*****North Texas Regional Institutional Review Board (NTR IRB)***

***Protocol Synopsis for Research Project Involving Human Subjects***

***For all research projects involving human subjects, provide information about the project using the template and guidelines (provided below). Note that a clear and complete protocol description facilitates a timely and effective review of protocols. Conversely, vague, confusing or missing elements will delay appropriate consideration and review. Please use Times New Roman or Arial font (11 or 12) for ease of review and copying.***

***Prior to completing this form, please consult the*** [***NTR IRB Master Protocol Synopsis Guidance Sheet***](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Master-Protocol-Synopsis-Guidance-Sheet-FINAL_-FEB-2022.docx)***, which includes guidance/instructions for developing your specific research project (e.g., Focus Groups/Interviews, Surveys, Registries/Repositories, Existing Materials, etc.). Please click*** [***here***](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Master-Protocol-Synopsis-Guidance-Sheet-FINAL_-FEB-2022.docx)***, or the above hyperlink to access.***

***Please DO NOT INCLUDE THESE INSTRUCTIONS in the materials that are submitted for review.***

**PROTOCOL INFORMATION**

*Title of Project:*

*Name of Principal Investigator:*

*Institution:*

*Department:*

*Funding Agency / Company (if applicable):*

*Funding Agency Proposal / Protocol Number (if applicable):*

1. **Purpose of the Study** – *State the specific scientific objectives of the research, and, if applicable, outline the specific aims.*
2. **Background and Significance –** *Briefly sketch the background leading to the present proposal, using documentation from the literature, where appropriate. Although it is helpful for the Board to have a decent understanding of the basis for conducting a research project, it is not necessary to have a full-blown literature review or extensive background and rationale for the proposed research plan of activity.*
3. **Preliminary Studies** – *Summarize preliminary studies conducted by the investigator pertinent to this proposal (e.g., You have completed a pilot project in preparation for this study, etc.). State "none" if applicable.*
4. **Investigator Experience** – *Provide a brief synopsis of the principal investigator’s expertise, experience, and capability to perform this research. Submit a copy of the curriculum vitae of the principal investigator in IRBNet.*

**E. Experimental Design and Methods**:

1. *Methods and Procedures* - *Describe the procedure (s) in sequential detail. Describe the methods. Clearly identify any experimental elements of the study. Include a thorough description of any investigational drugs, therapeutic procedures, monitoring techniques, test procedures or medical devices.*

[The description of investigational medical devices should include information about each important component, ingredient, principle of operation, and anticipated developmental changes in the device. On a separate page, describe and address issues associated with the device presenting “Significant Risk” or “Non-Significant Risk”. For additional guidance on this topic, please see the [FDA’s Information Sheet Guidance on Significant Risk and Nonsignificant Risk Medical Device Studies](https://www.fda.gov/media/75459/download).]

1. *Consenting Process -* *Please describe the consent process in detail including: the person who will conduct the consent interview, the person will provide consent or permission, any waiting period between informing the prospective subject and obtaining consent, steps taken to minimize the possibility of coercion or undue influence, the language used by those obtaining consent, the language understood by the prospective subject or the legally authorized representative, and the information to be communicated to the prospective subject or the legally authorized representative.*
2. *Data Analysis and Data Monitoring* - *Describe plans for statistical analysis of data when appropriate. If a data safety monitoring committee is appropriate to protect the safety and/or welfare of subjects, describe its operation (e.g., membership, stopping rules and frequency of review).*
3. *Data Storage and Confidentiality* - *Describe where the research data will be stored during the study and how it will be secured. The investigator must take necessary steps to maintain confidentiality of data. This includes coding data and choosing an appropriate and secure data storage mechanism which will prevent unauthorized access to data. State who will have access to the data. If data with subject identifiers will be released, specify the person (s) or agency to whom the information will be released and the purpose of the release. For specific language, please refer to the NTR IRB’s* [*Data Storage and Security Guidance*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Guidance-and-Procedures-for-Investigators-Data-Storage-and-Security-Final-October-2021.docx) *document.*
4. *Setting* - *Describe briefly where the study will be conducted (e.g., private outpatient clinics, physicians’ offices, etc.).*

*NOTE: If other institutional review boards (IRBs) or approvals are required, note them by name, affiliation and contact person. Also, be aware that the approval of other institutions’ IRBs must be obtained before initiation of the project (but are not essential for North Texas Regional IRB review to begin).*

1. *Laboratory methods and facilities* - *Indicate where specific laboratory tests will be performed (e.g., hospital chemistry laboratory, investigators' laboratory, radiology clinic, etc.). If None, state “N/A”.*
2. *Estimated Period of Time to Complete the Study* – *Describe the stages and total time of subject participation as well as overall time for the entire study (start to completion). Also, if the study involves more than one visit, describe time range estimates for each visit (e.g., 20-30 minutes; 2 – 3 hours, etc.). Where possible, use a table or “bullet-point” format to clearly illustrate the flow of activities and procedures.*

**F. Human Subjects** - *Describe the characteristics of the research population:*

1. *Sample Size*: *Specify the approximate number of subjects to be enrolled in this study at this site.*

Approximately \_\_\_\_ subjects at \_\_\_\_ sites in the U.S. will be enrolled/randomized in the study overall.

1. *Describe both Inclusion AND Exclusion Criteria.* *BE SPECIFIC! Include physical, mental, cognitive, medical, and other relevant Inclusion and Exclusion criteria.*
2. *Describe intended gender, age range, intended racial and ethnic distribution. If any vulnerable subjects are involved in this study (e.g., those with limited autonomy or decision-making capabilities),a justification must be provided.*
3. *Identify the source(s) from which you will obtain your study population.*
4. *Describe plans for recruitment of subjects.* *All materials (e.g., flyers, ads, emails, letters, postings, handouts, social media language, website link, etc.) that will be used for recruiting subjects must be submitted to the IRB for review. For specific guidance, please refer to the* [*NTR IRB Recruitment Guidance*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/Recruitment-Guidance-10.22.21-FINAL.docx) *document.*

**G. Risk/Benefit Assessment**

1. *Describe any* ***potential RISKS OR DISCOMFORTS*** *in detail. Please note that potential risks include informational risks (such as breach of confidentiality) as well as other risks, such as physical risks (direct injury or harm to the subject), reputational injury, and emotional risks. Describe the procedures for protecting against or minimizing potential risks. Use evidence from clinical and/or animal studies to evaluate the level of potential hazards associated with participation in the research protocol. Be sure to describe any anticipated adverse events that might occur during the course of the study, and describe the methods for detecting adverse reactions.*
2. *Describe the* ***level of risk.*** *(Either* ***Minimal*** *or* ***More than Minimal****; note that the federal regulations define minimal risk as, “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”.)*
3. *Describe the* ***proposed benefits*** *of the study, whether they are direct benefits to study participants and/or benefits to society/science.* *(If there is NO direct benefit to subjects, please include such a statement in this document as well as in the consent document(s), if any.)*
4. Describe **how the anticipated benefit justifies the risk**. Additionally, explain how the anticipated benefit of this research is at least as favorable to the subjects as that to be received by available alternative approaches for the subjects.
5. *If your project includes* ***vulnerable populations*** *as participants, describe the* ***additional safeguards*** *that will be implemented to protect the rights and welfare of these participants. Vulnerable populations as defined by the federal regulations include children, pregnant women & neonates, prisoners, and individuals with cognitive impairment or diminished capacity to consent. However, there are many other categories of participants who may be considered vulnerable, such as individuals who are physically disabled; socially or economically disadvantaged; terminally ill; minorities; refugees; and more. The participant’s current situation, timing, and cultural context may also influence their vulnerability at the time of study participation. Describe the additional protections that have been put in place to address the vulnerabilities of these participants.*

**H. Payment/Compensation** – *Describe any payments for subject participation (e.g., compensation for time and travel). Indicate any partial payment schedule for less than complete study participation. Recall that payments cannot be perceived as coercive (overpayment for time and effort).* ***Remember: payments are NOT benefits.***

1. **Subject Costs** - *Describe any anticipated costs to research subject, whether they be financial or something else. If none, state such.*

**J. List of KEY PERSONNEL** - *List all individuals directly involved in the conduct, design or reporting of research involving human subjects in this study, including anyone who may be consenting subjects. This list will include the Principal Investigator, Co-Investigators, collaborating investigators, study coordinators, etc. Please describe the roles/responsibilities of each person who is listed as key personnel on this project.*

**K. Literature Cited** - *If any, the references should be limited to relevant and current literature pertinent to the proposed research.*