HSRB Exempt Form 05

Human Subjects

Project Director/ Principal Investigator: _____

Faculty Staff Student College: _____

Address: _____

Office Phone: _____ Email: _____

Faculty Sponsor (Student/Class Project): _____

Department: _____

Address: _____

Office Phone: _____ Email: _____

FOR SUBMISSION DEADLINES AND COMMITTEE MEETING DATES CALL 859-256-3218
(Committee meetings scheduled once a semester as necessary: no meetings in the summer.)

1. **Source of Suppor**t: *Sponsored Research Sponsor: _____
*****University Funded Research *****Unfunded Research

2. **Type of Project:** *(Check all that apply)* 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. **DESCRIPTION OF PROTOCO**L: Attach, or provide below, a complete, detailed description of the research protocol including explanation of why the protocol should be regarded as exempt. It should be understandable to the non-specialist and not longer than three pages.

Certification of Exemption from Federal Regulations Regarding the Protection of Human Research Subjects: Check all applicable conditions. Exemptions may not be claimed for research involving prisoners, fetuses, pregnant women, the mentally retarded or disabled, or human in vitro fertilization.

7. **I certify that the project identified above, in which the only involvement of human subjects will be in one or more of the categories checked below, is exempt from federal regulations regarding the protection more of the categories checked below, is exempt from federal regulations regarding the protection of human research subjects and does not require full review by the Human Subjects Review Board.****

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
(i) research on regular or special education instructional strategies, or
(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, ***UNLESS***
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; ***AND***.
(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation
*Note: When a study uses subjects who are **MINORS**, category (2) only applies as follows: Studies using educational tests involving minors as subjects are exempt. Studies using survey or interview procedures with minors as subjects are **NOT** exempt. Studies using observations of public behavior involving minors are **NOT** exempt unless the investigator does not participate in the activities being observed.*

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observation of public behavior that is not exempt under (2), if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or
(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects. ***

(5) Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:
(i) public benefit or service programs;
(ii) procedures for obtaining benefits or services under those programs;
(iii) possible changes in or alternatives to those programs or procedures; or
(iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,
(i) if wholesome food without additives are consumed; or
(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

I certify that the project will not be changed to increase the risk, exceed or change the exempt condition(s) without filing an additional certification or application for approval by the Human Subjects Review Board. I understand that responsibility for protecting human subjects is shared by the entire research team.

Signature: _____
Project Director/ Principal Investigator Date

Signature: _____
KCTCS College President/CEO Date

Concurrence with claim of exemption

Signature: _____
Board Chair/ Authorized Reviewer Date

* The original Certification of Exemption is to be forwarded to HSRB Chair, KCTCS System Office, 300 N. Main St., Versailles, KY 40383 with copies of the proposal routed for review and approval. This project may be subject to review and confirmation of its exempt nature by the KCTCS Human Subjects Review Board and/or the sponsoring agency.

** If the Project Director has any questions about the Exempt status of the project, the appropriate Human Subjects Review Board Chair should be contacted.

*** If the records involved are those of KCTCS students, the project is not exempt and must be reviewed by the HSRB. Such research must conform with the Family Education Rights and Privacy Act of 1974 also known as the Buckley Amendment.