

Kentucky Community and Technical College System
**Request for Expedited or Full Review:
Investigation Involving Human Subjects**

Project Director/ Principal Investigator: _____

Faculty: _____ Staff: _____ Student: _____ College: _____

Address: _____

Office Phone: _____ Email: _____ Fax: _____

Faculty Sponsor (Student/Class Project): _____

Department: _____

Address: _____

Office Phone: _____ Email: _____ Fax: _____

Please submit documentation at least one month before project is to begin.

- | | | | |
|--|----------------------------|----------------------------|---------|
| 1. Source of Support: | Sponsored Research | Sponsor: | |
| | University Funded Research | Unfunded Research | |
| 2. Type of Project: <i>(Check all that apply)</i> | Original Submission | Resubmission | |
| | Student Project | Class Project ¹ | |
| | New | Continuation | Renewal |
| | | | |

¹*A class project requires HSRB review if it is a research project. Research is defined as "any systematic gathering and analysis of information, usually made under conditions determined by the investigator, that aims to test a hypothesis, to discover some unknown principle, or effect, or to re-examine some known or suggested principle." (Human Subjects Review Board: Handbook for Investigators, Part III, C.1)*

3. Research to be conducted in the U.S.? Yes No

If *No*, specify country or territory: _____

4. Has this study been previously reviewed by another HSRB? Yes No

If *Yes*, please identify: _____

5. **Project Title** _____

6. **Repository:** Following the completion of the study, Human Research documentation will be stored for a period of no less than three years in:

Repository: Room, Building, Organization

EXPEDITED REVIEW is conducted by the HSRB for protocols involving a normal population of subjects who are exposed to no more than minimal risk. **MINIMAL RISK** means that the probability and magnitude of harm or discomfort anticipated in the research is not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical psychological examinations or tests.

7. Human subjects involved in the proposed research protocol are:

Minors	Fetuses	Aborted	Pregnant Women
Prisoners	Mentally Retarded	Mentally Disabled	None of the Above

8. Expedited review is requested because human subject involvement is restricted to:

**Categories of Research That May Be Reviewed by the
Human Subjects Review Board (HSRB) through an
Expedited Review Procedure**

Applicability

- (A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the HSRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- (B) The categories in this list apply regardless of the age of subjects, except as noted.
- (C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- (D) The expedited review procedure may not be used for classified research involving human subjects.
- (E) HSRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the HSRB.
- (F) Categories one (1) through seven (7) pertain to both initial and continuing HSRB review.

Research Categories

- (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 Part 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 Part 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, or ear stick, or venipuncture as follows:
 - (a) from healthy, nonpregnant adults who weight at least 110 pounds. For these subjects, 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; or
 - (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, 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 noninvasive 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 sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine 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 subject or an invasion of the subject'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 non-research 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 on individual or group characteristics or behavior (including, but not limited to, research on perception, condition, 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 protections of human subjects. 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)
- (8) Continuing review of research previously approved by the convened HSRB as follows:
 (a) where
 (i) the research is permanently closed to the enrollment of new subjects;
 (ii) all subjects have completed all research-related interventions; and
 (iii) the research remains active only for long-term follow-up of subjects; or
 (b) where no subjects have been enrolled and no additional risks have been identified; or
 (c) where the remaining research activities are limited to data analysis.
- (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply by the HSRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
9. **Description of Protocol:** Attach, or provide below, a complete, detailed description of the research protocol. It should be understandable to the non-specialist and not longer than three pages.

A PROJECT MAY ONLY BEGIN AFTER YOU HAVE BEEN NOTIFIED THAT THE BOARD HAS REVIEWED AND APPROVED YOUR RESEARCH. APPROVAL IS EFFECTIVE FOR A MAXIMUM OF ONE YEAR FROM BOARD MEETING DATE.

“I affirm the accuracy of this application, and I accept the responsibility for the conduct of this research, the supervision of human participants, and maintenance of informed consent documentation as required by the HSRB. This is to certify that the project identified above will be carried out as approved by the HSRB, and will neither be modified nor carried out beyond the period approved below without express review and approval by the Board. I understand that responsibility for protecting human participants is shared by the entire research team.”

Signature: Principal Investigator _____ Date _____

Signature: Faculty Sponsor (if appropriate) _____ Date _____

Signature: KCTCS District CEO _____ Date _____

Protocol Approved

Protocol Disapproved

Signature: Board Chair/Authorized Reviewer _____ Date _____

Period of Approval: _____ Date of Next Review: _____