

# KCTCS NEWS

## HUMAN SUBJECTS REVIEW BOARD

### IF YOU CONDUCT RESEARCH – YOU ARE RESPONSIBLE KCTCS HUMAN SUBJECTS RESEARCH POLICY 1.8.2.3.2.1

#### 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 (859-256-3184).

[See Figure 1]

*‘Higher Education  
Begins Here’*

**Figure 1**

Does Your Research Involve  
Human Subjects?

↓  
**NO**

No further reporting  
is necessary to the  
HRSB Exec. Secretary

↓

Is Your Research Exempt?

↓  
**Yes**

Submit Exempt  
Application  
Form to HRSB  
Exec. Secretary  
for Approval

↓  
**No**

Submit Non-Exempt  
Application Form  
For Project Review to  
HRSB Exec. Secretary

#### 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.

*“A strong internal organization embraces responsible risk-taking, participative decision-making, and personal accountability.”*

Dr. Michael B. McCall,  
KCTCS President

## WHAT IS THE PROCESS?

Here is the simple **Seven Step** 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 System Chancellor.
4. If exempt – the Chancellor approves.
5. If non-exempt – the Human Subjects Review Board (HSRB) gives the approval or non-approval.
6. Employee/researcher will be notified of approval/non-approval in writing.
7. Appropriate documentation will be maintained by the employee/researcher and by the secretary of the Human Subjects Review Board.

## KCTCS POLICY FOR 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 PRINCIPALS 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.

### The Belmont Principles

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

**RESPECT FOR PERSONS,  
BENEFICENCE, AND  
JUSTICE.**

### How can an investigator obtain further information or advice regarding the use of human subjects?

CONTACT THE HUMAN SUBJECTS REVIEW BOARD  
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