

IF YOU CONDUCT RESEARCH – YOU ARE RESPONSIBLE

SUMMARY GUIDE FOR INVESTIGATORS

Who must follow the KCTCS policy and procedures for the protection of human subjects?

Any administrator, faculty, staff, or student of the Kentucky Community and Technical College System who is responsible for research activity involving human subjects must follow the KCTCS policy and procedures for any research activity that involves human subjects.

To what activities do the KCTCS policy and procedures apply?

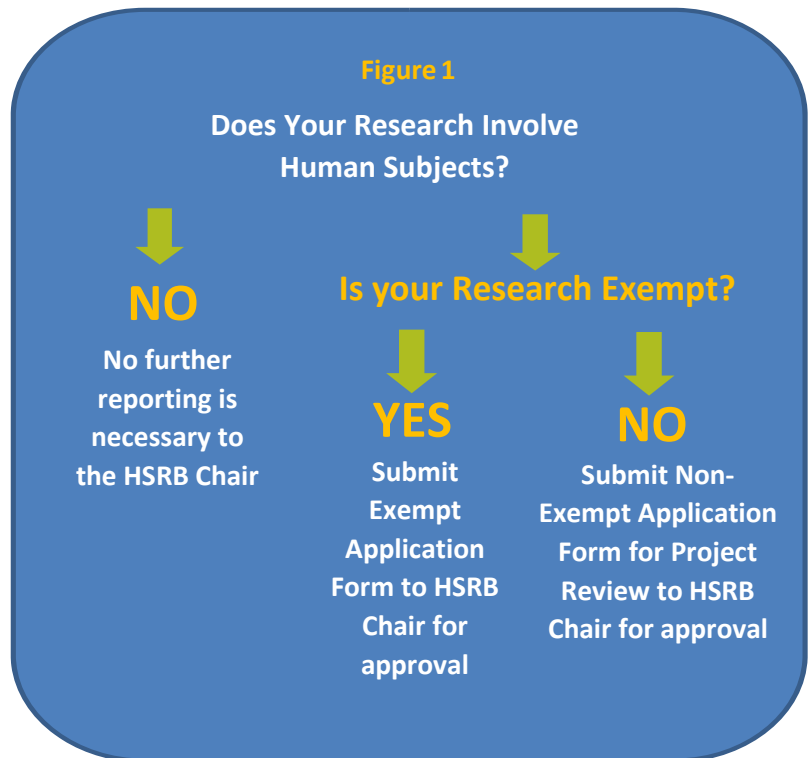
The policy applies to any research activity that involves human subjects, whether such research is undertaken on a large or small scale, whether it is preliminary or fully designed, whether it is student or faculty research, whether it is externally funded or not, and whether it involves minimal risk or more than minimal risk.

Who reviews human subjects research?

Determination of whether a research project is exempt from formal review must be made in consultation with the KCTCS Human Subjects Review Board (859-256-3187).

When must a research activity involving human subjects be reviewed?

Research must be approved **prior** to the initiation of activity, **prior** to the implementation of changes in previously approved procedure involving human subjects, and **at least annually** during the lifetime of the project.



KCTCS Policy for the Use of Human Subjects in Research

KCTCS Policy 1.8.2.3.2 applies to any research activity conducted at or sponsored by KCTCS that involves human subjects.

It is relevant whenever an investigator conducts research in which he or she:

- (1) obtains data through intervention or interaction with an individual, or
- (2) obtains private information by which an individual could be identified.

The policy is applicable to research involving living human beings whose physical, emotional, or behavioral conditions, responses, tissues, or fluids are investigated for research purposes (that is, for any reason other than the sole purpose of benefiting the subject as an individual).

It is applicable to the use of interviews, tests, observations, and inquiries designed to elicit or obtain nonpublic information about individuals or groups, as well as the study of existing public or privately held records where the identity of individuals is known.

What are the Fundamental Principles for the Use of Human Subjects in Research?

The use of human subjects in research is extremely important to the development of new knowledge in many areas. However, careful attention must be given to questions of ethics and human dignity whenever human subjects participate in research.

In 1978, the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research developed broad ethical principles to provide a basis on which specific rules could be developed.

WHAT IS THE PROCESS?

1. Employee/researcher selects and completes either the **Exempt** or **Non-Exempt** application form.
2. District/College CEO signs (and, therefore, approves) the application form.
3. The appropriate application form is submitted to the Office of Research and Policy Analysis in the KCTCS System Office.
4. It will be reviewed by certified Reviewers within two weeks.
5. The Chancellor and the Chair of the HSRB will approve or ask for additional information.
6. Principal Investigator on the project will be notified of approval/ nonapproval in writing.
7. Appropriate documentation will be maintained by the employee/researcher and by the secretary of the Human Subjects Review Board for one year.

The Belmont Principles

Three basic principles are particularly relevant to the ethics of research involving human subjects:

REPECT FOR PERSONS, BENEFICENCE, AND JUSTICE.

HUMAN SUBJECTS REVIEW BOARD

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