



801 Ostrum St.  
Bethlehem, PA 18015  
**Institutional Review Board**  
Rebecca Jeanmonod, MD, Chair  
William Peters, DO, Vice Chairman  
Phone: 610-776-4832 or 610-776-4856

## Initial IRB Application

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

<b>IRB Review Classification and Certification of Compliance with Regulatory Requirements:</b>  <b>Pick One:</b> <input type="checkbox"/> Full Board Review <input type="checkbox"/> Expedited Review ( <i>minimal risk studies only</i> ) <input type="checkbox"/> Check Box if Quality Improvement	<b>IRB #:</b> _____       Version date 10/22/2021
<b>All Must be Checked:</b> <input type="checkbox"/> FCOI is current for all listed personnel <input type="checkbox"/> No FCOI exists for any listed personnel <input type="checkbox"/> CITI training is current for all listed personnel	

**Attachments:**  
Check and include all that apply:

<input type="checkbox"/> Copy of the FDA IND/IDE Approval Letter (if applicable)	<input type="checkbox"/> New Study Feasibility Form (CTO trials only)
<input type="checkbox"/> Consent Form (if required)	<input type="checkbox"/> Advertisements
<input type="checkbox"/> Protocol	<input type="checkbox"/> Signed Letter of Support (Unfunded Trials only)
<input type="checkbox"/> Patient Materials (e.g. Questionnaires, diaries, phone scripts, etc.)	<input type="checkbox"/> Child Assent/Parental Permission Form
<input type="checkbox"/> Investigator Brochure/Device Brochure/Package Insert	<input type="checkbox"/> Other: _____

**PROTOCOL TITLE:**

**DEPARTMENT:**

**SPONSOR:**

*\*\*If this is an in-house Investigator-Initiated Trial, please list SLUHN as the sponsor above\*\**

**FUNDING SOURCE:**

- If this is an unfunded study, please list "Departmentally Funded" as the funding source above, and submit a letter of approval signed by the Department Chair and Service Line Administrator.

- If commercial, government, or grant funding is being provided for this study, please answer the following:

1. Has this been reviewed and approved by the Director of Clinical Trials and Research and the Director of Network Reimbursement?  YES  NO

***\*\*If you answered "NO" to the above question, please stop and obtain this approval prior to IRB submission\*\****

2. Please provide the account number to which the funds will be dispersed.

3. Will this research be supported by the centralized Clinical Trials Office?  YES  NO

<b>SECTION A: Study Personnel</b> <i>(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)</i>					
Name	Address	City	State	Zip	Phone



## **SECTION D: Risk, Benefits, and Alternatives**

1. Please check the appropriate box:

This research involves no more than minimal risk

***\*\*This may qualify for Expedited Review\*\****

This research involves more than minimal risk

2. What are the risks of the research?

3. Discuss how the study design minimizes risks and maximizes benefits associated with this study:

4. What are the potential benefits?

5. Explain how the risks of the research are justified by potential benefit to the subject or society:

6. How would you treat this patient in a non-investigational setting? Please describe the treatment that is considered standard of care, as well as any alternative procedures or drugs or other courses of therapy that might be used, if such alternatives exist (include palliative care):

7. How do the risks and side effects of the standard therapies compare to those associated with the study therapy?

8. If this is a placebo controlled trial, please provide rationale for use of placebo:

9. If subjects will not receive standard of care, provide rationale for this and address risks of not receiving standard of care:

10. Please address any risks associated with a "washout" period if applicable:

13. Will radiation be used in this study?  YES  NO

***If "YES" please answer the following:***

- Describe the radiation used and whether it is diagnostic or therapeutic:
- Will the subject receive radiation greater than normally received in the course of standard therapy or diagnostic procedures?  YES  NO
- Is the radiation modality used experimental?  YES  NO

***If "YES" please address the following:***

- What are the risks associated with the experimental modality?
- Please append a copy of the approval letter from the Radiation Safety Committee.

## **SECTION E: Subjects and Facilities**

1. What is the expected number of subjects to be enrolled? At SLUHN: \_\_\_\_\_ Nationally: \_\_\_\_\_
2. How has the research staff been trained regarding study protocol and their duties related to the protocol (in-service, investigator meeting, etc.)?
3. Describe provisions to protect the privacy of participants during the course of the study:
4. Which of the following groups are eligible to be subjects: (please check all that apply):
  - Decisionally-impaired (*include only if research targets this population or there is potential benefit to this population*)
  - Women of Reproductive Potential       Pregnant women/Fetuses/Neonates
  - Men of Reproductive Potential       This research involves no more than minimal risk
  - Minorities       Prisoners
  - Vulnerable populations (*trauma victims, students, aged infirm, substance abusers, impoverished, terminally ill, etc.*)
  - Healthy Controls/Volunteers       Employees/Students

**\*\*Employees/Students whom Key Personnel listed in SECTION A have a supervisory role may not be enrolled in a study\*\***

**\*\*If enrolling Decisionally-impaired subjects, please submit a Surrogate Consent\*\***

5. If Minorities and/or Women were not checked above, please provide rationale as these populations are required by the NIH to be adequately represented as research subjects:
6. Please provide and Explanation of Exclusion of any of the above listed categories:
7. If applicable, what additional protective mechanisms are in place to protect the rights and welfare of vulnerable populations?
8. Is the location and setting of the research equally accessible to all qualified subject populations?  YES     NO  
If "NO", what can be done to make the location and setting more accessible?

## **SECTION F: Recruitment and Consent**

1. Discuss the recruitment plan and describe recruitment methods and materials (e.g. physician referral, newspaper ad, radio, TV spot, e-mail, etc.):

**\*\*Please attach all relevant materials for IRB review and approval\*\***

2. Will all qualified subject populations have adequate access to recruitment materials?  YES  NO

**Please explain:**

3. 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**

Waiver: **Attach a Waiver of Subject Authorization Request Form**

4. If you are requesting a waiver of written consent, describe the information that will be provided to participants and the method this information will be communicated:

5. Do you anticipate the potential enrollment of non-English speaking subjects?  YES  NO

**If "YES" please submit a translated Short Form and script for use by the translation service**

6. Provide a step-by-step description of the consent process (**must include who will conduct the consent, who will provide the consent, and where the consent process will take place**):

7. Describe your plan to assess a person's capacity to consent:

8. Will you seek assent from decisionally-impaired individuals?  YES  NO

**If "YES", describe your plan for obtaining assent:**

9. Is surrogate consent involved?  YES  NO

**\*\*If you answered "YES" to Question #8, this must be answered as "YES" and a copy of the Surrogate Consent must be included with this application\*\***

10. Will subjects be paid or receive any other inducements for participating?  YES  NO

If yes, please explain:

11. Describe any steps taken to minimize the possibility of coercion or undue influence:

12. Will the subject bear any costs which are not part of routine care?  YES  NO

If "YES" please answer the following:

- Please list the relevant tests, procedures, hospitalizations, etc. for which they may be liable:
- Are there means for subsidizing these extra costs?  YES  NO

If "YES" please explain:

**SECTION G: Drugs and/or Devices**

**\*\*If there are no drugs or devices used in this research, please skip to Section H\*\***

1. Identify all investigational drugs and/or devices to be used in this study and complete the below table:

**\*\*NOTE: An FDA Approved drug is considered "Investigational" if it is the test article in a research study\*\***

DRUG OR DEVICE	IND or IDE #	IND or IDE Holder	FDA Approved?	Being Used within Approved Indication?
			<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO

**\*\*FDA Approval Letter of the ICD or IDE must be submitted with this application\*\***

**\*\*If the Investigator or SLUHN holds the IND or IDE, the investigator/SLUHN becomes the "Sponsor" of the research and assumes all associated responsibilities\*\***

2. Identify all non-investigational medications and/or devices that the subject will receive while on this study:

**DRUGS: (Skip this section if there are no investigational drugs used in this study)**

1. Will the study drugs be dispensed and maintained by the Investigational Pharmacist?  YES  NO

**If "NO" please answer the following:**

- Where will drug be stored?
- Who will have access to drug?
- Who will maintain drug accountability logs, and dispense drug?
- What measures to maintain security of drug storage and access are in place?

2. How will the drug be supplied?

3. If sponsor is not supplying test article, where will it be obtained and who will pay for it?

4. Please briefly summarize relevant human clinical data related to the study drug:

5. Please list the known side effects for each study drug:

6. Does this study include an off-label use of an FDA-approved drug?  YES  NO

**If "YES" please explain:**

7. If the investigational product is not FDA approved or is being used outside of its approved indication and does not have an IND#, please certify that its intended use meets at least one of the following FDA categories for IND exemption (21 CFR 312.2) by checking applicable statement(s):

**\*\*If none of the following categories apply, the sponsor must obtain an IND# or IND exemption letter from the FDA\*\***

- **Exemption Category 1** [21 CFR 312.2(b)(1)] – All criteria for this category must apply

- The drug product is lawfully marketed in the United States.
- It is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug;
- It is not intended to support a significant change in the advertising for the product;
- It does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
- It is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively]; and
- It is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7].

- **In Vitro Diagnostic Biological Product** [21 CFR 312.2(b)(2)]

- The study is a clinical investigation involving a (a) blood grouping serum; (b) reagent red blood cells; and/or (c) anti-human globulin and the product is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure and it is shipped in compliance with Sec. 312.160.

- **In Vitro and Animal Testing** [21 CFR 312.2(b)(3)]

- A drug intended solely for tests in vitro or in laboratory research animals is exempt from the requirements of this part if shipped in accordance with Sec. 312.160.

- **Use of Placebo** [21 CFR 312.2(b)(5)]

- A clinical investigation involving use of a placebo is exempt from IND requirements if the investigation does not otherwise require submission of an IND.

8. Do you intend to invoke the exception from informed consent requirements for emergency research [21 CFR 50.24]?

YES  NO

**\*\*If "YES" you must have an IND\*\***

**DEVICES: (Skip this section if there are no investigational devices used in this study)**

1. Please indicate whether the device is a Category A or Category B device:  Category A  Category B

**\*\*You must confirm Medicare coverage of items/services for either Category A or Category B devices on the CMS Coverage Website before submitting any study-related claims\*\***

2. Please indicate whether this is a Significant Risk (SR) or Non-Significant Risk (NSR) Device:  SR  NSR

- **If "NSR"** please provide either the FDA ruling of the NSR determination or provide rationale as to why this is a NSR device:

- **If "SR"** please provide the FDA IDE Approval letter for the device and IDE #:

3. Please briefly summarize relevant human clinical data for the study device:

4. Please list the known or potential side effects for the device:

5. How will the device be supplied?

6. Where will the device be stored?

7. What security measures are in place to prevent the device from being used in a patient who is not enrolled in the research study or by a physician not involved in the study?

8. Provide details as to how device will be tracked (logged in, stored, assigned to subject, implanted, etc.):

9. Who will teach investigators how to use the device and who will determine competence?

## **SECTION H: Data Collection and Storage of Specimens**

1. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data (check all that apply):

- |  |   |
|--|---|
| <input type="checkbox"/> Laboratory Tests  | <input type="checkbox"/> Medical Records              |
| <input type="checkbox"/> Radiology Tests   | <input type="checkbox"/> Tissue Specimens             |
| <input type="checkbox"/> Blood or Urine Specimens  | <input type="checkbox"/> Stool Specimens/Fecal Matter |
| <input type="checkbox"/> Audiotapes of subjects  | <input type="checkbox"/> Videotapes of subjects       |
| <input type="checkbox"/> Photographs of subjects   | <input type="checkbox"/> Tumor Biopsies               |
| <input type="checkbox"/> Sputum  | <input type="checkbox"/> Films/X-Rays                 |
| <input type="checkbox"/> Hospital Administrative/Billing Records   | <input type="checkbox"/> Other:                       |
| <input type="checkbox"/> Questionnaires: <b>Please ensure a copy is submitted with this application</b>                          |   |
| <input type="checkbox"/> Interviews: <b>Please submit a copy of the questions that will be asked along with this application</b> |   |
| <input type="checkbox"/> Observations:   |   |

Please describe:

2. Please indicate what this request is for by checking the appropriate box below:

- Data/Specimens that already exist/are currently stored (retrospective)  
**\*\*If this is a retrospective study, this may qualify for Expedited Review\*\***
- Data/Specimens to be obtained in the future (prospective)

3. If you propose to use stored research specimens or retrospective data, was informed consent initially obtained?

- Yes    No    Do not know

**\*\*If biological specimens or data will be sent outside of SLUHN with any identifiers, Informed Consent is required\*\***

4. Purpose of Data/Specimen Collection:

**If the purpose is for genetic research, please address the following:**

- Will the results be disclosed to the subjects?  YES    NO
- Will the subject have an option to not receive the information gathered about themselves?  YES    NO
- How will the possibility of psychological and/or social harm/risks be handled?

5. How many subject or database records will be reviewed, or how many specimens will be collected?

6. How will the data/specimens be obtained and recorded?

7. Who will have access to the data/specimens?

8. Will the subject Data/Specimens be sent outside of SLUHN for review, processing, or storage?  YES    NO

**If "YES" please address the following:**

- Where will the Data/Specimens be sent?
- Why is it necessary to send the Data/Specimens outside of SLUHN?
- How will data be sent?

9. Please explain how the confidentiality of the data/specimens will be maintained:

10. What procedures are in place to monitor the data/specimens?

11. How long will the data/specimens be retained?

12. Are there plans for future use of the data or specimens as part of the study or use beyond the study?  YES  NO

**If "YES" please answer the following:**

- What are the types and amounts of data/specimens to be collected?
- Will the data/specimens be linked in any way to the subjects?  YES  NO

**If "YES" how will they be linked and how will privacy be protected?**

- What future research using the collected data/specimens is anticipated?
- How will access to the data/specimens be governed?
- What procedures will be used if the patient withdraws consent after the data/specimen has been collected and stored?

13. How and when will the data/specimens be destroyed?

14. Will any of the following identifiers be maintained with the data collected (**choose all that apply**)?

**\*\*NOTE: If any of the below identifiers are checked, this does not qualify as "De-identified Research" and must be reviewed by the IRB. Additionally, either consent must be obtained from the subjects, or a Request for Waiver of Subject Authorization" must be submitted and approved. \*\***

- |  |   |
|--|---|
| <input type="checkbox"/> Name  | <input type="checkbox"/> Phone Number                                       |
| <input type="checkbox"/> Any geographic subdivision smaller than a state (e.g. street, zip code, city, etc.) | <input type="checkbox"/> Fax Number   |
| <input type="checkbox"/> Birth Date  | <input type="checkbox"/> Email  |
| <input type="checkbox"/> Admission Date  | <input type="checkbox"/> Social Security Number                             |
| <input type="checkbox"/> Discharge Date  | <input type="checkbox"/> Medical Record Number                              |
| <input type="checkbox"/> Date of Death   | <input type="checkbox"/> Health Plan Beneficiary Number                     |
| <input type="checkbox"/> Age if over 89 (or any date indicative of age)                                      | <input type="checkbox"/> Account Numbers                                    |
| <input type="checkbox"/> Vehicle Identifiers/Serial Numbers  | <input type="checkbox"/> Certificate/License Numbers                        |
| <input type="checkbox"/> URLs or IP Addresses  | <input type="checkbox"/> Device Identifiers/Serial Numbers                  |
| <input type="checkbox"/> Full Face Photos or equivalent  | <input type="checkbox"/> Biometric Identifiers (e.g. fingerprints or voice) |
|  | <input type="checkbox"/> Any other unique identifier                        |

## **SECTION I: Research Involving Children**

1. Does this research involve children (age 17 or under)?  YES  NO

**\*\*If "NO" skip this section\*\***

2. Is there a prospect of direct benefit to the enrolled child?  YES  NO

**If "YES" please describe:**

**If "NO" please describe the monitoring procedure which is likely to contribute to the well-being of the subject:**

3. Discuss your plan for recruitment of children:

4. Describe standard of care related to this research for children:

5. Justify the age range of children to be enrolled:

6. Indicate the expertise of the research team with regard to children:

7. Describe the facilities to be used for children in this study:

8. Indicate the number of children required to give sufficient power for meaningful analysis:

9. Describe how the parental permission and child assent process (for 7-17 year olds) will be carried out:

**\*\*You must submit a Child Assent Form and Parental Permission Form for approval\*\***

10. If this proposal is a Type I NIH application/proposal, you must include children, defined as individuals under the age of 21, as subjects unless there are scientific or ethical reasons for excluding them. If excluding children, please justify your exclusion by choosing one or more of the following exclusionary circumstances, as per NIH policy:

Not a Type 1 NIH study

The research topic is irrelevant for children

Children are barred by law from participation because of the risk

Study is redundant; knowledge is being obtained in another study or is already available

Separate age-specific children study is preferable

Rarity of disorder makes inclusion of children extremely difficult

The limited number of available children are already enrolled in a nation-wide pediatric disease network

Study design precludes direct applicability to children

Insufficient adult data to judge potential risk for children

Study design is a follow-up of an adult study

**SECTION J: Multi-site IITs with SLUHN as Lead Coordinating Center**

1. Please list all other study centers who will be participating in this research:
2. Where is the repository for adverse events and unanticipated problems and how will information be disseminated to other sites?
3. Who will tabulate and disseminate interim results?
4. Who will provide information to other sites concerning protocol modifications?
5. Describe how information that is relevant to participant safety will be managed (i.e., notifying site investigators of SAEs and Unanticipated Problems Involving Risks to Subjects or Others, communicating DSMB or Interim Reports, etc.)
6. Please list the FWA # for each participating site IRB of record, and a copy of the IRB approval letter:

**SECTION K: Signatures and Attestation**

The following are the minimum responsibilities of Principal Investigators as stated in the formal agreement between St. Luke's Hospital and Health Network and the federal Office of Human Research Protection (the "Assurance"). Please check each item to indicate that you have carefully read and understand your responsibilities.

- Principal Investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the Assurance.
- Principal Investigators who intend to involve human research subjects will be responsible for obtaining IRB review and approval prior to the initiation of research.
- Principal Investigators are responsible for providing a copy of the IRB-approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement, or the study is determined by IRB to be exempt. All signed consent documents are to be retained in a manner approved by the IRB.
- Unless otherwise authorized by the IRB, Principal Investigators are responsible for obtaining and documenting informed consent in accord with applicable federal regulations at 45 CFR §46.116 and 45 CFR §46.117.
- Principal Investigators shall be responsible for promptly reporting proposed changes in previously approved human subject research activities to the IRB. The proposed changes may not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects. See **Request Form for Approval of Amendment**.
- Principal Investigators will report to the IRB any unexpected and serious events or other unanticipated problems involving risks as outlined in the IRB Policies. See **Adverse Event Report Form**.

I have received the IRB Investigational Packet and agree to follow it. I, understand that as Principal Investigator: Amendments to the protocol and revisions to the informed consent form must be submitted to the IRB Committee for approval prior to use; Adverse events and/or complications, must be reported to the IRB immediately (within ten (10) days); Copies of brochures, pamphlets, or manuals for patients and copies of advertisements for recruitment of patients must be submitted to the IRB for approval prior to use. I will ensure that subjects are not enrolled until I receive written notification of approval and a validated consent form from the IRB. I understand that all human subject research will be approved by the IRB for no more than one year. I will not enroll subjects unless I have received written notification of the approval and a validated consent form the IRB.

<b>Principal Investigator Signature</b>	<b>Date</b>

**FOR RESEARCH PROCEDURES CONDUCTED WITHIN A SLHN FACILITY:** 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.

<b>Department / Division Chief</b>	<b>Date</b>

**FOR RESEARCH PROCEDURES CONDUCTED WITHIN A SLHN FACILITY:** I have reviewed this human subject research proposal and have determined that it meets the mission of this department/service line.

I have met with the appropriate departments and have found that the resources that are needed to conduct this research within SLHN are:  Readily Available (Attach Letter of Support)  Need to be Obtained  Require Funding

<b>Department/Division Service Line Administrator</b>	<b>Date</b>

<b>Person Preparing Submission Signature</b>	<b>Date</b>