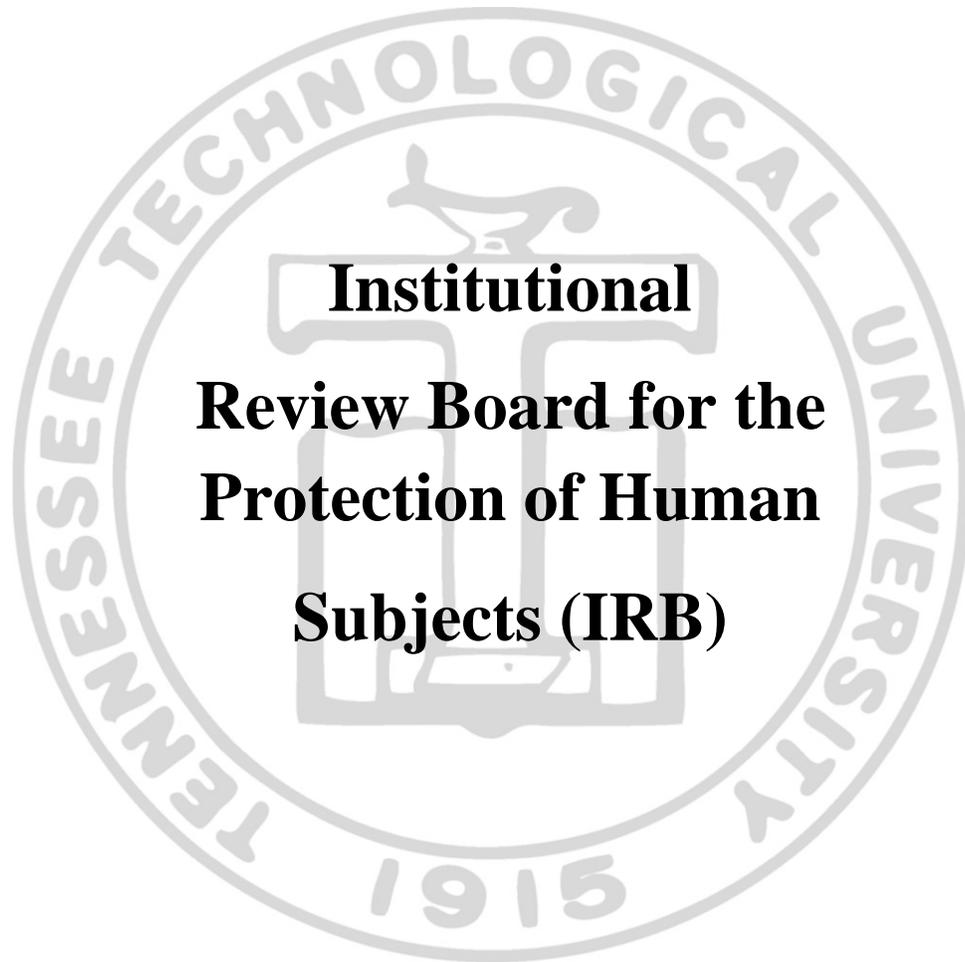


**Tennessee Technological University
Policy No. 730**



**Institutional
Review Board for the
Protection of Human
Subjects (IRB)**

Effective Date: January 1, 2018

Policy No.: 730

Policy Name: Institutional Review Board for the Protection of Human Subjects (IRB)

I. Purpose

The purpose of the Institutional Review Board for the Protection of Human Subjects (IRB) is to ensure that humans involved in research are afforded protection as described in the revised version of the Belmont Report, the Declaration of Helsinki, the International Conference on Harmonization (ICH) Guidelines as adopted by the Department of Health and Human Services, Good Clinical Practices (GCP), the Health Insurance Portability and Accountability Act (HIPAA) of 1996, all applicable federal regulations governing human subjects research, and the moral and ethical precepts of Tennessee Tech.

The IRB performs the following functions: (a) serves as the institutional review board for Tennessee Tech according to requirements for protection of human subjects as set forth by the federal regulations created by Congress (Code of Federal Regulations [CFR], Title 45, Part 46, and Title 21 CFR 50 and 56, and other pertinent regulations, guidance, state and local laws); (b) establishes and implements policies for protection of human subjects in funded and non-funded research; (c) establishes and recommends guidelines for classroom activities involving human subjects, and these guidelines are for implementation by academic units within Tennessee Tech; and (d) reviews and acts on matters on human subjects if referred by the Administrative Council, Academic Council, Office of Research, or President of the University.

This policy establishes the process and procedures for Tennessee Tech's IRB and appropriate review for research involving human subjects.

II. Review

This policy will be reviewed every three years or whenever circumstances require review, whichever is earlier, by the Tennessee Tech Institutional Review Board for the Protection of Human Subjects, with recommendations for revision presented to the Vice President for Research and Economic Development, Administrative Council, and University Assembly.

III. Definitions

- A. Institutional Review Board (IRB):** the board charged with protecting the rights and welfare of people involved in research. Institutions that accept research funding from the federal government must have an IRB to review all research involving human subjects (even if a given research project does not involve federal funds). The Food and Drug Administration, which is a DHHS agency, and the Office for Human Research Protections (OHRP) (part of the National Institutes of Health) set the guidelines and regulations governing human subject research when the research involves clinical investigations of products under its jurisdiction. The IRB is composed of a minimum of five members with varying experiences, expertise, and diversity (race, age, gender, and cultural backgrounds) to promote complete and accurate review of research, and it includes at least one member with purely scientific

interests, one member with non-scientific interests, one member who is not affiliated with Tennessee Tech and who is not part of the immediate family of a person affiliated with Tennessee Tech, and as many departments and college/school representatives with interests in human subjects as is appropriate to ensure disciplinary diversity.

- B. Research:** a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.
- C. Systematic investigation:** a predetermined method of studying a specific topic, answering a specific question(s), testing a specific hypothesis(es), or developing theory. It includes observational studies, interview or survey studies, group comparison studies, test development, and interventional research.
- D. Generalizable knowledge:** the intent and/or purpose of the systematic investigation such as dissemination of findings or results of the investigation through publication or presentation of the results.
- E. Human subject:** a living individual about whom an investigator/researcher (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

IV. Policy

- A.** Tennessee Tech hereby adopts Department of Health and Human Services “Basic HHS Policy for Protection of Human Research Subjects,” Code of Federal Regulations, Title 45, Part 46.
- B.** Tennessee Tech will comply with the federal guideline related to Institutional Review for Research (Title 45 CFR, Part 46, Title 21 CFR 50 and 56.108[a]).
- C.** All 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).
- D.** Researchers are responsible for protecting the rights and welfare of human subjects and complying with all federal laws and regulations, all Tennessee Tech policies and guidelines, and any other requirements related to human subjects research.
- E.** Before applying for grants that involve human subjects in research and before filing an application with the IRB to undertake human subjects research,

investigators must complete and pass training as directed by the Office of Research and Economic Development on the Training Requirements section of its Human Subjects Research/IRB web page.

- F. All human subjects research involving biomedical and social and behavioral research must be reviewed by the IRB.
- G. The President appoints members of the IRB subject to requirements found in Title 45 CFR, Part 46, as noted in the IRB Administrative Policies section of the Office of Research and Economic Development Human Subjects Research/IRB web page.
- H. Researchers must familiarize themselves and comply with applicable guidelines and policies including but not limited to:
 - 1. NSF Proposal and Award Policies and Proposal Guide
 - 2. Comprehensive IRB Review Procedures found on the Office of Research and Economic Development Human Subjects Research/IRB web page, as well as the decision charts from the U.S. HHS/OHRP to guide human subjects research adopted by Tennessee Tech

V. Authority and Responsibilities

- A. To carry out its charge of protecting human subjects as required under federal regulations, the IRB has the following responsibilities and authorities:
 - 1. Review and approve, require modifications of, or disapprove all University research involving human subjects
 - 2. Review, approve, request modification of, disapprove initial, on-going, or continuing proposals to conduct research on human subjects, along with protocols and/or consent documents to ensure compliance with regulatory and ethical guidelines
 - 3. Disapprove studies or requested changes/additions if the standards for human subjects protection are not met
 - 4. Review all on-going/continuing, non-exempt research approved by the IRB (full committee or expedited process), in conjunction with additional information and updates provided by the investigator, at least once per year and to observe or have a third party observe the consent process and the research
 - 5. Inspect research facilities and obtain records and other relevant information relating to the use of human subjects in research
 - 6. Suspend or terminate approval of an approved study at any time during its oversight of the research and the investigator, and this action may result from unanticipated

problems posing risks to subjects or others, or allegations of, or findings of, serious and/or continuing non-compliance

7. Report to appropriate University and/or federal government officials:
 - a. Any unanticipated problems involving risks to subjects
 - b. Serious or continuing non-compliance with IRB requirements
 - c. Any suspension or termination of IRB approval of research
 8. Take such actions that are necessary in its judgment to comply with federal regulations or other applicable laws, including action to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects
- B.** Non-compliance with IRB policy and procedures requires corrective action. The IRB will determine the actions required and will take into consideration the nature, severity, and frequency of the non-compliance and the risk that non-compliance poses to human subjects. Section #7 of the Comprehensive IRB Review Procedures found on the Office of Research and Economic Development Human Subjects Research/IRB web page outlines Tennessee Tech's reporting and possible responses to non-compliance.
- C.** Tennessee Tech will comply with TTU Policy 770 (Whistleblower Protection in Research).
- D.** Tennessee Tech is committed to the ethical use of human subjects in research, teaching, and other scholarly pursuits. Policy and procedures for preventing and reporting fraud, waste, and abuse can be found in TTU Policy 131 (Preventing and Reporting Fraud, Waste, or Abuse).
- E.** Comprehensive IRB procedures and guidelines can be accessed through Tennessee Tech's Research and Economic Development Human Subjects Research/IRB web page.

VI. Interpretation

The Vice President for Research and Economic Development or his/her designee has the final authority to interpret the terms of this policy.

VII. Citation of Authority for Policy

T.C.A. § 49-8-203 (a)(1)(E); Code of Federal Regulations Title 45 CFR, Part 46, especially Subpart A. 46.101 a(2), 46.101 (b and c), 46.102(d), 46.102 (f), 46.103 (b.1), 46.111, 46.112, 46.114, Subpart C; Title 21 CFR, Part 50 and Part 56.108 (a); Title 42 CFR Part 50.601 et seq.

Approved by:

Administrative Council: 11/15/17; 2/25/15

University Assembly: 11/29/17; 4/22/15