

Policy Title: General Policies Regarding Research

Policy Type: Academic **New/revised:** Revised

Old Policy #: 2:08:00:00

Approval level: ☒ Board of Trustees
☐ President
☐ Vice President
☐ Other (specify here)

Purpose: It is the intention of the East Tennessee State University Board of Trustees that ETSU adhere to federal standards on the ethical conduct of research and be responsible for promulgating policies that serve to effectuate federal law and regulations regarding all applicable aspects of research. This policy specifically addresses human subjects, animal subjects, and technology transfer; it is not meant to supplant federal regulations. Due to the complexity of the field of research, institutions and their faculty or staff engaged in conducting research are referred to the federal regulations, policies, and guidelines.

Policy:

- I. Protection of Human Subjects in Research
 - A. Research involving human subjects must comply with the standards concerning the conduct of research involving human subjects established by the United States Department of Health and Human Services (DHHS) within the "Protection of Human Subjects" (Title 45 CFR, Part 46).
 - B. This policy does not cover use of non-confidential data available under the Tennessee Public Records Act.
 - C. ETSU will place into effect an institutional review board (IRB) and the necessary procedures to ensure that the rights and welfare of human subjects are properly protected.
 1. Research involving human subjects conducted by personnel affiliated with the ETSU must be reviewed and, when appropriate, approved pursuant to 45 CFR 46.111 by the appropriate ETSU IRB.
 2. Research conducted by persons not affiliated with ETSU who are seeking to conduct human research utilizing individuals, groups, or existing confidential data within ETSU must obtain IRB approval pursuant to 45 CFR 46.111.
 3. Researchers publishing data analyses or reporting from data obtained from the ETSU, 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.
 - D. All research in which ETSU is engaged must be submitted by the researcher to the ETSU IRB and approval obtained prior to the initiation. In addition, studies in which ETSU is not engaged, but that meet the definition of ETSU research (Reference ETSU Introduction to Policies) must be submitted by the researcher to the ETSU IRB and approval obtained prior to initiation of the research study.
- II. Policy for Use of Animals for Research and Education
 - A. Depending on the animal definition, the Guide for the Care and Use of Laboratory Animals (2011 - [8th edition](#) or the most current version published by the Institute of

Laboratory Animal Research, Commission on Life Sciences, National Research Council) 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 and educational purposes at ETSU.

- B. Each researcher engaged in such research or educational activities is personally responsible for obtaining, perusing, and applying the principles, standards, and procedures of the Guide.
- C. ETSU will be required to place into effect an Institutional Animal Care Use Committee (IACUC) to review and approve all studies using animals in research or educational activities and follow the policies of Office of Laboratory Animal Welfare (OLAW) and the United States Department of Agriculture (USDA).

III. Technology Transfer

- A. ETSU must comply with federal laws concerning the protection of national security and military secrets by preventing foreign governments from accessing military and other technologies via the research processes of American universities.
- B. ETSU will have policies in relation to the transfer of technology. These policies must comply with the provisions of the Arms Export Control Act, 22 U.S.C. 2778, and all subsequent related Executive Orders and regulations.