

**Name of Committee:** Institutional Review Board for the Protection of Human Subjects

**Committee Procedures/Bylaws:**

**I. Name**

The name of this board shall be the Institutional Review Board (IRB) for the Protection of Human Subjects of Tennessee Technological University.

**II. Purpose**

The primary purpose of the board is to serve as the Institutional Review Board for the protection of human subjects in research, special projects, and related activities of the University. Other duties include:

- A. Serve as the institutional review board for the University according to requirements for the protection of human subjects as set forth by the federal regulations created by Congress (Code of Federal Regulations, Title 45 Part 46).
- B. Establish and implement policies and procedures for protection of human subjects in funded and non-funded research.
- C. Establish and -recommend guidelines for classroom activities involving human subjects. These guidelines are for implementation by academic departments within the University.
- D. Establish and recommend policies relating to ethics and misconduct in research and related activities dealing with human subjects.
- E. Review and act on matters referred by the Administrative Council, Academic Council, President of the University, Office of Research, Faculty Research Committee, administrators, and faculty.

**III. Membership**

The board shall consist of the following members appointed by the University President in accordance with the approved procedures for appointment:

- A. A minimum of five (5) persons as members with varying backgrounds to promote complete and accurate review of research and related activities.
- B. A membership that includes (1) at least one member with purely scientific interests, one member with non-scientific interests, and one member who is not affiliated with the University and who is not part of the immediate family of a person affiliated with the University (2) both male and female members, and (3) as many departments, college/school representatives with interests in human subjects as is appropriate to ensure disciplinary diversity.
- C. All members appointed to the board shall be able to ascertain acceptability of proposed research and related activities in terms of institutional commitment and regulations regarding research, applicable law, and standards of professional conduct and practice.
- D. All members shall be sufficiently qualified through experience and expertise, as well as through diversity (including consideration of race, gender, and cultural backgrounds), to possess a level of sensitivity to issues and attitudes that will promote respect for its counsel and advice in safeguarding the rights and welfare of all human subjects.
- E. Alternate member(s) may be appointed and their appointment should be based on expertise similar to that of the regular voting member(s). Alternate member may vote only when the regular voting member is absent.

F. Members shall serve on the board for a period of three years with appointments becoming effective at the beginning of each fall semester. Appointments are made so that terms of the members are staggered with no more than three members' terms expiring at the same time. All appointments are subject to renewal at the discretion of the President.

G. A roster of the Institutional Review Board (IRB) membership should be maintained that provides the names of the members, gender, degrees earned, primary scientific or non-scientific specialty, affiliation with the institution, and comments (e.g., prisoner representative, advocate, alternate member, etc.)

#### **IV. Officers**

##### **A. Chairperson**

The Chairperson shall be elected annually from and by the membership at the first meeting of the academic year. The Chairperson shall:

1. Preside at all meetings or designate a member to serve in his or her absence.
2. Prepare and distribute a tentative agenda to board members at least two working days prior to the meeting.
3. Make assignments of review subcommittees for expedited reviews.
4. Serve as departmental reviewer in cases where participation of a given departmental reviewer would present a conflict of interest.
5. Manage processing of continuation and change requests for ongoing human subjects research.
6. Call special meetings and appoint ad hoc sub-boards when necessary.
7. Inform the administration and faculty of actions taken by the board.
8. Assume responsibility for the preparation and distribution of the annual report (in collaboration with the Executive Officer) to the Administrative Council and the President of the University.
9. Assume responsibility for the execution of board policies through the Executive Officer.

##### **B. Executive Officer**

The President will appoint a staff member, who will normally be the Associate Vice President for Research, to serve as the Executive Officer. The Executive Officer shall:

1. Serve as a consultant to the board and provide assistance in the conduct of board business.
2. Attend all meetings without voting privileges.
3. Provide administrative support and assistance in matters related to human subjects research which are not among the enumerated duties of the chair. Such support would include, but would not be limited to tasks such as the following: a) responding to inquiries regarding human subjects research; b) investigating and managing issues which arise from time to time; c) managing multi-institutional agreements and processes for establishing them; d) updating the IRB website; e) modifying project

applications and publishing current versions on the website; f) managing approval of procedures revisions by Administrative Council; g) conducting investigations of ongoing research as needed; h) serving as primary contact for human subjects compliance, internally and externally; i) receive and prepare research proposals for review by the board; and, j) provide for the recording of minutes.

4. Provide annual training for IRB members and departmental reviewers, and provide training materials for those trainings.

5. Update registration of the Tennessee Tech IRB with OHRP in a timely fashion.

6. Manage recruitment of board members and manage recommendations to the President for appointment, re-appointment, and replacement of board members within the appropriate time frame.

7. Monitor IRB members' fulfillment of duties and responsibilities, and their ethical behavior, in consultation with the IRB chair (as appropriate). Make recommendations for removal and replacement of IRB members as needed.

8. Manage and expedite submission of IRB-approved procedure changes to the Administrative Council.

9. Monitor and manage the process of departmental review within each college and unit.

10. Maintain a list of trained, eligible departmental reviewers.

#### **V. Required Training and Certification**

A. Members of the IRB are required to take and pass the CITI Program training modules specified in the following list. Required passing score for each module is 80%. All modules must be completed in order

to earn the certification required for IRB members. Certification is valid for three years from date of completion.

#### **List of required CITI modules for IRB members.**

#### **VI. Meetings and Attendance**

##### **A. Meetings**

1 There will be a minimum of two meetings of the board each semester. Special board meetings and sub-board meetings may be called by the Chairperson as necessary for the performance of responsibilities. Meetings of the board will be held in September, November, February, and April. The exact day shall be determined each semester by the membership.

2. Changes in the date and time of regular meetings shall be made known to the membership as soon as the change is necessitated.

3 Research proposals shall be distributed and/or made available by the Executive Officer to members for review prior to scheduled meetings.

4. The agenda for the meeting shall be adopted at the beginning of each meeting.

5. At least one non-scientist must be present in order to conduct meetings.

6. Sixty percent (60%) of the membership shall constitute a quorum including the non-scientist.

##### **B. Attendance**

1. If a member must be absent from a meeting and an alternate member has been designated, notice should be given to the Chairperson or the Executive Officer and the name of the person who will attend for the member provided.
2. A "representative" for the absent member must be approved by the Chairperson since special expertise is required for board membership. The representative for the absent member shall have voting privileges.
3. Absence from fifty percent (50%) of regular meetings by a member without due cause will result in a request by the board to the President of the University for replacement of that member.

#### **VII. Amendment of Procedures**

These procedures shall be amended at any regular meeting of the board by a majority vote of the membership present provided that the amendment has been submitted in writing to the members at least one week prior to the meeting where the voting will take place.

#### **VIII. Effective Date of Implementation**

These procedures shall become effective upon review by the Administrative Council and approval by the President of the University.

#### **IX. Parliamentary Authority**

The rules contained in the most current edition of Roberts Rules of Order, Newly Revised shall govern the board in all cases to which they are applicable and in which they are not inconsistent with the procedures contained in this document.

Updated 07/19/2010

**Committee Composition:** See Procedures.

**Committee Minutes:**

**Committee Website:** <https://www.tntech.edu/research/research-compliance/humansubjects>