Protocol Title: Click here to enter text.
Principal Investigator: Click here to enter text.

INSTRUCTIONS:

- *Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, indicate not applicable (N/A) under the heading For simple research, such as a retrospective chart review, less than a page may be necessary to address the relevant sections.*
- *For any items described in the sponsor's protocol, grant, contract, or other documents submitted with the application, you may reference the title and page numbers of these documents. If you reference page numbers, attach those pages to this protocol. Limit attached pages to those referenced in this protocol.*
- *When you write a protocol, keep an electronic copy so you can modify this copy when making changes.*

1. Objectives

a. Describe the purpose,	*Click here to enter text.*
b. Describe the specific aims	Click here to enter text.
c. Describe the aims	Click here to enter text.
d. State the hypotheses to be tested.	Click here to enter text.

2. Background

a. Describe the relevant prior experience and gaps in current knowledge.	Click here to enter text.
b. Describe any relevant preliminary data.	Click here to enter text.
c. Describe any procedures that are important to the research that will be performed regardless of whether the subject takes part in the research.	Click here to enter text.
d. Describe any procedures that are important to the research that will be performed regardless of	Click here to enter text.

whether the subject takes part in the research.	

3. Inclusion and Exclusion Criteria

a. Describe how individuals will be screened for eligibility.	Click here to enter text.
b. Describe the criteria that define who will be included or excluded in your final study sample.	Click here to enter text.
c. Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.	Click here to enter text.
d. Describe any procedures that are important to the research that will be performed regardless of whether the subject takes part in the research.	Click here to enter text.
e. Indicate specifically the vulnerable populations you will include or exclude whether you will include or exclude *f. If there are vulnerable populations included indicate the vulnerable populations involved in the study and the applicable IRBNet Supplemental Forms completed for the vulnerable population(s).* *i. Pregnant Women* *ii. Neonates of Uncertain Viability* *iii. Nonviable Neonates*	Click here to enter text.

iv. Prisoners *v. Children* *vi. Wards* *vii. Adults Lacking Capacity to Consen*	

4. Number of Subjects

a. Indicate the total number of subjects to be accrued across all sites.	*Click here to enter text.*

5. Recruitment Methods

a. Describe when, where, and how potential subjects will be recruited.	Click here to enter text.
b. Describe the methods that will be used to identify potential subjects.	Click here to enter text.
c. Describe materials that will be used to recruit subjects.	Click here to enter text.
d. Describe the Procedures Involved	Click here to enter text.
e. Describe and explain the study design.	Click here to enter text.
f. Provide a description of all procedures being performed because the subject is taking part in the research, including procedures being performed to monitor subjects for safety or minimize risks. Describe when these procedures are performed	Click here to enter text.

Describe: *g. Procedures performed to lessen the probability or magnitude of risks.* *h. All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.* *i. The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)* *j. What data will be collected including long-term follow-up.*	Click here to enter text.
Describe: *k. The duration of an individual subject's participation in the study.* *l. The duration anticipated to enroll all study subjects.* *m. The estimated date for the investigators to complete this study (complete primary analyses)*	Click here to enter text.

6. Data and Specimen Management

a. Describe the data analysis plan, including any statistical procedures.	Click here to enter text.
b. When applicable, provide a power analysis	Click here to enter text.
c. Describe any procedures that will be used for quality control of collected data.	Click here to enter text.
d. Describe how data and specimens will be handled study-wide: *i. What information will be included in that data or associated with the specimens?* *ii. Where and how data or specimens will be stored?* *iii. How long the data or specimens will be stored?* *iv. Who will have access to the data or specimens?* *v. Who is responsible for receipt or transmission of the data or specimens?* *vi. How data and specimens will be transported?*	Click here to enter text.

7. Provisions to Monitor the Data to Ensure the Safety of Subjects

☐ *This study involves no more than minimal risk study and this section is not required.*

The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

a. Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.	Click here to enter text.
b. Describe what data are reviewed, including safety data, untoward events, and efficacy data.	Click here to enter text.
c. Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).	Click here to enter text.
d. Describe the frequency of data collection, including when safety data collection starts. *e. Describe who will review the data.*	Click here to enter text.
f. Describe the frequency or periodicity of review of cumulative data.	Click here to enter text.
g. Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.	Click here to enter text.
h. Describe any conditions that trigger an immediate suspension of the research.	Click here to enter text.

8. Withdrawal of Subjects ☐ N/A

a. *If applicable, describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.*	Click here to enter text.
b. *If applicable, describe any procedures for orderly termination.*	Click here to enter text.
c. *If applicable, describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*	Click here to enter text.

9. Risks to Subjects

a. *List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to the subjects' participation in the research. Include as may be useful for the IRB's consideration, describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.*	Click here to enter text.
b. *If applicable, describe any costs that subjects may be responsible for because of participation in the research.*	Click here to enter text.
c. *If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.*	Click here to enter text.

d. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.	Click here to enter text.
e. If applicable, describe risks to others who are not subjects.	Click here to enter text.

10.Potential Benefits to Subjects

a. Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits.	Click here to enter text.
b. Indicate if there is no direct benefit. Do not include benefits to society or others.	Click here to enter text.

11. Confidentiality

a. Describe the procedures for maintenance of confidentiality.	Click here to enter text.
b. Describe the steps that will be taken secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission	Click here to enter text.

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12. Provisions to Protect the Privacy Interests of Subjects

a. *Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.*	Click here to enter text.
b. *Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.*	Click here to enter text.
c. *Indicate how the research team is permitted to access any sources of information about the subjects.*	Click here to enter text.

13. Consent Process

a. *If you are obtaining consent of subjects describe the consenting process.*	Click here to enter text.
b. *If you are documenting consent of subjects in writing describe how consent will be documented.*	Click here to enter text.

If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. You may use the following documents as guides to create a consent document or script:

- *Informed Consent Document Template: GR Medical Center Participants*
- *Informed Consent Document Template: non-GR Medical Center Participants*
- *Children's Assent Document Template, (ages 7-12)*
- *Children's Assent Document Template, (ages 13-17)*
- *Paper Survey Consent Template*
- *Electronic Survey Consent Template*

c. *Indicate if you are requesting a Waiver of the Consent Process or Waiver of Documentation of Consent.*	Click here to enter text.
Non-English Speaking Subjects d. *If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language.* e. *Indicate the language that will be used by those obtaining consent.* f. *Indicate what language(s) other than English are understood by prospective subjects or representatives.*	Click here to enter text.
Subjects who are not yet adults (infants, children, teenagers) g. *Describe the criteria that will be used to determine whether*	Click here to enter text.

a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.) *h. Describe whether parental permission will be obtained from:* *i. Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.* *ii. One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.* *i. Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.* *j. Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some*	

children, indicate which children will be required to assent. k. *When assent of children is obtained describe whether and how it will be documented.*	
Cognitively Impaired Adults l. *Describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require children to sign assent documents.*	*Click here to enter text.*
Adults Unable to Consent m. *List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)* n. *Describe the process for assent of the subjects. Indicate whether:* i. *Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be*	*Click here to enter text.*

required to assent and which will not. *ii. If assent will not be obtained from some or all subjects, an explanation of why not.* *iii. Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.*	

14. Setting ☐ N/A

Describe the sites or locations where your research team will conduct the research.

a. Identify where your research team will identify and recruit potential subjects.	Click here to enter text.
b. Identify where research procedures will be performed.	Click here to enter text.
c. Describe the composition and involvement of any community advisory board	Click here to enter text.

d. For research conducted outside of the organization and its affiliates describe: *i. Site-specific regulations or customs affecting the research for research outside the organization.* *ii. Local scientific and ethical review structure outside the organization.*	*Click here to enter text.*

15. Compensation for Research-Related Injury ☐ N/A

This section is not required when research involves no more than Minimal Risk to subjects.

a. Describe the available compensation in the event of research related injury.	*Click here to enter text.*

16.Resources Available ☐ N/A

a. Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform their role. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research	*Click here to enter text.*
b. Describe other resources available to conduct the research: For example, as appropriate:	*Click here to enter text.*

i. Describe your facilities. *ii. Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.* *iii. Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*	

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17. Drugs or Devices ☐ N/A

a. If the research involves drugs or devices and is investigator-initiated, indicate whether there is any possibility that the results will be reported to FDA.	Click here to enter text.
b. If the research is conducted at a non-GR Medical Center site, involves drugs and you will not use the GR Medical Center Research Pharmacy, describe your plans to store, handle, and administer those drugs so that they will be used only on subjects and be used only by authorized investigators.	Click here to enter text.
c. If the research involves a device, describe your plans to store, handle, and administer the device so that they will be used only on subjects and be used only by authorized investigators.	*Click here to enter text.*

d. *If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:* i. *Identify the holder of the IND/IDE/Abbreviated IDE.* ii. *Explain procedures followed to comply with all applicable FDA sponsor requirements*	*Click here to enter text.*

18. Multi-Site Research ☐ N/A

a. *If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites, such as:* b. *All sites have the most current version of the protocol, consent document, and if applicable, HIPAA authorization.* c. *All required approvals have been obtained at each site (including approval by the site's IRB of record).* d. *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.* e. *All engaged participating*	*Click here to enter text.*

sites will safeguard data as required by local information security policies. *f. All local site investigators conduct the study appropriately.* *g. All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.*	
h. Describe the method for communicating to engaged participating sites: *i. Problems.* *ii. Interim results.* *iii. The closure of a study*	*Click here to enter text.*

19. Research Conducted in a Foreign Country ☐ N/A

Any project that will be conducted in whole, or in part, at a location outside the United States must include answers to the following questions:

a. List the study location and the primary language/dialect spoken by the proposed subject population.	Click here to enter text.
b. If this project has been, or will be, reviewed by a local IRB or Ethics Committee, provide the name, address, and contact information for the local IRB or ethics review committee at the foreign research site.	Click here to enter text.
c. If applicable, provide the name and contact information for any foreign investigator, collaborator, or institution	Click here to enter text.

assisting the PI in the conduct of the project.	
d. *Briefly describe your knowledge of the intended population including knowledge of local customs, practices, and religions as they relate to this project.*	Click here to enter text.
e. *Describe your proficiency with the local language, or how information and communication will be translated throughout the project.*	Click here to enter text.
f. *Describe how the community will be notified, and information disseminated, regarding the results of the research project.*	Click here to enter text.
g. *Address any cultural, regional, or unique risks the IRB should be aware of when evaluating this research project.*	Click here to enter text.
h. *State how you will communicate with the IRB if you need to report an unanticipated problem (associated with risk to subjects or others associated with the study) or an amendment to the study.*	Click here to enter text.
i. *For student investigators, explain how the faculty sponsor will provide oversight for the study while you (or representatives) are conducting the research in the foreign country.*	Click here to enter text.

20. Community-Based Participatory Research ☐ N/A

a. *Describe involvement of the community in the design and conduct of the research.* ***Note: "Community-based Participatory Research" is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.***	*Click here to enter text.*