PURPOSE:

The purpose of this policy is to outline roles, responsibilities, and expectations related to the recruitment, registration and follow up of research subjects.

DEFINITIONS/ABBREVIATIONS:

- **Adverse Event (AE):** Any untoward medical occurrence encountered by an individual during the course of a clinical trial which may or may not be associated with the study drug, procedure, or device. An AE can include previously undetected symptoms, or the exacerbation of a pre-existing condition. When an AE has been determined to be related to the investigational drug, it is considered an Adverse Drug Reaction.
- **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. Patient records are kept in a shadow chart.
- **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 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.
- **Clinical Research Associate (CRA):** Clinical Trials staff responsible for extracting and importing data for assigned protocols.
- **Electronic Medical Record (EMR):** A digital/electronic version of a paper chart and documents that contain all of the patient's medical history.
- **Epic:** SLUHN's registration, billing and electronic medical record system
- **Good Clinical Practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of research that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of subjects are protected
- **Health Insurance Portability and Accountability Act (HIPAA):** A rule that provides subjects with federal protection and rights with respect to their individually identifiable health information while permitting entities the disclosure of health information needed for patient care.

- **Informed Consent Form (ICF):** IRB approved form outlining all aspects of a clinical trial in lay language, signed by the subject consenting to participate.
- **Institutional Review Board (IRB):** Independent ethics committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects.
- **Investigator-Initiated Trial (IIT):** A clinical trial, either funded or unfunded, that is written by an SLUHN physician serving as both the PI and regulatory sponsor of the trial
- **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 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, or is a congenital anomaly/birth defect.
- **Standard Operating Procedures (SOPs):** Detailed, written instructions to achieve uniformity of the performance of a specific function.
- **St. Luke's University Health Network (SLUHN)**

SCOPE:

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

This policy describes the process:

- Starting from the time that a patient is identified for a clinical trial
- Ending when SLUHN has completed the close out visit of the clinical trial

This policy is applicable to all clinical trials supported by the SLUHN CTO.

NOTE: The Informed Consent process will not be described in this SOP. ***Please refer to SOP # 301***.

PERSONNEL RESPONSIBLE:

This SOP applies to the CTO personnel involved in the recruitment and ongoing subject management of clinical trial subjects, inclusive of referring clinicians and the PI and Sub-Is.

ROLES:

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

PI or designee: The PI shall be responsible for identifying the target population, providing sources for identification of potential subjects, and assisting in the screening process. The PI shall also evaluate and manage the subject per protocol, and be responsible for the overall oversight of the trial.

Research Finance Compliance Analyst (RFCA): The RFCA shall be responsible for regularly checking the Study Payment Trackers and invoicing the sponsor for procedures as necessary. All completed visits and invoiced services/procedures will be updated in the Payment Tracker.

Clinical Research Nurse/Coordinator (CRC): The CRC shall be responsible for the following:

- Screening subjects from a targeted population as outlined in the Subject Screening SOP. ***Please refer to SOP # 300.***
- Linking patients to the RSH Study record and Billing Protocol in Epic.
- Updating patients in Epic and Allscripts with appropriate patient status.
- Managing initial subject registration and maintaining ongoing subject data in DDOTS.
- Managing patients and visits in Outlook calendars.
- Flagging patient charts in Epic and in Allscripts as study patients.
- Copying Informed Consents with patient's name and DOB for medical records.
- Providing Clinical Trials Manager with new enrollment information.
- Contact appropriate staff of newly consented patients in screening and new patients randomized to start treatment.

Clinical Research Associate CRA: The CRA shall be responsible for updating the payment tracker for the assigned protocols once the study visit occurred and the data is completed.

Clinical Trials Manager: The Clinical Trials Manager shall be responsible for ensuring the study team is actively screening and enrolling patients, updating the Trial Portfolio Log with new enrollments, and performing regular QA and QC of patient management processes and accuracies.

Director of Clinical Trials and Research or designee: The Director of Clinical Trials and Research shall be responsible for the oversight of the CTO staff as it pertains to this SOP.

PROCEDURES:

- The CRC and PI shall use IRB approved recruitment materials as well as physician referrals and chart reviews to identify new potential clinical trial patients.
- The CRC shall provide subjects with all IRB approved study materials and obtain informed consent.
- The CRC shall link the patient to the RSH Study record and Billing Protocol in EPIC immediately upon patient signing the ICF.
- In DDOTS, the CRC or designee shall move the subject from "Pre-Study Patient" to the "Patient File Cabinet" or enter the subject in the "Patient File Cabinet" after subject is enrolled.
- The CRC shall add subject appointments to the Outlook calendar and invite research staff as necessary.
- The CRC shall contact all appropriate staff of newly consented patients in screening and new patients randomized to start treatment.
- The CRC shall contact office nurse regarding any medical authorization needed for treatment as needed.
- The CRC shall make a copy of the signed ICF, inclusive of patient name and DOB or Medical Record weekly pick-up.
- The CRC or designee shall update the Study Payment Tracker with completed subject visits.
- The CRC or designee shall follow subjects throughout the study as required by protocol, and update patient enrollment status in DDOTS and Epic as necessary.

RECRUITMENT

Role	Step	Activity
CRC, PI	1.0	Work in accordance with the IRB, local and federal regulations to screen and enroll subjects.
CRC, PI	1.1	Recruit subjects onto clinical trials using approved recruitment tools, such as: advertisement, meetings, educational forums, and Provider referrals.
CRC	1.2	Screen subjects from physician referrals, database reports, and chart reviews in accordance with the Subject Screening (***SOP 300)***.
CRC	1.3	Provide any potential study subject with appropriate IRB approved patient materials, including the ICF, and document this process as necessary.

Not Applicable	---	**NOTE:** The Informed Consent process will not be outlined in this SOP. Please refer to the Informed Consent (***SOP 301***) for consenting policies and procedures.

ONGOING SUBJECT MANAGEMENT

Role	Step	Activity
CRC	2.0	Link patient to the RSH Study record and Billing protocol in EPIC immediately upon patient signing the ICF. **NOTE:** Patient status in EPIC must be included and updated as necessary throughout the life of the study in real-time.
CRC or designee	2.1	Move patients from the "Pre-Study Patient" screening section of the DDOTS system to the "Patient File Cabinet" section once the patient is enrolled. **NOTE:** If the patient was not screened and thus not entered into the "Pre-Study Patient" section of DDOTS, enter the patient directly into the "Patient File Cabinet" **NOTE:** Patient status in DDOTS must be included and updated as necessary throughout the life of the study in real-time.
CRC	2.2	Add patient visits to designated Outlook calendar and send calendar invites to those necessary. **NOTE:** Patient visits must be entered and maintained in Outlook calendars on an ongoing basis. **NOTE:** Please refer to the Billing Compliance (***SOP # 107***) for specific information to be included in the Outlook calendar
CRC	2.3	Contact all appropriate staff of newly consented patients in screening and patients randomized to start treatment. **NOTE:** Please refer to the Billing Compliance

		(***SOP #107)*** for specific staff contacts.
CRC	2.4	Contact office nurse regarding any medical authorization needed for treatment.
CRC	2.5	Make a copy of the signed consent, inclusive of patient name and DOB for Medical Records weekly pick-up.
RFCA	2.6	Review patient visit calendar on a daily basis and add visits to the Study Payment Tracker (***see Attachment A***). **NOTE:** The CRC or designee shall be responsible for entering completed visits in the Study Payment Tracker for all registry studies and/or visits that do not entail billing compliance procedures (e.g. survival follow-up)
CRC or designee	2.7	Add the date of data entry into the Study Payment Tracker.
CRC or designee	2.8	Follow subjects throughout the study as required by protocol, and repeat ***2.2 through 2.7.***
Not Applicable	---	**NOTE:** Specific steps with regard to billing compliance processes will not be described in this SOP. Please refer to the Billing Compliance (***SOP # 107***).
Not Applicable	---	**NOTE:** Specific steps with regard to consenting and re-consenting patients throughout the life of a study will not be described in this SOP. Please refer to the Informed Consent (***SOP # 301***).

RESOURCES:
N/A

Endorsed by: SOP Committee (6/24/14; 4/17/15; 4/8/16)
Approved by: Tracy Butryn, Director of Clinical Trials and Research (8/4/14; 4/17/15; 7/12/16)

ATTACHMENT A

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