EAST TENNESSEE CHILDREN'S HOSPITAL
INSTITUTIONAL REVIEW BOARD

Application for Review of Research Involving Human Subjects

Date:

Protocol#:

I. Identification of Project

A. Protocol Title

B. Local Principal Investigator: Name, address, phone number, email:

C. Other Investigator: Name, address, phone number, email:

D. Intended starting date:

E. Estimated completion date:

F. Co-operating Institution, Agency:

G. Grant Submission deadline:

H. Copy of form 1572 or IND #:

I. Budget attached ◯ Yes ◯ No

J. Have you read the IRB Financial Conflict of Interest Policy: ◯ Yes ◯ No

K. Financial conflict of interest form attached: ◯ Yes ◯ No

L. Investigator Brochure attached: ◯ Yes ◯ No

M. Has this protocol been submitted to any other IRB? ◯ Yes ◯ No

II. Objective of Project

III. Description of Human Participants

A. Anticipated number of research participants (study wide):

B. Anticipated number of local participants:

C. Criteria for selection and/or exclusion:

D. Age:

E. Payment or incentives:

IV. Methods or Procedures

A. Uses of human participants:

B. Experimental manipulations:

C. Tests or measures: ◯ Yes ◯ No If yes, please attach.

D. Interviews/surveys: ◯ Yes ◯ No If yes, please attach.

E. Observations, photography, recordings: ◯ Yes ◯ No

If yes, please describe including specific confidentiality controls:

F. Differences in treatment between control group vs. experimental group:

V. Specific Risks and Protection Measures:

A. Physical or psychological risks to subjects greater than those encountered in daily life:

B. Means to evaluate risks:

C. Means to minimize risks including specific controls, screening methods & follow-up:

D. Means to assure anonymity and/or confidentiality of subjects and/or data:

VI. Benefits vs. Risks:

VII. Required Elements of "Informed Consent" from Subjects:

A. Please mark that the following required elements are included in the consent forms:

☐ A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

☐ A description of any reasonable foreseeable risks or discomforts to the subject;

☐ A description of any benefits to the subject or to others which may reasonably be expected from the research;

☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

☐ A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; where they will be stored; and who will have access to them;

☐ For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

☐ An explanation of whom to contact for answers to pertinent questions about the research and research subjects rights, and whom to contact in the event of a research-related injury to the subject; local contacts must be included;

☐ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

☐ The consent form shall include no language through which a subject is made to waive, or appear to waive any of his/her legal rights, including any release of the institution or its agents from liability for negligence.

☐ Copy of Informed Consent Form is attached

☐ Copy of Permission and/or Statement of Understanding (Assent) appropriate to age of research participant is attached

B. Procedure to be used in acquiring Informed Consent:

1. Consent Form presented by:

2. Any requirement for other personnel to be present? ◯ Yes ◯ No
   If yes, explain:

3. Forms to be stored where:

4. Forms are accessible to:
   - ☐ IRB members
   - ☐ DHHS and FDA personnel
   - ☐ Others?

VIII. Qualifications of the Investigator (Please attach the following as applicable)

Required qualifications for investigator and/or assisting personnel to perform specific tasks:

- ☐ Special Training
- ☐ Licensure
- ☐ Certification
- ☐ Copy of certificate of completion Investigator Research
- ☐ Copy of current CV

IX. Adequacy of Facilities to Support Research:

Brief description of facilities to be used and an evaluation of their adequacy for the intended project:

X. Responsibility of the Project Director:

By compliance with the policies established by the Institutional Board of East Tennessee Children's Hospital, the Project Director subscribes to the principles stated in The Belmont Report and the standards of professional ethics in all research, development, and related activities involving human subjects under the auspices of East Tennessee Children's Hospital.

☐ Approval will be obtained from the East Tennessee Children's Hospital Institutional Board prior to instituting a change in the research project.

☐ Development of any unexpected risks will be reported to the Chairperson of the East Tennessee Children's Hospital Institutional Review Board.

☐ A status report will be submitted at 12-month intervals or as requested attesting to the current status of the project.

☐ Signed consent forms will be kept for the duration of the project and for at least three years after completion of the study.

☐ Any real or potential conflict of interest will be disclosed**.**

Signatures:

Principal Investigator _____
Name

_____ _____
Signature Date

Co-Investigator _____
Name

_____ _____
Signature Date

Co-Investigator _____
Name

_____ _____
Signature Date

Co-Investigator _____
Name

_____ _____
Signature Date