

St. Luke's University Health Network

SOP 300: Subject Screening

Version # 3.0

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PURPOSE:

To outline the process and activities utilized for successful screening of subjects within St. Luke's University Health Network (SLUHN). The activities will be conducted by designated Clinical Trials Office (CTO) personnel, in compliance with Good Clinical Practice (GCP).

DEFINITIONS/ABBREVIATIONS:

- **Allscripts:** Electronic Medical Record (EMR) utilized by St. Luke's University Health Network (SLUHN) within the Physician Group practices and for out-patient orders
- **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.
- **Electronic Medical Record (EMR):** A digital/electronic version of a paper chart and documents that contain all of the patient's medical history (e.g. Epic and Allscripts).
- **Epic:** An integrated electronic health record system utilized by St. Luke's University Health Network (SLUHN) to support functions related to patient care.
- **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 patients 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.
- **Principal Investigator (PI):** Lead investigator, responsible for the sound conduct of the project in accordance with the protocol and regulations.
- **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.

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This policy describes the process:

- Starting from the time a patient is identified as a potential subject for a research study.
- Ending when subject enrollment or screen-failure occurs.

This policy is applicable to:

- The CTO personnel that are designated to have subject screening responsibility.

PERSONNEL RESPONSIBLE:

This SOP applies to all CTO personnel/designees who will be involved in the recruitment and screening of potential subjects. This includes, but is not limited to, the following:

- Principal Investigator (PI)
- Research Nurse/Coordinator

ROLES:

The following information describes the associated roles that shall adhere to this policy:

Principal Investigator or designee: The PI or designee shall be responsible for the following:

- Identifying the target population
- Providing list of potential participants
- Assisting in the screening process as needed

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

- Obtaining medical records for potential research subjects
- Pre-screening and identifying potential research subjects by reviewing medical records and physician schedules
- Consenting identified potential research subjects utilizing the current IRB approved ICF, prior to performing any study specific screening procedures in determining eligibility (e.g. labs, scans, u/s, x-ray, etc.)
- Entering screened patients that have been consented into DDOTS
- Completing screening logs (if required), and submitting them to sponsors as necessary

PROCEDURES:

- The PI or designee shall identify the target population based on the specific inclusion/exclusion criteria for the study, and shall provide a list for all potential patients and/or medical records (if applicable).
- The CRC or designee shall obtain medical records, maintaining HIPAA compliance, for the identified potential subjects by utilizing SLUHN Electronic Medical Records (EMR) and/or physicians' office records.

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- The CRC or designee shall initiate the pre-screening process by reviewing the medical records and identifying potential subjects meeting the basic preliminary inclusion/exclusion criteria for the specific study.
- The CRC or designee shall discuss eligibility and any issues with the PI prior to subject contact.
- The CRC or designee shall obtain subject's ICF prior to initiation or performing of any study specific non-standard of care screening procedures (e.g. labs, scans, etc.) needed to ensure that all inclusion/exclusion criteria are met prior to enrollment into a study.
- The CRC or designee shall enter orders (if needed) into the applicable EMR system (i.e. Epic, Allscripts) for the necessary screening tests per the study protocol.
- The PI or designee shall assist, as needed, in ordering and approving the tests necessary for screening as per the study protocol.
- The CRC or designee shall enter consented screened subjects into DDOTS and other CTO databases (Payment Tracker, Outlook calendar), and link the patient to the appropriate RSH Study Record in Epic
- The CRC or designee shall notify pertinent personnel (e.g. Pharmacy, Infusion Center, Billing, and Lab, if applicable) of newly consented patients.

SUBJECT IDENTIFICATION

Role	Step	Activity
PI or designee	1.0	Identify target population based on the specific inclusion/exclusion criteria set forth in the study protocol.
PI or designee	1.1	Provide research personnel with the identified potential subject list, along with any other pertinent information necessary to screen.
CRC or designee	1.2	Obtain list of potential subjects from existing database and/or referrals from the community or other health care providers.

PRE-SCREENING

Role	Step	Activity
PI or designee	2.0	Assist in obtaining medical records for the identified subjects as needed.
CRC or designee	2.1	Obtain and review medical records of identified potential subjects and remove subjects who do not meet any of the basic study eligibility criteria.

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CRC or designee	2.2	Identify subjects that would meet the basic inclusion/exclusion criteria and would be eligible for further screening.
CRC or designee	2.3	Maintain confidentiality of all medical records obtained and reviewed as per HIPAA regulations and SLUHN policies.

SCREENING

Role	Step	Activity
CRC or designee	3.0	Perform a more in depth review of medical history/records if applicable.
CRC or designee	3.1	Clarify outstanding questions and/or issues pertaining to eligibility.
CRC or designee	3.2	Obtain ICF from pre-screened subjects meeting basic eligibility criteria prior to initiating any screening tests or procedures that are needed to determine further eligibility.
CRC or designee	3.3	Link consented subjects to the RSH Study Record in Epic (in real time) and DDOTS, including the current subject status, as well as to the appropriate Payment Tracker and Outlook calendar. NOTE: The process of entering consented subjects into Epic will not be outlined in this SOP.
CRC of designee	3.4	Notify pertinent personnel (e.g. Pharmacy, Infusion Center, Billing, and lab, if applicable) of newly consented patients.
CRC or designee	3.5	Order any necessary screening tests that are needed to confirm further eligibility per the study protocol. NOTE: Refer to SOP 107, for billing compliance with ordering tests.
CRC or designee	3.6	Review and discuss all inclusion/exclusion criteria and any additional tests with the PI to ensure final eligibility is met.
CRC or designee	3.7	Update the patient status as a screen failure if any of the eligibility criteria are not met in Epic, DDOTS, and any other required data

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		systems, including the study Payment Tracker.
CRC or designee	3.8	Enroll subject into the study if all eligibility is met and update the subject status in Epic and DDOTS, and assign a protocol arm to subject, if applicable. NOTE: Also flag patient in Allscripts as a "Clinical Trial Patient".

SCREENING REPORT

Role	Step	Activity
CRC or designee	4.0	Document pre-screening and screening activities on a Screening Log (if required)
CRC or designee	4.1	Submit Screening Log to sponsors, if requested
CRC or designee	4.2	Maintain Screening Logs submitted to sponsors with all other study records as per study specifications and regulations.

RESOURCES:

N/A

Endorsed by: SOP Committee (9/20/13; 4/17/15; 4/8/16)

Approved by: Tracy Butryn, Director of Clinical Trials and research (9/23/13; 4/17/15; 6/29/16)

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