



United Tribes Technical College Institutional Review Board Bylaws

Article 1. Name

The name of this committee shall be UTTC Institutional Review Board.

Article 2. Purpose

The purpose of the UTTC IRB is to review proposed and ongoing research activities to ensure they meet specific criteria for approval as required by Federal law. The mission of the IRB is to ensure that human participants are treated with the utmost respect and fairness throughout the research process and to further protect the rights and welfare of human participants. The IRB oversees the research to ensure that ethical principles are met and that the research is in compliance with the Belmont Report, 45 CFR 46, 21 CFR 50 and 56, and other applicable regulations, guidance, state and local laws. The goal of IRB review at UTTC is to review proposed research protocols to assess safety, subject confidentiality, degree of benefit and risk, and the need for and quality of informed consent. Each proposal is reviewed using criteria listed in the Code of Federal Regulations (CFR) Title 45 Part 46, "Protection of Human Subjects" (1991, with minor updates since). Title 45 CFR Part 46 considers primarily the effects of research on individuals, including the three basic principles of: respect for individual persons; potential harms and benefits to individuals; and justice for individuals.

The committee will serve its purpose by accomplishing these goals:

- 1) Review applications for research to ensure the rights, privacy, dignity and welfare of students and employees of UTTC used as human subjects in research studies are protected; that risks have been considered and minimized; that the research is supervised by qualified persons, especially in mental or physical health care related studies; that all human subjects participate in research only after the subject has agreed and been provided with legally effective informed consent; that any research is conducted in an ethical manner and in compliance with established standards and that all private information will be handled in accordance with the regulatory standards for maintaining confidential material.
- 2) Monitor and review ongoing research conducted at UTTC, including changes in protocols and requests for continuing approval for multi-year projects.
- 3) Monitor closeout of research projects conducted at UTTC, including the collection of de-identified data and a report of the data analyses and findings.
- 4) Manage special problems (complaints, grievances, non-compliance, problems, violations, and adverse events) if they occur within approved research protocols at UTTC.
- 5) Monitor reports, presentations, poster sessions, and publications derived from research projects conducted at UTTC and/or approved by the UTTC IRB.

Article III. Membership

The IRB will have no less than 7 and no more than 12 members. Members are appointed by the UTTC President or can request approval from the UTTC President to serve on the IRB.

- 1) Membership shall include:
 - a. UTTC President (Institutional Official/Signatory Official);
 - b. UTTC Institutional Research Director
 - c. Project Development Coordinator / IRB Administrator;
 - d. UTTC Land Grant Director;
 - e. Minimum of five UTTC faculty and staff;
 - f. At least one member with primary expertise in science or health-related field;
 - g. At least one member with primary expertise in a social or behavioral field;
 - h. At least one member will be an external member otherwise unaffiliated with UTTC;
 - i. One member can represent more than one required role (i.e. external and science).
- 2) Filling IRB Vacancies and Qualifications for Membership
 - a. Members in good standing shall serve an indeterminate amount of time.
 - b. Vacancies shall be filled by appointment or approval of the UTTC President.
 - c. Individuals may request to serve on the IRB.
 - d. CITI Completion Certificate must be presented as proof of current (within three years) IRB member training within 90 days of appointment or approval.
 - e. Failure to complete the CITI Certification within the 90 days of appointment or approval will result in removal from IRB membership.
- 3) Guest members may be invited on an “as needed” basis as a resource or to provide specialized expertise.
- 4) Privileges and Responsibilities of Membership:
 - a. Voting Rights
 - i. Each IRB regular member shall have voting rights.
 - ii. A quorum of half plus one of regular membership must exist for a vote to be held.
 - iii. Items that require a vote must have majority of those present to carry.
 - iv. Guest members shall not have voting rights or count toward quorum.
 - v. Members with a conflict of interest do not count toward the quorum for the review of that study and must recuse themselves from the vote.
 - b. Voting Actions on Research Proposals
 - i. Approve: The proposal is complete, the IRB is satisfied that all criteria for approval have been met, and the research activity may commence.
 - ii. Require Modifications to Secure Approval
 1. IRB-directed non-substantive (minor) revisions (approval of research with conditions) are required and concurrence or confirmation of certain issues by researcher is needed.
 2. The IRB requires information that is substantive to the review of the proposal and is needed to allow the IRB to determine that all criteria for approval and all other required findings are met. In this case, the response by the researcher must be brought back to full IRB for further deliberation by the membership.
 - iii. Disapprove: A study is disapproved when the IRB has all the information it needs (no clarifications are explanations are needed), and the study does not meet all the

criteria for approval or other required findings.

c. Participation

- i. Members must actively attend and participate in meetings.
- ii. Members must be adequately prepared for meetings to ensure timely business completion.
- iii. Members may be assigned as primary exempt or expedited reviews.
- iv. Members who have a conflict of interest in a research project may provide information to the IRB, but cannot participate in the review of the plan or be present for voting.
- v. If a member fails to attend three consecutive meetings, the committee members will seek a qualified and interested replacement.

5) Terms and Calendar

- a. The IRB shall meet a minimum of monthly during the academic calendar.
- b. The IRB Chair may call other meetings (i.e. summer or emergency).

Article IV. Officers

1) Titles: The UTTC IRB shall have the following officers elected from the current membership:

- a. Chair
- b. Vice Chair
- c. Secretary

2) Qualifications

- a. The officers shall have been elected by the committee and will serve a two-year term.
- b. Officers must be in good standing with active participation and evidence of IRB training.
- c. Officers will complete CITI training for IRB Chair and IRB Administration within 90 days of election.

3) Duties of Officers

- a. The Chair shall preside at all meetings, review exempt protocols for approval, be responsible for assigning expedited reviews, and perform other duties typically required of this office. The Chair will work with the IRB Administrator to coordinate documentation and communication of protocol approvals, continuation approvals, protocol disapprovals, and any actions taken as a result of unexpected problems.
- b. The Vice Chair shall assist the Chair in all meetings, programs, and exempt protocols as needed. The Vice Chair will also facilitate meetings when the Chair is absent.
- c. The Secretary shall record and distribute meeting minutes in accordance with federal regulations: document attendance of members and guests, time started and ended, and details of the review for each agenda item. For each proposal reviewed, the minutes must document the review decision (that is, approved, modifications required, resubmission, disapproval), reasons for that decision, and approval period, when applicable. In the minutes, additional documentation must be made of the vote count in support of that determination, including reasons for member recusal (for example, due to conflict of interest). Minutes must document risk level for each research study and controverted issues pertaining to review along with the final resolution to such issues.

4) Terms of Office

- a. Officers shall be elected bi-annually by the voting members of the UTTC IRB. The terms shall be 2-year terms. Officers may be re-elected consecutively to the same office for an additional term(s).
- b. Each officer shall take office in September of the corresponding election year and serve a two-year term.
- c. Election for any officer vacancy during mid-year will be done at the next regularly scheduled meeting following the vacancy.
- d. Upon removal or resignation of the Chair, the Vice Chair will assume the role of the Chair and conclude the term for the original Chair.

Article VI. Sub-Committees

- 1) The Chair, subject to the approval of the IRB, shall appoint such sub or ad hoc committees as required in the bylaws, as he or she finds necessary. Sub-committee chairperson's position shall be appointed by and responsible to the IRB Chair.
- 2) A vacancy in a sub-committee chairperson position shall be filled by appointment of the IRB Chair with input from the outgoing sub-committee chairperson if possible.

Article V. Parliamentary Authority

- 1) The rules contained in Robert's Rules of Order, Revised, shall govern the IRB in cases to which they are applicable and in which they are not inconsistent with the bylaws or the special rules of order of UTTC.
- 2) Robert's Rules for voting and minutes are superseded by regulations in 45 CFR 46, 21 CFR 50 and 56, and other applicable regulations.

Article VIII. Responsibility of the IRB

- 1) This committee shall abide by all applicable policies instituted by UTTC.

Article IX. Amendments

- 1) These bylaws may be amended by a vote of two-thirds of the members of the committee present at any regular meeting or at a special meeting called for that purpose. The membership shall be notified of adopted bylaw amendments by the most feasible means.