PURPOSE:
To outline the activities required to develop, update, and approve Clinical Trials Office (CTO) Standard Operating Procedures (SOPs) and policies, as well as train the CTO staff, to ensure compliance with all FDA regulations and guidelines, as well as institutional policies and procedures.

This SOP describes the function of the Clinical Trials SOP Committee in the development, maintenance, approval, and training of CTO SOPs.

DEFINITIONS/ABBREVIATIONS:
- **Clinical Trials Office (CTO):** Centralized clinical trials staff, responsible for the conduct and support of SLUHN clinical trial functions
- **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 SOP Committee members and CTO staff.

This policy describes the process:
- Starting from the identification of a new policy or procedure to be developed
- This is an ongoing process with an indefinite end date

This policy is applicable to:
- The Clinical Trials SOP Committee and CTO staff

PERSONNEL RESPONSIBLE:
This SOP applies to those members of the Clinical Trials SOP Committee involved in the development, maintenance, and approval of all SLUHN CTO SOPs. This Committee includes the following (***see Attachment B***):
- Director of Clinical Trials and Research
- Clinical Trials Managers
- Designated Clinical Trials Office Staff

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 serve as the Chair of the Clinical Trials SOP Committee, and shall be responsible for the overall approval of all clinical trials SOPs.

Clinical Trials Managers: The Clinical Trials Managers or designee shall serve as the Co-Chairs of the Clinical Trials SOP Committee, and may serve as the Chair as necessary in the absence of the Director. They shall be responsible for the timely completion of all assigned SOPs, reviewing all SOPs and SOP revisions, attending SOP Committee Meetings, oversight of SOP Maintenance and bringing updates to the Committee, as well as ensuring the proper training and compliance with all approved SOPs. The Managers will also serve as the primary liaison between the Committee and all CTO staff not on the SOP committee

Designated Clinical Trials Office Staff: The CTO staff serving as designated members of the SOP Committee shall be responsible for the timely completion of all assigned SOPs, reviewing all SOPs and SOP revisions, attending SOP Committee Meetings, and bringing updates to the Committee.

PROCEDURES:

Initial SOP Development and Training:

- The SOP Committee shall meet monthly until all SOPs are developed and implemented.
- The SOP Committee shall discuss all new SOPs to be developed, and the Director shall assign specific SOPs to Committee members for drafting with deadlines for completion.
- Each Committee member shall develop assigned SOPs by the assigned deadlines, and email the SOP draft to Committee members for review prior to the next SOP Committee meeting.
- SOP Committee members shall discuss all SOP drafts during the scheduled monthly meetings, and the Committee member assigned to the SOP discussed shall revise the SOP until acceptable by all members.
- All Finalized SOPs shall have a final review and receive final approval by the Director of Clinical Trials and Research (SOP Committee Chair).
- Approved SOPs shall be distributed to all SOP Committee members, and Clinical Trials Managers, or designee shall be responsible for ensuring all CTO staff is trained and that training is documented ***(see Attachment A)***.

Ongoing SOP Review, Revisions, and Training:

- Once all SOPs are finalized and approved, the SOP Committee shall meet quarterly to review all current SOPs for any necessary revisions.
- Major, non-administrative SOP Revisions will follow the above steps until finalized and approved by the Director, and implemented amongst the CTO staff by the Managers.
- Minor administrative changes may be made on an ongoing basis by the Director of Clinical Trials and Research, in which the formal revision, review, and training

process would not apply. Such revisions would be sent to the SOP Committee as an FYI only.

- SOP Committee membership may be revised as necessary in scenarios of staff turnover or changes in roles and responsibilities; however, final membership must be approved by the Director of Clinical Trials and Research (SOP Committee Chair)

SOP PREPARATION/REVISIONS

Role	Step	Activity
Director of Clinical Trials and Research (SOP Committee Chair)	1.0	Assign SOPs to designated SOP Committee members and provide deadline for completion.
SOP Committee Member	1.1	Draft assigned SOP using the following format: Each SOP shall include the following in the header: • SOP Number • Title • Version Number • Pagination Each SOP shall include the following in the footer: • Effective Date • Revision Dates The body of each SOP shall use the following format: • Purpose • Definition/Abbreviations • Scope • Personnel Responsible • Roles • Procedures (Outline and Charted Steps) • Resources • Endorsed by/Approved by • Attachments
SOP Committee Member	1.2	Send draft SOP to SOP Committee members via email no less than one week prior to the next SOP Committee meeting
SOP Committee	1.3	Review all draft SOPs prior to next SOP

		Committee Meeting
SOP Committee	1.4	Discuss all draft SOPs during meeting and make any suggested changes
SOP Committee Member	1.5	Revise draft SOP as necessary from meeting discussions, and send to SOP Committee via email for review no later than two weeks after the meeting at which it was discussed
SOP Committee	1.6	Review and send comments, changes, or endorsement of draft SOP via email to SOP Committee **NOTE:** All SOP Committee members must endorse approval of an SOP before it can be approved by the Director.
Director of Clinical Trials and Research (SOP Committee Chair)	1.7	Approve SOP, assign an approval and effective date, and distribute the final SOP to SOP Committee. **NOTE:** Effective Date shall be one month after the final Approval Date. **NOTE:** All SOPs shall be re-reviewed at least yearly.
Director of Clinical Trials and Research (SOP Committee Chair)	1.8	File new SOP in SOP binder, upload into Common Drive, and archive older versions of SOP. **NOTE:** Archived versions of SOPs shall be maintained electronically by the Director of Clinical Trials and Research to be available in case of an audit.
Clinical Trials Managers or designee	1.9	Distribute new SOP to Clinical Trials staff, and determine training date/time.

SOP TRAINING

Role	Step	Activity
Clinical Trials Managers or designee	2.0	Provide training to all members of the research team within three weeks of a new or revised SOP being approved, and no later than the assigned effective date.
Clinical Trials Managers and Clinical Trials Staff	2.1	Document each staff member's training using the Documentation of SOP Training Form ***(see***

		Attachment A).
Clinical Trials Managers or designee	2.2	Provide the Director of Clinical Trials and Research with completed original Documentation of SOP Training Form ***(see Attachment A)*** at least one day prior to the SOP Effective Date.
Director of Clinical Trials and Research	2.3	Maintain a record of original SOP training documentation for all Clinical Trials staff within the SOP Binder, and save a copy on the Common Drive. **NOTE:** Any new CTO staff will be trained on all current SOPs (follow Steps 2.0 through 2.3)

SOP ONGOING MAINTENANCE

Role	Step	Activity
SOP Committee	3.0	Review all current SOPs at least every year (365 days from Effective Date) **NOTE:** SOP Committee will review any CTO staff comments/suggestions regarding current SOPs during next quarterly SOP Committee meeting if comments/suggestions are made prior to next yearly review
SOP Committee	3.1	If revisions are necessary: Repeat Steps 1.0 through 2.3
Not Applicable	---	**NOTE:** Administrative changes to SOPs may be made by the Director of Clinical Trials and Research (SOP Committee Chair) as necessary without endorsement/approval by full SOP Committee. Such changes will be distributed to SOP Committee via email. **NOTE:** Documentation of Training is not required for such administrative changes

RESOURCES:
N/A

Endorsed by: SOP Committee (8/16/13; 3/21/14; 4/17/15; 4/8/16)
Approved by: Tracy Butryn, Director of Clinical Trials and Research (8/16/13; 5/9/14; 8/7/14; 4/17/15; 11/10/15; 6/24/16)

Effective Date:	Revision Date(s):
9/16/13	5/9/14; 8/7/14; 4/17/15; 11/10/15; 4/8/16

ATTACHMENT A

SOP TRAINING COMPLIANCE FORM

SOP Number and Title: _____

Version #: _____

Employee Name	SOP Training Date	Employee Signature/Date	Manager Initials

Manager Signature: _____ DATE:_____/_____/_____

Director Signature: _____ DATE:_____/_____/_____

Effective Date:	Revision Date(s):
9/16/13	5/9/14; 8/7/14; 4/17/15; 11/10/15; 4/8/16

ATTACHMENT B

SOP Committee Roster

Tracy Butryn, MS, CCRP, CHRC	Network Director of Clinical Trials and Research (SOP Committee Chair)
Rose Cabral, RN, BSN, OCN	Manager – Integrated Clinical Trials (Oncology)
Elana Pessin, BS, MPA	Study Start-up Project Coordinator
Robyn Rex, RN, BSN, OCN, CCRP	Research Nurse (Oncology)
Carolyn Seith, MSPH	Clinical Research Coordinator (Oncology)
Anthony Collura, BS	Research Finance Compliance Analyst
Karla Cressman, BS	Regulatory Coordinator
Nicole Kern, B.S.	Clinical Research Associate (Oncology)