**Instructions:**

* Keep an electronic copy. You will need to modify this copy when making changes.
* All referenced checklists, templates, and policies, can be found on the IRB website.
* **Remove all instructions in italics so they are not contained in the final version of your protocol.**
* Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “N/A”. Do not deletethe section headers.
* *When you save and upload this document, add the protocol version date to the title.*

**PROTOCOL TITLE:**

**PRINCIPAL INVESTIGATOR:**

Name

Department

Telephone Number

Email Address

**STUDY SUMMARY:**

*Please provide a brief summary of the study in the table below.*

|  |  |
| --- | --- |
| **Research Site** |  |
| **Primary Objective** |  |
| **Secondary Objective(s)** |  |
| **Research Intervention(s)/ Interactions** |  |
| **Investigational Agent(s)** |  |
| **IND/IDE #’s** |  |
| **Clinical Trials NCT#** |  |
| **Study Population** |  |
| **Type of Consent** |  |
| **Sample Size** |  |
| **Study Duration for individual subjects** |  |
| **Funding Source** |  |

**REVISION HISTORY**

***\*This table should only be used during submission of an Amendment application to the IRB.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Version #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**PRIMARY OBJECTIVES:**

*Describe the purpose, specific aims, objectives, and/or hypotheses.*

*(There should be one or two primary objectives with additional objectives listed as secondary.)*

**SECONDARY OBJECTIVES:**

**BACKGROUND:**

*Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how this project will add to existing knowledge.*

*Describe any relevant preliminary data (e.g. pilot data).*

*Note: this section should be limited to only information directly related to the research questions and objectives. Do not include your thesis/dissertation proposal.*

**STUDY ENDPOINTS:**

*Describe the primary and secondary study and/or safety endpoints.*

**STUDY INVESTIGATIONAL AGENTS:**

*Describe the study intervention and/or investigational device/drug that is being evaluated.*

*Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on participants and be used only by authorized investigators.*

*If the drug has an IND or the device has an IDE, include the following information:*

* *Identify the holder of the IND/IDE and the number.*
* *Explain procedures followed to comply with sponsor requirements for FDA-regulated research.*

*Is this a Non-significant risk device (i.e. abbreviated IDE) Device?*

* *If yes, provide rationale for your determination.*
* *Identify where research procedures will be performed*.

*Qualifications & Training:*

* *Describe qualifications of study personnel in the use and/or handling of study investigational agents.*
* *Describe any special training required before use of the investigational agents in the research.*

**PROCEDURES INVOLVED:**

*Describe recruitment methods:*

* *Describe when, where, and how potential participants will be recruited.*
* *Describe the source of participants.*
* *Describe the methods that will be used to identify potential participants.*
* *Describe materials that will be used to recruit participants. (Attach copies of these documents.)*

*Describe and explain the study design and include a study schema, if possible.*

*Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or minimize risks.*

*Describe:*

* *Define which procedures are considered standard of care and which are considered research-related. (For example, if the frequency of CT scans is within standard of care, this should be indicated)*
* *All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.*
* *The source records that will be used to collect data about participants. (Attach all surveys, scripts, and data collection forms.)*
* *Procedures performed to lessen the probability or magnitude of risks.*

*What data will be collected during the study and how that data will be obtained.*

* *If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.)*

*Audio/Video Recording/Photography: If applicable, describe:*

* *the type of recording/photography being utilized*
* *why the type of recording is necessary to the research*
* *how the recordings/photograph(s) will be utilized in the research (e.g., data analysis only)*
* *how and where the recordings/photograph(s) are stored, who has access to them, and if/when they will be destroyed.*

*Confidentiality:*

* *Describe the steps that will be taken to 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.*

**DATA AND SPECIMEN BANKING:**

*If data or specimens will be banked for future use, describe*

* *where the specimens will be stored,*
* *how long they will be stored,*
* *how the specimens will be accessed,*
* *who will have access to the specimens, and*
* *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.*

**SHARING OF RESULTS WITH PARTICIPANTS:**

*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 participants or others (e.g., the participant’s primary care physicians).*

*Describe how the results will be shared If applicable (e.g. for studies involving scans and/or panels of exploratory testing on specimens).*

**STUDY TIMELINES:**

*Describe:*

* *The duration of an individual subject’s participation in the study.*
* *The duration anticipated to enroll all study subjects.*
* *The estimated date for the investigators to complete this study’s’ primary analyses.*

**INCLUSION AND EXCLUSION CRITERIA:**

*Describe how individuals will be screened for eligibility.*

*Describe the criteria that define who will be included or excluded in your final study sample.*

*Indicate whether you will include or exclude each of the following special populations:*

* *Adults unable to consent*
* *Individuals who are not yet adults (infants, children, teenagers)*
* *Pregnant women*
* *Prisoners*
* *Vulnerable Populations*

*Community Participation: For studies aimed at addressing issues that affect a certain community or group: How, if at all, will this study involve people from the target community in the design of the study? Conduct of the study? How will the results of the research be shared with the participants and/or the target community/ies?*

**VULNERABLE POPULATIONS:**

*If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.*

*Vulnerable populations may include:*

* *Prisoners*
* *Pregnant Women/Fetuses*
* *Children/Neonates*
* *Cognitively/Decisionally impaired adults*
* *Your own students/employees*
* *Undocumented immigrants*
* *Illiterate individuals*
* *Individuals experiencing addictions/substance abuse*
* *Domestic violence victims*

*Additional safeguards include (but not limited to) considerations involving:*

* *Recruitment: Where/how precisely does recruitment to the study take place? Are participants recruited separately or in the presence of a Parent/LAR/Advocate?*
* *Assent/Permission Process: Does this take place separately or in the presence of a Parent/LAR? How will you tailor the assent process to the developmental stages and capacity of the children you seek to enroll? Describe this process in detail and how you are documenting it. A formal assent process with documents uploaded for 7-17 year old participants is the expectation. If any participants are under 7 years old, provide a description of how the study will be verbally explained to them, as appropriate.*
* *Data Collection: Explain how the method of data collection is appropriate for this population. Describe whether it is appropriate for interactions/interventions to occur alone with the participant.*

**LOCAL NUMBER OF PARTICIPANTS:**

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

*If applicable, distinguish between the number of participants who are expected to be enrolled and screened, and the number of participants needed to complete the research procedures (i.e., numbers of participants excluding screen failures.)*

**WITHDRAWAL OF SUBJECTS:**

*Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.*

*Describe any procedures for orderly termination.*

*Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.*

**PROVISIONS FOR DATA MONITORING TO ENSURE THE SAFETY OF SUBJECTS:**

*This section is required when research involves more than Minimal Risk to participants.*

*Describe:*

* *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe.* 
  + *The plan might include establishing a data monitoring committee (DMC), data and safety monitoring board (DSMB) and/or an independent data monitoring committee (IDMC).*
* *The plan for reporting data monitoring committee findings to the IRB and the sponsor.*
* *The frequency of meeting.*
* *What data are monitored, including safety data, untoward events, and efficacy data.*
* *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).*
* *The frequency of data collection, including when safety data collection starts.*
* *Who will monitor the data?*
* *The frequency or periodicity of review of cumulative data.*
* *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
* *Any conditions that trigger an immediate suspension of the research*.

**COMPENSATION FOR RESEARCH-RELATED INJURY:**

*This section is required when research involves more than Minimal Risk to participants.*

*Describe the available compensation or treatment available in the event of research-related injury*.

**ECONOMIC BURDEN TO PARTICIPANTS:**

*Describe any costs that participants may be responsible for because of participation in the research*.

**CONSENT PROCESS:**

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

* + - *Where will the consent process take place?*
    - *Any waiting period available between informing the prospective subject and obtaining the consent.*
    - *Any process to ensure ongoing consent.*
    - *Please describe:*
      * *The role of the individuals listed in the application as being involved in the consent process.*
      * *The time that will be devoted to the consent discussion.*
      * *Steps that will be taken to minimize the possibility of coercion or undue influence.*

**RESOURCES AVAILABLE:**

*Describe the resources available to conduct the research:*

* + - *Justify the feasibility of recruiting the required number of suitable participants within the agreed recruitment period.* 
      * *For example, how many potential participants do you have access to? What percentage of those potential participants do you need to recruit?*
    - *Describe the time that you will devote to conducting and completing the research.*
    - *Describe your facilities.*
    - *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*
    - *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.*

**REFERENCES:**

*Add references*