PURPOSE:

To outline the management of investigational devices used in clinical trials in line with GCP, local, and Federal regulations. The investigational device must be accounted for at all times and handled according to applicable regulations, sponsor/funding agency requirements, and institutional policies. The participating investigator will not represent the investigational device as safe or effective for the purposes for which it is under clinical study or for any other use. Investigational devices must be stored in a secure environment, where access is limited to key study personnel, according to the storage requirements detailed in the protocol or other instructions supplied by its provider. Procedures for destruction of any investigational products must comply with institutional requirements and with the express written authorization of the research sponsor, or other supplier.

DEFINITIONS:

- **Centers for Medicare and Medicaid Services (CMS):** A federal agency within the United States Department of Health and Human Services (DHHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program (SCHIP), and health insurance portability standards.
- **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
- **Food and Drug Administration (FDA):** Agency of the United States Department of Health and Human Services (DHHS), responsible for the regulation of clinical trials.
- **Institutional Review Board (IRB):** Independent ethics committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects.
- **Investigational Device Exemption (IDE):** Allows an investigational device to be used in a clinical study to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to the FDA. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated
- **Operating Room (OR):** Location of device implantation if surgical procedure is required
- **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)**

SCOPE:

This SOP applies to all site personnel who conduct or are involved in clinical research of human subjects involving investigational devices approved for dispensing by means of an Investigational Device Exemption (IDE) clinical trial.

This policy describes the process:

- Starting from trial start-up
- Ending when the trials is closed

This policy is applicable to the following studies:

- All clinical trials conducted at SLUHN and run through the SLUHN CTO using an investigational device

PERSONNEL RESPONSIBLE:

This SOP applies to those members of the clinical research team involved in clinical trials, facilitating the maintenance and management of the investigational device. This includes the following:

- Principal Investigator (PI)
- Clinical Trials Management
- Research Nurse/Coordinator

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 be responsible for oversight of this policy, as well as reviewing the CMS website for approval.

Clinical Trials Manager: The Clinical Trials Manager or designee shall be responsible for ensuring the investigational device is properly stored, maintained, and destroyed, and that all billing compliance processes are followed.

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

- Ensuring the investigational device is handled in accordance with the protocol and all applicable regulations.
- Ensuring the appropriate billing compliance forms are completed and maintained.
- Maintaining Device Accountability Logs (e.g. Inventory and Disposition Logs) in the Regulatory Binder and ensure all logs and associated correspondence are available for review by monitors or other inspection agencies.

Principal Investigator or designee: The principal investigator or designee shall be responsible for:

- Overall oversight and responsibility for clinical trial conduct at SLUHN
- Securing and maintaining any and all investigational product while in the possession of the investigational site
- Appropriate device implantation and/or use
- Safety oversight of the device
- Disposition of all investigational products during the course of the study, from the time of receipt to the time of final disposition (return to Sponsor, on-site destruction, etc.)

PROCEDURES:

- Review protocol for operational feasibility and practical requirements
- Determine device storage location and ensure storage requirements are met if the sponsor does not deliver the device directly to the OR at the time of surgery
- Review device management procedures with clinical trials staff and ancillary staff (e.g. OR staff)
- Ensure CMS approval for Medicare coverage prior to enrolling Medicare patients
- Perform inventory review upon receipt of investigational device
- Maintain inventory/disposition logs of investigational device
- Ensure devices are administered only to subjects who have agreed to participate in the study and signed an Informed Consent Form
- Complete and sign the Device Medicare Patient Notification Form after device use, and send to appropriate billing staff
- Return unused devices to sponsor or destroy onsite if authorized by the sponsor in writing

PROTOCOL REVIEW AND START-UP PREP

Role	Step	Activity
Clinical Trials Manager	1.0	Review protocol for operational feasibility ***(see SOP 200),*** and determine specific device management needs. **NOTE:** The device management shall be discussed with Materials Management or other ancillary departments as necessary prior to trial activation during the Internal Feasibility Review process.
Clinical Trials Manager	1.1	Determine whether the device will need to be stored and maintained onsite, or if it will be delivered by the sponsor directly to the OR at the time of surgery **NOTE:** If device is to be stored onsite, proceed to

		Step 1.2. If being delivered by the sponsor, skip to Step 3.4
Clinical Trials Manager	1.2	Identify a secure location for device storage with restricted access to authorized personnel only **NOTE:** Do not store Investigational Devices with approved devices used in standard medical care
Clinical Trials Manager	1.3	Develop and discuss the ongoing monitoring plan for the investigational device, and inventory control maintenance

CMS APPROVAL

Role	Step	Activity
Director of Clinical Trials and Research or designee	2.0	Review CMS website for approval of Medicare coverage
Director of Clinical Trials and Research or designee	2.1	Reach out to study sponsor for CMS approval status if the study is not listed on the CMS website as an approved study for Medicare billing
Director of Clinical Trials and Research or designee	2.2	Print CMS approval documentation for study record maintenance

INVESTIGATIONAL DEVICE RECEIPT AND STORAGE

Role	Step	Activity
CRC	3.0	Perform an inventory of the devices upon receipt, and record receipt of the devices on the Device Inventory/Disposition Log provided by the sponsor **NOTE:** This inventory should include verifying serial numbers, subject numbers and the contents of each kit, against the information provided on the Investigational Product Release Form, labels and labeling.
CRC	3.1	Ensure that the information on the packing slip matches exactly with the shipment that has been sent to the site, including: • Amount • Lot numbers • Quantity per carrier/container (if easily verified) • Integrity of the packaging seal

		• Protocol number **NOTE:** Promptly bring any discrepancies to the attention of the sponsor.
CRC	3.2	Retain shipping records (including packaging list and FedEx/UPS shipping receipt) to be maintained with the inventory log(s)
CRC	3.3	Ensure that investigational device is stored at the appropriate temperature, maintaining a storage area temperature log, if appropriate.
CRC	3.4	Ensure the Device Inventory/Disposition Log is signed and dated by the Sponsor if the Sponsor delivers the implantable portion of the product to the OR, or as applicable
CRC	3.5	Ensure the Device Inventory/Disposition Log(s) are up to date and readily accessible for monitor, IRB, or FDA audits **NOTE:** The ID Log shall include the following: • Type and quantity of the device, the dates of receipt, and the batch number or code mark • The initials and/or subject number of all persons who received, used, or disposed of each device • Number of units returned to the sponsor, repaired, or otherwise disposed of along with an explanation for each entry.
CRC	3.6	Verify that investigational product is dispensed or otherwise provided only to subjects enrolled in the clinical study
PI or designee	3.7	Verify the use of the investigational device occurs under the direct supervision of the investigator or other approved designee(s).
CRC	3.8	Ensure that the randomization code has been received, if applicable **NOTE:** If applicable, if emergency breaking of the test article blind is medically necessary follow the study specific unblinding procedures per the protocol, and assure that unblinding procedures are clearly communicated in writing

CRC	3.9	Ensure the following on an ongoing basis: • That the device supply is adequate and has not exceeded the expiration date • Document all circumstances related to damaged devices, packages opened inadvertently, etc. • Alert the designated sponsor representative when additional supplies of study drug/device will be required

RETURN OR DESTRUCTION OF INVESTIGATIONAL DEVICE

Role	Step	Activity
Clinical Trials Manager or Designee	4.0	Account for all supplies of investigational devices and return to Sponsor or destroy on-site if authorized by Sponsor in writing.
CRC	4.1	Record return or destruction of product on Product Disposition Log
PI	4.2	Sign and date the Inventory/Disposition Log upon trial termination and device return/destruction, if applicable.
CRC	4.3	Maintain a record of the return or destruction of test articles in the regulatory files upon trial termination.

DEVICE BILLING COMPLIANCE – MEDICARE PATIENTS ONLY

Role	Step	Activity
CRC	5.0	Complete the Device Medicare Patient Notification Form **(*Attachment A*) and send to Manager** within 48 hours of device use.
Clinical Trials Manager	5.1	Sign the Device Medicare Patient Notification Form and send via email per instructions on the form within 48 hours of device use.

RESOURCES:

- 21 CFR 800 General Medical Devices
- 21 CFR 803 Medical Device Reporting
- 21 CFR 812 Investigational Device Exemptions
- 21 CFR 312.57 Recordkeeping and Record Retention
- 21 CFR 312.62 Investigator Recordkeeping and Record Retention
- 21 CFR 812.110 Specific Responsibilities of Investigators

- 21 CFR 812.140 Records
- ICH E6, 2.12 The Principles of ICH GCP
- ICH E6, 4.6 Investigational Product
- ICH E6, 5.14 Handling Investigational Product(s)

Endorsed by: SOP Committee (8/15/14; 4/17/15; 4/8/16)
Approved by: Tracy Butryn, Director of Clinical Trials and Research (8/27/14; 4/17/15; 6/29/16)

ATTACHMENT A

Device Medicare Patient Notification Form

Instructions: Please complete this form in its entirety for every **Medicare** patient who receives a device for a Clinical Trial or Post-Market Study, regardless of whether it is SOC or non-SOC. Once completed, please send a signed copy via email to Tracy Butryn (Tracy.Butryn@sluhn.org), Anthony Collura (Anthony.Collura@sluhn.org), Denise Warner (Denise.Warner@sluhn.org), and Susan Strasburg (Susan.Strasburg@sluhn.org).

This form should be completed and sent **after** the device is received by the patient, but **no later than 48 hours** after receipt.

Protocol Title:

PI Name: Coordinator Name:

Device Name:

IDE/PMA/510(k) Number: _____

How is device being supplied? **Free of Charge or Purchased**

Notes: If device is provided free of charge or with full credit, Condition Code 53 is required on claim. The hospital charge for a device furnished to the hospital at no cost should equal $0.00.

Patient Initials: _____ Patient MR#: _____

Patient D.O.B.: _____

Date Device implanted/used: _____

_____ _____
Manager Signature Date

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