FRA and Director of Clinical Trials and Research. For additional information in regards to investigational device management, ***please refer to SOP 405.***
CRC	4.2	Complete a separate research order form (***Attachment C***) for each registration area, staple to

		the accompanying Allscripts order, and provide to the patient with instructions for registration submission. **NOTE:** Copies of all research order forms will be filed in the patient's research shadow chart by the CRC, and also uploaded into EPIC by the registration staff. It is the responsibility of the CRC to sign the form. The PI is also required to sign the form.
CRC	4.3	Inform the PPA team via email (***see Attachment J)*** of any patients that are scheduled to have study paid radiological services by close of business the day before the scheduled date of service. **NOTE:** Carbon Copy (CC) the Director of Clinical Trials, the Manager of Clinical Trials, and the RFCA on the email.
CRC	4.4	Contact the SLPG team via email ***(see Attachment K)*** by close of business the day before the patient's scheduled encounter to inform them of any study-paid office visits and/or services that will generate an SLPG professional fee (e.g. EKGs and ECHOs). **NOTE:** If the patient is required to have regularly scheduled study-paid office visits, the CRC shall work with the physician office staff to schedule future appointments at the time of checkout. **NOTE:** Provide the Non-Standard of Care Office Visit for Clinical Trials Patients form ***(Attachment D)*** **NOTE:** A copy of this form will be filed in the patient's research shadow chart as noted in ***Step 4.2*** above.
SLPG and/or PPA Billing parties	4.5	Send the CTO an invoice for study paid services via a 1500 Form, or other invoice method for payment.

DAILY BILLING COMPLIANCE REVIEW

Role	Step	Activity
RFCA or designee	5.0	Review the CRC Outlook calendars to identify patient visits that have occurred during the prior day **NOTE:** CRC to ensure the Outlook calendar includes the patient name, patient DOB, Study, and visit info
RFCA or designee	5.1	Review the BCA to confirm whether or not the visits listed in on the CRC's Outlook calendars are associated with hospital or professional charges.
RFCA or designee	5.2	Run and review the Patients Needing Research Billing Review Report in EPIC to verify that all patient encounters documented in the CRC's Outlook calendars populate on this report.
RFCA or designee	5.3	Place a Stop Bill on any patient accounts with research related charges that did not populate on the Patients Needing Research Billing Review report. **NOTE:** These accounts are to remain on hold until they have been reviewed for billing accuracy.
RFCA or designee	5.4	Review the BCA to verify that all procedures and services were charged and routed to the appropriate account(s). **NOTE:** For SLPG Charges, review the patient's charges in IDX (if applicable) to verify that any study paid procedures were charged to the clinical trials account.
RFCA or designee	5.5	Log each patient's hospital account number along with each study-paid procedure reviewed in to the Daily Review spreadsheet ***(Attachment F)***, and document any account discrepancies (missing charges, incorrect charges, research form not updated to media tab, etc.) associated with the patient's account. **NOTE:** If discrepancies are discovered, proceed to Steps 5.6 through 5.8. If no discrepancies exist, skip to Step 5.11.

RFCA or designee	5.6	Re-route charges to the appropriate accounts using the Research Correction function in EPIC.
RFCA or designee	5.7	Contact the appropriate responsible party with the following information to correct any missing charges: • Patient Name • Patient DOB • Service Location • Description of Issue
RFCA or designee	5.8	Review the account to verify that all appropriate corrections have been made and that the changes have taken effect in EPIC and IDX within 24 hours of the initial request.
RFCA or designee	5.9	Update the Daily Review spreadsheet with account corrections (i.e. corrected by Jane Doe – XX/XX/XX).
RFCA or designee	5.10	Update pertinent payment tracker(s) with patient visit information once the encounter has been verified that it had occurred via charges in EPIC/IDX or confirmation from the CRC.

MONTHLY RESEARCH CHARGES REPORT AND INVOICING

Role	Step	Activity
RFCA or designee	6.0	Review and utilize the Daily Review spreadsheet as a detailed listing of study-paid patient procedures and charges that occurred during the month being reviewed.
RFCA or designee	6.1	Run the monthly research charges report in EPIC each quarter for the previous three months.
RFCA or designee	6.2	Identify any discrepancies on the monthly research charges report that were missed during the daily review(e.g. procedures that should have been billed to the patient's insurance or any procedures that should have been billed to the study account or are not listed), as well as any tests/procedures that need to be invoiced to the study sponsor per the executed Clinical Trial Agreement (CTA)
RFCA or designee	6.3	Update the monthly research charges report with the following: 1. "Need to Invoice" if the test/procedure is invoiceable per the CTA

		2. "Bill to Insurance" if the test/procedure was incorrectly billed to the contract account and should have been billed to insurance 3. Floor rate **NOTE:** If charges were missed during the daily review and did not populate on this report, proceed to ***Steps 6.4 and 6.5***. If all study-paid charges are listed in the monthly research charges report, ***skip to Step 4.7***.
RFCA or designee	6.4	Review the patient's account to determine if any missing procedures were charged. If it was not charged, review patient's results within the appropriate Chart Review tab in EPIC. If a result is not listed, collaborate with the responsible CRC to determine if any identified missing services and procedures actually occurred. Email the appropriate CRC and request the following information: • Did the test/procedure occur? • Date of Service • Location of Service • Copy of the research order form
RFCA or designee	6.5	Notify responsible parties (listed below) of any missing charges, and request that the appropriate adjustments (rerouting of charges) are made: • Infusion Center Managers – Infusion Charges • Pharmacy Department Clinical Trials Coordinator – Pharmacy Charges • Manager, Physician Billing & Director of Physician Coding & Compliance – Saint Luke's Physician Group Charges • Office Coordinator & COO, Progressive Physician Associates (PPA) - PPA Charges Include the following: • Patient Name • Patient DOB

		• Service Location • Description of Service **NOTE:** If the research order form was used by the clinical trials staff for the charges in question, indicate this in the correspondence as a breakdown has occurred in the registration process (i.e. registration staff did not link encounter to study protocol timeline).
RFCA or designee	6.6	Send the updated monthly research charges report to the Network Accountant, upload a copy to the Common Drive, and provide a printed copy to the Director of Clinical Trials and Research once it has been updated, inclusive of a table listing each study account with the associated research charges during the month in review. **NOTE:** File in the appropriate service line binder. **NOTE:** Carbon Copy (CC) the Director of Clinical Trials on email to Network Accountant.
RFCA or designee	6.7	Send a summary email to the SLPG team ***(see Attachment L).*** **NOTE:** Carbon Copy (CC) the Director of Clinical Trials.
RFCA or designee	6.8	Send a summary email to the PPA team. ***(See Attachment M).*** **NOTE:** Carbon Copy (CC) the Director of Clinical Trials.

PROTOCOL AMENDMENTS

Regulatory Coordinator	7.0	Notify the appropriate manager and RFCA of any new protocol amendments received.
Regulatory Coordinator	7.1	Update the Budget Amendment Review log (***see Attachment G***) with the necessary amendment information as follows: • date the amendment was received • date sent to manager for review

Manager of Clinical Trials and Research and RFCA or designee	7.2	Review the amended protocol and update the Budget Amendment Review log (***see Attachment G***) with the following information within 5 business days of amendment receipt: • Date reviewed • Changes Affecting the budget (if any) **NOTE:** If the changes do not affect the budget, this shall be noted in the Budget Amendment Review Log. **NOTE:** If the changes do not affect the budget, no further Steps in this SOP are necessary.
RFCA or designee	7.3	Update the BCA with the required changes from the amendment/updated protocol (if applicable).
RFCA or designee & PI	7.4	Review the updated BCA to ensure procedures are coded correctly. Email the PI the revised BCA along with a summary of changes per the amendment. Include an updated BCA coversheet with a new page that lists the amended changes. Request the PI to sign the last page to approve the amendment changes to the BCA.
RFCA or designee	7.5	Provide the updated BCA to Director of Clinical Trials and Research as an email attachment and indicate whether the changes affect the current budget. The BCA shall be attached in an email with all changes documented in red font. A summary of changes within the body of the email will also be provided. **NOTE:** If the changes will affect the budget, the budget will need to be revised and the protocol amendment will be held from IRB submission until the revised budget is finalized
RFCA or designee	7.6	Revise the study protocol timeline within the POC environment in EPIC, and request the publishing and release of the study protocol timeline.
RFCA or designee	7.7	Insert the date the protocol was revised under the "EPIC Protocol Revised" column within the Budget Amendment Review log.
Not Applicable	---	**NOTE:** Specific steps with regard to budget re-negotiation and/or IRB submission of the protocol

		amendment are not outlined in this SOP. ***Please refer to SOPs 106, 201, and 204.***

RESOURCES:
N/A

Endorsed by: SOP Committee (6/24/14; 2/20/15; 4/8/16)
Approved by: Tracy Butryn, Director of Clinical Trials and Research (8/4/14; 2/20/15; 7/12/16)

ATTACHMENT A

Clinical Trial Billing Coverage Analysis (BCA) Cover Sheet

Drug & Procedure Study Information

Study Title:

Principal Investigator: **Protocol #:**

Sponsor(s):

Protocol Version Date:

Name of Investigational Item or Procedure:

ICF Version Date: **Clinicaltrials.gov #:**

Phase: **BCA Version:**

1. Is the item under investigation for the evaluation of an item or service that falls within a Medicare benefit category (e.g. drugs and biological, inpatient or outpatient services, physician services, diagnostic test)?

If Yes, the category is: - Continue to step 2.

If No - **Stop, trial doesn't qualify**

2. Does the study have therapeutic intent?

If Yes, include statement – Continue to step 3 If No - **Stop, trial doesn't qualify**

Statement(s):

3. Does the study enroll subjects with a diagnosed disease (not health volunteers only)?

If Yes the disease under study is:

If No - Stop, trial doesn't qualify

4. Is the study funded by NIH (or NIH subgroups), CDC, AHRQ, CMS, DOD, or the VA?

If Yes include funding source – **This is a Qualifying Clinical Trial** If No – Go to step 5

Funding Source:

5. Is the study conducted under an investigational new drug (IND) application reviewed by the FDA?

If Yes the IND# is: **This is a Qualifying Clinical Trial** If No – Go to step 6

6. Is the study exempt from having an IND under 21 CFD 312.2(b)(1)?

If Yes – **This is a Qualifying Clinical Trial** If No – Go to step 7

7. If the answers to steps 4, 5, and 6 were all **NO**, then this is **Not a Qualifying Clinical Trial.**

Informed Consent Document

The benefits section of the ICF states:

The cost section of the ICF states:

I, as Principal Investigator, certify that I have reviewed the attached Billing Coverage Analysis along with the Research Finance Compliance Analyst, and have provided my clinical input with regard to standard of care and medical necessity, to the best of my judgment and normal clinical practice guidelines.

Signature **Date**

I as Research Finance Compliance Analyst, certify that I have reviewed the attached Billing Coverage Analysis along with the Principal Investigator, and confirm to the above to be in compliance with current Medicare regulations and coverage determinations to the best of my knowledge.

Signature **Date**

ATTACHMENT B

PI:
Sponsor:
Protocol Number:
Protocol Title:

The billing coverage analysis is intended as a general guideline for use in determining which items and services are allowed to be billed to insurance based on current benefit policies, coverage determination, coverage decisions, and federal guidelines. All items and services billed to insurance must be supported by medical necessity in the clinical documentation and may not be limited to what appears on the billing grid. The clinical needs of the individual patient and the judgment of the clinical provider ultimately determine medical necessity.

1 Cycle = X Days

Visit Assessments	Screening	Cycle 1	Cycle 2	Cycle 3	End of Treatment	Follow-Up	Comments

KEY
NA = Bundled with another payment.
NB = Not Billable to anyone.
S = Charged to study fund.
INV = Invoiceable to sponsor.
TE = Bill for time and effort only (Items and services not associated with a CPT/HCPCs code).
INV/TE = Invoiceable to sponsor for time and effort only (i.e. optional central lab)

ATTACHMENT C

RESEARCH ORDER FORM

Date: _____

Patient Name: _____

Patient Date of Birth: _____

REGISTRATION INSTRUCTIONS

- Associate the patient's encounter to a ***research study*** by selecting the research study below in the ***Providers/Research pathway***.

  Research Study: _____

- When prompted to select a ***treatment day***, please select:

  Visit/Cycle#_____

Physician
Name/Signature _____

Research Coordinator
Name/Signature _____

Please contact Anthony Collura, Research Finance Compliance Analyst, at 484-526-6398 with any questions or concerns

Updated December 2015

ATTACHMENT D

Non-Standard of Care Office Visit for Clinical Trial Patients
(Study-Paid Office Visits)

******SCHEDULE PATIENT USING ENCOUNTER CODE CTOV & INSURANCE CODE SLCT******

******PLEASE DO NOT CHARGE THIS OFFICE VISIT TO INSURANCE OR THE PATIENT******

Patient Name: _____

Date of Birth: _____

Performing Provider: _____

Research Nurse: _____

Date of Office Visit: _____

Location of Visit: _____

Diagnosis Code: _____

Research Staff Name & Signature:	**Research Staff Phone Number:**
Scheduler Name:	**Date Scheduled:**

Please contact Anthony Collura, Research Finance Compliance Analyst, at 484-526-6398 with any questions or concerns

ATTACHMENT E

Device Medicare Patient Notification Form

Instructions: Please complete this form in its entirety for every **Medicare** patient who receives a device for a Clinical Trial or Post-Market Study, regardless of whether it is SOC or non-SOC. Once completed, please send a signed copy via email to Tracy Butryn (Tracy.Butryn@sluhn.org), Anthony Collura (Anthony.Collura@sluhn.org), Denise Warner (Denise.Warner@sluhn.org), and Susan Strasburg (Susan.Strasburg@sluhn.org)

This form should be completed and sent **after** the device is received by the patient, but **no later than 48 hours** after receipt.

Protocol Title:

PI Name: Coordinator Name:

Device Name:

IDE/PMA/510(k) Number: ____ _____

How is device being supplied? **Free of Charge or Purchased**

Notes: If device is provided free of charge or with full credit, Condition Code 53 is required on claim. The hospital charge for a device furnished to the hospital at no cost should equal $0.00.

Patient Initials: _____ Patient MR#: _____

Patient D.O.B.: _____

Date Device implanted/used: _____

_____ _____
Manager Signature Date

Version 4.0
June 2016

ATTACHMENT F

Service Line	Campus	EPIC Account Number	Patient	EPIC Tx Day (Study Visit)	DOS	Study	Procedure	Initially Charged To	Charge Rerouted? Account.	Tx Day Selected	Service Location	Coordinator	Research Order Form Provided to Patient	Research Order Form Scanned in EPIC	Marked as Reviewed	Comments

ATTACHMENT G

Protocol	Date Amendment Received	Date Sent to Manager for for Review	Date Reviewed	Changes Effecting Budget	EPIC Protocol Revised	Tracy Comments	IRB Submission Date

ATTACHMENT H

Email Subject: New Patient Consented to Study

Hi,

The patient below has been consented to (name of trial/study) and will be going through the screening process.

Pt name	
DOB	
MB	
Disease	
Study	
Campus	
Chemotherapy	

Thanks,
Coordinator Name

ATTACHMENT I

Email Subject: New Patient Starting Treatment

Hi,

The patient below is now enrolled in a research clinical trial (name of trial/study).

Patients Name	
DOB	
MD	
Disease	
Study	
Campus	
Insurance Paid Drugs	
Study Paid Drugs	
Start Date	

Any additional medications ordered outside the protocol specific drugs listed above are to be authorized by office staff.

Thanks,
Coordinator Name

ATTACHMENT J

Email Subject: Study Paid [CT, MRI, X-Ray, etc.]

Hi,

The patient below is enrolled in a research clinical trial (name of trial/study) and will be undergoing a study paid testing that should not be charged to the patient or patients' insurance.

Pt name	
DOB	
Test Name	
Test Location	
Test Date	

Thanks,
Coordinator Name

ATTACHMENT K

Email Subject: Study Paid [Office Visit, EKG, ECHO, etc.]

Hi,

The patient below is enrolled in a research clinical trial (name of trial/study) and will be undergoing a study paid [**office visit, EKG, ECHO, biopsy**] that should not be charged to the patient or patients' insurance.

Pt name	
DOB	
Procedure	
Location	
Date	

Thanks,
Coordinator Name

ATTACHMENT L

Email Subject: Clinical Trials [Month] Billing Compliance Review – SLPG Charges

Hello,

We have received the HCFAs for all professional charges with the exception of the charges highlighted in yellow. Can you please ensure these are charged to SLCT and the HCFAs are sent to us?

Patient Name	DOS	Description	Email Notification Sent to SLPG?	HCFA Received?

Thanks,
RFCA or designee

ATTACHMENT M

Email Subject: Clinical Trials [Month] Billing Compliance Review – PPA Charges

Hello,

We have received the HCFAs for all professional charges with the exception of the charges highlighted in yellow. Can you please ensure these are charged to the clinical trials office and the HCFAs are sent to us?

Patient Name	DOS	Description	Email Notification Sent to PPA?	HCFA Received?

Thanks,
RFCA or designee