INSTITUTIONAL REVIEW BOARD

EXPEDITED REVIEW APPLICATION FOR RESEARCH PROTOCOLS

Complete this form to request expedited review of your proposed research. Select the category on the following page that best describes your research project. If the research meets the conditions for expedited review, review of your protocol will be carried out by the IRB chairman or an experienced IRB member designated by the IRB chairman.

Additional elements required for project approval include:

- **a copy of the CV of key study personnel**
- **completion of human subjects research training (online ETCH training available at http://www.etch.com/IRB)**
- **confidentiality agreement**
- **budget (if applicable)**

All forms may be requested from the IRB office. Please refer to ETCH IRB policy for more information or contact the IRB office at (865) 541 - 8290 (Jacque Van Audenhove)/email: jaudenhove@etch.com for further assistance.

CONDITIONS REQUIRED FOR EXPEDITED IRB REVIEW

- The research may not involve more than "minimal risk". "Minimal risk" means that 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." (45 CFR 46.102 (i) and 21 CFR 56.102 (i)).

- The entire research project must be consistent with one or more of the federally defined categories.

SELECT THE CATEGORY THAT BEST DESCRIBES YOUR RESEARCH PROJECT	
☐	(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
☐	(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week. (b) from other adults and children (defined as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a)), considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
☐	(3) Prospective collection of biological specimens for research purposes by non-invasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
☐	(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
☐	(5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
☐	(6) Collection of data from voice, video, digital or image recordings made for research purposes.
☐	(7) Research made on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Title of Study:

Principal Investigator Information:

First Name:	Middle Initial:	Last Name:
Degree(s): ___ M.D. ___ D.O. ___ Ph.D. ___ R.N. ___ Other, specify:		
Human Subjects Research Training? __ Yes __No		Email :
Address:		City:
State:	Zip:	Phone:

Other Key Study Personnel:

Name (First, MI, Last)/Degree	Department or Affiliation	Role In Project	Human Subjects Research Training
			__Yes ___ No
			__Yes ___ No
			__Yes ___ No

Purpose and Background of the Study: (Describe specific scientific objectives and research question)

Subject Population(s): (Age range and number of local participants)

Participant Identification, Inclusion/Exclusion Criteria, and Recruitment:
(Describe the specific steps to be used to identify and/or contact prospective participants. Also describe how you have access to lists of potential participants)

Research Methods and Procedures:

Will a waiver or alteration of the consent process be used?

___ No (If no, attach consent form)

___ Yes (If yes, complete Consent Waiver Form)

- Please attach consent form or consent waiver form if applicable

Does this research use or disclose Protected Health Information (PHI)?

(PHI is individually identifiable health information that is or has been collected or maintained by East Tennessee Children's Hospital, including information that is collected for research purposes only, and can be linked back to the individual participant.

Use ___ **No** ___ **Yes**

Disclose ___ **No** ___ **Yes** (If yes please describe what information will be disclosed and to whom):

- Please attach HIPAA authorization statement or waiver of HIPAA authorization form if applicable

PRINCIPAL INVESTIGATOR'S ASSURANCE STATEMENT

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.

A. Approval will be obtained from the East Tennessee Children's Hospital Institutional Board prior to instituting a change in the research project.
B. Development of any unexpected risks will be reported to the Chairperson of the East Tennessee Children's Hospital Institutional Review Board.
C. A status report will be submitted at 12-month intervals or as requested attesting to the current status of the project.
D. Signed consent forms will be kept for the duration of the project and for at least three years after completion of the study.
E. Any real or potential conflict of interest will be disclosed**.**

Principal Investigator _____

Name

_____ _____

Signature **Date**

Co-Investigator _____

Name

_____ _____

Signature **Date**

Co-Investigator _____

Name

_____ _____

Signature **Date**

Co-Investigator _____

Name

_____ _____

Signature **Date**

EAST TENNESSEE CHILDREN'S HOSPITAL'S IRB REVIEW

The application described above has been subjected to IRB review and has been approved as expedited category #____.

Designated Administrator _____
Printed Name

_____ _____
Signature Date