Revision Responsibility: Executive Director of Strategic Planning, Institutional Effectiveness, and Special Projects **Responsible Executive Office:** President

Source/Reference: TBR Policy 2:08:00:00
TBR Guideline A-110

PURPOSE

To establish responsibility for the assurance of the rights and wellbeing of individuals when conducting investigations that involve human subjects, animals, or technology transfer in compliance with the United States Department of Health and Human Services, Title 45 CFR, Part 45.

POLICY

I. The College's Institutional Review Board (IRB) will review and approve, when appropriate:

A. research involving human subjects conducted under the name of Columbia State Community College, or by any employee of the College;

B. research conducted by people not affiliated with Columbia State Community College, but who are seeking to conduct human research utilizing personnel, students, or existing confidential data within the College;

C. research reports and data analyses obtained from Columbia State Community College or the Tennessee Board of Regents (TBR) through either electronic or print media;

D. research using Columbia State Community College students, faculty, or staff as research subjects/participants, or any members of these groups identifiable individually as being affiliated with the Tennessee Board of Regents or any of its campuses. The TNeCampus and research or data requests relevant to any TBR campus must seek approval from the TBR Office of Academic Affairs in addition to the individual College or University IRB; TBR IRB approval applies to research conducted by students, TBR personnel, and non-TBR personnel. (See TBR Policy No. 2:08:00:00 General Policies Regarding Research.)

II. The College's Animal Care and Use Committee will review and approve any research involving the use of animals, and will meet the criteria specified in the most recent version of the Guide for the Care and Use of Laboratory Animals, published by the Institute of Laboratory Animal Research, Commission on Life Science, National Research Council.

PROCEDURES

I. In the case where an IRB review is deemed to be necessary, the Executive Director of Strategic Planning, Institutional Effectiveness, and Special Projects will assemble a review committee consisting of the following personnel: the Director of Institutional Research, the Division Dean for the faculty member proposing the research, and a faculty member from each academic division. Appropriate faculty or staff members may serve in an advisory capacity as needed and/or inclusion of a professional reviewer from another TBR institution may occur if needed.

A. The Executive Director of Strategic Planning, Institutional Effectiveness, and Special Projects will serve as IRB Chair.

B. The Chair will keep minutes of all meetings, forward proposals to the Executive Team for final review, and notify proposal originators of review outcomes.

C. Researchers proposing a research project using human subjects must define the risks to the subjects, show that the significance of the research warrants the risks, describe safeguards and procedures to minimize the risk, explain how subjects will be informed about the risks, show how subjects' consent will be obtained, submit the proposal for review and obtain approval prior to beginning the research.

II. Four types of IRB Review

A. Exempt occurs when there is little or no risk as determined by the IRB Committee Chair. Generally, research associated with educational practice such as instructional strategies or the effectiveness of instructional techniques, curricula, or classroom management; educational tests including voluntary surveys, interviews, or observation of public behavior; use of existing data including pathological or diagnostic specimens that do not personally identify subjects; state or federally approved research projects that have potential for public benefit; and taste and food quality evaluation and/or consumer acceptance where the food item is wholesome and approved as safe by the Food and Drug Administration, Environmental Protection Agency, Food Safety and Inspection Service of the U.S. Department of Agriculture.

B. Expedited reviews can occur when no more than a minimal risk to participants involved in such ways as collection of biological samples by non-invasive means; blood samples by venipuncture from participants 18 years or older, in good health and not pregnant; clinical studies of drugs and medical devices that are exempt from new drug or device investigational testing; collection of data from voice recordings made for research purposes only; moderate exercise by healthy volunteers; the study of existing data, documents, records, pathological specimens, or diagnostic specimens; recording data from participants 18 years or older through noninvasive means routinely employed in

clinical practice such as physical sensors applied externally, weighing, tests of sensory acuity, electrocardiography, electroencephalography, thermography, detecting radioactivity, diagnostic echography, and electroretinography. Specifically excluded are exposures to electromagnetic radiation outside the visible range (e.g., x-rays, microwaves).

C. Full Review occurs if the project entails more than minimal risk to human subjects or if it does not fall into one of the categories for Exempt or Expedited review. Proposals must be submitted at least thirty (30) days before the project deadline.

D. Continuing reviews occur annually for research previously approved by the IRB. Projects deemed "exempt" do not require a continuing review.

III. Some situations require full IRB review regardless of exemptions and have special regulations.

A. When subjects are under eighteen years of age
B. When deception of subjects may be an element of the research
C. When subjects are elected or appointed public officials or candidates for public office
D. When subjects are under federal statutes which require the confidentiality of personally identifiable information
E. When the activity may expose subjects to discomfort or harassment beyond levels encountered in daily life
F. When fetuses, pregnant women, human in vitro fertilization, children, of persons involuntarily confined, or detained in penal institutions are subjects

IV. Regardless of the exemption status, researchers must ensure the welfare of subjects and use appropriate methods to gain consent.

V. Proposal Submission

A. For initial review, submit the following:
1. one-page application obtained from the Executive Director of Strategic Planning, Institutional Effectiveness, and Special Projects
2. one-page summary of the research project
3. procedures involving human subjects
4. informed consent form(s)
5. questionnaires or survey instruments
6. Do not submit a complete research proposal. Submit only material dealing with the treatment of human subjects.

B. For continuing review of projects extending one year or more submit the following:
   1. A new one-page application
   2. A one-page summary of activities
   3. A copy of the consent form
   4. Any new changes in the procedure

August 23, 2010 (new policy); September 20, 2011 (new policy format); December 2018 Revised; June 15, 2021 Reviewed; accepted by Cabinet, approved and signed by the President. Reviewed, minor editorial changes, approved, accepted and signed by the President July 2024.