

## **1 04 01 INSTITUTIONAL REVIEW BOARD PROCEDURES**

### Purpose

The purpose of this policy is to protect the rights and welfare of human subjects used in research and to ensure the protection and safety of Volunteer State Community College (VSCC) personnel and students in studies involving nonhuman subjects.

### Definitions

- Human subject - a living individual about whom an investigator (whether professional or student) conducting research obtains data either directly through interaction with the individual or indirectly through identifiable private information
- Research - a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- Principal Investigator – the primary individual responsible for the preparation, conduct, and administration of a research project in compliance with applicable laws and regulations and institutional policy governing the conduct of research.

### Institutional Review Board (IRB) Membership

The IRB shall consist of at least five diverse members, including consideration of race, gender, cultural backgrounds, and sensitivity to community issues.

1. Members will be invited to join the board by the President.
2. Members shall be from various disciplines and have the professional capacity to review IRB requests and make decisions based on internal, state, and federal policies.
3. At least one member shall be from a scientific background and at least one from a nonscientific background.
4. No IRB member shall participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

5. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues requiring expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

## Policies

All research involving human and nonhuman subjects conducted at or sponsored by VSCC will adhere to [Federal](#), [Tennessee Board of Regents](#) (TBR), and VSCC policy and guidelines.

### 1. Policy for use of Human Subjects in Research

- A. Research involving human subjects conducted at or sponsored by VSCC must be approved in writing by the IRB and the College President.
- B. Anyone conducting research or responsible for research involving human subjects must adhere to VSCC IRB policy. The VSCC IRB will make a recommendation for approval or disapproval to the College's President.
- C. Only research proposals consistent with the mission of the College will be submitted for review by the Institutional Review Board.
- D. Responsibility for coordination of the IRB review process lies with the Office of Institutional Effectiveness, Research, Planning and Assessment.
- E. All approved research must be conducted in an ethical manner with minimal reasonable risk to the subjects and participants.
- F. All reasonable efforts must be made to ensure the confidentiality of the subjects' identities. All subjects must sign a consent form before they can be included in any study.
- G. The IRB must conduct continuing review of non-exempt research at intervals appropriate to the degree of risk.
- H. The IRB is responsible for the protection of VSCC employees and students from retribution or any negative repercussions resulting from their participation or refusal to participate in a research study.
- I. Researchers publishing data analyses or reporting from data obtained from the TBR System Office or TBR institutions, either electronically or in print, must comply with the federal guidelines in the protection of editable, small cell data,

including but not limited to the federal Gramm Leach Bliley Act, 15 U.S.C. 6801-6809 (see [TBR Guideline G-030](#), Section (III)(I)).

- J. All requests for TBR system confidential data by researchers (students, TBR personnel and non-TBR personnel) must be reviewed by the TBR IRB.
2. Policy for Use of Animals for Research
    - A. Depending on the animal definition, the [Guide for the Care and Use of Laboratory Animals](#) and/or the Animal Welfare Act ([Title 9 CFR Chapter 1 Subchapter A](#)) shall be the criteria for researchers to follow regarding the humane treatment of animals for scientific research purposes.
    - B. Each researcher engaged in such research is personally responsible for obtaining, perusing, and applying the principles, standards, and procedures of the Guide.

## Procedures

Both internal and external requests for research must be submitted for review. Faculty and staff (both full-time and part-time) using human subjects or identifiable, private information about human subjects to conduct research outside the course and scope of their duties are required to have prior approval from the IRB before research is initiated. Both internal and external researchers must submit a Request to Conduct Research, along with documentation showing that IRB approval has been obtained by their home institution's IRB, if applicable. Projects must be approved regardless of whether the research is funded and regardless of the source of funds. This policy also applies to students whose research is conducted under the advisement of a faculty member except when research is for classroom instructional purposes only. Research that is conducted without IRB exemption or approval is not in compliance with VSCC policy and federal regulations.

1. The principal investigator must obtain approval for conducting research concerning human subjects, including VSCC personnel or students, prior to collecting any data.
  - A. To obtain approval, the principal investigator must submit a completed Request to Conduct Research form to the Office of Institutional Effectiveness, Research, Planning, and Assessment.
2. The IRB will review completed Request to Conduct Research upon receipt.

3. After the Request to Conduct Research has been reviewed, the IRB will designate the research proposal as:
  - A. Approved – No changes in the research study are needed.
  - B. Changes Required – The proposed study requires changes. The IRB will provide details that identify the type of changes necessary before approval can be granted.
  - C. Rejected – The IRB will provide comments concerning the rejection.
4. The principal investigator must request re-approval by completing and submitting the Request to Conduct Research form to the Office of Institutional Effectiveness, Research, Planning, and Assessment before the approval expiration date.
  - A. If re-approval fails to occur by the continuing date specified by the IRB, all research activities must stop, unless the IRB finds that it is in the best interest of individual participants to continue participating in the research interventions or interaction.
5. All requested changes in the conduct of a study and/or changes to study documents must be approved by the IRB prior to implementation of that modification.
  - A. The only exception is a change necessary to eliminate apparent immediate hazards to the research subject ([21 CFR 56.108 \(a\) \(4\)](#)).
6. Researchers must notify the IRB of any unanticipated problems involving risks to subjects or others, and other events.

TBR Source: TBR Meeting, September 25, 2009

VSCC Source: President's Cabinet, November 14, 2016