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.*
- *When you write a protocol, keep an electronic copy so you can modify this copy when making changes.*
- *Delete the INSTRUCTIONS and add a version date before submitting the protocol.*

Protocol Title: Click here to enter text.

Principal Investigator: Click here to enter text.

1. Objectives

Describe the purpose, specific aims, and hypothesis:
Click here to enter text.

2. Background

Describe the background and rationale for the study:
Click here to enter text.

3. Inclusion and Exclusion Criteria

List the inclusion/exclusion criteria:
Click here to enter text.

4. Number of Subjects/Records/Samples Collected

Indicate the total number of subjects to be accrued/records reviewed/samples collected across all sites:
Click here to enter text.

5. Recruitment Methods

Describe when, where, and how potential subjects will be recruited:

Click here to enter text.

6. Multiple Site ☐ N/A

A site is defined as an institution/organization/university that is collaborating with Augusta University

If this research involves multiple sites, specify which is the lead site and describe the roles of each site in the study.

If Augusta University will serve as the lead site, indicate that all required approvals are already obtained or will be obtained at each site prior to project implementation. In addition:

Describe the processes you have in place to ensure successful coordination of activities among sites. For example, do all sites have the most current version of the protocol, consent document, and HIPAA authorization? How will modifications be communicated to sites and approved prior to implementation? How will participating sites be kept abreast of any problems, interim results, or the eventual closure of the study?

Describe the mechanisms you have in place to ensure that all local site investigators conduct the study appropriately and that engaged participating sites safeguard data as required by local information security policies. Please confirm that all non-compliance and /or unanticipated problems associated with the study protocol or applicable requirements will be reported in accordance with local policy.

Click here to enter text.

7. Reliance Agreements/Single IRB ☐ N/A

Reliance agreements (i.e. IRB Authorization Agreement (IAA), Individual Investigator Agreement (IIA), etc.) are formal arrangements between institutions allowing the IRB of one institution to rely on the IRB of another institution for review of human subjects research. Investigators working at multiple institutions, each having an IRB, may choose to have one IRB become the IRB of record over some or all participating sites. This means that the AU IRB is either the reviewing IRB (IRB of Record) or is relying on another IRB for IRB oversight of the research activity.

If the study will utilize a reliance agreement or a single IRB, please describe which institution(s) will be relying on another IRB for review and which institution will be responsible for the IRB oversight of the relying IRB(s).

Note: Requests for Reliance Agreements should be submitted by the Augusta University study team. All request for Reliance Agreements should be submitted through IRB Net following the procedures outlined in Forms and Templates

Click here to enter text.

8. Procedures Involved

a. *Describe the procedures involved to include those procedures that are standard evaluation and/or care and those that are solely for research purposes:*

Click here to enter text.

b. *Describe and explain the study design:*
If the study involves multiple conditions where each condition involves different procedures, please provide a table that breaks down the procedures by condition and in chronological order. Include when and where they are performed.

Click here to enter text.

c. *Data Types and Source Records:*

Briefly describe the actual source records or measures that will be used to collect data about participants. (All surveys, interview scripts, and data collection forms will be attached elsewhere in the application. Do not add other documents to the protocol.) Describe what data will be collected and how it will be collected at all measurement/data collection time-points.

d. *Describe the procedures performed to lessen the probability or magnitude of risks:*

Click here to enter text.

e. *Describe the duration of an individual subject's participation in the study and the time involved also include the overall duration of the project:*

Click here to enter text.

9. Data and Specimen Management

a. *Describe the data analysis plan, including any statistical procedures:* Click here to enter text.	☐ N/A
b. *When applicable, provide a power analysis:* Click here to enter text.	☐ N/A
c. *Describe how data and specimens will be handled:*	☐ N/A

i. *What information will be included in that data or associated with the specimens?*

Click here to enter text.

ii. *Where and how data and/or specimens will be stored?*

Click here to enter text.

iii. *How long will the data and/or specimens be stored?*

Click here to enter text.

iv. *Who will have access to the data or specimens?*

Click here to enter text.
v. *Who is responsible for receipt or transmission of the data and/or specimens?* Click here to enter text.
vi. *How will data and/or specimens be transported?* Click here to enter text.

10. Provisions to Monitor the Data to Ensure the Safety of Subjects ☐ N/A

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.* Click here to enter text.
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 any conditions that trigger an immediate suspension of the research.* Click here to enter text.

11. 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.	☐ N/A
b. *If applicable, describe any procedures for orderly termination.* Click here to enter text.	☐ N/A
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.	☐ N/A

12. Risks to Subjects

a. *List the reasonably foreseeable 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.	☐ N/A
c. *If applicable, describe risks to others who are not subjects.* Click here to enter text.	☐ N/A

13. Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research.
Click here to enter text.

14. Confidentiality

Describe the procedures for maintenance of confidentiality.
Click here to enter text.

15. Incomplete Disclosure, Authorized Deception, or Deception

☐ **N/A**

See the Deception Policy on Augusta University Website.

If the study will use incomplete disclosure or deception, describe the incomplete disclosure or deception, and provide a rationale explaining why it is necessary to the research.

Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

Click here to enter text.

16. Consent Process

If you are obtaining consent of subjects describe the consenting process. Be sure to include the process to be used if enrolling illiterate,non-English speakers, individuals with impaired decision making capacity to consent, as applicable.

Click here to enter text.

17. Compensation for Research-Related Injury

This section is not required when research involves no more than Minimal Risk to subjects. ☐ **N/A**

a. *Describe the available compensation in the event of research related injury.*

Click here to enter text.

18.Qualifications to Conduct Research and Resources Available

Describe the qualifications of you and your staff to conduct this research. The IRB is looking for information such as area(s) of expertise, past research experience, relevant certifications, etc.

For international research or research with vulnerable populations, describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to conduct the research. When applicable describe the knowledge of the local study sites, culture, and society. Provide enough information so the IRB knows that you have qualified staff for the proposed research.

Note: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify people by role (e.g., coordinator, research assistant, Sub-Investigator, or pharmacist), a change to that person will not require prior approval by the IRB, provided that person meets the qualifications described above to fulfill their roles.

Click here to enter text.

a. *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*

Click here to enter text.

b. 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.

Click here to enter text.

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