PURPOSE:

To outline the Institutional Review Board (IRB) approval distribution process to ensure that all pertinent individuals and departments are aware of new trial activity and/or changes, and have access to all necessary trial documents.

DEFINITIONS:

- **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
- **Informed Consent Form (ICF):** IRB approved form outlining all aspects of a clinical trial in lay language, signed by the subject consenting to participate
- **Institutional Review Board (IRB):** Independent ethics committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects
- **National Clinical Trials Network (NCTN):** A National Cancer Institute (NCI) program that gives funds and other support to cancer research organizations to conduct cancer clinical trials. The groups in the NCTN include the Alliance for Clinical Trials in Oncology, ECOG-ACRIN Cancer Research Group, NRG Oncology, SWOG, Children's Oncology Group (COG), and the NCI of Canada-Clinical Trials Group (NCIC-CTG). The NCTN was previously known as the NCI Clinical Trials Cooperative Group Program.
- **Principal Investigator (PI):** Lead investigator, responsible for the sound conduct of the project in accordance with the protocol and regulations
- **Sitecore:** The SLUHN internet for the public to view. The CTO lists the protocols which are open to accrual, by disease site, along with IRB number, title, physician and coordinator contact information, synopsis, inclusion criteria and exclusion criteria. Research website that lists current, active clinical trials by disease sub-category
- **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 St. Luke's University Health Network (SLUHN) clinical research site personnel involved in the conduct of clinical research within the centralized Clinical Trials Office (CTO).

This policy describes the process:

- Starting from Initial IRB approval
- Ending with all research staff having proper training

Effective Date:	Revision Date(s):
1/28/15	4/17/15; 4/8/16

This policy is applicable to the following studies:

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

PERSONNEL RESPONSIBLE:

This SOP applies to those members of the clinical research team involved in facilitating the IRB approval distribution process. This includes the following:

- Director of Clinical Trials and Research
- Regulatory Coordinator
- Study Start-up Project Coordinator
- Principal Investigator (PI)
- Research Nurse/Coordinator
- IRB Administrator

ROLES:

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

Director of Clinical Trials and Research: The Director or designee shall be responsible for oversight of this policy.

Regulatory Coordinator: The Regulatory Coordinator shall be responsible for the IRB submission, as well as filing of all approval letters and approved documents in the regulatory binder. The Regulatory Coordinator shall also be responsible for the distribution of new approvals and documents to the appropriate staff, obtaining documentation of training, updating Sitecore, if applicable, and uploading documents to the Common Drive, as applicable. The Regulatory Coordinator shall also be responsible for oversight and coordination of assigned protocols and training.

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

Study Start-Up Project Coordinator: The Study Start-Up Project Coordinator shall be responsible for coordinating all study start-up activities, ensuring all new initial approval documents are uploaded to the Common Drive and the trial is added to Sitecore.

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

PROCEDURES:

- The IRB Administrator or designee delivers the original approval letters and corresponding approved documents to the CTO for full-board submissions.
- The Study Start-up Project Coordinator/Regulatory Coordinator receive DDOTS acknowledgement via email, and reviews the approval letters and corresponding approved documents for accuracy and any discrepancies
- The Study Start-up Project Coordinator or designee obtain signatures from the PI on the IRB Approval Letter (initial approvals only)
- Study Start-up project Coordinator/Regulatory Coordinator notifies research team of submission approval and sends training documentation
- Study Start-up Project Coordinator/Regulatory Coordinator uploads necessary documents to the Common Drive, as applicable, and adds/updates Sitecore, as applicable.
- All pertinent Research staff must complete the protocol site training

INITIAL SUBMISSIONS

Role	Step	Activity
IRB Administrator	1.0	Follow IRB policies to provide approval status of initial submission. **NOTE:** IRB Policies and Procedures will not be described in this SOP. Please refer to the IRB Policy and Procedure Manual for IRB-specific procedures and policies.
Study Start-up Project Coordinator /Regulatory Coordinator	1.1	Review IRB approval letter and corresponding approved documents for accuracy once delivered from the IRB **NOTE:** If any discrepancies, explain and return to IRB Administrator **NOTE:** Approval letters should always contain national ID, SLUHN local IRB #, protocol title, content of the submission and version dates of documents, protocol status, protocol approval period, protocol expiration date, standard IRB language and IRB signatory
Study Start-up Project Coordinator	1.2	Enclose IRB approval letter in designated folder and send to PI for signature
Study Start-up Project Coordinator / Regulatory Coordinator	1.3	Update IRB Meeting Submission Log for clinical team

CRC	1.4	Complete a 310 Form ***(see Attachment A)***, if applicable (for NCTN trials only), and send to IRB Administrator for IRB signatory
Study Start-up Project Coordinator/ Regulatory Coordinator	1.5	Email/Fax the approval documents to Sponsor, if applicable- • Signed 310 Form (NCTN Trials only) • IRB approval letter • Stamped ICF
Study Start-up Project Coordinator/ Regulatory Coordinator	1.6	Upload Protocol and Consent(s) to the common drive, as appropriate, and add/update Sitecore, as applicable.
Study Start-up Project Coordinator/ Regulatory Coordinator	1.7	Add/update the IRB number, title, physician and coordinator contact information, synopsis, inclusion criteria and exclusion criteria, as applicable, to Sitecore. Upload IRB approved current Protocol and Consent to and Common Drive, as appropriate.
Study Start-up Project Coordinator/ Regulatory Coordinator	1.8	File the approval documents in the appropriate section of the Regulatory Binder
Not Applicable	---	**NOTE:** Specific steps regarding the initial approval and Study Start-up activities will not be recorded in this SOP. Please refer to the SOP 200: Study Start Up. Also, specific steps carried out by the IRB and other steps to achieve IRB approval of the protocol will not be recorded in this SOP. ***Please refer to the SOP 201: Regulatory Start Up and Initial IRB Submission and SOP 202: IRB Approval Distribution.***

AMENDMENT SUBMISSIONS

Role	Step	Activity
IRB Administrator	2.0	Follow IRB policies to provide approval status of amendment submission **NOTE:** IRB Policies and Procedures will not be described in this SOP. Please refer to the IRB Policy and Procedure Manual for IRB-specific procedures and policies.
Not Applicable	---	Repeat Steps 1.1 through 1.5

		NOTE: If amendment did not include an updated ICF, please skip to Step 2.2
Regulatory Coordinator	2.1	Send CRCs updated ICF via email
Regulatory Coordinator	2.2	Send the research team an email notification of amendment, stamped consent form, and IRB approval letter along with the protocol and summary of changes ***(see Attachment B)***
Regulatory Coordinator	2.3	Create a site training log and circulate for Principal Investigator signature ***(see Attachment C)***
Regulatory Coordinator	2.4	Upload protocol amendment and updated ICF to Common Drive and update Sitecore, as applicable. **NOTE:** If amendment affects the Inclusion/Exclusion criteria or any other pertinent information for the SLUHN Research Website, such updates shall be made in SiteCore.
Regulatory Coordinator	2.5	File the approval documents and site training log in the appropriate section of the study Regulatory Binder
Not Applicable	---	**NOTE:** Specific steps regarding the amendment submission process will not be recorded in this SOP***. Please refer to the SOP 204: Ongoing Regulatory Submissions.*** Also, specific steps carried out by the IRB and other steps to achieve IRB approval of the amendment will not be recorded in this SOP. ***Please refer to SOP 202: IRB Approval Distribution.***

ANNUAL PERIODIC REVIEW

Role	Step	Activity
IRB Administrator	3.0	Follow IRB policies to provide approval status of annual periodic review submission **NOTE:** IRB Policies and Procedures will not be described in this SOP. Please refer to the IRB Policy and Procedure Manual for IRB-specific procedures and policies.
Not Applicable	---	Repeat Steps 1.1 through 1.5.
Not Applicable	---	**NOTE**: Specific steps regarding the annual periodic review submission process will not be recorded in this SOP. ***Please refer to the SOP 204: Ongoing Regulatory Submissions.*** Also, specific steps carried out by the IRB and other steps to achieve IRB approval of the annual review will not be recorded in this SOP. ***Please refer to SOP 202: IRB Approval Distribution.***

RESOURCES:
21 CFR Part 56
21 CFR Part 50
E6: Good Clinical Practice
21 CFR 312.60

Endorsed by: SOP Committee (11/21/14; 4/17/15; 4/8/16)
Approved by: Tracy Butryn, Director of Clinical Trials and Research (12/8/14; 4/17/15; 7/12/16)

ATTACHMENT A:

Cancer Trials Support Unit ***Institutional Review Board Certification***	***Mail or Fax to:*** Cancer Trials Support Unit ATTN: Coalition of National Cancer Cooperative Groups 1818 Market Street Suite 1100 Philadelphia, PA 19103 FAX: 1-215-569-0206
1) Protocol #:	2) Protocol Version Date:
3) Protocol Title:	
4) Institution Name: **St. Luke's University Health Network**	5) NCI Institution code: **PA054** 6) FWA: **00003557**
7) Principal Investigator:	8) NCI Investigator #:
This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations or subparts:	
9) Approval Type: [ ] Original [ ] Amendment [ ] Renewal	
10) Review Type: (Must include justification in comments for facilitated or expedited review) [ ] Full Board [ ] Expedited (provide number from categories in box 22) [ ] Facilitated	
11) Date of local IRB review:	12) IRB Number: **00002757**
13) Approval Period: Effective Date: Expiration Date:	14) Comments: (additional items reviewed)
15) Was the protocol approved with contingencies? [ ] Yes [ ] No Date all contingencies were met:	
The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided. Question #1 through #20 must be completed for this form to be accepted. *Check here if the person signing this form is not the IRB signatory as documented on the institutional assurance with OHRP. [ ]*	
16) Name of IRB Signatory: **Manny Changalis**	17) Name of approving IRB: **St. Luke's University Health Network**
18) Title of IRB Signatory: **Assistant Vice President – Medical Affairs**	19) Phone: **484-526-4944**
20) Signature:	21) Date:
22) Expedited Review Categories (Pick only one for box #10): 8a. Where (i) the research is permanently closed to the enrollments 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 8b. Where no subjects have been enrolled and no additional risks have been identified 8c. Where the remaining research activities are limited to data analysis	

ATTACHMENT B:

To:
Subject: Protocol /Amendment

Hello All,

You are all listed as investigators and or listed on the DOAL for the above referenced protocol, and thus are responsible for understanding and compliance with each protocol version.

(Name of Protocol) has released a new protocol version (version and date).

This email will serve as documentation of the date of training.

Please feel free to contact me with any questions.

ATTACHMENT C:

St Luke's UNIVERSITY HEALTH NETWORK

801 Ostrum Street, EW2
Bethlehem, PA 18015
484-526-4000

July 7, 2016

Re: Protocol Training Documentation

Protocol Title:

Title of Training:

Date of Training:

This Note to File will serve as documentation that the following individuals have been trained on the above referenced protocol. The attached email containing the training slides and or protocol amendment was sent via email, which shall serve as the date of training for the below listed individuals.

_____

Principal Investigator