External IRB Screening Question

*** Is this an External IRB submission?**

◯ Yes ◯ No

Humanitarian Use Device (HUD) Screening Question

*** Is this a Humanitarian Use Device (HUD) submission?**

◯ Yes ◯ No

Study Funding

Sponsor Name:

View Details	Sponsor Name	Sponsor Type	Funding Through	Contract Type:	Project Number	Award Number

No Prime Sponsor has been added to this Study

*** Is this study FDA regulated?**

☐ Yes
☐ No

*** Is this a federally-funded clinical trial?**

◯ Yes ◯ No

If so, please explain how a copy of the informed consent form will be posted to a publicly available, federal website post-recruitment no later than 60 days after the last study visit by any subject. If a non-Summa institution will be responsible for this posting, please explain.

If so, please contact **research@summahealth.org,** as all PHS funded research must be conducted out of the Summa Health Clinical Research Center (SHCRC).

Click here to access the text editor.

External IRB of Record

*** Select the External IRB of Record (choose one):**

◯ NCI CIRB
◯ Advarra IRB Single Site (Federally-funded or FDA-regulated research)
◯ Advarra IRB as a Central IRB (Federally-funded or FDA-regulated research)

◯ Other Commercial IRB (e.g., WIRB)

◯ Other Non-Commercial IRB (e.g., Ohio State University, NEOMED)

If "Other" please list name below:

Click here to access the text editor.

*** List the Summa Health location(s) where the research will take place (e.g., Summa Health System-Akron Campus, Summa Health Green Emergency Department).**

Click here to access the text editor.

*** Will any non-Summa Health sites be involved in the study (e.g., NEOMED)?**

◯ Yes ◯ No

If yes, please list those sites:

Click here to access the text editor.

*** Will any non-Summa Health employees be involved in the study?**

◯ Yes ◯ No

If yes, please list those individuals and their employers:

Click here to access the text editor.

Describe who will pay for the cost of medical treatment and/or compensation in the event of a research related injury:

Click here to access the text editor.

◯ Not Applicable- No consent form is being used and/or project involves prospective collection of data/samples that involves consenting, but there is no possibility of research-related injury.

*** Does this study require registration on www.clinicaltrials.gov?**

(Phase 2-4 trials of drugs and biologics (controlled clinical investigations other than Phase 1 investigations of a product subject to FDA regulation) AND trials of devices (controlled trials with health outcomes, other than small feasibility studies and pediatric post-marketing surveillance) must be registered per the FDA Act of 2007. Note clinical trials should only be registered once even if they are multi-site studies).

◯ Yes

◯ No

◯ N/A- Study does not meet the definition of an Applicable Clinical Trial (ACT).

If yes, provide the NCT number for this study and the name of the Responsible Party (i.e., Sponsor) who registered the study:

Click here to access the text editor.

If no, please explain:

Click here to access the text editor.

*** Did any investigator or staff member report a financial interest on their project-specific disclosure form (a.k.a., positive disclosure)?**

◯ Yes - Please attach a copy of all positive disclosure form(s).

◯ No

*** The regulatory binder must contain all of the following:**

- **A completed and signed financial disclosure form for each investigator/study staff member**
- **Current CVs and medical licenses**
- **All applicable training certificates (e.g., CITI) that document that each study team member has completed required training per the *Human Subjects Research Training and Education Policy*. Note that training must be current such that it will not expire within 60 days from the date of this submission.**
- **Investigator Participation Attestation**

◯ Check to indicate the regulatory binder contains all the information listed above.

External IRB Ancillary Reviews

Check all of the following required ancillary reviews that are applicable to this submission:

Office of Clinical Research Billing (OCRB)

Research involving any item that is typically considered a billable item to an insurance company (e.g., blood draws, images) must have a Coverage Analysis signed and on file prior to IRB submission. Please contact researchbilling@summahealth.org or call 330-375-4045 for guidance.

Do you have clinical billable items as part of the research study?

◯ Yes ◯ No

Radiation Safety

Research involving non-standard of care radioactive materials (which includes the terms "radioisotopes", "radionuclides", "radiopharmaceuticals", and "nuclear medicine studies", e.g. "PET", "MUGA", "Zevalin", and/or specific radionuclides such as "F-18", "Tc-99m", "Th-201", "I-131", "Ra-223", "Y-90", etc.) will need by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC). Contact Ron Scala, Radiation Safety Officer, to request a Radiation Safety review: scalar@summahealth.org or 330-375-7029. Attach copy of approval letter to this submission.

○ Yes ○ No

Pharmacy

Summa Health requires that all research involving the administration of medications within the hospital (including outpatient areas such as the Jean and Milton Cooper Pavilion, etc.) be reviewed and approved by the Pharmacy, and that all doses are coordinated, controlled, and dispensed by the hospital's research pharmacy. Please contact Jacqueline Ewald, Investigational Pharmacist, at ewaldj@summahealth.org or 330-375-6138 and add John Feucht to submission sign-off page in iRIS so that pharmacy approval can be documented within the system.

Research involving the administration of medication to a Summa Health subject must be conducted through the Summa Health Clinical Research Center (SHCRC) and be reviewed and approved by the Summa Health Pharmacy. Please contact research@summahealth.org for assistance.

Does this study involve administration of medication?

○ Yes ○ No

Health Technology Managment

Research involving non-standard of care equipment will need to be validated by Health Technology Management. Please contact Anson Sheck at 330-375-3310. Attach copy of approval letter to this submission.

Does this study require Health Technology Management approval?

○ Yes ○ No

Institutional Biosafety

Experiments involving the deliberate transfer of Recombinant or Synthetic Nucleic Acid Molecules (e.g., Gene Transfer), or DNA or RNA derived from Recombinant or Synthetic Nucleic Acid Molecules, or Microorganisms containing Recombinant or Synthetic Nucleic Acid Molecules and/or infectious agents (including select agents and toxins as defined by CDC and/or Animal and Plant Health Inspection Service (APHIS)) into one or more human research participants must be reviewed by the Institutional Biosafety Committee (IBC). All research requiring IRB review must be conducted through the SHCRC. Please contact research@summahealth.org for assistance. SHCRC staff, attach copy of WIRB IRB approval letter to this submission.

Does this research require IBC approval?

○ Yes ○ No

External IRB HIPAA Screening Questions

*** Which method of HIPAA documentation are you requesting to use in this study?**

- ☐ Written HIPAA Authorization using Summa approved authorization language
- ☐ Waiver of authorization by external IRB
- ☐ Waiver of authorization by Summa Health IRB

External IRB Waiver of HIPAA Authorization

*** To request a waiver of HIPAA authorization please provide a response to each of the following questions:**

Explain why the research cannot be practicably conducted without the waiver:

Click here to access the text editor.

Describe the plan to protect identifiers from improper use and disclosure:

Click here to access the text editor.

Describe the plan to destroy the identifiers at the earliest opportunity:

Click here to access the text editor.

Explain why this research could not be carried out without access to and use of PHI:

Click here to access the text editor.

Please list all PHI that will be created, used or disclosed for this study:

Click here to access the text editor.

NCI CIRB Study Attachment Checklist

Please check all documents below that apply to this submission and attach a copy of each:

- [ ] Informed Consent Form (ICF) Cost Clarification Sheet
- [ ] Project-Specific Disclosure Form if they contain positive disclosure(s)
- [ ] All Advertisements, Scripts, Recruitment Flyers or other subject facing materials for the research
- [ ] Summa Health-Specific Consent Document(s), prepared in accordance with required Summa Health Boilerplate Consent language

Number of draft consent documents submitted

Advarra IRB Study Attachment Checklist

Please check all documents below that apply to this submission and attach a copy of each:

- [ ] Project-Specific Disclosure Form if they contain positive disclosure(s)
- [ ] All Advertisements, Scripts, Recruitment Flyers or other subject facing materials for the research

- [ ] Summa Health-Specific Consent Document(s), prepared in accordance with required Summa Health Boilerplate Consent language

Number of draft consent documents submitted

Other External IRB Study Attachment Checklist

Please check all documents below that apply to this submission and attach a copy of each:

- [ ] Project-Specific Disclosure Form if they contain positive disclosure(s)
- [ ] All Advertisements, Scripts, Recruitment Flyers or other subject facing materials for the research
- [ ] Summa Health-Specific Consent Document(s), prepared in accordance with required Summa Health Boilerplate Consent language

Number of draft consent documents submitted

Significant Financial Interests

*** A Project-Specific Disclosure Form must be completed for this study.**

- ◯ Check to indicate 1) that all study team members (i.e., PI, co-investigators, coordinators, research nurses, data managers, students) have reviewed and signed the Project-Specific Disclosure Form for this study and 2) you understand that a copy of your study's fully-executed Project-Specific Disclosure Form must be attached to this application before IRB review will be initiated.

Ancillary Reviews

*** Was this study designed by a nurse at Summa and require review by the Nursing Research Committee?**

- [ ] Yes
- [ ] No
- [ ] Don't Know

*** Is there a Clinical Trial Registration (NCT) number for this study per ClinicalTrials.gov requirements?**

- [ ] Yes
- [ ] No
- [ ] N/A- Study does not meet the definition of an Applicable Clinical Trial (ACT). Click Help text for more information.

If yes, provide the NCT number for this study and the name of the Responsible Party (i.e., sponsor) who registered the study:

Click here to access the text editor.

If no, please explain:

Click here to access the text editor.

HUD Application

*** Research Sites (select or list all that apply):**

- [ ] Summa Health System- Akron Campus
- [ ] Summa Health System- St. Thomas Campus
- [ ] Summa Health System- Barberton Campus
- [ ] Other

If "Other" please list below:

Click here to access the text editor.

*** Provide the device information:**

View Details	Device Name	Is the Device FDA Approved	Is this a new device or a new use of an already approved device	IDE Number

No devices have been added to this Study

*** Is the HUD being studied for the indication(s) in its approved labeling for care?**

○ Yes ○ No

If no, please explain:

Click here to access the text editor.

*** What is the disease or condition that the device is intended to treat or diagnose?**

Click here to access the text editor.

*** Provide a summary of how the physician will use the device, including screening and follow-up visits, tests or procedures.**

Click here to access the text editor.

*** Describe the potential risks associated with the implantation and use of this device. Estimate the probability that a given harm may occur and its potential reversibility, when possible.**

Click here to access the text editor.

*** Describe the potential benefits associated with the use of the device.**

Click here to access the text editor.

* **What alternatives are available to treat or diagnose the patient's disease or condition?**

Click here to access the text editor.

* **Describe the training required to use the device and attach a copy of training certificates for clinical team members. If no certificates issued, please attach other documentation that demonstrates that adequate training was obtained.**

Click here to access the text editor.

* **Is the HDE holder required to provide training on the use of the device prior to use?**

○ Yes ○ No

* **Will you provide the patient with any written information about this HUD?**

○ Yes ○ No

If Yes, attach the information under the Study Documents tab.

If No, provide a brief summary of information that will be provided to the patient regarding this HUD.

Click here to access the text editor.

* **Research involving non-standard of care equipment will need to be validated by Health Technology Management. Please contact Anson Sheck at 330-375-3310 and attach a copy of the approval letter to this submission.**

Does this submission require Health Technology Management approval?

○ Yes ○ No

* **Checklist of documents that must be attached to the submission:**

- ☐ HDE approval order
- ☐ Product labeling/HUD Brochure
- ☐ Patient information packet and/or Informed Consent Form

Key Study Information

Please answer all questions with detailed responses reflecting the local conduct of this study.

(Providing page numbers from the Investigator's Brochure or Study Protocol will not be accepted.)**

Are you requesting a determination as to whether this study qualifies for an exemption?

○ Yes ○ No

Clear

*** List the Summa Health location(s) where the research will take place (e.g., Summa Health System-Akron Campus, Summa Health Green Emergency Department).**

Click here to access the text editor.

*** Will any research take place at a non-Summa Health site (e.g., NEOMED)?**

○ Yes ○ No

If yes, please list the site(s):

Click here to access the text editor.

Who developed/ wrote the research protocol:

- ☐ Investigator Initiated (regardless of funding)
- ☐ Industry (pharmaceutical or device company)
- ☐ Cooperative Agreement (SWOG, NRG, ECOG, etc...)
- ☐ Other

*** Study Purpose and Specific Aims**

Describe the overall purpose of the study and then list all specific aims.

Click here to access the text editor.

*** Study Background and Significance**

Describe relationship of proposed research to previous studies in the field and specifically identify the information gaps which this study is intended to fill (i.e., significance of research).

Click here to access the text editor.

*** Provide a detailed summary of how the study will be conducted at all Summa sites, include a description of the intended treatment plan and/or experimental procedures. Also include the time commitment requirement for subjects per visit and in total, as applicable:**

Click here to access the text editor.

Study References

List all references utilized to collect and analyze background information for this study. Please list protocol page numbers if a sponsored study. If an Investigator Initiated study, you may list the references here or attach at the end of the application under Other Study Documents.

Click here to access the text editor.

Data Analysis Plan

Describe what statistical/analytical methods will be used and provide information regarding sample size calculation, if applicable:

Click here to access the text editor.

◯ N/A- Feasibility/Pilot Study

Study Population

*** Total number of subjects to be enrolled at all Summa sites, provide numbers per Arm or Group as appropriate. For a chart review study, include the number of charts to be reviewed.**

If this is a multi-center study, provide a total number of subjects that will be enrolled at all sites:

◯ N/A

*** Provide age range of potential subjects:**

Check all types of subjects that may be enrolled:

☐ Inpatients
☐ Outpatients
☐ Healthy Volunteers
☐ Other

If other, please specify:

*** Will any of the following vulnerable populations be the focus of this study?**

- [ ] Children/Minors (under age 18) - Please contact the IRB for consultation
- [ ] Decisionally Impaired
- [ ] Illiterate (Witness who is not a member of research team required)
- [ ] Non-English Speaking (Translated Consent or Short Form Required)
- [ ] Pregnant Women, Neonates or Fetuses (Attach Pregnant Women, Neonates, and/or Human Placenta or Fetal Material Form)
- [ ] Seeing Impaired (Witness who is not a member of research team required)
- [ ] Severe acute illness associated with cognitive impairment (emergent and non-emergent cases)
- [ ] Subject physically unable to sign consent (Witness who is not a member of research team required)
- [ ] Summa/Affiliated Institution Staff or Students
- [ ] No

If so, explain why it is necessary to involve vulnerable populations and what additional safeguards will be used at all Summa sites to minimize possible risks (e.g., supplemental informed consent process).

Click here to access the text editor.

Provide source of subjects for this study (select all that apply):

- [ ] Subjects from practice of study investigator
- [ ] Subjects referrred or recruited from other physician practices
- [ ] Subject recruitment by advertisements, flyers, etc.
- [ ] Subjects identified from medical records or database outside the investigator's division or group
- [ ] Other

If other, please explain:

*** List all specific inclusion criteria at all Summa sites:**

Click here to access the text editor.

*** List all specific exclusion criteria at all Summa sites:**

Click here to access the text editor.

If non-English speaking individuals will not be eligible to participate, please provide justification as to why this population will be excluded:

Click here to access the text editor.

Who is responsible for determining each subject's eligibility? Describe how this will be documented and when it will occur in the research process?

Click here to access the text editor.

Recruitment- Describe how, when, where and by whom will subjects be recruited:

Click here to access the text editor.

Will ads, flyers or notices be utilized?

○ Yes ○ No

Clear

If yes, please attach a copy and describe where this information will be posted:

Click here to access the text editor.

Study Procedures

A Test Article is the investigational drug/device, software or test that is being evaluated in a study. Please list all Test Articles for this study:

Click here to access the text editor.

*** Will drugs or biologics be used as test articles in this study?**

○ Yes ○ No

View Details	Drug Name	FDA Approved	A new drug or a new use of approved drug:	IND Number

No drugs have been added to this Study

*** Will investigational medical devices or approved medical devices be used as test articles in this study?**

☐ Yes

☐ No

View Details	Device Name	Is the Device FDA Approved	Is this a new device or a new use of an already approved device	IDE Number

No devices have been added to this Study

Non-Significant Risk Device Determination Screening Question

*** Are you requesting a non-significant risk determination for one or more of the devices used in this study?**

Yes No

Non-Significant Risk Device

*** Is the device intended as an implant?**

Yes No

Explain:

Click here to access the text editor.

*** Is the device to be used to support or sustain human life?**

Yes No

Explain:

Click here to access the text editor.

*** Is the device of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human life?**

Yes No

Explain:

Click here to access the text editor.

*** Does the device present a potential for serious risk to the health, safety, or welfare of a subject?**

Yes No

Explain:

Click here to access the text editor.

Risks

*** Are human subjects at more than minimal risk?**

Yes No

*** Describe any risks and/or discomforts subjects may experience in this study. For each risk that is more than minimal risk, specify its frequency (e.g., likely, less likely, rare) and severity (e.g., serious, minor).**

Click here to access the text editor.

*** Explain why the risks to subjects in this study are reasonable and what steps will be taken at this site to minimize these risks. Include plans to address serious effects should they occur.**

Click here to access the text editor.

Benefits and Alternatives

*** Describe any potential benefits to subjects and/or to society overall as result of this study.**

Click here to access the text editor.

*** Describe other alternatives to study participation at all Summa sites that are available to prospective subjects.**

Click here to access the text editor.

Describe possible causes for subjects to be withdrawn from the proposed research (such as withdrawn by PI or subject withdraws from participation) and describe procedures for following subjects after study withdrawal.

- [ ] N/A Not an intervention or interaction study

Click here to access the text editor.

Privacy, Confidentiality and Data Security

*** "Privacy" refers to an individual's right to control access of others to themselves, such as the ability to control who sees them, hears them, touches them, and has access to their private information.**

Will subjects be consented in a private area away from the public?

- [ ] N/A- there is no consent for this study
- [ ] Yes
- [ ] No

If no, provide an explanation:

Click here to access the text editor.

Will study-related interventions and/or interactions be conducted in a private area?

- [ ] Yes
- [ ] NO

If no, provide an explanation:

Click here to access the text editor.

Will the private information collected be limited to what is required by the research?

☐ Yes

☐ NO

If no, provide an explanation:

Click here to access the text editor.

Other than above, are there additional provisions to protect the privacy of subjects?

☐ Yes

☐ No

If yes, describe:

Click here to access the text editor.

*** Confidentiality" and "Data Security" pertain to how a subject's identifiable information will be managed and protected at the research site (Summa) and outside the research site (i.e., providing data to sponsor). Describe the methods to be used for collecting, recording and maintaining data. List who will have access to the data and describe the long-range plan to protect confidentiality.**

Click here to access the text editor.

Subject Cost and Compensation

*** Will subjects or their insurance be charged for any study-related procedures?**

○ Yes ○ No

*** Will subjects receive reimbursement or compensation for participation?**

○ Yes ○ No

If yes, please describe in detail the plan for both reimbursement (compensation for expenses, like parking and meals) and compensation for time and discomfort. Include the payment schedule, amount of total payments and method of subject payment:

Click here to access the text editor.

If the project involves the possibility of research-related injury, describe who will pay for the costs of medical treatment and/or compensation in the event of a research related injury:

Click here to access the text editor.

○ N/A- Not Applicable- No consent form is being used and/or project involves prospective collection of data samples that involves consenting, but there is no possibility of research-related injury.

HIPAA Screening Question

*** Does this study collect, access, use or distribute any Protected Health Information (PHI)?**

○ Yes ○ No

Use of PHI for Recruitment Screening Question

* Will PHI be accessed or recorded, prior to obtaining written authorization from the subject, for the purpose of recruitment?

○ Yes ○ No

Use of PHI for Recruitment

* Please answer the following questions:

Please list all PHI that will be recorded and maintained by the research team prior to obtaining written authorization.

Click here to access the text editor.

Describe how the PHI recorded for individuals who do not give their authorization/consent to participate will be managed and destroyed:

Click here to access the text editor.

Summa Workforce

*** Do all members of the study team meet the Summa Workforce definition?**

○ Yes ○ No

Partial Waiver of Authorization

* A partial waiver of authorization from the IRB is required to use subject's PHI/contact information for recruitment conducted by non-Summa Workforce Members. Please check to acknowledge accounting requirements and answer the following questions to apply for a partial waiver:

○ Please check here to indicate that you understand and will comply with accounting of disclosure requirements associated with this waiver.

Clear

Explain why recruitment cannot be practicably conducted without the waiver:

Click here to access the text editor.

Describe the plan to protect identifiers from improper use and disclosure:

Click here to access the text editor.

Describe the plan to destroy the identifiers at the earliest opportunity:

Click here to access the text editor.

Explain why this research could not be carried out without access to and use of PHI:

Click here to access the text editor.

Please list all PHI that will be used/recorded for recruitment purposes:

Click here to access the text editor.

Written HIPAA Authorization Screening Question

*** Will written HIPAA Authorization be obtained from the research subjects?**

○ Yes ○ No

Written HIPAA Authorization

*** Check the written HIPAA Authorization method that will be used for this study:**

☐ Standard Summa HIPAA template will be completed and included in the written consent document.

☐ Non-Standard HIPAA template language will be included in the written document. **Study team must attach separate copy of authorization language that highlights and labels the 6 required elements and 3 required statements.

Provide written justification for not using the standard HIPAA template here:

Click here to access the text editor.

Waiver of Authorization Screening Question

*** Are you requesting a waiver of HIPAA authorization?**

○ Yes ○ No

Waiver of HIPAA Authorization

*** To request a waiver of HIPAA authorization please provide a response to each of the following questions:**

Explain why the research cannot be practicably conducted without the waiver:

Click here to access the text editor.

Describe the plan to protect identifiers from improper use and disclosure:

Click here to access the text editor.

Describe the plan to destroy the identifiers at the earliest opportunity:

Click here to access the text editor.

Explain why this research could not be carried out without access to and use of PHI:

Click here to access the text editor.

Please list all PHI that will be created, used or disclosed for this study:

Click here to access the text editor.

*** Will a Limited Data Set be used for this study?**

○ Yes ○ No

If yes, please list the source of the data set and attach a copy of the Data Use Agreement. Please contact Research Administration for the Data Use Agreement template.

Click here to access the text editor.

Informed Consent

*** How will informed consent be obtained? (select all that apply)**

- ☐ Written and Signed Informed Consent - Attach copy to application
- ☐ Waiver of Documentation of Informed Consent - No Signature Required
- ☐ Full or Partial Waiver of Informed consent (Note: Waiver not generally applicable for FDA-regulated research)
- ☐ Asssent of Minors and Written Parental Permission (Please contact the IRB for consultation)
- ☐ Exempt- No consent required

List all study team members who will obtain informed consent for this study:

Click here to access the text editor.

Please provide a detailed plan describing the informed consent process at this site. The plan should describe who will conduct the consent interview, the timing of obtaining informed consent, and any waiting period between informing the subject and obtaining the consent:

Click here to access the text editor.

How will study staff ensure that potential subjects understand the information prior to giving their consent:

Click here to access the text editor.

Waiver of Documentation of Informed Consent- No Signature Required

The only record linking the subject and the research would be the consent document and the principal risk would

be potential harm resulting from a breach of confidentiality.

Please explain why:

Click here to access the text editor.

The research presents no more than minimal risk or harm to subjects and involves no procedures for which written consent is normally required outside the research context.

Please explain why:

Click here to access the text editor.

Full or Partial Waiver of Informed Consent

*** Explain why the research involves no more than minimal risk:**

Click here to access the text editor.

*** Explain how the waiver or alteration will not adversely affect the rights and welfare of subjects:**

Click here to access the text editor.

*** Explain why the research could not be practicably carried out without identifiable information or identifiable biospecimens:**

Click here to access the text editor.

*** Explain why the research could not be practicably carried out without the waiver of alteration:**

Click here to access the text editor.

*** Will subjects be provided with additional pertinent information after participation?**

○ Yes ○ No

If yes, attach a copy of this information and describe plan to provide this information:

Click here to access the text editor.

Use of a Legally Authorized Representative (LAR)

* Are you requesting permission to obtain written consent from a subject's Legally Authorized Representative (LAR) for this study?

○ Yes ○ No

If no, save and move to next section. If yes, select all types of LARs that may be utilized for this study and answer all related questions below:

Select all types of LARs that may be utilized for this study:

- ☐ Court-Appointed Legal Guardian (Copy of documentation must be maintained with signed consent form)
- ☐ Person with Healthcare Power of Attorney (Copy of documentation must be maintained with signed consent)
- ☐ Spouse (Driver's License (or other valid ID) check documented in study file)
- ☐ Adult Child (Driver's License (or other valid ID) check documented in study file)
- ☐ Parent (Driver's License (or other valid ID) check documented in study file)
- ☐ Adult Sibling (Driver's License (or other valid ID) check documented in study file)

Explain why use of LARs is necessary for this study, including why the research question cannot be answered utilizing subjects who are able to consent for themselves:

Click here to access the text editor.

If a subject regains capacity to consent during their participation in the study, he/she must be asked to provide written consent. Explain the process the study team will use to monitor a subject's capacity to consent during the conduct of the study. If subjects will not be consented, provide a justification as to why it would not be feasible:

Click here to access the text editor.

○ Check to confirm that all members of the study team who will obtain consent will be trained and understand the IRB-approved use of LARs for this study prior to their involvement in the consent process and that this training will be documented in the study delegation log.

Clear

Data and Safety Monitoring

*** A clinical intervention study is a study designed to answer specific questions about the effects or impact of a particular biomedical or behavioral intervention (i.e., drugs, devices, treatments or procedures, behavioral or nutritional strategies), or designed to answer specific questions about human physiology. A Data and Safety Monitoring Plan is required for all clinical intervention studies that involve more than minimal risk to subjects. Is this study a clinical intervention that involves more than minimal risk to subjects?**

○ Yes ○ No

Who will be responsible for monitoring this study (check at least one option)?

○ Principal Investigator

Clear

○ Sponsor

Clear

○ Independent Monitor or Monitoring Group

Clear

Provide Name:

Click here to access the text editor.

◯ Data Safety Monitoring Board/Committee (Note: Required for NIH Phase III Studies)

Clear

◯ Other

Clear

Explain:

Click here to access the text editor.

List the type of data and events (i.e., efficacy data, adverse events, unanticipated problems involving risk to participants or others) that are to be captured under the monitoring plan:

Click here to access the text editor.

Describe the frequency of the assessments of these data and events, such as points in time or after a specific number of participants are enrolled:

Click here to access the text editor.

Describe plan to communicate outcomes of monitoring reviews to the IRB, the study sponsor and/or other appropriate entities:

Click here to access the text editor.

As applicable, define specific triggers or stopping rules that will dictate when some action is required:

Click here to access the text editor.

◯ N/A

Clear

Screening for Specimens

* Does this study involve the collection of specimens for future research, a repository or storage bank?

◯ Yes ◯ No

Specimen Collection for Future Research and/or Specimen Repository/Bank Administration

Specimens are (check all that apply):

☐ Specimens collected for clinical purposes

- [ ] Specimens collected for research purposes only
- [ ] Other:

Click here to access the text editor.

Where will specimens be stored and will they be shipped outside of Summa?

Click here to access the text editor.

Direct identifiers will be sent with specimens or shared with other researchers and/or outside entitites:

- [ ] Yes
- [ ] No
- [ ] N/A- Specimens will not be shared with others

If yes, provide the identifiers and a justification for sending direct identifiers with the specimens:

Click here to access the text editor.