

**UNIVERSITY OF NORTH TEXAS HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
NEW RESEARCH STUDY PROTOCOL REVIEW FORM**

IRB Number:

SECTION A: Project – Protocol Information

TITLE OF PROJECT / PROTOCOL:

Keywords:

1. FUNDING INFORMATION: Indicate the category of the sponsor:

Industry (other than pharmaceutical) State Government Local Government
Non-Profit Federal Agency (If NIH, List specific Institute): _____
UNTHSC internal grant program (describe: _____)
Pharmaceutical Company /Sponsor: _____
SPONSOR PROTOCOL # _____

2. TYPE OF RESEARCH PROJECT:

Investigator-Initiated Study Student Research Project Clinical Trial (Drug or Device)
IF Drug Trial, Please check as applicable): Phase I Phase II Phase III Phase IV
IF Device Trial - check as applicable:
Not Applicable (No FDA-regulated devices involved) Non-Significant Risk
Significant Risk (i.e., presents serious risk to subject's health, safety, or welfare by: use as in implant;
supporting or sustaining human life; diagnosing, curing, mitigating or treating disease;
preventing health impairment; or other means)

3. PRINCIPAL INVESTIGATOR INFORMATION:

Name _____ Department: _____

E-mail: _____ Phone # _____ Fax # _____

Study Coordinator Name: _____

E-mail: _____ Phone # _____ Fax # _____

NOTE: (If the Principal Investigator is conducting this project for a student to meet the requirements of a UNTHSC academic program, also list the name and information for the Student Investigator.)

Student Investigator _____ Department _____

Email: _____ Phone # _____ Fax # _____

4. LOCATION (S) where you will be conducting this research (e.g., UNTHSC, off-campus site, etc.)

UNTHSC facilities Multi-center clinical trial Other sites: (Please list)

Name(s) of Site(s): _____

Address(s): _____

Has approval/agreement been obtained from off-campus sites/ facilities? (Attach written documentation).
Are other IRBs involved in the approval of this project? If so, attach written verification of approval by other Institutional Review Boards.

5. PURPOSE OF STUDY: (Please describe in brief layman's terms)

6. DURATION OF STUDY:

Date of Expected START of the study : _____ (Note: if an ongoing study.

Date of Expected COMPLETION of the study: _____ indicate start date only)

7. PROPOSED INFORMED CONSENT STATEMENT: Is a signed consent being used? Yes No

If NO, please provide rationale [see 45CFR46.116(d)].

What is the reading grade level of the informed consent document? _____

8. For those studies that involve information that needs to be protected from subpoena, will a Certificate of Confidentiality be requested from NIH? (note that a protocol does *not* have to be NIH funded in order to obtain a Certificate) Yes No (for information on Certificates of Confidentiality see <http://grants1.nih.gov/grants/policy/coc/index.htm>)

If a Consent Form will be used, answer the following items:

- a) Does the consent form tell the participant of situations where the PI may voluntarily comply with state laws, such as the reporting of child abuse, elder abuse, or immediate danger to self or others? Yes No
- b) Has the confidentiality statement been modified to be consistent with the Certificate of Confidentiality protections (if applicable)? Yes No
- c) Does the consent form include HIPAA Privacy Rule information for the use of Protected Health Information (PHI)? Yes No

9. Does the study involve storage or banking of human specimens or identifiable private information for use in future studies (e.g., submission to a repository)? No Yes

If yes, please describe and note page where discussed in informed consent document: _____

10. Does the study involve genetic testing or DNA/RNA extraction? No Yes

- Test results will be given directly to subjects
- Test results will be given to treating physicians
- Test results will not be given outside the research

If yes, please describe

- (i) The testing or extraction process;
- (ii) Arrangements for storage of DNA/RNA samples and
- (iii) Duration of storage; and note page where discussed in informed consent document: _____

FDA Products: If Applicable or Available

IND Sponsor _____ IDE Sponsor _____

Please list all study drugs or devices by generic name only (If no name, list study drug number)

	FDA Approved?		FDA Approved for this Indication		Is the drug being compared to placebo?	
	Yes	No	Yes	No	Yes	No
1. _____	Yes	No	Yes	No	Yes	No
2. _____	Yes	No	Yes	No	Yes	No
3. _____	Yes	No	Yes	No	Yes	No
4. _____	Yes	No	Yes	No	Yes	No
5. _____	Yes	No	Yes	No	Yes	No
6. _____	Yes	No	Yes	No	Yes	No

Add additional page(s) if necessary

SUBJECT SELECTION AND RECRUITMENT

11. MAXIMUM number of subjects: _____
(For Clinical Trials, Number to be Randomized): _____
12. Age Range of Subjects:
13. Ethnicity/Race of Subjects:
14. Will this research study recruit any subjects from the following categories? Check all that apply:
Pregnant Women Minors (< 18) Cognitively Impaired Prisoners
Employees of research site or sponsor UNTHSC students Military Personnel
Third Party Subjects Economically disadvantaged (homeless, evacuees)
Describe: _____
15. This study also includes any of the following:
Normal Volunteers Patients Fetuses Genetics
16. For research involving minors (< 18), please indicate which of the categories listed below accurately describes this protocol: NO Minors Involved Minors Involved (complete following):
not involving greater than minimal risk
involving greater than minimal risk but of direct benefit to individual subjects
involving greater than minimal risk, no direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject disorder or condition
involving research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of minors
17. How will you recruit and correspond with subjects for this study?
Referrals (note that referral **fees** are not allowed) Advertising Private Practice
Corporate Practice Telephone Other: _____
Advertising: Newspaper E-mail Web Site Poster Brochure
Radio or TV (script; tape) Patient Recruitment Letter No Advertising
Other _____
- NOTE: If protocol recruitment involves *any* advertising, attach copies of all ad/recruitment materials.
18. Will Subjects be compensated (paid) for their participation in this study? Yes No
If YES please describe payment schedule, including TOTAL Amount :

19. Describe and Justify and anticipated COSTS to study subjects (if not applicable, state N/A):
20. How long will each subject be involved in the study? (describe time and extent of subjects participation: number of visits, hours per visit, total time frame, etc.)

RESEARCH DESIGN AND ETHICAL ISSUES

21. Will audio taping or videotaping of subjects occur? Yes No
If so, how long will recordings be maintained? _____
22. Will any of the following instruments or methods be used? Check all that apply. Include copies with the protocol:
Interview (attach script/guide) Focus Group (attach guide)
Surveys/Questionnaires Standardized (published) tests or assessments (please list: _____)

23. ETHICAL ISSUES (Please respond to ALL Items)

- A. Does the study involve: (check all that apply) None of these
Painful or aversive stimuli Emotional stress Deception False information
False feedback Withholding of critical information

Please explain all those that have been checked and address the question of potential psychological harm to participants _____

- B. What residual effects of the procedures have been explored?
- C. How will the project be monitored so that any unexpected or adverse events that pose a risk to subjects are promptly brought to the attention of the principal investigator?
- D. What safeguards have been taken to insure protection against risks for any participant who is especially sensitive or vulnerable?

- E. If the study involves deception, false information, false feedback, or withholding of critical information, will the participant be told why or debriefed? Yes No.
Please explain:
- F. Are participants aware that data are being recorded or that they are under observation? Yes No
If NO, please explain
- G. Will any other data of a personal nature be gathered about the participant from other sources? Yes No
If YES, please explain:
- H. If the answer to item G is "Yes", will the participant be asked to consent to this collection of personal data from other sources? Yes No.
If NO, please explain:
- I. Are there any aspects of the study which might constitute an invasion of the participant's privacy for which consent has not expressly and implicitly been given? Yes No.
If YES, please explain:

J. Participants must be able to withdraw at any time without difficulty, undue embarrassment, or negative consequences. How are participants made aware of their right to withdraw from the study?

OTHER KEY PERSONNEL

24. List all OTHER KEY PERSONNEL associated with this project (Co-Investigators, Study Coordinator, Study Physician, etc.). Please Print All Names and Information Clearly

CO-INVESTIGATOR (SUB-INVESTIGATOR)

Name & Degree _____
Department _____
Responsibility in Project _____

CO-INVESTIGATOR (SUB-INVESTIGATOR)

Name & Degree _____
Department _____
Responsibility in Project _____

CO-INVESTIGATOR (SUB-INVESTIGATOR)

Name & Degree _____
Department _____
Responsibility in Project _____

STUDY COORDINATOR

Name & Degree _____
Department _____
Responsibility in Project _____

OTHER

Name & Degree _____
Department _____
Responsibility in Project _____

Add other page(s) as needed

HUMAN SUBJECT TRAINING: Have all the above personnel completed the UNTHSC IRB Education Requirements on Human Subjects Research Protection? Yes No Documentation attached

SIGNATURES AND CERTIFICATION

- A. The principal investigator agrees to accept responsibility for the scientific conduct of the project, that the scientific portion of the protocol is original and contains no false, fictitious, or fraudulent statements or data. Signature certifies that all listed investigators have reviewed the proposal and that the research will be conducted in full compliance with UNTHSC policies and federal regulations.
- B. The principal investigator certifies that the Conflict of Interest Disclosure Statements enclosed are up-to-date for all key personnel on this project.
- C. The principal investigator certifies that the Principal Investigator has sufficient staff and facilities to conduct the research.
- D. The principal investigator certifies that all project personnel have the proper education, experience and expertise to conduct the study.
- E. Continuing review is required in order to maintain the approval status and that the Principal Investigator is aware that progress reports must be submitted to the IRB in a timely manner.
- F. The principal investigator certifies that ALL personnel involved in carrying out the research are familiar with the ethical guidelines for research involving human participants and have taken such training and other related training required by the UNTHSC IRB and OPHS.
- G. All changes in the study must be approved by the UNTHSC-IRB **prior** to implementation.
- H. Adverse events must be reported to the UNTHSC-IRB.

Principal Investigator

Date

Student Investigator (if applicable)

Date

Department Director (if required)

Date

Other Required Departmental Signatures (If Applicable)

PLEASE SUBMIT THIS SIGNED ORIGINAL PLUS 20 COPIES OF THIS DOCUMENT ALONG WITH:

- **TWENTY (20) COPIES of:**
 - **Protocol Synopsis**
 - **Informed Consent Documents**
 - **Recruitment ads, flyers, questionnaires, etc.**
- **FOUR (4) COPIES of:**
 - **Federal grant application (If applicable)**
 - **Clinical Protocol (for Clinical Trials)**
 - **Investigator's Brochure (If applicable and for Clinical Trials)**
 - **All correspondence related to this protocol from the Sponsor**
- **ONE (1) COPY OF:**
 - **Curriculum Vitae of Principal Investigator**
 - **Conflict of Interest (COI) statement(s) for EACH Listed Project personnel**
 - **Certificate of Training (Human Subjects Research) for EACH Listed Project Personnel**

Send all materials to: Office for the Protection of Human Subjects (OPHS)