**INSTRUCTIONS:**

* This protocol template should be used for investigator-initiated biomedical or behavioral research. .
* Required sections are shown in **RED** and are applicable to all IRB applications. (While a section may be marked as required, specific bullets within that section may not be applicable to every study.) Other sections may not be applicable to your research. If so, mark as “NA” or delete section.
* Remove all instructions in italics so that they are not contained in the final version of your protocol.

**PROTOCOL TITLE:**

*Include the full protocol title.*

**PRINCIPAL INVESTIGATOR:**

* *Name*
* *Do not include local co-investigators—they will be listed in the eIRB application under study personnel*

# Objectives / Specific Aims

* + Describe the purpose, specific aims, or objectives.
  + State the hypotheses to be tested.

# 2.0 Background

Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how this study will add to existing knowledge. If the PI has relevant preliminary data, describe that here has well.

# 3.0 Intervention to be studied (if applicable)

* + Provide information (using relevant citations) on the intervention to be studied.
  + Include the FDA status for all medications and/or devices under study as well as their approved indications.
  + For medication trials, describe the rationale for using the proposed medication(s) and proposed dosing, as well as the pharmacology and safety profile of the agent(s) being used.
  + For device trials, describe the proposed use of the device as well as its safety.
  + For other intervention trials (e.g. behavioral or surgical), provide the rationale for the proposed intervention as well as any relevant information on other uses of the intervention, safety of the intervention, and relevant experience the investigators have in carrying out the intervention.
  + When appropriate, describe the control/placebo to which you are comparing your intervention.

# 4.0 Study Endpoints (if applicable)

* + Describe the primary and secondary study endpoints (outcome variables).
  + Describe any primary or secondary safety endpoints (outcome variables).

# 5.0 Inclusion and Exclusion Criteria/ Study Population

* + Describe how individuals will be screened for eligibility.
  + List all inclusion and exclusion criteria – If there are different groups or cohorts, provide separate inclusion and exclusion criteria for each one. Consider the following types of inclusion/exclusion criteria and include **as applicable:**

**Inclusion Criteria**

* + - * Age range of study population
      * The disease or disorder under study and how it will be documented/ determined
      * Clinical indicators of current status, as measured within [XX] days of randomization (if applicable). Consider listing the allowable duration of prior therapy for the specific population to be studied.
      * Any other characteristic required for study inclusion

**Exclusion Criteria**

* + - * List specific contraindications
      * Use of excluded drugs/devices within XX days of randomization
      * Clinical/laboratory indicators of current status, obtained within [XX] days prior to randomization. List the specific tests to be performed and the narrowest acceptable range of laboratory values for exclusion, consistent with safety
      * Specify exclusions related to pregnancy, lactation or plans to become pregnant
      * Inability or unwillingness of subject or legal guardian/representative to give informed consent

***Exclusion and inclusion criteria should not overlap. That is, if there is an inclusion criterion that specifies that a certain demographic or clinical characteristic must be in place, there should not be an exclusion criterion stating that those without the characteristic will be excluded.***

* Describe plan to include a diverse population (if applicable).
  + - If you propose to exclude any sex/gender or racial/ethnic group, include a compelling rationale for the proposed exclusion. For example, 1) the research question addressed is relevant to only one gender or 2) evidence from prior research strongly demonstrates no difference between genders.
* Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that 'prisoners' includes all subjects involuntarily incarcerated as well as subjects who become incarcerated after the study begins.
  + - Provide either a description of the plans to include children or, if children will be excluded from the proposed research, then it is recommended that you provide an acceptable justification for the exclusion. For example, 1) the condition is rare in children as compared to adults or 2) insufficient data are available in adults to judge risk in children.

# 6.0 Number of Subjects

Indicate the total number of subjects to be accrued locally.

# 7.0 Setting

* + Describe the setting(s) where your research team will conduct the research (e.g. ER, ICU, Research Nexus, etc.).

**Study Sites**

* + If this is community engaged research, please also complete the Community Engaged Research Protocol Addendum found on the IRB forms page and upload with your protocol into the eIRB application.

# 8.0 Recruitment Methods

* + Describe when, where, and how potential subjects will be recruited.
  + Describe the methods that will be used to identify potential subjects (e.g. chart review).
  + Describe materials that will be used to recruit subjects. (Attach copies of these documents in the eIRB application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video file. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video file.)

# 9.0 Consent Process

Indicate whether you will you be obtaining informed consent, and if so, describe:

* + - * The method of obtaining consent
      * Where the consent process will take place
      * If consent will be obtained from someone other than the participant (e.g. a parent or legally authorized representative).
      * Any waiting period available between informing the prospective subject and obtaining the consent
      * Any process to ensure ongoing consent
      * Any steps taken to ensure study subjects’ understanding (if applicable)
      * If enrolling subjects vulnerable to undue influence or coercion, include steps to be taken to minimize possibility of coercion or undue influence.

**For subjects who are not yet adults (infants, children, teenagers)**

* + - Describe how parental permission will be obtained.
    - 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.
    - Describe process for re-consent as an adult if the subject reaches the age of majority during the study.

**For Cognitively Impaired Adults**

* + - Describe the process to determine whether an adult has capacity to consent.
    - Discuss whether there is a plan to obtain assent from the cognitively impaired subject.
    - Describe process for re-consent if subject regains decision capacity.

# 10.0 Study Design / Methods

* + Describe and explain the study design.
  + If the study will be designed in phases and each phase will require separate IRB approval, please specifically indicate this in the description.
  + Where applicable, clearly distinguish research procedures from non-research procedures that may also occur during a study visit (e.g. clinical procedures that would occur whether or not the individual was a study participant).
  + Provide a description of all research procedures being performed, when they are performed, and duration of individual subjects’ participation. For behavioral studies, describe behavioral interaction/components (e.g. focus groups, interviews, etc.). If interactions with subjects will be audio or videotaped, describe and justify. For studies with more than 1 visit, a schedule of events table is recommended.
* Describe:
  + - Procedures performed to lessen the probability or magnitude of risks.
    - How all drugs and devices will be used in the research (e.g. dose, dosage form, etc.)
    - The source records, including medical or educational records that will be used to collect data about subjects.
* Describe data collection procedures (e.g. chart review, subject interview, etc.). Provide a description of all assessment instruments to be used. (Upload in eIRB all surveys, scripts, etc.) Include what data will be collected.

# 11.0 Specimen Collection and Banking (if applicable)

If specimens will be collected at MUSC:

* + - What type of specimens will be collected?
    - What information will be included in that data or associated with the specimens?
    - Where and how will specimens and associated data be stored?
    - How long the data or specimens will be stored?
    - Who (role on the study) will have access to the specimens and associated data?
    - Who (role on the study) is responsible for receipt or transmission of the data or specimens?
    - Will specimens or associated data be sent to an outside facility?
    - How will specimens and associated data be transported?

**Specimen/Banking for Future Use**

If specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, when they will be destroyed (if ever), how the specimens will be accessed, and who will have access to the specimens.

* + - Describe the linkages to subjects and who will have access to subject identities.
    - List the data to be stored or associated with each specimen.
    - Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens, including whether those data will be identifiable to others.
    - State whether samples could be used for genetic analysis.
    - Can specimens be withdraw? If so, what is the process.

# 12.0 Data Management

* + Describe the data analysis plan, including any statistical procedures.
  + Provide a power analysis, or justification of sample size.
  + Describe the steps that will be taken to secure the data to maintain confidentiality (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.
  + Describe any procedures that will be used for quality control of collected data (where applicable).
  + If data will leave MUSC, clarify what data will be sent, how it will be sent, and whether or not the data will include any identifiers.

# 13.0 Provisions to Monitor the Data to Ensure the Safety of Subjects (if applicable)

* For any research that is greater than minimal risk, clinical research, a clinical investigation funded by the NIH, or a clinical investigation regulated by the FDA, there must be a data safety and monitoring plan. This plan should describe:
  + - The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.
    - Reporting plan for communicating findings to IRB/sponsor/federal agencies.
    - Reporting plan for adverse events.
    - What data are reviewed, including safety data, untoward events, and efficacy data.
    - Who will review the data.
    - Any conditions that trigger an immediate suspension of the research and who would make the determination for suspension (e.g. DSMB).
  + Studies that involve clinical trials must include a description of the plan for subject safety and minimizing risks of the research, including data monitoring and adverse event reporting to ensure the safety of subjects. The complexity of the plan should be determined by the level of risk to subjects. The plan should specify: 1) what will be monitored, 2) how frequently the monitoring will occur, 3) who will be responsible for the monitoring, and 4) study endpoints proposed.

# 14.0 Withdrawal of Subjects (if applicable)

* + - Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent, including stopping participation for safety reasons.
    - Describe any procedures for orderly termination of subjects by investigator.
    - Describe procedures that will be followed when subjects voluntarily withdraw from the research, including partial withdrawal from procedures with continued data collection.

# 15.0 Risks to Subjects

* + - List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the research. Describe the probability, magnitude, duration, and reversibility of the risks (as applicable). Consider physical, psychological, social, legal, and economic risks. Include loss of confidentiality.
    - Indicate if the study may have risks to the subjects that are currently unforeseeable (note that minimal risk studies should not have unforeseeable risks).
    - If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
    - If applicable, describe risks to others who are not subjects, (e.g. risks to ethnic or cultural groups, risks to sexual partners of subjects, etc.).

# 16.0 Potential Benefits to Subjects or Others

* + - Discuss the potential benefits of the research to the subjects and others.
    - Indicate if there is no direct benefit to the subject.
    - Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

# 17.0 Sharing of Results with Subjects

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g. the subject’s primary care physicians) and if so, describe how it will be shared.

# 18.0 Drugs or Devices (if applicable)

* + - If the research involves drugs or devices, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.
    - If the drug is investigational (has an IND) or the device has an IDE or a claim of an abbreviated IDE (non-significant risk device), include the identity of the holder of the IND/ IDE.

# References