PURPOSE:

This standard operating procedure (SOP) serves as a companion to the Standard Operating Procedure for Data Management. The St. Luke's University Health Network (SLUHN) Clinical Trials Office (CTO) may refer to this SOP for additional guidance concomitantly required when all, or portions, of the data that are required by an FDA predicate rule for submission or inspection, are collected, managed and/or transmitted electronically, or include the use of electronic signatures in required records.

DEFINITIONS/ABBREVIATIONS:

- **Audit Trail:** A secure, computer generated, time-stamped electronic record that allows reconstruction of the source of events relating to the creation, modification, and deletion of an electronic record.
- **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.
- **Certified Copy**: A copy of the original information that has been verified, as indicated by dated signature as an exact copy having all of the same attributes and information as the original.
- **Clinical Research Nurse/Coordinator (CRC):** Clinical Trials staff responsible for oversight and coordination of assigned protocols
- **Clinical Research Associate (CRA):** Clinical Trials staff responsible for assisting with assigned research processes such as data management as necessary.
- **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
- **Electronic Medical Record (EMR):** A digital/electronic version of a paper chart and documents that contain all of the patient's medical history.
- **Electronic Signature:** A computer data compilation of any characters executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.
- **Epic:** An integrated electronic health record system utilized by St Luke's University Health Network (SLUHN) to support functions related to patient care.
- **National Clinical Trials Network (NCTN):** a group sponsored by the National Cancer Institute to allow members to participate in large national studies
- **Original Data**: Those values that represent the first recording of study data. FDA is allowing original documents and the original data recorded on those documents to

be replaced by copies provided the copies are identical and have been verified as such.

- **Principal Investigator (PI):** Lead investigator, responsible for the sound conduct of the project in accordance with the protocol and regulations.
- **Source Documents**: Original documents and records including, but not limited to, hospital records, clinical and office charts, laboratory notes, subject's diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, magnetic media, x-ray, subject files, and records kept at the pharmacy, laboratories, and medico-technical departments involved in a clinical trial.
- **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.

This policy describes the process:

- Starting from the time the research nurse/coordinator consents a patient onto a clinical trial
- Ending when SLUHN has completed the close out visit of the clinical trial

This policy is applicable to:

- All clinical trials at SLUHN conducted by the CTO, which may include Industry or Government Sponsored trials, NCTN trials and Investigator Initiated Trials

PERSONNEL RESPONSIBLE:

This SOP applies to members of the clinical trials research team involved in the documentation of a subject's participation in a clinical trial. This includes the following:

- Principal Investigator
- Research Nurse/Coordinator
- Clinical Research Associate

ROLES:

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

Principal Investigator: The Principal Investigator or designee shall be responsible for clinical trials conduct and overall oversight at SLUHN. S/he will ensure that an original or certified copy of all electronic source documents and audit trail records are retained on file.

Research Nurse/Coordinator: The Research Nurse/Coordinator shall be responsible for maintaining source documents in the patient's research shadow chart; this includes copies of information from EMR.
Clinical Research Associate: The Clinical Research Associate shall be responsible for entering data utilizing information from the EMR

PROCEDURES:

- When data are entered directly into a computer system (e.g. EMR), the electronic data in the computer system is the original source document.
- The EMR system must be a closed, validated system with audit trails and certified as such.
- A paper record (printout/hard copy/"print screen") of the electronic data is considered to be a copy. Copies should be certified as identical to original source documents.(***See Attachment A***)
- Requirements for documentation, record keeping and record retention apply to computer records as they do for paper systems.
- Computer records may be signed with an electronic signature.
- One type of an electronic signature is when a user signs-on to a computer system using two (2) distinct identification components, such as an identification code (user name) AND a password.
- Each electronic signature shall be unique and shall not be reused by, reassigned to, or shared with anyone else.
- Signed electronic records must contain information associated with the signing that clearly indicates all of the following:
    - Printed name of the signee.
    - Date and time when the signature was executed.
- Sponsor/CRO monitors shall not have direct access to the EMR except in certain circumstances, such as trauma (or other long-stay inpatient) studies. In such circumstances, such access must be limited to the specific research patients and specific visits dates, or the CRC must be available during the monitoring visit to shadow the EMR review.

RESEARCH SHADOW CHARTS

Role	Step	Activity
Principal Investigator	1.0	Sign Certification of Verification of Copies ***(Attachment A)*** at time of SIV.
Research Nurse/Coordinator or designee	1.1	Make copies of information needed for source documents directly from the EMR with no alterations. **NOTE:** Research shadow charts shall only

		contain study-relevant information from the EMR.
Research Nurse/Coordinator or designee	1.2	File and maintain EMR copies in patient-specific research shadow chart.

MONITOR VISIT

Role	Step	Activity
Research Nurse/Coordinator or designee	2.0	Retain copies of Certification of Compliance with 21 CFR 11 ***(Attachment B)*** and Certification of Verification of Copies (***Attachment A***).
Research Nurse/Coordinator or designee	2.1	Provide copy of SLUHN Certification of Compliance with 21 CFR Part 11 ***(Attachment B)*** to monitor upon request.
Research Nurse/Coordinator or designee	2.2	Provide copy of SLUHN Certification of Verification of Copies ***(Attachment A)*** if the monitor requests access to EMR. **NOTE:** An exception to this policy is trauma or other long length of stay inpatient studies where limited access may be granted upon approval (See Steps 3.0 and 3.1).

MONITOR VISIT – LONG-STAY INPATIENT STUDIES

Role	Step	Activity
Research Nurse/Coordinator or designee	3.0	Contact Director of Medical Records with a list of patients to be monitored and the date of admission.
Research Nurse/Coordinator or designee	3.1	Obtain generic access from Director of Medical Records and provide to the monitor for view-only access of those patients identified from Step 3.0.

RESOURCES:
21 CFR. Part 11
FDA Compliance Policy Guide #7150.13

Endorsed by: SOP Committee (5/12/14; 2/20/15; 4/8/16)
Approved by: Tracy Butryn, Director of Clinical Trials (6/10/14; 2/20/15; 6/29/16)

ATTACHMENT A

Certification of Verification of Copies

Protocol Title: _____
_____
_____

Sponsor: _____

Protocol Number: _____

The FDA allows original documents and the original data on those documents to be replaced by copies provided the copies are identical and have been verified as such. (FDA Compliance Policy Guide #7150.13)

(Insert PI Name) hereby verifies that copies of original data used as source documents in research shadow charts are identical to the originals having all of the same attributes and information as the originals.

_____ _____
Principal Investigator Date

ATTACHMENT B

St Luke's HOSPITAL & Health Network

801 Ostrum Street
Bethlehem, PA 18015
484-526-4000

Certification of Compliance with 21 CFR Part 11

21 CFR Part 11, Electronic Records, Electronic Signatures("Part 11") applies to electronic records that are created, maintained , or transmitted under any regulation of the Food and Drug Administration, or that are submitted to the FDA. St. Luke's Hospital & Health Network herby certifies as follows:

- The software has been validated to ensure that it performs in a reliable , accurate and consistent manner, in accordance with the requirements of Part 11;
- The Software is a "closed system" as defined in Part 11; and
- The Software includes features that facilitate compliance with requirements applicable to "closed Systems" as set forth in Section 11.10 of Part 11.

Chad Brigandine, VP, CIO

Nicole Huff, Chief Compliance Officer

My Health. My Hospital.