PURPOSE: To outline the process for submitting research documents to the St. Luke's University Health Network Institutional Review Board for approval throughout the conduct of the trial.

DEFINITIONS/ABBREVIATIONS:

- **Clinical Research Nurse/Coordinator (CRC):** Clinical Trials staff responsible for oversight and coordination of assigned protocols
- **Clinical Trials Administrative Assistant:** The Clinical Trials Administrative Assistant shall be responsible for logging the IND safety reports on a spreadsheet
- **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
- **Data and Safety Monitoring Board (DSMB) Reports:** Reports from an independent group of experts who monitor patient safety and treatment efficacy data while a clinical trial is ongoing
- **Informed Consent Form (ICF):** A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subjects decision to participate
- **Institutional Review Board (IRB):** Independent ethics committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects
- **Investigational New Drug Safety Report (INDSR):** Any adverse drug experience occurring at any dose
- **Investigator Brochure (IB):** A comprehensive document summarizing the body of information about an investigational product ("IP" or "study drug") obtained during a drug trial.
- **Principal Investigator (PI):** Lead investigator, responsible for the sound conduct of the project in accordance with the protocol and regulations
- **Protocol:** A document that describes the objective(s), design, methodology, statistical considerations and organization of a trial
- **Protocol Amendment:** A written description of a change(s) to or formal clarification of a protocol
- **Regulatory Coordinator (RC):** Clinical Trials staff responsible for the regulatory functions and oversight of clinical trials
- **Serious Adverse Event (SAE):** An adverse event or adverse reaction that results in death, is life-threatening*, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect
- **St. Luke's University Health Network (SLUHN)**

- **Unanticipated Problem (UAP):** Any event, experience, issue, instance, problem or outcome related or possibly related to a subjects participation in the research

SCOPE:

This SOP applies to the interactions with the IRB throughout the research process in order to ensure compliance with the regulations and to protect the safety and well-being of study subjects.

This policy describes the process:

- Starting after the protocol receives initial IRB approval
- Ending with the final closure of the protocol with the IRB

This policy is applicable to:

- Industry Funded clinical trials
- NCTN clinical trials under local IRB
- Government funded clinical trials

PERSONNEL RESPONSIBLE:

This SOP applies to members of the clinical research team involved in communicating with the IRB to ensure appropriate management of all clinical trial activity. This includes the following:

- Clinical Research Nurse/Coordinator
- Clinical Trials Administrative Assistant
- IRB Secretary
- Principal Investigator
- Regulatory Coordinator

ROLES:

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

Clinical Research Nurse/Coordinator (CRC): The Clinical Research Nurse/Coordinator shall be responsible for sending the completed SAE and UAP forms to the Regulatory coordinator, as well as maintaining AE and UAP logs (***see "AE, SAE, and UAP Reporting" SOP #305***)

Clinical Trials Administrative Assistant: The Clinical Trials Administrative Assistant shall be responsible for logging the INDSRs on the pertinent spreadsheet

IRB Administrator: The IRB Administrator shall be responsible for following IRB policies to provide the CTO approval status of submissions

Principal Investigator (PI): The Principal Investigator shall be responsible for the sound conduct of the project in accordance with the protocol and regulations

Regulatory Coordinator: The Regulatory Coordinator shall be responsible for the IRB submission, as well as filing and maintaining all required documents in the regulatory binder and/or saving/uploading documents electronically. The Regulatory Coordinator shall also be responsible for the distribution of new approvals and documents to the appropriate staff, obtaining documentation of training, and updating Sitecore and the Common Drive, as applicable. Once study status submissions have been made (i.e. enrollment closure/final report), update the Trial Portfolio Log with the change of study status and move study to the appropriate tab.

PROCEDURES:

Periodic Review

Role	Step	Activity
Regulatory Coordinator	1.0	Review Trial Portfolio Log for all studies expiring, and complete the Periodic Review Form (***see attachment A***), and save working version in the I-Drive
Regulatory Coordinator	1.1	Obtain PI's signature and date on the IRB Periodic Review Form
Regulatory Coordinator	1.2	Review document for accuracy, upload and save in pertinent folder in the I-drive, and file signed original along with all submission documents in the regulatory binder. **NOTE:** Submission documents include the following: • Current protocol • Current approved consent form(s) for restamping with updated submission tracker (open to accrual studies only) • FDA annual reports (if applicable) • DSMB reports since last review • IND safety reports since last review • AE Log since last review • UAP Log since last review Basic requirements for the annual renewal are: • Study enrollment status (open or closed to accrual • Description of any SAEs or unanticipated problems involving risk to human subjects • The number of subjects enrolled/participating during the past year and cumulatively • Total number enrolled nationwide to date • The number of subjects that withdrew or terminated

		early • Any new information or literature on possible risks to human subjects associated with the study • Any audit information **NOTE:** Please reference the Accrual Closure Policy SOP # 104, for specific steps for protocols that are not meeting accrual goals.
Regulatory Coordinator	1.3	Submit required documents to the IRB via DDOTS under "Review History" by the 20th of the month prior to the IRB meeting date occurring prior to expiration.
Regulatory Coordinator	1.4	Choose the appropriate IRB Meeting date and level of Board review: • Expedited (closed to accrual, studies with no enrollment, or studies that had expedited review initially) • Full Board **NOTE:** All pertinent information should be entered into the agenda box. This shall include the following: "Please see the attached Continuing review packet which includes the following documents": (List all documents being submitted with their version number/version date).
Regulatory Coordinator	1.5	Notify yourself, Medical Director of Research & Innovation and IRB Administrative Staff via DDOTS notification system of the submission.
Regulatory Coordinator	1.6	Print DDOTS electronic notification of submission and file with approval/new stamped consents (open to accrual studies) once received, in the Regulatory Binder.
Regulatory Coordinator	1.7	Update Regulatory Submission Log with submission information for clinical staff and invoicing purposes. **NOTE:** Specific steps for IRB invoicing will not be outlined in this SOP. ***Please reference Clinical Trials Invoicing SOP# 108.***
Regulatory Coordinator	1.8	Update Trial Portfolio Log with new Expiration Date

Amendments

Role	Step	Activity
Not Applicable	---	**NOTE:** Specific steps to amend the budget/CTA will not be outlined in this SOP. ***Please reference CTA and***

		Budget Negotiation SOP# 106
Not Applicable	---	**NOTE:** Specific steps to distribute IRB approvals and obtain documentation of Training will not be outlined in this SOP. ***Please reference IRB Approval Distribution SOP# 202***
Regulatory Coordinator	2.0	Add new amendment to Budget Amendment Tracking log (***see Attachment B***) upon receipt of amendment
Regulatory Coordinator	2.1	Send amendment documents to pertinent team members to review budget revision necessity
Research Finance Compliance Analyst	2.2	Review amendment and update Budget Amendment log with budget revision necessity
Regulatory Coordinator	2.3	Complete and compile the following documents, as applicable, for IRB submission: • Amendment Form ***(see attachment C)*** • Investigator letter/Sponsor Memo • Sponsor Summary of Changes • Updated protocol with tracked changes • Updated clean protocol • Updated ICF with tracked changes • Updated clean consent for stamping • Updated/New Patient or recruitment/advertising materials • Updated IB/Device Brochure • IB Summary of Changes • Any other pertinent documents related to the amendment **NOTE:** Amendments shall not be submitted until any pertinent budget/contract amendments have been executed if applicable, unless otherwise approved. **NOTE:** No amendment shall be implemented until the PI has received written approval from the IRB.
Regulatory Coordinator	2.4	Obtain PI's signature and date on the amendment form.
Regulatory Coordinator	2.5	Review documents for accuracy, upload and save in pertinent folder in the I-drive, and file signed original amendment and key personnel forms along with all submission documents in the regulatory binder.
Regulatory Coordinator	2.6	Submit required documents to the IRB via DDOTS under

		"Revision Log" once complete.
Regulatory Coordinator	2.7	Select the appropriate meeting date, and level of review: • Expedited (minimal risk, administrative changes, updated IB or patient materials, updated Key Personnel) • Full Board (more than minimal risk, major protocol and/or ICF changes, safety information that would affect patients) **NOTE:** All pertinent information should be entered into the agenda box. This shall include the following: "Please see the attached amendment form and supporting documents for review and approval (List all documents being submitted with their version number/version date).
Regulatory Coordinator	2.8	Notify yourself, Medical Director of Research & Innovation and IRB Administrative Staff via DDOTS notification system of the submission.
Regulatory Coordinator	2.9	Print DDOT's electronic notification of submission and file with approval once received, along with the new stamped consent (if applicable) and file with the IRB submission documents in the Regulatory Binder.
Regulatory Coordinator	2.10	Update Regulatory Submission Log with submission information and whether reconsent is needed for clinical staff and invoicing purposes.
Regulatory Coordinator	2.11	Update Trial Portfolio Log with the change of study status and move study to the Closed to Accrual tab if the amendment was closing the study to accrual.

SAE's and UAP's

Role	Step	Activity
Not Applicable	---	**NOTE:** Specific steps for completion of SAE/UAP forms, and timelines for submission will not be outlined in this SOP. ***Please refer to "AE, SAE, and UAP Reporting" SOP #305.***
Regulatory Coordinator	3.0	Upload and save completed forms in pertinent folder on the I-drive, and file submission document in the regulatory binder.
Regulatory Coordinator	3.1	Submit required documents to the IRB via DDOTS in the "Patient File Cabinet" under AE/UAP.
Regulatory Coordinator	3.2	Choose expedited review and the appropriate meeting date. Ensure all fields highlighted in red are complete.

		NOTE: All pertinent information should be entered into the agenda box. This shall include the following: • For SAE: "IAE: SLUHN number, patient number, see attached form" • For UAP: "UAP: SLUHN number, patient number, see attached form"
Regulatory Coordinator	3.3	Notify yourself, CTO Manager, Medical Director of Research & Innovation and IRB Administrative Staff, and Research Coordinator via DDOTS notification system of the submission.
Regulatory Coordinator	3.4	Print DDOTS electronic notification of submission and acknowledgment notification once received, and file with the IRB submission document in the Regulatory Binder.
Regulatory Coordinator	3.5	Update Regulatory Submission Log with submission information for clinical staff and invoicing purposes.

Monitoring Visit Follow-up Letters and Trial Status/Safety Correspondence

Role	Step	Activity
Not Applicable	---	**NOTE:** General study correspondence not involving safety changes, newsletters, sponsor memos are not required to be submitted to the IRB **NOTE:** DSMB correspondence and INDSRs, although they include safety information, shall be submitted as part of the Periodic Review.
Regulatory Coordinator	4.0	Submit all Monitoring Visit Follow-up Letters and/or other trial status updates/safety- related correspondence to the IRB via DDOTS under "Revision Log" choosing expedited review for the appropriate meeting date. **NOTE:** All pertinent information should be entered into the agenda box. This shall include the following: "Please see the attached documents for review and approval" (List all documents being submitted with the date). These documents include; • Internal Monitoring Visit Letters • Study closure information from the sponsor. • Investigator /Coordinator memos and letters form

		the sponsor pertaining to patient risk or important study related information (e.g. dosing changes, cohort closures, new reported risks)
Regulatory Coordinator	4.1	Upload and save completed forms in pertinent folder in the I-drive, and file submission document in the regulatory binder.
Regulatory Coordinator	4.2	Notify yourself, Medical Director of Research & Innovation and IRB Administrative Staff via DDOTS notification system of the submission.
Regulatory Coordinator	4.3	Print DDOTS electronic upload notification and acknowledgment notification once received, and file with the IRB submission documents in the Regulatory Binder.
Regulatory Coordinator	4.4	Update Regulatory Submission Log with submission information, if applicable, for clinical staff and invoicing purposes.

INDSRs

Role	Step	Activity
Not Applicable	---	**NOTE:** Specific steps to submit the INDSRs will not be outlined in this section. Please refer to Periodic Review Section 1.0
Regulatory Coordinator	5.0	Print all INDSRs received via sponsor portals/and or email on an ongoing basis and provide to the Administrative Assistant
Administrative Assistant	5.1	Input pertinent information from the INDSRs onto the INDSR spreadsheet located on the I-drive
Regulatory Coordinator	5.2	Retrieve spreadsheet from Administrative Assistant and print prior to study expiration and Periodic Review prep
Regulatory Coordinator	5.3	Obtain PI signature on copy of spreadsheet and file signed original with the respective reports in the appropriate INDSR binder

Final Report

Role	Step	Activity
Regulatory Coordinator	6.0	Complete and compile the following documents for IRB submission: • IRB Final Report Form ***(see attachment D)*** • Close Out Visit Letter • AE/UAP logs since last review • INDSRs since last review • Sponsor correspondence (e.g. DSMB reports) since

		last review **NOTE:** The following must be completed/confirmed prior to submission of the Final Report: • COV and receipt of COV FUL • Review and reconciliation of all payments
Regulatory Coordinator	6.1	Obtain PI's signature and date on Final Report form.
Regulatory Coordinator	6.2	Submit to the IRB via DDOTS under "Review History" choosing expedited review and the appropriate meeting date. **NOTE:** All pertinent information should be entered into the agenda box. This shall include the following: "Terminated: Please see the attached Final Report Form for study closure, and the following documents for review and approval (List all documents being submitted with the date).
Regulatory Coordinator	6.3	Upload and save completed forms in pertinent folder in the I-drive, and file submission document in the regulatory binder.
Regulatory Coordinator	6.4	Notify yourself, Medical Director of Research & Innovation and IRB Administrative Staff via DDOTS notification system of the submission.
Regulatory Coordinator	6.5	Print DDOTS electronic upload notification and acknowledgment notification once received, and file with the IRB submission documents in the Regulatory Binder.
Regulatory Coordinator	6.6	Update Regulatory Submission Log with submission information for clinical staff and invoicing purposes.
Regulatory Coordinator	6.7	Update Trial Portfolio Log with the date of IRB submission for termination and move the study to Closed tab.

RESOURCES:
SLUHN IRB Policies and Procedures Manual

Endorsed by: SOP Committee (1/29/16; 4/8/16)
Approved by: Tracy Butryn, Director of Clinical Trials and Research (1/29/16; 7/12/16)

ATTACHMENT A

Institutional Review Board
801 Ostrum Street, Bethlehem, PA 18015
Phone: 484-526-4944
Fax: 484-526-4979

IRB Continuing Periodic Review Form

Submit this Periodic Review form (signed) with all required documents to the IRB Office

IRB Review Classification Certification of Compliance with Regulatory Requirements:

IRB #: _____

IRB Use Only:
DATE RECEIVED STAMP:

Pick One:

☐ Full Board Review

☐ Expedited Review ***(please select reason below)***

- ☐ Minimal Risk Study
- ☐ **45 CFR 46.110, List of Categories (8a)** Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects
- ☐ **45 CFR 46.110, List of Categories (8b)** Where no subjects have been enrolled and no additional risks have been identified
- ☐ **45 CFR 46.110, List of Categories (8c)** Where the remaining research activities are limited to data analysis.

All Must be Checked:

☐ FCOI is current for all listed personnel

☐ No FCOI exists for any listed personnel

☐ CITI training is current for all listed personnel

Attachments:
Check and include all that apply:

☐ Current Protocol
☐ Copy of Current Stamped Consent
☐ AE and UAP Spreadsheets since last review
☐ Audit/Monitoring Visit Reports (if applicable)
☐ Accrual Policy Justification (if applicable)
☐ Publications/Presentations
☐ Current IB/Device Brochure/Package Insert
☐ Current Consent for Re-Stamping (open to accrual studies only)
☐ Off-Site INDSR Spreadsheet since last review
☐ DSMB Reports
☐ FDA Correspondence/Annual Report
☐ Other: _____

PROTOCOL TITLE:

DEPARTMENT:

SECTION A: Current Study Personnel

(Include the Principal Investigator, all Sub-Investigators, Research Nurses and Coordinators, Data personnel, Regulatory personnel, and any other personnel directly involved in the conduct of the research)

Name	Address	City	State	Zip	Phone

SECTION B: Enrollment Information

1. Period of most recent approval: ☐ 1 year ☐ 6 months ☐ Other
2. Date of first ***on-site*** subject enrollment:
3. Date of most recent ***on-site*** subject enrollment:
4. IRB-approved enrollment number:
5. If the study does not involve interaction with subjects (e.g. database or chart review), indicate the number of subjects entered or charts reviewed to date: ***(Skip to Section D, Progress Report.)***
6. If the study is a collection of pre-existing (stored) biological specimens, indicate the number of specimens collected to date: ***(Skip to Section D, Progress Report.)***

******All other studies, please complete the chart below******

	Since Last Approva	Total to Date

	I	
7. Total number of subjects enrolled ***at SLUHN***: ***Note:* for the purposes of the Continuing Review, "subjects enrolled" is defined as subjects who have signed a consent form, successfully screened and been randomized or allocated or begun study procedures.**		
***Note:* Do not respond in shaded columns for below items** ***Note:* The total for Items 8-11 should equal the Total number of subjects enrolled from Item #7.** 8. Number of subjects currently receiving study intervention: 9. Number of subjects on follow-up not receiving intervention: 10. Number of subjects completed (no longer being followed): 11. Number of withdrawals, lost to follow-up, deaths:		
12. Number of serious adverse events occurring at SLUHN within the past year currently noted in consent form:		
13. Number of serious adverse events occurring at SLUHN within the past year ***not*** currently noted in consent form:		

SECTION C: Progress Report (Interventional Studies)

1. Provide synopsis describing what has or has not occurred in the study, plus data related to subject responses to intervention, if applicable.

2. Please explain any withdrawals, subjects lost to follow-up, or deaths.
3. Describe any subject grievances or complaints.
4. Provide an itemization of amendments submitted within the past year.
5. Provide a list of all investigator/co-investigator additions/removals submitted within the past year.
6. Please summarize UAPs since last IRB review.
7. Please summarize all reported SAEs since last IRB review.
8. Have you had any audits or monitoring visits (internal or external) within the past year that have not been previously reported? ☐ YES ☐ NO

   If "YES" please attach report(s).

9. Has a Data & Safety Monitoring Board (DSMB) or sponsor reviewed study-wide adverse events and interim findings?

☐ YES ☐ NO ☐ NA ***If "YES" please attach report(s).***

10. Have there been any protocol violations? If so, itemize the events and indicate any corrective measures taken.

11. Has the enrollment for the past year been less than projected? ☐ YES ☐ NO

If "YES" please attach Justification letter as to why the study should remain open per SLUHN Accrual Policy

12. Have you changed any recruitment strategies? ☐ YES ☐ NO

If "YES" please describe:

13. Are facilities and number of support staff the same as at the time of the original application? ☐ YES ☐ NO

If "NO" please describe:

14. If drug or device trial, has there been any change in FDA status? ☐ YES ☐ NO

If "YES" please explain and attach copies of any correspondence with the FDA. Include copy of annual report to FDA.

15. Please indicate whether the Risk/Benefit ratio for the study has changed from last IRB review by checking the appropriate box below.

☐ No change in the risk/benefit ratio for subjects on this study, and no cause for subjects to reconsider their participation in the study.

☐ Change in the risk/benefit ratio for subjects on this study and/or cause for subjects to reconsider their participation in the study. Please explain:

SECTION D: Progress Report (Data/Chart/Specimen Collection)

1. Provide a synopsis of results so far and describe any data analysis that has taken place.

If no data have been collected or analyzed, please indicate why:

2. Have any publications or presentations resulted from the research? ☐ YES ☐ NO

If "YES" please attach copies.

SECTION E: Current Study Status (please check appropriate status below)

☐ Study is active and subject recruitment/chart review/tissue collection is ongoing.

☐ Chart review/tissue collection is completed. Study is in data analysis.

☐ Enrollment is closed. However, subjects are currently receiving study treatment or are undergoing study procedures. (*A new stamped consent form will not be issued*.)

☐ Enrollment is closed. Subjects are not receiving study treatment and are not undergoing any study procedures. Study is in

long term follow-up (to determine survivorship) or data analysis phases only. (*A new stamped consent form will not be issued*.)

☐ Study enrollment is suspended. *(Please provide reason and relevant sponsor correspondence.)*

☐ Study enrollment was suspended by the IRB because continuing review was not submitted prior to expiration date. PI certifies that no subjects were enrolled after the expiration date.

SECTION F: Signature and Attestation

I certify that the information contained above is correct, that the consent form currently reflects any and all modifications since the last approval by the Institutional Review Board, and that I will only conduct study-related activities with an active IRB approval.

Principal Investigator Signature	**Date**
Person Completing this Form	**Date**

ATTACHMENT B

Budget Amendment Review Log

Protocol	Date Amendment Received	Date Sent to Manager for Review	Date Reviewed	Changes Effecting Budget	EPIC Protocol Revised	Tracy Comments	IRB Submission Date

ATTACHMENT C

Institutional Review Board
801 Ostrum Street, Bethlehem, PA 18015
Phone: 484-526-4944
Fax: 484-526-4979

IRB Amendment Form

Submit this Amendment form (signed) with all required documents to the IRB Office

IRB Review Classification Certification of Compliance with Regulatory Requirements:

IRB #: _____

IRB Use Only:
DATE RECEIVED STAMP:

Pick One:

- ☐ Full Board Review
- ☐ Expedited Review ***(please select reason below)***
  - ☐ Minimal Risk Study
  - ☐ Minor or Administrative Changes (e.g. advertising, informational materials, grammar/syntax corrections to protocol and/or consent form)

All Must be Checked:

- ☐ FCOI is current for all listed personnel
- ☐ No FCOI exists for any listed personnel
- ☐ CITI training is current for all listed personnel

Attachments:
Check and include all that apply:

- ☐ New Revised Protocol
- ☐ Protocol Amendment Summary of Changes
- ☐ Copy of Current Stamped Consent
- ☐ Other: _____
- ☐ Updated IB/Device Brochure/Package Insert
- ☐ Revised Consent(s) with changes in TRACKED changes
- ☐ CLEAN Revised Consent for Stamping

******Is a Continuing Periodic Review being submitted simultaneously with this amendment?*** ☐ YES ☐ NO

PROTOCOL TITLE:

DEPARTMENT:

SECTION A: Current Study Personnel
(Include the Principal Investigator, all Sub-Investigators, Research Nurses and Coordinators, Data personnel, Regulatory personnel, and any other personnel directly involved in the conduct of the research)

Name	Address	City	State	Zip	Phone

SECTION B: Summary of Amendment Changes and Study Status

1. Summarize key points of the amendment.
2. Address the main changes affecting the subjects, the protocol, and the consent form(s) and provide rationale for the main changes (e.g. dose-limiting toxicities, suspension of enrollment for interim analysis, etc.).
3. Summarize ANY change involving risk.
4. Number of SLUHN subjects enrolled to date:
5. Number of SLUHN subjects currently receiving study treatment:
6. In your opinion, does this amendment add increased risk to the study? ☐ YES ☐ NO

   Please explain:

For amendments relating to new risk information, please attach all relevant information that would allow the Board to assess the risk data (SAE reports, IND Safety Reports, correspondence from sponsor, DSMB reports, data from previous studies, publications, etc.).

SECTION C: Current Study Status (please check appropriate status below)

☐ Study is active and subject recruitment/chart review/tissue collection is ongoing.

☐ Chart review/tissue collection is completed. Study is in data analysis.

☐ Enrollment is closed. However, subjects are currently receiving study treatment or are undergoing study procedures.

☐ Enrollment is closed. Subjects are not receiving study treatment and are not undergoing any study procedures. Study is in long term follow-up (to determine survivorship) or data analysis phases only.

☐ Study enrollment is suspended. *(Please provide reason and relevant sponsor correspondence.)*

☐ Study enrollment was suspended by the IRB because continuing review was not submitted prior to expiration date. PI certifies that no subjects were enrolled after the expiration date.

SECTION D: Re-Consent Determination For Revised Consents ONLY (please check appropriate box below)

To maintain our primary objective of human subject protection, the following subjects will be re-consented in order to provide information which may relate to the subjects' willingness to continue participation:

- ☐ All subjects who received study intervention
- ☐ All active subjects (not subjects 30 days* post last treatment, in follow-up, withdrawn or off study)
- ☐ All active subjects including subjects 30 days* post last treatment (not subjects withdrawn or off study)
- ☐ Subjects will not be re-consented
- ☐ Subjects will not be re-consented, but will be informed of the change(s)

Please describe method of communication to the subject of the change and how it will be documented

SECTION E: Signature and Attestation

I certify that, in my opinion, this amendment:

- ☐ Is consistent with the re-consent determination indicated above.
- ☐ Increases the risk of the study.
- ☐ Does not increase the risk of the study.

Principal Investigator Signature	Date
Person Completing This Form	**Date**

ATTACHMENT D

Institutional Review Board
801 Ostrum Street, Bethlehem, PA 18015
Phone: 484-526-4944
Fax: 484-526-4979

IRB Final Report Form

Submit this Final Report (signed) with all required documents to the IRB Office for Expedited Review

IRB Certification of Compliance with Regulatory Requirements:	**IRB #:** _____
All Must be Checked: ☐ FCOI is current for all listed personnel ☐ No FCOI exists for any listed personnel ☐ CITI training is current for all listed personnel	**IRB Use Only:** DATE RECEIVED STAMP:

Attachments:
Check and include all that apply:

- ☐ Current Protocol
- ☐ Copy of Current Stamped Consent
- ☐ Off-Site INDSR Spreadsheet since last review
- ☐ DSMB Reports
- ☐ Publications/Presentations
- ☐ Current IB/Device Brochure/Package Insert
- ☐ AE and UAP Spreadsheets since last review
- ☐ Audit/Monitoring Visit Reports
- ☐ FDA Correspondence/Annual Report
- ☐ Other: _____

PROTOCOL TITLE:

DEPARTMENT:

SECTION A: Current Study Personnel
(Include the Principal Investigator, all Sub-Investigators, Research Nurses and Coordinators, Data personnel, Regulatory personnel, and any other personnel directly involved in the conduct of the research)

Name	Address	City	State	Zip	Phone

SECTION B: Enrollment Information

1. Period of previous approval: ☐ 1 year ☐ 6 months ☐ Other
2. Date of first ***on-site*** subject enrollment:
3. Date of most recent ***on-site*** subject enrollment:
4. IRB-approved enrollment number:
5. If the study does not involve interaction with subjects (e.g. database or chart review), indicate the number of subjects entered or charts reviewed to date: ***(Skip to Section D, Progress Report.)***
6. If the study is a collection of pre-existing (stored) biological specimens, indicate the number of specimens collected to date: ***(Skip to Section D, Progress Report.)***

******All other studies, please complete the chart below******

	Since Last Approval	Total to Date
7. Total number of subjects enrolled ***at SLUHN***: ***Note: for the purposes of the Final Report, "subjects enrolled" is defined as subjects who have signed a consent form, successfully screened and been randomized or allocated or begun study procedures.***		
Note: Do not respond in shaded columns for below items ***Note: The total for Items 8-9 should equal the Total number of subjects enrolled from Item #7.*** 8. Number of subjects completed (no longer being followed): 9. Number of withdrawals, lost to follow-up, deaths:		
10. Number of serious adverse events occurring at SLUHN since last review currently noted in consent form:		

	11. Number of serious adverse events occurring at SLUHN since last review ***not*** currently noted in consent form:			

SECTION C: Progress Report (Interventional Studies)

1. Provide synopsis describing what has or has not occurred in the study, plus data related to subject responses to intervention, if applicable.
2. Please explain any withdrawals, subjects lost to follow-up, or deaths.
3. Describe any subject grievances or complaints.
4. Provide an itemization of amendments submitted since last review.
5. Provide a list of all investigator/co-investigator additions/removals submitted within the past year.
6. Please summarize UAPs since last IRB review.
7. Please summarize all reported SAEs since last IRB review.
8. Have you had any audits or monitoring visits (internal or external) since last review that have not been reported?
☐ YES ☐ NO

If "YES" please attach report(s).

9. Has a Data & Safety Monitoring Board (DSMB) or sponsor reviewed study-wide adverse events and interim findings?

☐ YES ☐ NO ☐ NA ***If "YES" please attach report(s).***

10. Have there been any protocol violations? If so, itemize the events and indicate any corrective measures taken.

11. Has the enrollment been less than projected? ☐ YES ☐ NO

12. Have you changed any recruitment strategies since last review? ☐ YES ☐ NO

If "YES" please describe:

13. Are facilities and number of support staff the same as at the time of the original application? ☐ YES ☐ NO

If "NO" please describe:

14. If drug or device trial, has there been any change in FDA status? ☐ YES ☐ NO

If "YES" please explain and attach copies of any correspondence with the FDA. Include copy of annual report to FDA.

15. Please indicate whether the Risk/Benefit ratio for the study has changed from last IRB review by checking the appropriate box below.

☐ No change in the risk/benefit ratio for subjects on this study, and no cause for subjects to reconsider their participation in the study.

☐ Change in the risk/benefit ratio for subjects on this study and/or cause for subjects to reconsider their participation in the study. Please explain:

SECTION D: Progress Report (Data/Chart/Specimen Collection)

1. Provide a synopsis of results so far and describe any data analysis that has taken place.

If no data have been collected or analyzed, please indicate why:

2. Have any publications or presentations resulted from the research? ☐ YES ☐ NO

If "YES" please attach copies.

SECTION E: Final Study Impact and Future Plans

1. Please provide a bibliography of publications, abstracts and presentations to date.
2. If no publications to date, are publications planned or in preparation? ☐ YES ☐ NO

If "YES" please describe:

3. Are future trials or grant applications related to this research planned? ☐ YES ☐ NO

If "YES" please describe:

4. Have the data collected changed clinical practice? ☐ YES ☐ NO

If "YES" please describe:

SECTION F: Signature and Attestation

I certify that the information contained above is correct, that the consent form currently reflects any and all modifications since the last approval by the Institutional Review Board, and that all study activities are complete, and this represents the Final Report.

Principal Investigator Signature	Date
Person Completing This Form	**Date**