

University of North Texas Health Science Center

Office for the Protection of Human Subjects / Institutional Review Board (IRB)

Protocol Synopsis for Research Project Involving Human Subjects

For all research projects involving human subjects, provide information using the following format and guidelines for a protocol summary (synopsis). 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. Use standard white paper with no smaller than 1/2" margins all around. Please use Times New Roman or Arial font (11 or 12) for ease of review and copying. Please DO NOT INCLUDE THESE INSTRUCTIONS in the packet that is photocopied and submitted to the OPHS-IRB.

PROTOCOL INFORMATION

Title of Research Activity

Name of Principal Investigator

Names of each Co-Investigator

Sponsoring Agency / Company (if applicable)

Sponsor's Protocol Number (if applicable)

- A. Specific Aims** – State the specific scientific objectives of the research.
- B. Background and Significance** - *Briefly* sketch the background leading to the present proposal. Describe the contributions that the study will make to the health of human beings and/or to the scientific data base, 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.
- C. Preliminary Studies** - Summarize preliminary studies conducted by the investigator pertinent to this proposal. State "none" if applicable.
- D. Investigator Experience** - Provide a brief synopsis of the principal investigator's expertise, experience, and capability to perform this research. Attach a copy of the curriculum vitae of the principal investigator to this application.

E. Experimental Design and Methods - Detailed protocol for this project / subject-related studies.

- 1) *Methods and Procedures* - Describe the procedure (s) in sequential detail. Clearly identify any experimental element 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 on 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”]

- 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.
- 4) *Setting* - Describe briefly where the study will be conducted, e.g., private outpatient clinics, physicians offices.

NOTE: If other institutional review committees (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 UNTHSC IRB review to begin).

- 5) *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
- 6) *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 study involves more than one visit, describe time range estimates for each visit (e.g., 20-30 minutes; 2 – 3 hrs, 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) *Description of subjects* is to include the projected sample size, plans for the selection of subjects, and inclusion and exclusion criteria.
- 2) *Sample Size*: Number of subjects to be enrolled in this study at this site. Approximately ____ subjects at ____ sites in the U.S. will be enrolled in the study overall.

For Clinical Trial studies, indicate number of subjects to be randomized _____

- 3) Describe both *Inclusion / Exclusion Criteria*. BE SPECIFIC ! Also, if children (persons under age 18) are excluded from this study provide scientific justification for such exclusion. Include physical, mental, cognitive, medical, and other relevant Inclusion and Exclusion criteria.

- 4) 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) are included, justification must be provided.
- 5) Identify the *source(s) from which you will obtain your study population*.
- 6) Describe plans for *recruitment of subjects*. All materials (e.g., flyers, ads, emails, letters, postings, handouts, etc.) to be used for recruiting subjects must be submitted to the IRB for review.

G. Risk/Benefit Assessment

- 1) Describe the *level of risk*, and if more than minimal, describe how this research holds the prospect of a *direct benefit for the subjects*. If there is NO direct benefit to subjects, state such in protocol and in the consent documents.
- 2) Describe how the anticipated benefit justifies the risk.
- 3) Describe 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.
- 4) Describe any potential RISKS OR DISCOMFORTS in detail. Use evidence from clinical and/or animal studies to evaluate the level of potential hazards associated with participation in the research protocol. Indicate the methods for detecting adverse reactions. Describe the procedures for protecting against or minimizing potential risks (e.g., confidentiality, reputational injury, direct injury or harm to subject, etc.) and assess their effectiveness. Discuss why the risks to the subjects are reasonable in relation to proposed benefits to mankind. Be sure to describe any anticipated adverse events that might occur during the course of the study.

H. Payment/Compensation - Describe any financial 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.

I. Subject Costs - Describe any anticipated costs to research subject. 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.

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

Attachments (in this order):

- I. *Consent Form* - THE CONSENT FORM IS TO BE A SEPARATE DOCUMENT. It is important that this form follows the IRB prescribed format and includes all the required elements and certain other elements when appropriate.
- II. *Recruitment Materials* (ads, flyers, emails, etc.) to be used in this Study
- III. *Study Documents* (questionnaires, survey instruments, clinical trial protocol, investigator's brochure, etc.)
- IV. *Evidence of Human Subject Training* for ALL Key Personnel listed in the protocol.
- V. *Conflict of Interest Form*, completed and signed by EACH Key personnel listed in the protocol.