PURPOSE: The purpose of this policy is to outline requirements and responsibilities to achieve active status as a St. Luke's University Health Network Clinical Trials Investigator.

DEFINITIONS/ABBREVIATIONS:

- **ALLIANCE for Clinical Trials in Oncology:** Part of the National Clinical Trials Network (NCTN) sponsored by the National Cancer Institute (NCI) through the merger of three cooperative groups: American College of Surgeons Oncology Group (ACOSOG), Cancer and Leukemia Group B (CALGB) & North Central Cancer Treatment Group (NCCTG)
- **Cancer Therapy Evaluation Program (CTEP) :** A program to improve the lives of cancer patients by finding better ways to treat, control and cure cancer, by funding an extensive national program of cancer research and by sponsoring clinical trials to evaluate new anti-cancer agents, with a particular emphasis on translational research to elucidate molecular targets and mechanisms of drug effects.
- **Cancer Trials Support Unit (CTSU):** An integral support system for NCI cancer clinical trials
- **Clinical Research Coordinator (CRC):** Clinical Trials staff responsible for oversight and coordination of assigned protocols, as well as NCTN regulatory requirements.
- **Clinical Trials Office (CTO):** Centralized clinical trials staff, responsible for the conduct and support of SLUHN clinical trial functions
- **Collaborative Institutional Training Initiative (CITI)**: Web-based Training Program providing ethics education to all members of the research community.
- **Curriculum Vitae (CV):** A detailed description of your work experience, educational background and skills, it is more detailed than a resume
- **Eastern Cooperative Oncology Group (ECOG):** One of the largest clinical cancer research organizations in the United States that conducts clinical trials in all types of adult cancers, which is now considered a legacy group with the NCTN through the NCI after the group merged into ECOG-ACRIN.
- **ECOG-ACRIN Cancer Research Group:** Part of the National Clinical Trials Network (NCTN) sponsored by the National Cancer Institute (NCI) through the merger of the Eastern Cooperative Oncology Group (ECOG) and American College of Radiology Imaging Network (ACRIN)
- **Financial Conflict of Interest (FCOI):** Significant Financial Interest of an Investigator that could directly and significantly affect the design, conduct, or reporting of Research
- **Financial Disclosure Form (FDF):** A document giving financial details about a person or company
- **Good Clinical Practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials or studies

- **Gynecologic Oncology Group (GOG):** One of the National Cancer Institute's (NCI) funded cooperative cancer research groups which serves as the only group focusing its research on women with pelvic malignancies, such as cancer of the ovary, uterus, and cervix. GOG is now considered a legacy group with the NCTN through the NCI after the group merged into NRG.
- **Institutional Review Board (IRB):** Independent ethics committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects
- **Medical License (ML):** A legal document for a person who is legally qualified to practice medicine; doctor of medicine.
- **National Cancer Institute (NCI):** The National Cancer Institute coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.
- **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.
- **NRG Oncology -** Part of the National Clinical Trials Network (NCTN) sponsored by the National Cancer Institute (NCI) through the merger of the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Radiation Therapy Oncology Group (RTOG), and the Gynecologic Oncology Group (GOG)
- **Pharmaceutical Management Branch (PMB):** Provides pharmaceutical support for clinical trials sponsored by CTEP. Collects and maintains registration documentation for all investigators participating in CTEP clinical trials.
- **Principal Investigator (PI):** Lead investigator responsible for the sound conduct of the project in accordance with the protocol and regulations
- **Radiation Therapy Oncology Group (RTOG):** A national clinical cooperative group funded by the National Cancer Institute (NCI) to increase the survival and improve the quality of life of patients diagnosed with cancer. The primary areas of research for RTOG investigators are: brain tumors, head and neck cancer, lung cancer, cancers of the gastrointestinal system, genitourinary tract cancers, sarcomas, gynecologic cancer (cervix) and breast cancer. RTOG is now considered a legacy group with the NCTN through the NCI after the group merged into NRG.
- **Supplemental Investigator Data Form (SIDF):** A form used to identify qualified investigators and associates to participate in clinical investigation at the NCI and to

ensure the investigational agents are under the control and accounted for by competent authority

- **St. Luke's University Health Network (SLUHN)**
- **Standard Operating Procedure (SOP):** Established procedures to be followed in carrying out a given operation or in a given situation
- **Sub Investigator (Sub-I):** A member of the study team who assists the investigator with the study and can make decisions about the clinical research.

SCOPE:

This SOP applies to all St. Luke's University Health Network physicians participating in clinical research supported by the CTO.

This policy describes the process:

- Starting when an investigator joins clinical research at St. Luke's University Health Network
- Continues as the Investigator remains actively involved within clinical research

This policy is applicable to the following studies:

- Investigators/key personnel utilizing the CTO for support of clinical trials that require IRB approval, including investigator initiated, NCTN, and industry or government sponsored protocols

PERSONNEL RESPONSIBLE:

This SOP applies to those members of the clinical research team involved in the timely completion of requirements for participation in clinical trials. This includes the following:

- Clinical Research Assistant
- Clinical Trials Manager
- Regulatory Coordinator
- Director of Clinical Trials
- Investigator/Key Personnel
- Institutional Review Board (IRB)
- Study Start-Up Project Coordinator

ROLES:

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

- **Clinical Research Assistant:** The Clinical Trials Research Assistant shall assist in the maintenance of updating CV's, Medical licenses, and Laboratory Certificates, as well as CITI training. These shall be maintained on the Common Drive, as well as in hard copy format in a centralized binder.

- **Clinical Trials Manager:** The Clinical Trials Manager shall serve as the primary liaison between the Physicians, Regulatory Coordinator, and the Study Start-Up Project Coordinator, and shall be responsible for ensuring timely completion of required items from investigators, and obtaining required signatures as needed.
- **Regulatory Coordinator:** The CTO Regulatory Coordinator or designee shall be responsible for supplying new Investigators interested in participating in research with all requirements outlined in this procedure along with instructions for completion; respond to questions and offer guidance as needed; collect information and documents pertaining to all outlined requirements and keep on file in CTO; facilitate collection and dissemination of documents needed to complete NCI Investigator registration; maintain a tracking system of requirements and expiration dates; and escalate non-compliance to the Clinical Trials Manager and the Director of Clinical Trials.
- **Director of Clinical Trials:** The Director or designee, along with the IRB, shall be responsible for ensuring compliance with all aspects of this policy
- **Institutional Review Board (IRB):** The IRB shall be responsible for ensuring that protocols are not approved unless all requirements of this policy are met.
- **Study Start-Up Project Coordinator:** The Study Start-Up Project Coordinator shall be responsible for ensuring all investigators listed on new protocols are compliant with requirements prior to inclusion on any new protocols being submitted to the IRB, and escalate noncompliance to the Clinical Trials Manager, Director of Clinical Trials, and the Regulatory Coordinator prior to study start up.

PROCEDURES:

REQUIREMENTS FOR COMPLIANCE

Role	Step	Activity
Investigator/Key Personnel	1.0	Complete and provide the following to the CTO: • CITI training (GCP Module) • FCOI (Disclosure and Training) • Up-to-date, signed and dated, CV (within 2 years) • Current Medical License (Not applicable to Key Personnel)

NEW PROTOCOL SUBMISSION

Role	Step	Activity
Clinical Trials Manager	2.0	Identify investigators and Key Personnel on the New Study Feasibility Checklist ***(please refer to the Study Start-up SOP #200)***.
Study Start-up Coordinator	2.1	Send links and instructions to investigators for: • CITI training (GCP Module) • FCOI (Disclosure and Training) ***See ATTACHMENTS A through C*** **NOTE:** Follow up will be done weekly to ensure compliance. PI must be compliant or the study will not be submitted to IRB. If a Sub-I is noncompliant he/she will not be included on the protocol
Investigator/Key Personnel	2.2	Provide CTO with the following • Documentation of CITI training (GCP Module) • Completed FCOI disclosure form and Training documentation • Copy of current CV, signed and hand dated within 2 years. • Copy of current Medical License (Not applicable to Key Personnel)
Study Start-up Coordinator	2.3	Provide all documents to the CTO Clinical Research Assistant within 48 hours of receipt
Clinical Research Assistant	2.4	Upload all documents, with the exception of the FCOI (Disclosure and Training), to the common drive, update the appropriate tracking log, send a copy of the FCOI documents and the CITI training to the IRB, and file a hard copy in the appropriate centralized binder, as required. **NOTE:** • Each Physician will have a file folder within the common drive with their documents enclosed • CV's expire every two years and will need to be updated, hand dated and

		signed every 2 years • Medical license expiration dates will be monitored • FCOI Disclosure must be renewed every year or upon any change in Financial Conflicts of Interest • Financial Conflict of Interest training must be completed every 4 years • CITI GCP training must be completed every 4 years
Not Applicable	---	**NOTE:** Specific steps for IRB submission are not outlined in this SOP ***(See SOP #204)***

ADDING NEW INVESTIGATORS/KEY PERSONNEL ON EXISTING PROTOCOLS

Role	Step	Activity
Clinical Trials Manager or designee	3.0	Inform Regulatory Coordinator or designee of any investigators needing to be added onto existing protocols
Regulatory Coordinator or designee	3.1	Review tracking logs and folders in the common drive for any outstanding items as outlined in this SOP **NOTE:** If any items are not completed or up-to-date, please repeat Steps 2.1 through 2.4
Not Applicable	---	**NOTE:** Specific steps for IRB submission are not outlined in this SOP ***(See SOP #204)***

REMOVING INVESTIGATORS/KEY PERSONNEL FROM EXISTING PROTOCOLS

Role	Step	Activity
Clinical Trials Manager or designee	3.0	Inform Regulatory Coordinator or designee of any investigators/key personnel needing to be removed from existing protocols
Regulatory Coordinator or designee	3.1	Remove investigators/key personnel from all regulatory documents and notify the IRB
Not Applicable	---	**NOTE:** Specific steps for IRB submission are not outlined in this SOP ***(See SOP #204)***

NCTN NCI REGISTRATION (ONCOLOGY ONLY)

Role	Step	Activity
Regulatory Coordinator	4.0	Facilitate NCI Investigator Registration • Populate required documents for NCI Investigator registration(1572, Financial Disclosure, and SIDF) • Send to Investigator for review and signature
Regulatory Coordinator	4.1	Submit required documents (1572, Financial Disclosure, and SIDF) to CTEP PMB and request to be the designated Registration Coordinator for the Investigator
Regulatory Coordinator	4.2	Contact CTEP PMB within 5 working days to assure NCI Registration has been processed and obtain Investigator NCI number; **NOTE:** Provide the Investigator and any appropriate CTO staff with the assigned Investigator NCI number
Regulatory Coordinator	4.3	Determine the appropriate information needed to register investigators on NCTN rosters.
Regulatory Coordinator	4.4	Add Investigator to NCTN roster as applicable and submit applicable training and appropriate paperwork
Regulatory Coordinator	4.5	Provide Investigational Pharmacist with all NCTN Roster Registration information. **NOTE:** The Investigational Pharmacist maintains a list of all NCI registered investigators and their expiration dates

INVESTIGATOR/KEY PERSONNEL COMPLIANCE MAINTENANCE

Role	Step	Activity
Regulatory Coordinator or designee	5.0	Review the ML/CV tracking logs and NCI Investigator Registration tracking log monthly for any outstanding items for all investigators and key personnel
Clinical Trials Manager	5.1	Review the FCOI and CITI tracking log monthly for any outstanding items for all investigators and key personnel.
Clinical Trials Manager and Regulatory Coordinator	5.2	Email investigators/key personnel at least one month prior to any regulatory requirement

		expiration with instructions for completion, and provide a deadline of 10 business days.
Investigator/Key Personnel	5.3	Complete the required task and send the Regulatory Coordinator or Clinical Trials Manager all necessary documentation ***(see Step 2.2)***. **NOTE:** If updated NCI registration was requested, the Regulatory Coordinator will submit the required NCI registration documents to the NCI on the investigator's behalf ***(see Steps 4.0 through 4.5)***
Regulatory Coordinator or designee	5.4	Follow-up with Investigator/Key Personnel if request from Step 5.1 is not completed within 10 business days. **NOTE:** Once outstanding documents are received, repeat Steps 2.3 and 2.4)

RESOURCES:
N/A

Endorsed by: SOP Committee (12/20/13; 3/21/14; 4/17/15; 4/8/16)
Approved by: Tracy Butryn, Director of Clinical Trials (12/30/13; 5/21/14; 4/17/15; 7/12/16)

ATTACHMENT A

Email Template Example:

Hello,

In order to participate in clinical trials at SLUHN, we will need the following items at your earliest convenience:

1) Signed and boxes ticked COI form (attached) – Leave Study Protocol box blank since this form is not study-specific

2) NIH COI tutorial – please print certificate on last page of PowerPoint http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

3) Good Clinical Practice (GCP) course through CITI: www.citiprogram.org
   a. If you have never done this course before, please register and enter St. Luke's information. You are only required to do the GCP module. If another module populates, please only do the GCP course, course #2.
   b. Please print your certificate. This takes under 1 hour and is good for 4 years.

4) A copy of your CV, signed and dated

Please provide me with all requested documents by email or interoffice mail. I am happy to offer any assistance that you may need.

BELOW SECTION ONLY APPLICABLE TO ONCOLOGY INVESTOGATORS

******NCI Investigator Registration (Oncology Trials Only)******

In order to enroll patients on CTEP-sponsored clinical trials, an Investigator must be NCI-registered with an "active" investigator status. Investigators must re-register annually. The CTO will facilitate the registration process on your behalf.

Documents required to be completed and sent to the CTO:

- Signed and dated Form FDA1572
- Signed and dated NCI Financial Disclosure form
- Signed and dated Supplemental Data form
- Current CV signed and dated
- Copy of current medical license

The CTO will facilitate this process by populating all required documents and, after obtaining signature, will send to PMB on the Investigator's behalf.

When an NCI # is obtained, the Investigator will be notified.

The CTO will then be designated as the "registration coordinator" and will coordinate the re-registration process annually 60 days prior to expiration.

******NCI NCTN Roster Registration (Oncology Trials Only)******

In addition to registering with the NCI, investigators must also register with the individual NCTN groups for which protocols they will participate. Investigators who are already registered with the NCTN Groups listed below will only require a roster update in order to change their practicing facility. Below is a list of requirements for each NCTN Group which we are members.

NOTE: This process will be facilitated by the CTO

ECOG-ACRIN Cancer Research Group (ECOG-ACRIN):

- Copy of CITI human subject training (Alliance Rosters Only)
- NCI investigator #
- Roster Update Form

NRG:

- NCI investigator #
- Roster Update Form

ATTACHMENT B (page 1 of 6)

St. Luke's University Health Network
INVESTIGATOR or IRB MEMBER CONFLICT OF INTERESTS DISCLOSURE STATEMENT

To be completed by all Investigators, Investigator's Staff and IRB members as defined in St. Luke's Policy- Investigator Conflicts of Interest in Clinical Research

Investigator's Name	
Study Protocol(s)	

This statement is to be completed in connection with the St. Luke's University Health Network (St. Luke's) policy Investigator Conflicts of Interest in Clinical Research, which is available on the http://www.medaffairs.slhn.org/manny/irb/coi.htm website. This statement is to be completed by Investigators and IRB members for themselves and on behalf of your Immediate Family (spouse and dependent children). Complete your answers based on the time frames indicated below. St. Luke's and its agents intend to treat, as confidential, all information disclosed in this Statement, to use such disclosure to meet the requirements under 21 CFR Part 54 and 42 CFR Part 50, and to disclose such information to the extent required by applicable law.

Definitions of key terms are found at the end of this statement and in Policy Investigator Conflicts of Interest in Clinical Research. Your disclosure of a Significant Financial Interest does not automatically imply that the interest is improper or impermissible. However, failure to report a Significant Financial Interest or furnishing false, misleading or incomplete information may constitute professional misconduct and be cause for disciplinary action or other action as set forth in the Policy.

Return the completed form to the IRB Vice Chairman at St. Luke's University and Health Network (Attn: Medical Affairs Department), 801 Ostrum Street, Bethlehem, PA 18015. You may call the IRB Vice Chairman with any questions at (484) 526-4669.

Reason for Disclosure:

☐ Annual Disclosure

☐ Change in Significant Financial Interest

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Indicate by marking YES or NO if you, your spouse or your dependent children have any of the following Significant Financial Interests with an individual or entity sponsoring, conducting or seeking to engage in a Clinical Study at an St. Luke's Research Site that reasonably appears to be related to the your Institutional Responsibilities and (i) for Public Health Service ("PHS") funded research is conveyed during the one (1) year period prior to the date of this disclosure, or (ii) for Food and Drug Administration ("FDA") regulated research is conveyed during the course of the Clinical Study and for one (1) year after completion of the Clinical Study: (Note: Income from investment vehicles, such as mutual funds and retirement accounts, does not need to be disclosed as long as the Investigator does not directly control the investment decisions made in these vehicles)

YES	NO	
☐	☐	**Publicly traded entity, PHS funded research:** Have you or your Immediate Family received any remuneration in the one (1) year period prior to the date of this disclosure from a publicly traded entity, and do you or your Immediate Family have any equity interest in the publicly traded entity as of the date of this disclosure that, when aggregated with any remuneration, exceeds $5,000 in value? For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
YES	NO	
☐	☐	**Publicly traded entity, FDA regulated research:** For FDA regulated research, do you or your Immediate Family hold any equity interest in a publicly traded entity during the time of carrying out the Clinical Study that exceeds $50,000 in value, or do you anticipate you or your Immediate Family will hold any equity interest in a publicly traded entity during the one (1) year period following completion of the Clinical Study that exceeds $50,000 in value? Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
YES	NO	
☐	☐	**Non-publicly traded entity, PHS funded research:** Have you or your Immediate Family received any remuneration from a non-publicly traded entity in the one (1) year period prior to the date of this disclosure that, when aggregated, exceeds $5,000, *or* do you or your Immediate Family hold any equity interest in the non-publicly traded entity (e.g., stock, stock option, or other ownership interest)?
YES	NO	
☐	☐	**Non-publicly traded entity, FDA regulated research:** Do you or your Immediate Family hold any equity interest in the sponsor of a Clinical Study (i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices) during the time of carrying out the Clinical Study or do you anticipate that you or your Immediate Family will hold such an interest during the one (1) year period following the completion of the Clinical Study?
YES	NO	
☐	☐	**For PHS funded and/or FDA regulated research:** Have you been reimbursed for any travel or sponsored for any travel involving you or your Immediate Family? Sponsored travel is any travel that is paid on your behalf or on behalf of your Immediate Family and not reimbursed so that the exact monetary value may not be readily available. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a government agency, institution of higher education, academic teaching hospital, medical center or research institute affiliated with an institution of higher education. The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and monetary value, if known. The Institution's RIO or Clinical Research Integrity Committee will determine if further information is needed in order to determine whether the travel constitutes a Financial Conflict of Interest.
YES	NO	
☐	☐	**For PHS funded and/or FDA regulated research:** Do you or your Immediate Family have any intellectual property or other proprietary rights and interests (e.g. patents, copyrights, royalties, or licensing agreement) in the item being studied or tested, and/or any receipt of income related to such rights or interest?

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YES	NO	
☐	☐	**For PHS funded and/or FDA regulated research:** Have you or your Immediate Family received any compensation or remuneration in which the value of the compensation or remuneration could be affected by the Clinical Study outcome?

For those statements checked YES, please attach details of the terms and conditions of the Significant Financial Interest, specifically describing all financial terms. In addition, please state whether you believe that the Clinical Study results may be biased as a result of the disclosed Significant Financial Interest, and if so, provide a description of steps you intend to take or have taken to minimize the potential for such bias.

CERTIFICATION

I certify that I have read St. Luke's Policy IRB member Conflicts of Interest in Clinical Research. In accordance with 21 CFR parts 54.1 to 54.6, I certify that the information provided on this form is, to the best of my knowledge and belief, true, correct and complete. Furthermore, if Significant Financial Interests or those of my spouse or dependent children change from the information provided above during the course of a Clinical Study or within one year of Clinical Study completion, I will notify the St. Luke's Research Integrity Officer. I agree to comply with any conditions or restrictions imposed by St. Luke have to manage, reduce or eliminate actual or potential Conflicts of Interest.

Signature: _____

Print Name: _____

Date: _____

Received by Research Integrity Officer or designee:

Signature: _____

Date: _____

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Definitions of Key Terms:

A. **Clinical Study** means Clinical Research being conducted or intending to be conducted at a Research Site.

B. **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.

C. **Financial Conflict of Interest (FCOI)** means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of Clinical Research.

D. **Immediate Family:** the spouse and dependent children of an Investigator.

E. **Institution** means St. Luke's and its affiliates that is applying for or that receives, PHS research funding.

F. **Investigator** means the project director, Principal Investigator or sub-investigator, Senior/Key Personnel, Clinical Study coordinators, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of Clinical Research, which may include, for example, collaborators or consultants. "Investigator" also includes Subrecipient Investigators, who are those individuals or companies that St. Luke's may contract with to carry out a Clinical Study.

G. **PHS Funded Research** means research that is funded by the Public Health Service ("PHS") of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health ("NIH").

H. **Research Site** means the facility or site engaged in Clinical Research that is (i) under the jurisdiction of the St. Luke's IRB; or (ii) contractually or otherwise affiliated with St. Luke's for the purpose of engaging in Clinical Research, including subcontractors or Subrecipients.

I. **Senior/Key personnel** means Investigators and any other person(s) identified by the Institution as Senior/Key personnel who are essential to the performance of the research project in the grant application, progress report or any other report submitted to the PHS or FDA.

J. **Significant Financial Interest** that is required to be disclosed means:

   A. A financial interest of one or more of the following interests of an Investigator ***(and those of the Investigator's Immediate Family)*** that is with an individual or entity sponsoring, conducting or seeking to engage in a Clinical Study at an St. Luke's Research Site; reasonably appears to be related to the Investigator's Institutional Responsibilities; and (i) for PHS funded research is conveyed in the one year prior to the disclosure required under this policy, or (ii) for FDA regulated research is conveyed during the course of the Clinical Study and for one year after completion of the Clinical Study:

      1. Publicly traded entity:

         a) For PHS funded research, a disclosure of Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds $5,000 in value. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

         b) For FDA regulated research, a disclosure of Significant Financial Interest exists if the value of any equity interest in the entity during the time of carrying out the Clinical Study and for one year following completion of the Clinical Study exceeds $50,000 in value. Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

      2. Non-publicly traded entity:

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a) For PHS funded research, a disclosure of Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator or Investigator's immediate family holds any equity interest in the entity (e.g., stock, stock option, or other ownership interest) or intellectual property rights and interests (e.g., patents, copy rights) upon receipt of income related to such rights and interests; and

b) For FDA regulated research, a disclosure of Significant Financial Interest exists if the Investigator holds any equity interest in the sponsor of a Clinical Study (i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices) during the time of carrying out the Clinical Study and for one (1) year following completion of the Clinical Study.

3. For PHS funded and FDA regulated research, Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available); provided, however, this disclosure requirement does not apply to travel that is reimbursed or sponsored by a government agency, institution of higher education, academic teaching hospital, medical center or research institute affiliated with an institution of higher education. The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institution's RIO and Clinical Research Integrity Committee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI.
4. For PHS funded and FDA regulated research, a disclosure of Significant Financial Interest consists of intellectual property or other proprietary rights and interests (e.g. patents, copyrights, royalties, or licensing agreement) in the item being studied or tested, and any receipt of income related to such rights or interest.
5. For PHS funded and FDA regulated research, a disclosure of Significant Financial Interest consists of any compensation or remuneration made to the Investigator in which the value of the compensation or remuneration could be affected by the Clinical Study outcome.

B. A Significant Financial Interest does not include the following interests, which are not required to be disclosed:
1. Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
2. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
3. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
4. Income from seminars, lectures, or teaching engagements sponsored by a government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
5. Income from service on advisory committees or review panels for a government

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agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

K. **Sponsor** means any person or entity that initiates, funds, or otherwise supports the Clinical Research, including the PHS, or an owner, patent-holder, license holder or other controller of the drug, device, biologic or treatment that is the subject of the Clinical Study.

L. **Subrecipient or Subrecipient Investigators** means entities or individuals that St. Luke's contracts with to carry out Clinical Study activities.

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ATTACHMENT C

St Luke's
UNIVERSITY HEALTH NETWORK

Institutional Review Board

The **Collaborative Institutional Training Initiative (CITI)** Web-based Training Program is a subscription service providing ethics education to all members of the research community. To participate fully, learners must be affiliated with a CITI participating organization.

The following are basic learner instructions to logon to St. Luke's University Health Network IRB's CITI site. This will allow you to access/download aggregate training data for all St. Luke's University Health Network IRB learners.

- Go to www.citiprogram.org
- Once there, click on the tab labeled New Users "Register Here"
- On the "Select your institution or organization" page, select "St. Luke's University Health Network" in the "Participating Institutions" drop down box.
- Proceed to create a username and password
- On the next screen add name and email, this will be followed by another page with further biographical information. Under the drop down menu for "Which course do you plan to take" on this page, choose Biomedical Investigator Course Only

To Start the Course:

1. You will be presented with a series of questions or options to enroll in the **Learner Group** appropriate to your interests or role in human subject research. **To skip an optional section, leave its question blank**: (see chart below for requirements and answer choices)

	Clinical Researchers, PI's, Co-Investigators,	IRB Members	Study Nurses, Site Coordinators, Study Coordinator, Research Assistants, Data Managers	Data Researchers Only (Conducting Retrospecitive Chart Review or QI Studies)
Question 1 (Basic Curriculum)	Required for Non-Multicenter Trials (Group 1)	Required (Group 4)	Required for Non-Multicenter Trials (Group 1)	Required (Group 3)
Question 2 (GCP Curriculum)	Required	Optional	Required	Optional
Question 3 (HIPS Curriculum)	Optional	Optional	Optional	Optional
Question 4 (RCR Curriculum)	Optional	Optional	Optional	Optional

2. After you submit, you will be given the opportunity to affiliate with a VA Medical Center. If you are not doing work at a VA Medical center, answer **NO** and **Submit**.

3. The next page is the **Learner Menu**. This page lists the courses you have chosen. The Learner menu also provides a number of **Course Utilities** designed to help you.
   * You may affiliate with another institution. The software will sum up the requirements of both institutions so that you need not retake modules common to the requirements of both institutions.

* You may **View/Update your Learner Group** This link will take you to the enrollment questions and permit you to change your **Learner Group** by providing new responses to the enrollment questions.

4. The link to the **Grade Book** will permit you to **Begin the Course.**
5. Complete the required modules and associated quizzes.
6. Complete any **Elective** modules of your choosing. Take note of the electives entitled **"Vulnerable Subjects – Research with Minors"**, **"Vulnerable Subjects – Research Involving Prisoners"**, and **"Vulnerable Subjects – Research Involving Pregnant Women and Fetuses in Utero"** as these will be required for research involving these groups.
7. When you complete all Required Modules in your curriculum, you will be shown a link to **Review Completed and Optional Modules** in the Optional Course Catalog. You may return to the course site at a future time to review these modules.
8. When you complete all required modules successfully, you will be shown a link to **View course completion history and print completion certificates.** The Basic Course will require 4-6 hours to complete. You are encouraged to use multiple log on sessions.

To Complete the Course:

* The minimum passing aggregate score for the quizzes is 80%. A running tally is compiled in the Grade Book. If you want to improve a score on a quiz, you may repeat any quiz in which you didn't score 100 % correct.
* Print or download a **Course Completion Report** as evidence that you have met your institutional requirements. A copy will be sent to your institutional administrator. You may return to the course site in the future to obtain a copy of the completion report.
* Submit a voluntary, anonymous user satisfaction survey.

Questions:

- Questions regarding your requirements should be addressed to Manny Changalis in the Medical Affairs Office 484-526-4669.
- Technical issues should be addressed to citisupport@med.miami.edu or to 305 243-7970.