PURPOSE: To outline the activities required to complete all study start-up essential regulatory documents and initial IRB submission. Streamlined study start-up coordination through a centralized resource is necessary to ensure quick timelines and compliance with all internal and external requirements.

NOTE: Some steps will be described in a separate corresponding SOP in greater detail. ***Please refer to the SOP 200: Study Start Up.*** This SOP outlines the general process of completing pertinent regulatory documents and initial study submission to the IRB.

DEFINITIONS/ABBREVIATIONS:

- **Central Institutional Review Board (CIRB):** The CIRB Initiative is a partnership between the NCI CIRB and local institutions based on the signed Authorization Agreement and Division of Responsibilities document. The CIRB conducts all IRB reviews of selected NCI-sponsored trials.
- **Clinical Laboratory Improvement Amendments (CLIA):** Responsible for the regulations of laboratory testing and require clinical laboratories to be certificated by their state as well as the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing.
- **Clinical Research Nurse/Coordinator (CRC):** Clinical Trials staff responsible for oversight and coordination of assigned protocols
- **Clinical Research Organization (CRO):** An organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.
- **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 and Good Clinical Practice (GCP) education to all members of the research community.
- **College of American Pathologist (CAP):** The world's largest association responsible for the inspection and accreditation of medical laboratories under deemed authority of the Centers for Medicare & Medicaid Services (CMS), with a goal to improve patient safety by advancing the quality of pathology and laboratory services through education, standard setting, and ensuring laboratories meet or exceed regulatory requirements.
- **Curriculum Vitae (CV):** A document that overviews one's education, experience, training, and qualifications.
- **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.

- **Delegation of Authority Log (DOAL):** Detailed, written form that outlines what individuals are responsible and able to perform study-related tasks and procedures as authorized by the principal investigator.
- **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 form that discloses an absence or presence of financial interest or arrangement that an individual may have that could affect the reliability of data submitted to FDA.
- **Food and Drug Administration (FDA):** Agency of the United States Department of Health and Human Services (DHHS), responsible for the regulation of clinical trials.
- **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.
- **International Air Transport Association (IATA):** The governing body that creates regulation for international air transport, including regulations controlling the transport of Dangerous Goods By Air
- **Investigational New Drug Safety Reports (INDSRs):** Sponsor notifications to the FDA and all participating investigators of potential serious risks, from clinical trials or any other source. In each INDSR, the sponsor must identify all INDSRs previously submitted to FDA concerning a similar suspected adverse reaction, and must analyze the significance of the suspected adverse reaction in light of previous, similar reports or any other relevant information.
- **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
- **Pharmaceutical Management Branch (PMB):** Provides pharmaceutical support for clinical trials sponsored by the National Cancer Institute's (NCI) Cancer Therapy Evaluation Program (CTEP).
- **Principal Investigator (PI):** Lead investigator, responsible for the sound conduct of the project in accordance with the protocol and regulations.
- **Regulatory Coordinator (RC):** Clinical Trials staff responsible for the regulatory functions and oversight of clinical trials
- **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

- **Site Initiation Visit (SIV):** A visit that occurs prior to site activation for a specific protocol that is used to orient and train staff on the protocol and study related processes; to confirm readiness for study implementation; and to identify additional requirements that must be satisfied prior to site activation and subject recruitment.
- **Standard Operating Procedures (SOPs):** Detailed, written instructions to achieve uniformity of the performance of a specific function.
- **St. Luke's University Health Network (SLUHN)**
- **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 clinical research site personnel involved in the conduct of clinical research run through the centralized CTO.

This policy describes the process:

- Starting with the receipt of new study regulatory documents
- Ending with the initial IRB submission

This policy is applicable to:

- Industry Funded clinical trials
- NCTN clinical trials
- Government funded clinical trials

PERSONNEL RESPONSIBLE:

This SOP applies to those members of the clinical research team involved in facilitating any of the study start-up activities necessary to activate a new trial. This includes the following:

- Clinical Trials Administrative Assistant
- Clinical Trials Manager
- Clinical Research Nurse/Coordinator
- Principal Investigator
- Regulatory Coordinator
- Study Start-Up Project 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 out new study protocol training and completing the documentation of training.

Clinical Trials Administrative Assistant: The Clinical Trials Administrative Assistant shall be responsible for the uploading and maintaining CITI Training, CV's and Medical Licenses in the I Drive.

Clinical Trials Manager: The Clinical Trials Manager or designee shall serve as the primary liaison between the physicians, study staff, and Study Start-up Project Coordinator, and shall be responsible for ensuring timely completion of all pertinent clinical study start-up documents.

Principal Investigator (PI): Lead investigator, shall be responsible for completion and maintaining all required credentialing and signing off on necessary documents, as well as overall study conduct.

Regulatory Coordinator (RC): The RC shall be responsible for Completion of the NCTN Investigators NCI Registration and preparing all regulatory documents for making the Initial IRB Submission for NCTN trials.

Study Start-Up Project Coordinator: The Study Start-Up Project Coordinator shall be responsible for coordinating all study start-up activities and ensuring timely throughput time from initial sponsor contact, through protocol inception to study activation, serving as the primary liaison between the sponsor, PI, and study team, responsible for the timely completion of regulatory documents and Initial IRB submission.

PROCEDURES:

FDA Form 1572, FDF, DOAL

- The Study Start-Up Project Coordinator shall be responsible for completing the required documents, obtaining signatures, saving an electronic working copy in the pertinent folder in the I-Drive, and filing the signed original or copied documents in regulatory binder. The Study Start-Up Project Coordinator emails copies of the signed, completed documents to the study sponsor.

Documentation of Training

- The Manager/ Study Start-Up Project Coordinator shall complete the SIV training log.
- The CRC shall send an email blast ***(see Attachment E)*** including all training documents to all study personnel whom were unable to attend SIV, and complete the documentation of training memo.

- Once PI signature is obtained, the CRC shall give the Study Start-Up Project Coordinator/RC the original documents to be filed in the regulatory binder

CV's and Medical Licenses

- The Study Start-Up Project Coordinator or Clinical Trials Manager shall request CV's and Medical Licenses if not already on file in I-drive or expired
- The Administrative Assistant shall scan and upload a copy of the CV and Medical License to the I-Drive in their respective folders.
- The Study Start-Up Project Coordinator shall file a hard copy of the CV and Medical License in the appropriate binder.

Lab Documents

- The Study Start-Up Project Coordinator shall request Lab Documents, including CLIA, CAP, Laboratory Permit, and Laboratory Reference Ranges, if not already on file in I-drive or expired
- The Administrative Assistant shall scan and upload all required lab documents to the I-Drive in their respective folders.

Protocol & IB Signature Pages

- The Study Start-Up Project Coordinator shall be responsible for obtaining signatures on these documents, checking for accuracy, and filing the signed original or copied documents in regulatory binder.

Initial IRB Submission

- The Study Start-Up Project Coordinator/RC shall be responsible for completing the required documents for IRB submission and notifying the necessary staff of a new submission upload in DDOTS.

FDA FORM 1572

Role	Step	Activity
Study Start-Up Project Coordinator	1.0	Receive a 1572 template from the sponsor to complete for each new study, if applicable (***see Attachment A***). The 1572 contains the following sections: • Section 1- Name and Address of Investigator • Section 2- Education, training, and experience that qualify the Investigator as an expert in the clinical investigation **NOTE:** The CV option is always checked. Please refer

		to the CV's and Medical Licenses section of this SOP for specific detail/requirements on these documents. • Section 3- Name and address of any medical school, hospital, or other research facility where the clinical investigation(s) will be conducted • Section 4- Name and address of clinical laboratory facilities to be used in this study **NOTE:** Only list locations and their corresponding laboratory for which the research activities will take place under the above mentioned sections (***see Attachment B for SLUHN Affiliation***). • Section 5- Name and address of the Institutional Review Board (IRB) responsible for the review and approval of the study • Section 6- Names of the Sub-I's who will be assisting the investigator in the conduct of the investigation **NOTE:** SLUHN does not list RN's, pharmacy or support staff under the above mentioned section. • Section 7- Name and code number, if any, of the protocol in the IND for study to be conducted by the investigator • Section 8- Clinical protocol information **NOTE:** Review any prepopulated sections completed by Sponsor for accuracy, and revise as necessary.
Study Start-Up Project Coordinator	1.1	Obtain PI's signature and date on the 1572.
Study Start-Up Project Coordinator	1.2	Check for accuracy of the completed document, upload an electronic working copy with information included for each section, and save in the pertinent folder in the I-Drive, and file the signed original or copied document in regulatory binder. Email a copy to study sponsor.

FINANCIAL DISCLOSURE FORM

Role	Step	Activity
Study Start-Up Project Coordinator	2.0	Receive an FDF template from the sponsor to complete for each new study. **NOTE:** An FDF should be completed for the PI and all Sub-I's (e.g. all those listed in Section 6 of the FDA Form 1572).
Study Start-Up Project Coordinator	2.1	Obtain signatures for all completed FDF's.
Study Start-Up Project Coordinator	2.2	Check for accuracy of the completed documents, upload an electronic working copy with completed information included for each investigator, and save in the pertinent folder in the I-Drive, and file the original or copied documents in regulatory binder. Email copies to the study sponsor.

DELEGATION OF AUTHORITY LOG

Role	Step	Activity
Study Start-Up Project Coordinator	3.0	Complete a DOAL for all investigators (PI and Sub-Is), Key Personnel, Investigational Pharmacist, etc. as listed on the New Study Feasibility Checklist (***see Attachment C***). **NOTE:** SLUHN uses an internal DOAL (***see Attachment D***)
Study Start-Up Project Coordinator	3.1	Obtain signatures for all completed DOAL's.
Study Start-Up Project Coordinator	3.2	Check for accuracy of the completed documents, upload an electronic working copy with all completed information included for each research staff, and save in the pertinent folder in the I-Drive, and file the signed original documents in regulatory binder. Email copies to study sponsor.

DOCUMENTATION OF TRAINING

Role	Step	Activity
Manager or Study Start-Up Project Coordinator	4.0	Complete the SIV Training Log with those personnel that attended the SIV.

CRC or designee	4.1	Send an email blast containing all pertinent training documents (***see Attachment E***) to all study personnel whom were unable to attend SIV.
CRC or designee	4.2	Complete the Documentation of Training Memo (***see Attachment F***).
CRC or designee	4.3	Obtain PI signature on Documentation of Training Memo.
CRC or designee	4.4	Give the completed memo to the Study Start-Up Project Coordinator.
Study Start-Up Project Coordinator	4.5	Check for accuracy of the completed document and file original document in regulatory binder.

CV'S AND MEDICAL LICENSES

Role	Step	Activity
Study Start-Up Project Coordinator or designee	5.0	Request medical license and signed/dated CV, if not already on file in I-drive or expired. **NOTE:** CV's must be updated and signed every 2 years. **NOTE:** If Sponsor requires abbreviated CV, Sponsor shall be responsible for completing template based on full CVs provided by site; if Sponsor does not agree, a fee shall be charged for the time and effort of completing sponsor required document.
Clinical Trials Administrative Assistant	5.1	Upload original/updated document onto the I-Drive in pertinent staff folder.
Study Start-Up Project Coordinator or designee	5.2	File document(s) in master binder.

LAB DOCUMENTS

Role	Step	Activity
Study Start-Up Project Coordinator or designee	6.0	Request lab documents, if not already on file in I-drive or expired. The lab documents consist of: • CAP • CLIA • Clinical Lab Permit • Lab Normal Reference Ranges (LNRRs) • IATA Certificate, if applicable

		NOTE: Lab ranges differ between Cetronia Road and all other locations. Before sending LNRR's to Sponsor, check MyNet for updated version.
Clinical Trials Administrative Assistant	6.1	Upload original/updated document(s) onto the I-Drive. File document(s) in hard copy lab binder.

SIGNATURE PAGES (PROTOCOL AND IB)

Role	Step	Activity
Study Start-Up Project Coordinator	7.0	Receive Protocol/IB Signature page, if applicable, from sponsor.
Study Start-Up Project Coordinator	7.1	Obtain PI's signature and date on the Protocol/IB Signature page.
Study Start-Up Project Coordinator	7.2	Check for accuracy of the completed documents, upload an electronic working copy and save in the pertinent folder in the I-Drive, and file the signed original documents in regulatory binder. Email copies to study sponsor.

INDUSTRY INITIAL IRB SUBMISSSION

Role	Step	Activity
Study Start-Up Project Coordinator	8.0	Complete and/or compile the following documents as required for initial IRB submission: • Initial IRB Application • IRB Policy Acknowledgement Form • ICF(s) in the SLUHN Template(s) • Patient materials, if applicable • Protocol • IB(s), if applicable
Study Start-Up Project Coordinator	8.1	Submit all required documents to the IRB via DDOTS by the 20th of the month prior to the IRB meeting date.
Study Start-Up Project Coordinator	8.2	Submit in DDOTS under the review history page for the appropriate meeting date. The following are options for choosing the Board Review: • Exempt [see Exemption criteria as defined in 45 CFR 46.101(b)]

		• Expedited (e.g. Registry, observational, non-interventional/non-treatment trials that are minimal risk) • Full Board (e.g. Investigational Drug/Device Trials that are greater than minimal risk) **NOTE:** If the research qualifies as exempt, please complete the Request for IRB Exemption ***(see Attachment G),*** and submit any other required documents as outlined on the Request for IRB Exemption Form. **NOTE:** All pertinent information should be typed into the agenda box within DDOTS. This shall include the following: "Please see attachments for full-board/expedited/exempt (choose one) review of new study: (List all documents being submitted with their version number/version date)."
Study Start-Up Project Coordinator	8.3	Notify yourself, CTO Administrative Assistant, CTO Regulatory Coordinator, Medical Director of Research & Innovation and IRB Administrative staff via the DDOTS notification system of the submission.
Study Start-Up Project Coordinator	8.4	Print DDOTS electronic upload notification and file with initial IRB submission documents in the Regulatory Binder.

NCTN CREDENTIALING

Role	Step	Activity
RC	9.0	Download the following documents from the PMB website: • FDA Form 1572 (each PI has their own 1572) • Supplemental Investigator Registration Form (***see Attachment H)*** • Financial Disclosure Form (***see Attachment I)*** • CV & Medical license (on site) • Human Subjects Training (new investigators only) (on site) **NOTE:** Investigators cannot order drug or enroll patients on study without registration approval.

		Registration renewal is required annually.
RC	9.1	Obtain PI signature/date on documents, if applicable, upload an electronic copy within completed information included, save in the pertinent folder in the I-Drive, and send originals to PMB. **NOTE:** Hard copies of the original signed FDA Form 1572, Supplemental Investigator Registration Form, and FDF documents are housed in a master binder.

NCTN DOCUMENTATION OF TRAINING

Role	Step	Activity
Manager or Regulatory Coordinator	10.0	Complete the SIV Training Log with those personnel that attended the SIV.
CRC or designee	10.1	Send an email blast ***(see Attachment E)*** to all study personnel to all study personnel whom were unable to attend SIV.
CRC or designee	10.2	Complete the Documentation of Training Memo ***(see Attachment F)***
CRC or designee	10.3	Obtain PI signature on Documentation of Training Memo
CRC or designee	10.4	Give the completed memo to the Regulatory Coordinator
Regulatory Coordinator	10.5	Check for accuracy of the completed document and file original document in regulatory binder.

NCTN INITIAL IRB SUBMISSSION

Role	Step	Activity
Not Applicable	---	**NOTE:** If a new study is CIRB Approved, please refer to the ***CIRB SOP 205***.
RC	11.0	Complete and/or compile the following documents as required for initial IRB submission: • Initial IRB Application • IRB Policy Acknowledgement Form • ICF(s) in the SLUHN Template(s) • Patient materials, if applicable • Protocol

		• IB(s), if applicable
RC	11.1	Submit all required documents to the IRB via DDOTS by the 20th of the month prior to the IRB meeting date.
RC	11.2	Submit in DDOTS under the review history page for the appropriate meeting date. The following are options for choosing the Board Review: • Expedited (e.g. Registry, observational, non-interventional/non-treatment trials that are minimal risk) • Full Board (e.g. Investigational Drug/Device Trials that are greater than minimal risk) **NOTE:** All pertinent information should be typed into the agenda box in DDOTS. This shall include the following: "Please see attachments for full-board/expedited/exempt (choose one) review of new study: (List all documents being submitted with their version number/version date)."
RC	11.3	Notify yourself, CTO Administrative Assistant, CTO Regulatory Coordinator, IRB Secretary and the , Medical Director of Research & Innovation and IRB Administrative staff via the DDOTS notification system of the submission.
RC	11.4	Print DDOTS electronic upload notification and file with initial IRB submission documents in the Regulatory Binder.

RESOURCES:
N/A

Endorsed by: SOP Committee (8/24/15; 4/8/16)
Approved by: Tracy Butryn, Director of Clinical Trials (9/22/15; 7/12/16)

ATTACHMENT A:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR
(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)
(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: April 30, 2015
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Principal Investigator

Address 1 | Address 2

City | State/Province/Region | Country | ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select one of the following.)*

☐ Curriculum Vitae ☐ Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED — CONTINUATION PAGE for Item 3

Name of Medical School, Hospital, or Other Research Facility

Address 1 | Address 2

City | State/Province/Region | Country | ZIP or Postal Code

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY — CONTINUATION PAGE for Item 4

Name of Clinical Laboratory Facility

Address 1 | Address 2

City | State/Province/Region | Country | ZIP or Postal Code

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES) — CONTINUATION PAGE for Item 5

Name of IRB

Address 1 | Address 2

City | State/Province/Region | Country | ZIP or Postal Code

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

CONTINUATION PAGE – for Item 6

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

FORM FDA 1572 (7/13) PREVIOUS EDITION IS OBSOLETE. Page 1 of 2

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. *(Select one of the following.)*

☐ For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.

☐ For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.
2. Provide curriculum vitae or other statement of qualifications as described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE *(mm/dd/yyyy)*	11. SIGNATURE OF INVESTIGATOR Sign

(**WARNING:** A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.

FORM FDA 1572 (7/13) **PREVIOUS EDITION IS OBSOLETE.** **Page 2 of 2**

ATTACHMENT B:

St Luke's UNIVERSITY HEALTH NETWORK

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

July 6, 2016

Note to File;

This is to clarify site affiliations for the following investigators;

Sanjiv Agarwala, MD
St. Luke's Hospital – Bethlehem Campus, 801 Ostrum Street, Bethlehem, PA 18015
St. Luke's Hospital – Anderson Campus, 1600 St. Luke's Blvd., Easton, PA 18045
St. Luke's Physician Group – Cancer Care Associates, 701 Ostrum Street, Bethlehem, PA 18015
St. Luke's Hospital – Anderson Campus, 1872 St. Luke's Blvd., Easton, PA 18045

Asim Ali, MD
St. Luke's Hospital – Bethlehem Campus, 801 Ostrum Street, Bethlehem, PA 18015
St. Luke's Hospital – Anderson Campus, 1600 St. Luke's Blvd., Easton, PA 18045
St. Luke's Hospital – Anderson Campus, 1872 St. Luke's Blvd., Easton, PA 18045
St. Luke's Physician Group – Cancer Care Associates, 701 Ostrum Street, Bethlehem, PA 18015
St. Luke's Hospital – Quakertown Campus, 1021 Park Avenue, Quakertown, PA 18951

Neil Berman, DO
St. Luke's Hospital – Bethlehem Campus, 801 Ostrum Street, Bethlehem, PA 18015
St. Luke's Physician Group – Cancer Care Associates, 701 Ostrum Street, Bethlehem, PA 18015
St. Luke's Physician Group – Cancer Care Associates, 240 Cetronia Road, Allentown, PA 18104
St. Luke's Hospital – Allentown Campus, 1736 Hamilton Street, Allentown, PA 18104
St. Luke's Hospital – Miners Campus, 360 W. Ruddle Street, Coaldale, PA 18218
St. Luke's Hospital – Anderson Campus, 1600 St. Luke's Blvd., Easton, PA 18045
St. Luke's Hospital – Anderson Campus, 1872 St. Luke's Blvd., Easton, PA 18045

Yacoub Farouz, MD
St. Luke's Hospital – Bethlehem Campus, 801 Ostrum Street, Bethlehem, PA 18015
St. Luke's Physician Group – Cancer Care Associates, 701 Ostrum Street, Bethlehem, PA 18015
St. Luke's Physician Group – Cancer Care Associates, 240 Cetronia Road, Allentown, PA 18104
St. Luke's Hospital – Anderson Campus, 1600 St. Luke's Blvd., Easton, PA 18045
St. Luke's Hospital – Anderson Campus, 1872 St. Luke's Blvd., Easton, PA 18045
St. Luke's Hospital – Allentown Campus, 1736 Hamilton Street, Allentown, PA 18104

Although not specified on their CV's, the investigators will be conducting research at these locations.

_____
Elana Pessin, Study Start Up Project Coordinator
Clinical Trials, St. Luke's University Health Network

ATTACHMENT B Cont'd:

St Luke's UNIVERSITY HEALTH NETWORK

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

July 6, 2016

Note to File;

This is to clarify site affiliations for the following investigators;

Hikaru Nakajima, MD
St. Luke's Hospital – Bethlehem Campus, 801 Ostrum Street, Bethlehem, PA 18015
St. Luke's Physician Group – Cancer Care Associates, 701 Ostrum Street, Bethlehem, PA 18015
St. Luke's Physician Group – Cancer Care Associates, 240 Cetronia Road, Allentown, PA 18104
St. Luke's Hospital – Anderson Campus, 1872 St. Luke's Blvd., Easton, PA 18045
St. Luke's Hospital – Anderson Campus, 1600 St. Luke's Blvd., Easton, PA 18045
St. Luke's Hospital – Allentown Campus, 1736 Hamilton Street, Allentown, PA 18104

Subhash Prasdki, MD
St. Luke's Hospital – Bethlehem Campus, 801 Ostrum Street, Bethlehem, PA 18015
St. Luke's Physician Group – Cancer Care Associates, 701 Ostrum Street, Bethlehem, PA 18015
St. Luke's Physician Group – Cancer Care Associates, 240 Cetronia Road, Allentown, PA 18104
St. Luke's Hospital – Allentown Campus, 1736 Hamilton Street, Allentown, PA 18104

Dennis Giangiulio, MD
St. Luke's Hospital – Bethlehem Campus, 801 Ostrum Street, Bethlehem, PA 18015
St. Luke's Physician Group – Cancer Care Associates, 240 Cetronia Road, Allentown, PA 18104
St. Luke's Physician Group – Cancer Care Associates, 701 Ostrum Street, Bethlehem, PA 18015
St. Luke's Hospital – Allentown Campus, 1736 Hamilton Street, Allentown, PA 18104
St. Luke's Hospital – Miners Campus, 360 W. Ruddle Street, Coaldale, PA 18218

Amy Schippers, PA-C
St. Luke's Hospital – Bethlehem Campus, 801 Ostrum Street, Bethlehem, PA 18015
St. Luke's Hospital – Anderson Campus, 1600 St. Luke's Blvd., Easton, PA 18045
St. Luke's Hospital – Anderson Campus, 1872 St. Luke's Blvd., Easton, PA 18045
St. Luke's Physician Group – Cancer Care Associates, 701 Ostrum Street, Bethlehem, PA 18015

John Smith, Jr., MD
St. Luke's Hospital – Bethlehem Campus, 801 Ostrum Street, Bethlehem, PA 18015
St. Luke's Physician Group – Cancer Care Associates, 701 Ostrum Street, Bethlehem, PA 18015
St. Luke's Hospital – Warren Campus, 185 Roseberry Street, Phillipsburg, NJ 08865
St. Luke's Hospital – Warren Campus, 755 Memorial Parkway, Phillipsburg, NJ 08865

Michelle Pearsree, PA-C
St. Luke's Hospital – Bethlehem Campus, 801 Ostrum Street, Bethlehem, PA 18015
St. Luke's Physician Group – Cancer Care Associates, 701 Ostrum Street, Bethlehem, PA 18015
St. Luke's Hospital – Miners Campus, 360 W. Ruddle Street, Coaldale, PA 18218
St. Luke's Hospital – Anderson Campus, 1600 St. Luke's Blvd., Easton, PA 18045
St. Luke's Hospital – Anderson Campus, 1872 St. Luke's Blvd., Easton, PA 18045

Although not specified on their CV's, the investigators will be conducting research at these locations.

_____
Elana Pessin, Study Start Up Project Coordinator
Clinical Trials, St. Luke's University Health Network

My Health. My Hospital.™

ATTACHMENTC:

St Luke's HOSPITAL & Health Network

New Study Feasibility Checklist

Trial Title:				
Department:				
Sponsor:				
SLHN PI:		IVRS ☐	EDC ☐	Imaging ☐
SLHN Co-I:		IVRS ☐	EDC ☐	Imaging ☐
Lead Research Coordinator:		IVRS ☐	EDC ☐	Imaging ☐
Backup Research Coordinator		IVRS ☐	EDC ☐	Imaging ☐
Pharmacist		IVRS ☐	EDC ☐	Imaging ☐
Data Manager		IVRS ☐	EDC ☐	Imaging ☐
Laboratory Coordinator		IVRS ☐	EDC ☐	Imaging ☐
Key Personnel *everyone listed must have CITI & FCOI training*		IVRS ☐	EDC ☐	Imaging ☐
Treatment locations/campus' (e.g. where IP will be given)				
Additional non-treatment research locations (e.g. imaging, labs, physical exams)				
Location of IP drug storage:				
When will drug be shipped?	Per Patient ☐	Upon First Patient Enrolled ☐	Upon Activation ☐	
Patient Payments?	Yes ☐	No ☐		
	If yes, number of onsite visits:			

Please Note: Trials REQUIRING the use of a central IRB in lieu of the SLHN IRB CANNOT be done at SLHN

Study Summary

Study Objective Short description of the study/protocol intended for the lay public. Include a brief statement of the study hypothesis.	
General Eligibility Criteria Interventional Studies: Summary criteria for participant selection. The prefered format includes lists of inclusion and exclusion criteria. Observational Studies:	

St Luke's HOSPITAL & Health Network

New Study Feasibility Checklist

Study Population Description: A description of the population from which the groups or cohorts will be selected (e.g., primary care clinic, community sample, residents of a certain town).	

Study Characteristics

Does this trial address an area where we currently have no treatment option or need an additional clinical trial option?	Yes ☐	No ☐
If No, Describe how study differs from current options:		
Does this trial compete with an existing or pending trial?	Yes ☐	No ☐
If Yes, provide priority list including the competing trials and provide justification why this trial should be opened.		
Does the use of the investigational agent(s) in this protocol require an application to and approval by the BRANY Institutional Biosafety Committee (IBC)?	Yes ☐	No ☐
If Yes,		
o Recombinant DNA not exempt by the NIH Guidelines or requiring Biosafety Level or above (this includes transgenic plants and animals)	Yes ☐	No ☐
i. Infectious Agents including:		
• Human blood, body fluids, or unfixed tissue	Yes ☐	No ☐
• Tissues, organs or cell cultures of human origin	Yes ☐	No ☐
• Human Gene Transfer	Yes ☐	No ☐
Does the protocol call for the submission of pathology blocks?	Yes ☐	No ☐
If Yes, please contact Pathology to determine if this is feasible		
Does the protocol require extra radiology tests or procedures?	Yes ☐	No ☐
If Yes, separate arrangements will need to be made with Radiology		
Does the protocol utilize a central or local lab?	Central ☐	Local ☐
Does the protocol require correlative PKs?	Yes ☐	No ☐
Is PI credentialing required?	Yes ☐	No ☐
Is Radiation Safety Committee review/approval required?	Yes ☐	No ☐
Does this trial utilize an Investigational Device?	Yes ☐	No ☐
a) *If Yes, answer the following:*		
i. Will the device be supplied by the sponsor or purchased? _____		
ii. Will the device require storage space?	Yes ☐	No ☐
1. If yes, *Where will the device be stored?* _____		

ATTACHMENT C Cont'd:

St Luke's HOSPITAL & Health Network

New Study Feasibility Checklist

Does the protocol have any "Other" unique requirements that are not listed above?	Yes	☐	No	☐
*If Yes, please list*_____ *& ensure arrangements & contacts are made*				

Sponsorship

Is this an Industry Sponsored Trial?	Yes	☐	No	☐
Who is the Contact at the Sponsor?				
Is this a Cooperative Group study (oncology only)?	Yes	☐	No	☐
If Yes, what is the National Target accrual?				
Is this an Investigator Initiated Trial?	Yes	☐	No	☐
If Yes,				
o Who will serve as the lead site (e.g. sponsor) and who is the contact?				
Please note: SLHN-sponsored interventional IITs must be discussed with the Tracy Bozyn (Mgr), Director of Clinical Trials before moving forward				
o Is there funding for this trial?	Yes	☐	No	☐

Accrual

What is the expected total accrual for SLHN?	Patients
Please note: It will be expected that you enroll at least 20% of this target accrual per year, or the trial shall be reviewed for closure per Accrual Closure Policy (Attached)	

Is the PI and/or Co-I prepared to review and sign off on all required study documents in a timely manner and on a regularly scheduled basis as required by regulatory authorities, the study protocol, and/or institutional policies?	Yes	☐	No	☐
Signature of Principal Investigator:				

SLHN New Study Feasibility Checklist Page 3 of 3 March 30, 2016

ATTACHMENT D:

St. Luke's University Health Network
Delegation of Authority Log

Protocol Number:	**Sponsor:**
Printed Name:	**Role:**
Start Date:	**End Date:**
Protocol Title:	

PI CERTIFICATION:

As Principal Investigator (PI) for the above mentioned investigational study, I have authorized the following staff to assume the indicated study responsibilities for which they are qualified by means of training and experience. I understand that this in no way alters my responsibilities as defined by ICH GCP, applicable regulations, and the clinical trial agreement (or equivalent).

Principal Investigator Name: _____

Principal Investigator Signature: _____ **Date:** _____

- ☐ Consent Subjects
- ☐ Subject Eligibility
- ☐ Complete/Correct CRFs and Queries
- ☐ Review/Sign CRFs and Queries
- ☐ IRB/Regulatory
- ☐ Physical Exam
- ☐ Adverse Event Reporting
- ☐ Evaluate the causality of adverse event(s) in relationship to the test product(s)
- ☐ Lab Collection/Processing/Shipping
- ☐ Dispense/Return IP
- ☐ Drug Preparation/Accountability
- ☐ Other: _____

Signature: _____ **Initials:** _____ **Date:** _____

ATTACHMENT D Cont'd:

St Luke's UNIVERSITY HEALTH NETWORK

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

Note to File

April 28, 2015

RE: Delegation of Authority Log

Please let this note to file serve as documentation that the centralized Clinical Trials Office (CTO) shall utilize their internal Delegation of Authority Log (DOAL) for all clinical trials run through the CTO requiring such a log. The internal template is in accordance with Federal, state, and local regulations surrounding the delegation of duties for clinical trials.

Electronically Signed*

Tracy Butryn, MS, CCRP
Director of Clinical Trials and Research
St. Luke's University Health Network

ATTACHMENT E:

To:
Subject:

Hi All,

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

This email will serve as documentation of the date of training. Please feel free to contact me with any questions.

Thank you,

ATTACHMENT F:

St Luke's
UNIVERSITY HEALTH NETWORK

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

Date

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.

List Research Staff

_____
XXX
Principal Investigator

ATTACHMENT G:

St Luke's UNIVERSITY HEALTH NETWORK
526-4979

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

Request for IRB Exemption

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

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:

☐ Project Proposal/Summary
☐ Patient Materials (e.g. Questionnaires, diaries, phone scripts, etc.)
☐ Other: _____
☐ Waiver of Subject Authorization Request Form
☐ HIPAA De-identification Certification Form

PROTOCOL TITLE:

DEPARTMENT:

SECTION A: 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: Sites where the research will be conducted (please check all applicable boxes)	
☐ SLH - Allentown	☐ SLH - Miners
☐ SLH - Bethlehem	☐ SLH - Anderson
☐ SLH - Quakertown	☐ SLH - Warren
☐ Private Office (Specify Location(s):	☐ Other (e.g. private offices and/or other institutions for multi-center IITs):

SECTION C: Exemption Justification

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from IRB review. Please check those items that apply to your research. ***These categories are taken from 45 CFR 46.101(b)***

☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

NOTE: Audio, video and/or digital recording removes a study from consideration for exemption. The study should be submitted as expedited or full review

NOTE: In order for research involving children as participants to be exempt, the procedures must be limited to observation of public behavior where the investigators do not participate in the activities being observed and educational tests. Surveys or

interviews of children do not qualify for exemption

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

NOTE: In order to meet this category, tissue and/or data must exist at the time the research is proposed to the IRB.

☐ Research and demonstration projects which are conducted by or subject to the approval of federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Federal public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

NOTE: In order to meet this category, the research must: 1) be conducted pursuant to specific federal statutory authority; 2) not involve significant physical invasions or intrusions upon the privacy interests of participant; 3) have authorization or concurrence by the funding agency.

☐ Taste and food quality evaluation and consumer acceptance studies, if (i) wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U. S. Department of Agriculture.

1. Investigator's Justification for Exemption:
2. How will privacy of participants be maintained?
3. Explain criteria for participant selection:
4. Will consent be obtained? ☐ YES ☐ NO

If "YES" what form of consent is being requested with this application?

☐ Written: ***Attach a copy of the consent in the SLUHN template***

☐ Verbal: ***Attach a script that will be used to verbally communicate the consent***

*****If "NO" attach a Waiver of Subject Authorization Request Form*****

SECTION K: Signatures and Attestation

I will ensure that subjects are not enrolled until I receive written notification of approval and a validated consent form from the IRB (if applicable).

Principal Investigator Signature	Date

I have reviewed this human subject research proposal and have determined that 1) the listed investigators are members or associates of the medical staff of the hospital where the research will be conducted and have been appropriately granted hospital privileges to perform the procedures outlined in the research proposal; and/or 2) the listed investigators are employees of the hospital whose job descriptions and competencies qualify them to perform the procedures outlined in the research proposal.

Department / Division Chief	Date

I have reviewed this human subject research proposal and have determined that it meets the mission of this department/service line.

Department/Division Service Line Administrator	Date

ATTACHMENT H:

SUPPLEMENTAL INVESTIGATOR DATA FORM

Date (MM/DD/YYYY): ___ / ___ / ____

Sections 1 – 12: REQUIRED INFORMATION (Collected for all investigators participating in CTEP-sponsored clinical trials.)

1. Investigator Name (Last, First, Middle, Suffix):
2. Degree(s):
3. CTEP Investigator ID:
4. Date of Birth (MM/YYYY): ___ / ____
5. Provider No. (NPI):
6. Are you currently licensed to practice medicine? ☐ YES ☐ NO

7. Primary Specialty Practice(s): Check all that apply.

	Board Eligible:	Board Certified:		Board Eligible:	Board Certified:
Anatomic and/or Clinical Pathology	☐	☐	Obstetrics and Gynecology	☐	☐
Clinical Genetics	☐	☐	Orthopedic Surgery	☐	☐
Colon and Rectal Surgery	☐	☐	Otolaryngology	☐	☐
Dermatology	☐	☐	Pediatric Hematology-Oncology	☐	☐
Diagnostic Radiology	☐	☐	Pediatrics	☐	☐
Family Practice	☐	☐	Psychiatry	☐	☐
Gastroenterology	☐	☐	Public Health and General Preventative Medicine	☐	☐
Gynecological Oncology	☐	☐	Radiation Oncology	☐	☐
Hematology	☐	☐	Surgery	☐	☐
Internal Medicine	☐	☐	Surgical Oncology	☐	☐
Medical Oncology	☐	☐	Thoracic Surgery	☐	☐
Neurological Surgery	☐	☐	Urology	☐	☐
Neurology	☐	☐	Other _____	☐	☐

8. Have you received training in:

Completion of this training is mandatory for all CTEP-registered investigators.

"Protection of Human Research Participants"? ☐ YES DATE COMPLETED (MM/YYYY): ___ / ____

In sections 9 – 12, use this side to either enter new information or view current information.

In sections 9 – 12, use this side to make changes to current information only.

9. Office Address: The office address and contact information will be used for receipt of all official correspondence.

Institution:		Institution:	
Internal Office:		Internal Office:	
Street Address:		Street Address:	
Street Address:		Street Address:	
City:		City:	
State/Province:		State/Province:	
Zip/Postal Code:		Zip/Postal Code:	
Country:		Country:	
Office Phone No.:		Office Phone No.:	
Office FAX No.:		Office FAX No.:	
Office E-mail:		Office E-mail:	

10. Research Contact: Provide a phone number and email address, suitable for display on a publicly accessible website (e.g., www.cancer.gov), which can be used by a patient to contact the investigator's research staff to inquire about clinical trials approved by their IRB and open for enrollment at their institution.

Research Contact Phone No.	Research Contact Phone No.
Research Contact E-mail address	Research Contact E-mail address

Page 1 of 3

11. Primary Shipping Address: The primary shipping address will be used for receipt of all CTEP-supplied investigational agents.

Institution:		Institution:	
Internal Office:		Internal Office:	
Street Address:		Street Address:	
Street Address:		Street Address:	
City:		City:	
State/Province:		State/Province:	
Zip/Postal Code:		Zip/Postal Code:	
Country:		Country:	

Shipping Designee: Provide name of shipping designee (preferably a pharmacist) approved to order and receive CTEP-supplied investigational agents.

Shipping Designee Name:		Shipping Designee Name:	
Shipping Designee Phone No.:		Shipping Designee Phone No.:	
Shipping Designee FAX No.:		Shipping Designee FAX No.:	
Shipping Designee E-mail:		Shipping Designee E-mail:	

CTEP USE ONLY: ☐ PSD ☐ SD ☐ IA

12. Ordering Designee(s): Provide name(s) of ordering designee(s) approved to order CTEP-supplied investigational agents. Note that a "Clinical Drug Request (CDR) Form" for a CTEP-supplied agent must be signed by either the investigator, the authorized shipping designee (from item #11), or an ordering designee (from item #12). An ordering designee must use the primary shipping address (from item #11).

A. Ordering Designee Name:		A. Ordering Designee Name:	
Ordering Designee Phone No.:		Ordering Designee Phone No.:	
Ordering Designee Fax No.:		Ordering Designee Fax No.:	
Ordering Designee E-mail:		Ordering Designee E-mail:	
B. Ordering Designee Name:		B. Ordering Designee Name:	
Ordering Designee Phone No.:		Ordering Designee Phone No.:	
Ordering Designee Fax No.:		Ordering Designee Fax No.:	
Ordering Designee E-mail:		Ordering Designee E-mail:	
C. Ordering Designee Name:		C. Ordering Designee Name:	
Ordering Designee Phone No.:		Ordering Designee Phone No.:	
Ordering Designee Fax No.:		Ordering Designee Fax No.:	
Ordering Designee E-mail:		Ordering Designee E-mail:	

Please be sure you have also included:

1. Completed FDA Form 1572 with original signature.
2. Current Curriculum Vitae (CV).
3. Completed FinaCTEPal Disclosure Form with original signature.

I certify that the information on this "Supplemental Investigator Data Form" is true and correct to the best of my knowledge.

Investigator: _____ Date: _____

(Signature)

Section	INSTRUCTIONS FOR COMPLETING THE "SUPPLEMENTAL INVESTIGATOR DATA FORM"
1.	Investigator Name: Provide legal last name, first name, middle initial or name, and suffix (if applicable).
2.	Degree(s): Provide degree(s) (e.g., M.D., D.O., foreign M.D. equivalent).
3.	CTEP Investigator ID: Provide the unique CTEP investigator number assigned to the investigator by the Pharmaceutical Management Branch (PMB), CTEP, DCTD, CTEP at the time of initial registration. ***(If an investigator has never registered to participate in CTEP-sponsored clinical trials, leave field blank. An CTEP Investigator ID will be assigned by the PMB as part of the registration process.)***
4.	Date of Birth: Indicate the investigator's date of birth (in MM/YYYY format).
5.	Provider No. (NPI): Indicate the investigator's National Provider Identifier (NPI).
6.	Medical License: Indicate if the investigator is currently licensed to practice medicine.
7.	Primary Specialty Practice(s): Indicate the investigator's primary specialty practice(s). Board Eligibile: Indicate if the investigator is eligible for Board Certification in the primary specialty practice(s) selected. Board Certified: Indicate if the investigator is Board Certified in the primary specialty practice(s) selected.
8.	Investigator Training: Indicate if the investigator has completed the NIH-mandated training in the protection of human research participants, including date completed (in MM/YYYY format). If needed, additional information and online training are available at http://phrp.nihtraining.com . The online training takes approximately one hour to complete. ***Completion of protection of human research participants training is mandatory for ALL CTEP-registered investigators.***
9.	Office Address: The office address will be used for receipt of all official correspondence (e.g., annual registration and protocol documents). Include institution, internal office, street, city, state/province, zip/postal code, and country. Office Phone No.: Provide daytime phone number at which the investigator can be reached during normal business hours, including area code. Investigators from outside the United States should also include the country code. Office Fax No.: Provide Fax number at which the investigator usually receives faxes, including area code. Investigators from outside the United States should also include the country code. Office E-mail: Provide E-mail address at which the investigator usually receives e-mail. This address will be used to send information regarding protocols, investigator brochures, stock recovery letters, investigator expiry information, and general information for the investigator.
10.	Research Contact: Provide a phone number and email address, suitable for display on a publicly accessible website (e.g., www.cancer.gov), which can be used by a patient to contact the investigator's research staff to inquire about clinical trials approved by their IRB and open for enrollment at their institution.
11.	Primary Shipping Address: The primary shipping address will be used for receipt of all CTEP-supplied investigational agents. Include institution, internal office, street, city, state/province, zip/postal code, and country. Shipping Designee: Provide name of shipping designee (preferably a pharmacist) approved to order and receive CTEP-supplied agents. ***Note that a "Clinical Drug Request (CDR) Form" for a CTEP-supplied agent must be signed by either the investigator, the authorized shipping designee (from item #11), or an ordering designee (from item #12).*** Shipping Designee Phone No.: Provide daytime phone number at which the shipping designee can be reached during normal business hours, including area code. Shipping designees from outside the United States should also include the country code. Shipping Designee Fax No.: Provide Fax number at which the shipping designee usually receives faxes, including area code. Shipping designees from outside the United States should also include the country code. Shipping Designee E-mail: Provide E-mail address at which the shipping designee usually receives e-mail. This address will be used to send information regarding drug shipments, protocols, stock recovery letters, and general information for shipping designees.
12.	Ordering Designee(s): Provide name(s) of ordering designee(s) approved to order CTEP-supplied agents. ***Note that a "Clinical Drug Request (CDR) Form" for a CTEP-supplied agent must be signed by either the investigator, the authorized shipping designee (from item #11), or an ordering designee (from item #12). An ordering designee must use the primary shipping address (from item #11).*** Ordering Designee Phone No.: Provide daytime phone number at which the ordering designee can be reached during normal business hours, including area code. Ordering designees from outside the United States should also include the country code. Ordering Designee Fax No.: Provide Fax number at which the ordering designee usually receives faxes, including area code. Ordering designees from outside the United States should also include the country code. Ordering Designee E-mail: Provide E-mail address at which the ordering designee usually receives e-mail. This address will be used to send information regarding drug shipments, protocols and general information for ordering designees.

ATTACHMENT I:

Collection of this information is authorized under 21 CFR 54.4. The use of this information is to disclose or certify information concerning the financial interests of the clinical investigators associated with clinical studies. This information may be disclosed to sponsors of clinical trials, National Cancer Institute, Food and Drug Administration's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, and the Department of Health and Human Services.

Submission of this information is voluntary, however, in order for us to qualify you to conduct a study in accordance with the relevant, current protocol(s), you must complete all fields.

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0613). Do not return the completed form to this address.

CONFIDENTIAL
FINANCIAL DISCLOSURE FORM

The FDA requires that the following confidential financial disclosure information be collected for all investigators (see 21CFR 54.4). Any pharmaceutical company that submits a marketing application for any drug, biologic product, or device is required to submit certain information concerning the compensation to, and financial interests of, any clinical investigator participating in any clinical study submitted in the marketing application. The Cancer Therapy Evaluation Program (CTEP) is collecting this confidential information annually for all CTEP-registered investigators.

Please indicate below if you, your spouse, or dependent children have any of the following disclosable financial arrangements.

Yes___ No___ **Do you currently have or have you at any time in the past year had any compensation made to you by a pharmaceutical company in which the value of the compensation could be affected by the study outcome?**

Yes___ No___ **Do you currently have or have you at any time in the past year had a proprietary interest in any drug, biologic product, or device, including, but not limited to, a patent, trademark, copyright, or licensing agreement?**

Yes___ No___ **Do you currently have or have you at any time in the past year had any equity interest in a pharmaceutical company that exceeds $50,000 in value?**

Yes___ No___ **Do you currently have or have you at any time in the past year had significant payments of other sorts totaling $25,000 or more from any single pharmaceutical company to you or to your institution to support activities exclusive of the costs of conducting clinical studies, such as a grant to fund your ongoing research, compensation in the form of any equipment not directly related to the conduct of the clinical trial, or retainers to you for ongoing consultation or honoraria?**

If you answered "Yes" to any of the questions above, please provide the name of the pharmaceutical company or companies with whom the financial arrangement exists (add an attachment if needed).

Pharmaceutical Company(ies) _____

This form must be signed (original signature required) and dated and submitted with your signed FDA Form 1572 (original signature required) and Supplemental Investigator Data Form as part of your annual CTEP investigator registration packet. Completed forms will be maintained by the Pharmaceutical Management Branch, CTEP as part of your confidential investigator registration file. This information will only be provided (1) to a pharmaceutical company which has an agreement (e.g., a Clinical Trials Agreement [CTA] or a Cooperative Research and Development Agreement [CRADA]) with CTEP if CTEP is notified that a licensing application is being prepared by that company or (2) to a Cooperative Group of which you are a member if CTEP is notified that a clinical trial is being developed by that Group and a pharmaceutical company with whom you have indicated a financial arrangement. You may be contacted in the future by a pharmaceutical company representative or by your Cooperative Group administrative staff for additional information.

_____ _____ _____

Signature **Date** **Printed Name**