PURPOSE:

To outline the process of archiving and storage of all clinical trial documents after a trial has been completed in line with Federal Regulations, Good Clinical Practice (GCP) guidelines, the executed Clinical Trial Agreement (CTA), and Institutional Polices within St. Luke's University Health Network (SLUHN).

DEFINITIONS/ABBREVIATIONS:

- **Clinical Research Assistant (CRA):** Clinical Trials staff responsible for assisting with assigned research processes
- **Clinical Research Nurse/Coordinator (CRC):** Clinical Trials staff responsible for oversight and coordination of assigned protocols
- **Clinical Trial Agreement (CTA):** The legally binding agreements between a sponsor and an institution (site) as to how certain business and property rights will be handled between the parties. These agreements are separate from Investigator Agreements and Confidentiality Agreements and are not regulated by or disclosable to FDA. CTAs allocate risk, responsibility, financial support, and obligations of the parties; and they protect the rights of the parties.
- **Clinical Trials Office (CTO):** Centralized clinical trials staff, responsible for the conduct and support of SLUHN clinical trial functions
- **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.
- **Guaranteed Records Management (GRM):** Commercial company utilized by SLUHN for all document storage and archiving.
- **Institutional Review Board (IRB):** Independent ethics committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects.
- **Regulatory Coordinator (RC):** Clinical Trials staff responsible for the regulatory functions and oversight of clinical trials
- **St. Luke's University Health Network (SLUHN)**

SCOPE:

This SOP describes the process:

- Starting with the termination of a trial by the SLUHN IRB
- Ending with the disposition of all study documents and records by the archiving facility.

This policy is applicable to the following studies:

- All clinical trials supported by the SLUHN CTO

PERSONNEL RESPONSIBLE:

This SOP applies to the CTO personnel involved in the archiving and retrieval of trial documents after study closure has occurred. This includes the CRA, CRC and RC.

ROLES:

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

- **Clinical Research Assistant (CRA):** The CRA shall be responsible for obtaining the information necessary for archiving from the CRC and RC, and entering all information into the GRM system, listing all pertinent information for easy retrieval of study documents, and communicating with the archiving company as necessary. The CRA shall also be responsible for facilitating the destruction report to determine if any archived documents can be destroyed.
- **Clinical Research Nurse/Coordinator (CRC)**: The CRC shall be responsible for ensuring all patient-related and or data-related documents are accounted for and organized in boxes for the CRA to archive. The CRC shall also be responsible for providing the CRA with the number of boxes needed for organizing and boxing all patient-related and/or data-related documents and study materials on a quarterly basis or as needed.
- **Regulatory Coordinator (RC):** The RC shall be responsible for providing the CRC and CRA a list of protocols to be archived on a quarterly basis or as needed. The RC shall also be responsible for ensuring all regulatory documents are accounted for and organized in boxes for the CRA to archive, and for providing the CRA with the number of boxes needed for organizing and boxing all regulatory documents.

PROCEDURES:

Organizing and Archiving

Role	Step	Activity
RC	1.0	Provide the CRA with a list of trials to be shipped to GRM, based on the IRB termination date, to include the following information: • Study name and IRB number

		• Department (i.e. Cardiology, Oncology, Neurology, etc.) • Approximate number of boxes needed • Major Description: Identify the contents of what is being archived (e.g. CRF binders, Reg files, patient charts, IND safety reports)
CRC/CRA/ RC	1.1	Organize study documents from list in Step 1.0, file in Bankers Storage Boxes, and send to CRA. For Patient related boxes, include the following information inside the box: • Patient Initials • Patient Date of Birth • Patient Protocol ID # • SLUHN IRB # • National ID **NOTE:** If the binder the documents are stored in is in reusable condition, remove documents from binders and secure with a rubber band prior to filing.
CRA	1.2	Confirm that all documents for closure have been obtained from the RC and CRC.
CRA	1.3	Contact the GRM customer service department for barcodes for boxes. **NOTE:** The phone, fax, and e-mail contact information is located on the GRM Quick Reference Card **(*ATTACHMENT A*)** **NOTE:** The address for GRM is: GRM Information Management Services 3449 Fox Street Philadelphia, PA 19129
CRA	1.4	Document the bar code, along with a detailed list of what is being stored in each box in the GRM electronic tracking log.
CRA	1.5	Add destruction date in GRM database. **NOTE:** This date should be 15 years from the date of archive, or as otherwise stated in the terms of the executed CTA.

Archival Pick-up

CRA	2.0	Electronically request pick-up of GRM boxes for archiving via GRM System – www.grmdocument.com at the time of inputting items to be archived
CRA	2.1	Indicate the number and size of boxes to be removed when arranging the pick-up.
CRA	2.2	Stack boxes in allocated spot for pick-up (designated location will be determined by the CRA).
CRA	2.3	Contact GRM for retrieval confirmation if not received within 24 hours. **NOTE**: Confirmation of retrieval of boxes shall occur within 24 hours.

Retrieval of Archived Documents

CRC/RA	3.0	Inform CRA what study needs to be retrieved from GRM, clearly indicating exactly what needs to be retrieved (e.g. patient charts, regulatory binders, CRFs, IND Safety Reports, etc.).
CRA	3.1	Call, fax or email request for retrieval the same way you would request a pick-up ***(see ATTACHMENT A and Step 2.0)***. **NOTE:** Retrieving boxes previously sent to GRM may be necessary to add more documents to the box, purposes of audit, etc.
CRA	3.2	Provide the bar code number in your retrieval request.
CRA/CRC	3.3	Repeat Steps 2.0 to 2.3 to have boxes picked-up for re-storage.

Destruction of Archived Documents

GRM	4.0	Run a destruction report every 6 months and send out a listing to SLUHN CTO regarding what is eligible for destruction, if applicable.
CRA	4.1	Send destruction report to Director of Clinical Trials and Research or designee for review/approval prior to destruction.
Director of Clinical Trials and	4.2	Inform sponsor prior to destruction if applicable and per executed contract

Research or designee		
CRA	4.3	Approve destruction report from GRM and review and sign work order, and then return to GRM.
GRM	4.4	Destroy the boxes that were approved for destruction.

RESOURCES:
GRM references

Endorsed by: SOP Committee (10/25/13; 3/21/14; 2/20/15; 4/8/16)
Approved by: Tracy Butryn, Director of Clinical Trials and Research (11/4/13; 5/9/14; 2/20/15; 12/24/15; 7/12/16)

ATTACHMENT A

GRM

www.grmdocumentmanagement.com

Quick Reference Card

Customer Service: Phone # - 215-223-8800 Fax # - 215-223-8099

General Services **GRM's Support Team**

Order Placement and Delivery Confirmation Call: 215-223-8800
Name: Kathy Roberson
Name: Danielle Ripley
Name: Nick Beattie

Pathology Order Placement and Delivery Confirmation
Name: Kathy Montanez
Name: Nancy Santiago

Web Support- Online e-Access
Name: Michael O'Donnell **Office:** 215-223-8800 Ex. 204
Name: Kathy Roberson **Office:** 215-223-8800

Operational Support
Name: Wayne Black **Office:** 215-908-6665

Accounting Support
Name: Kathy Roberson **Office:** 215-223-8800

General and Sales Management
Name: Michael O'Donnell **Office:** 215-223-8800 Ex. 204

IN CASE OF EMERGENCIES AFTER HOURS PLEASE CONTACT
24/7 Hotline # - 215-223-8800. Tell them the emergency and they will contact the managers

Web Access **Online Support**
Web site ordering e-mail: PHonline@grmdocument.com
GRM general e-mail: PHonline@grmdocument.com