**Protocol Template:**

**Version date:**

**Title**

**Investigator names**

**Location**

**Objectives / Specific Aims**

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

**Background and Significance**

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.

# Intervention to be studied

* + Provide information (using relevant citations) on the intervention to be studied.
	+ 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.

**Study Endpoints**

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

**Number of subjects**

* Indicate the total number of subjects to be accrued locally.

**Inclusion / Exclusion Criteria**

* + 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 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.

**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.

**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.
			* The use of translators

**For Cognitively Impaired Adults**

* + - Describe the process to determine whether an adult has capacity to consent by referring to the information in green below.
		- Describe process for re-consent if subject regains decision capacity.

**When there is an indication that capacity to consent is diminished, the subject’s capacity should be evaluated. The evaluation of capacity must be documented and such documentation included in the subject’s research records. The subject’s capacity to consent to participation in a clinical trial will be evaluated by using the following standards:**

* + - 1. **The research subject must evidence the ability to make a conscious choice to participate in the study.**
			2. **The research subject must demonstrate basic understanding of the study.**

**iii. The subject must grasp sufficient information to form the basis of a reasoned decision and comprehend and remember (even with assistance):**

 **a. That participation is voluntary**

 **b. The major procedures**

 **c. The main risks and benefits**

**iv. The research subject must show the ability to compare risks and benefits of study participation in order to reach a rational decision regarding participation.**

 **v. The research subject must demonstrate the understanding and awareness of the consequences of a treatment decision; e.g., the emotional impact, rational requirements and future consequences.**

**Subjects assessed to lack capacity to consent to participate in research may participate if they assent to participating and their surrogate (LAR) decision maker provides informed consent. Subjects who are not capable of consent to research participation must demonstrate either the willingness to participate or, at least, a lack of objection. Passive lack of objection is acceptable in an alert patient. Indication of distress such as crying or attempts to escape the situation should be taken as refusals to assent to the study.**

**Methodology**

* + 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.
		- 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.

**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.

**Benefits to subjects**

* + - 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.

**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).

#  Protocol Deviations

* Describe how protocol deviations will be processed. A protocol deviation is failure to follow procedures specified in the approved research protocol. which include (but are not limited to), deviations from study inclusion/exclusion criteria, or failure to follow criteria for subject follow-up, withdrawal, or timely monitoring procedures. Protocol deviations must be reported to the IRB by the PI *within 5 working days* from the day the investigator becomes aware of the event. Protocol deviation reports to the IRB must include the subject identifier, date of deviation, impact on the subject’s safety, and the plan for preventing the deviation in the future (if applicable).

# Adverse Events and Serious Adverse Events

* If applicable, define and describe the process for reporting adverse and serious adverse events. An adverse event (AE) is any untoward medical occurrence that may present itself during the course of a research study. An AE can be any unfavorable and unintended sign, symptom, or disease temporally associated with the patient’s participation in the research study, regardless of the suspected cause.

# Withdrawal of Subjects

* + - 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.

**References**