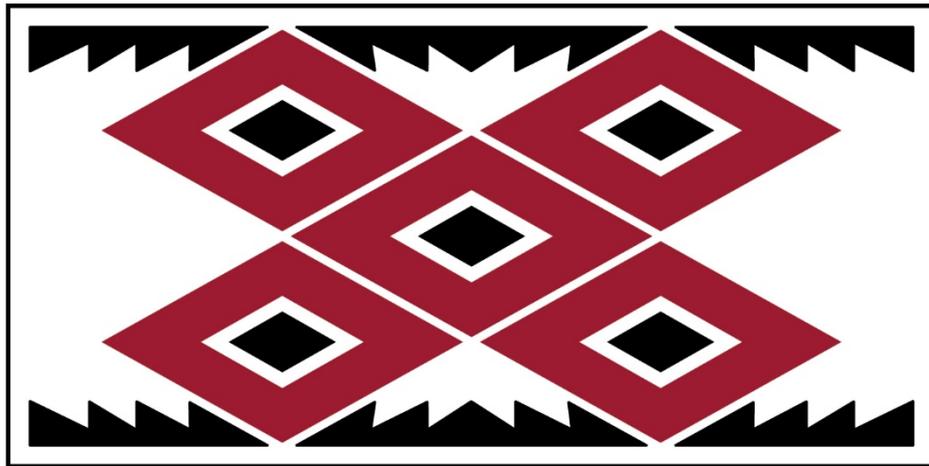

INSTITUTIONAL REVIEW BOARD POLICY MANUAL

Updated for Review November 2018



**UNITED TRIBES[®]
TECHNICAL COLLEGE**

This manual complies with the Office of Human Research Protection's (OHRP's) regulatory guidance on written procedures in "Guidance on Written IRB Procedures".

Purpose of the UTTC Institutional Review Board (IRB)

I. SAFETY ASSURANCE

United Tribes Technical College (UTTC) encourages scholarly endeavors of students, employees and community foundations/organizations. Pursuit of scholarly work and research will often involve the use of human subjects, either students or employees, for data collection and analysis. Researchers seeking to conduct research with Native American and other members of the UTTC community must respect and recognize the unique cultural context. The research must protect and benefit UTTC and/or its students, respect Tribal sovereignty and strengths, promote resiliency, and ensure reciprocity in sharing of what is learned through the project. *The federal registration number for the United Tribes Technical College Institutional Review Board is 0005063.*

The President and IRB shall 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.

UTTC recognizes the importance of conducting research using human participants to further the knowledge base of the academic and larger community. The college accepts the responsibility to assure that research conducted under its auspices protects the rights and welfare of human participants in accordance with federal regulations and ethical standards. The UTTC IRB will oversee this process by reviewing research involving human participants conducted by faculty, staff, and students. All research done on the UTTC campus, specifically with UTTC students and/or employees, or sponsored by UTTC must be approved by the UTTC Institutional Review Board (IRB) prior to the research being conducted.

II. UTTC IRB MISSION

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 UTTC IRB is only concerned with Human Participant Research (“HPR”). A researcher conducting non-human participant research (NHPR) research is excluded from IRB review.

UTTC IRB Processes

I. STRUCTURE OF THE UTTC IRB

A. IRB MEMBERSHIP

The UTTC President will appoint all members and officers of the IRB. The IRB will have no less than seven (7) and no more than twelve (12) members. Members serve on the UTTC IRB Committee for a non-specific length of time. Members will include the UTTC President, the Institutional Research Director, and a minimum of five other UTTC faculty and staff members. At least one member will have primary expertise in scientific or health-related fields and at least one will have primary expertise in qualitative research. At least one member will be an external member and otherwise unaffiliated with UTTC. Guest members may be invited on an “as needed” basis as a resource or for specialized expertise. In cases of potential conflict of interest, an IRB member may be recused from a meeting so that a conflicting interest does not vote or count towards the quorum. UTTC IRB committee members will provide proof of appropriate and current Collaborative Institutional Training Initiative (“CITI”) certification annually during the IRB meeting at the beginning of each academic year. CITI certification must be renewed every three years.

B. IRB COMMITTEE MEETINGS

The IRB Committee will meet monthly at a time and day to be determined annually. The IRB meeting schedule will be posted on the UTTC website under the Institutional Review Board link. Applicants submitting research proposals are advised to complete the forms found on the website and to return the completed forms via email to irb@uttc.edu at least two (2) weeks prior to the committee meeting where the research proposal will be considered and discussed by the IRB Committee.

Upon receipt of completed forms and support materials, the UTTC IRB Chair distributes the proposal electronically to each UTTC IRB Committee member. Committee members will read the proposal and prepare for discussion as part of the next scheduled meeting. A quorum of at least a majority of the committee members is required to take action on expedited and full review proposals. An exempt proposal may be processed through committee or desk review with committee notification depending on risk assessment. The Principal Investigator (“PI”) will be notified in writing of actions determined by the committee. Data collection and research may proceed only after receipt of an approval letter from the UTTC IRB. All active projects are tracked by the UTTC IRB and project status is published on the UTTC website.

C. IRB AGREEMENTS AND APPROVAL FROM OUTSIDE INSTITUTIONS

IRB approval from another college or institution **does not** meet the requirements for UTTC IRB if data will be gathered on the UTTC campus or if the research participants include UTTC students, faculty, or staff. If a research project has undergone IRB review at another institution, an IRB approval letter from the cooperating or partner institution may be submitted with the UTTC application form to the UTTC IRB with a request for exempt review. A campus sponsor is required for researchers and PIs not affiliated with UTTC.

II. IRB REVIEW OF RESEARCH PLANS OR PROTOCOLS

A. CRITERIA FOR "HUMAN SUBJECT RESEARCH"

The IRB will review research that meets regulations by UTTC, the federal government, funding agency, or is covered by UTTC's Federal Wide Assurance (FWA A00027336). According to federal regulations, research is any systematic investigation designed to develop or contribute to generalizable knowledge. The UTTC's IRB has oversight for any research that involves the collection of data about or from human beings as research subjects. A **human subject** is defined in 45 CFR 102(f) as a living individual about whom an investigator (whether a professional or a student) conducting research obtains data through intervention or interaction with the individual or from identifiable private information.

The following questions can help determine whether data gathering as part of a training, demonstration, or service projects meets the definition of research as related to human subjects:

- Will the researcher(s) seek out subjects or settings that contain human subjects for the project, rather than the subjects asking to give input to the service or project?
- Will the findings of the investigation be disseminated (on-campus poster sessions, newsletters, program design are considered dissemination)?

A "yes" answer to any of these questions indicates a research component using human subjects, and the project must be approved by the IRB before any work is begun. Some examples of data gathering from human beings which **do not** constitute research within the context of human subject review requirements are provided below:

- Data gathered for classroom training in a research methods course for which the only foreseeable purpose is to facilitate the student's learning about research methodologies. The IRB process is not necessary, if neither the instructor nor the student intends to disseminate the data gathered in any means including newsletters, meeting reports, etc.
- Data gathered for administrative purposes only to learn what is happening within a unit or institution and/or to improve services or operations. These data collection procedures should be reviewed by and stored with Human Resources to ensure employee privacy and confidentiality is maintained. This data is to be used for reporting purposes and may never

be used in the body of a scholarly report, dissertation or thesis, unless IRB process was properly used.

- Evaluation of data gathered for a contractor about a project or operation for which he or she is responsible, if neither the college nor the contractor intends to disseminate the data in any manner other than completion of the project. If the data is used for educational or informational reports, conferences or sharing with others the IRB process must be used.

B. CRITERIA FOR IRB APPROVAL OF RESEARCH

The goal of the UTTC IRB Committee is to ensure safe and ethical treatment for research study participants at UTTC. The IRB will consider each of the following factors of the proposed research when reviewing research protocols:

1. Study Design –The research protocol supports indigenous views of taking care of our relatives and community;
2. Potential Harms – Risks and benefits to individuals, tribes, and communities are identified and the research process and protocol does not harm participants in any way;
3. Equitable Selection – Human participants are recruited and treated ethically;
4. Confidentiality and Privacy – Participants are assured of confidentiality and fully informed of research purpose throughout the process;
5. Informed Consent – Purpose of research, as well as an option to opt-out of research without consequence, is clearly stated and approved in writing by the participant(s).
6. Dissemination Plans – UTTC IRB requires principle investigators to obtain prior approval for sharing and presenting the study data beyond the study report and;
7. Additional UTTC IRB Requirements – UTTC requires progress reports, posters, and publications to be provided to UTTC for storage and curation;

C. GENERAL REQUIREMENTS OF VOLUNTARY INFORMED CONSENT

The research must present information on research goals and activities in a clear and understandable way to potential participants/research subjects or legal parent or guardian and ask potential participants to voluntarily consent or to give permission (if legal parent/guardian of potential subject) for participation along with assent of the participant. There must also be a clear statement for subject's right to discontinue participation at any time.

Voluntary informed consent or permission/assent by subjects must be documented in writing. The forms used to obtain voluntary informed consent must be approved by the UTTC IRB. The UTTC IRB may decide to waive this requirement under limited circumstances, and only when permitted by the federal regulations.

D. APPLICATION TO THE UTTC IRB FOR APPROVAL OF A PROTOCOL

UTTC has a formal process for researchers to use when applying to the UTTC IRB for approval of their protocol. The process includes completing the Coversheet (Form A) and one of the other forms appropriate to the level of risk to human subjects as described below.

Form A - Coversheet

The coversheet (Form A) asks for introductory and summary information about the project. This includes the Principal Investigator's contact information, other investigators that are involved, a project description, reason for the IRB request, and external funding agency if applicable. Start and end dates are also required.

Form B - Exempt Review

An exempt review is appropriate when the research involves the use of anonymous existing data or specimens. Anonymous means the study information can never be linked to identifiers such as name, social security number, medical records or other identifying information. An exempt review may be conducted without the involvement of the full IRB committee. However, even if an exempt review is conducted through desk, the chair will notify the committee of the action.

Form C - Expedited Review

An expedited review is appropriate when the research involves only minimal risk to research participants. This can include research that involves the use of confidential records, data, specimens or other identifying information. The researcher must describe how confidential and identifying information will be protected, how the original data will be secured, and how the benefits justify the risks. A copy of the consent form or script must be provided.

Form D - Full Review

A full review is required for any research involving more than minimal risk to the subjects. More than minimal risk includes which can reasonably place subjects at risk of criminal or civil liability, damage a subject's reputation or financial standing or employability, or has the probability and magnitude of harm or discomfort anticipated as greater than those ordinarily encountered in daily life or routine examinations. A full review is required when the research involves the collection of information regarding sensitive aspects of the subject's behavior such as substance abuse, illegal conduct, or sexual behavior. Research that involves protected populations such as children, prisoners, or disabled individuals must undergo full IRB review.

E. UTTC IRB ACTIONS AND CHANGES IN APPROVED RESEARCH ACTIVITIES

IRB decisions regarding research proposals are made based on discussion and consensus vote. Applicants are informed via emailed letter of the committee's decision for approval, denial, or pending approval with stipulations for change. Applications identified as pending approval can be resubmitted with the suggested or required changes at any time for approval at the Chair's

discretion through committee email correspondence or at the next scheduled IRB meeting. Denial letters will include a reason for disapproval and a process for the researcher to respond.

Project protocol changes may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to participants. Researchers who have received IRB project approvals should advise the IRB promptly of any unanticipated problems involving risks to participants. If changes need to be made to the research protocol previously approved by the UTTC IRB Committee, the PI must submit a request for change using the appropriate form provided on the UTTC website. The Chair of the IRB will review the proposed changes and provide a prompt response regarding approval or other action. Depending on the changes requested, it may be approved immediately, it may be held for discussion as an agenda item at the next scheduled IRB meeting, or it may be addressed quickly through an impromptu meeting. As in the original application, a letter will be provided indicating the committee's decision. Unanticipated problems involving risks to human subjects, serious or continuing noncompliance, and any suspension or termination of IRB approval will be reported to the UTTC Board of Directors and, as applicable, to the funding agency or federal department.

F. EXTENDED IRB APPROVAL

Under UTTC's Federal Wide Assurance (FWA A00027336) a researcher may request an extended IRB approval time. In order to be eligible for extended time past one year, the research must meet certain conditions. First, the research must involve no more than minimal risk to participants (exempt or expedited level of review as defined by 45 CFR 46.102). Second, the research must not be subject to federal oversight (implemented at the direction of federal agencies). Third, the protocols and methods of the research must not have significantly changed since the original application. A continuing protocol application must be submitted at least 4 weeks prior to the study's expiration date if the study is still active. The continuing protocol application will be reviewed by the IRB chair. The chair has the discretion to approve the continuing protocol or to hold it for the next regular committee meeting. If approved, the expiration date will be reset to one year from the renewed approval date. As in the original application, a letter will be provided indicating the committee's decision.

G. CONFIDENTIALITY OF IRB MEETINGS

The content of IRB discussions and of the applications being reviewed will be held confidential. IRB meeting minutes with confidential or private information redacted will be available to the public as requested. IRB decisions will be made available to the public on the UTTC website. Each approved project will receive a number using the year approved and numerically ordered numbers (i.e. 2018-01, 2018-02, etc.) The project's PI, title, approval date, length of approval time, sponsor, reporting due dates, and final report submission dates will be published on the UTTC website in the Active Projects and Tracking list.

H. IRB APPROVAL OF REPORTS, PRESENTATIONS, AND PUBLICATIONS

To minimize harms to individuals and communities, the UTTC IRB must approve any publications, reports, presentations, and poster sessions derived from the research projects conducted at UTTC and/or approved by the UTTC IRB. The researcher will submit for approval the aforementioned to the UTTC IRB prior to dissemination, publication, or presentation.

I. RESEARCH CLOSEOUT AND TRANSFER

The IRB project closeout form must be submitted as part of the project closeout procedure. The IRB procedure for project closeout for oversight of the research includes submission of a final report to the IRB. The final report will include the data analysis and findings as well as a copy of the de-identified data collected through the study. In addition, the researcher will provide assurance that the IRB will be notified of any additional presentations, poster sessions, and publications derived from the research projects conducted at UTTC and/or approved by the UTTC IRB.

III. IRB REPORTING

A. IRB REPORTS

The IRB will periodically share information upon request about UTTC IRB activities with the UTTC Board of Directors, interested tribal governments, and organizations for which it reviews research. Reports may include findings or results derived from the projects approved by the IRB. If any findings or results are deemed important to or could impact the tribes or organizations involved, UTTC will ensure that the information is shared with them. The IRB will report changes of IRB membership to the Office of Human Research Protection.

B. IRB CORRESPONDENCE

The IRB will maintain up-to-date written and email correspondence to and from researchers, and as needed, to and from other IRBs, tribes, and institutions.

C. RETENTION AND STORAGE OF IRB RECORDS

The UTTC IRB will retain in a secure area

- o Records of research by UTTC student researchers for 3 years
- o Records of research by other researchers for 7 years
- o Records of research involved in litigation and that had a serious violation or problem for an indefinite period without transfer to another storage facility.

D. IRB INFORMATION MANAGEMENT

The UTTC IRB shall maintain a secure web portal to house IRB information and documents. This portal will help to ensure continuous functionality even when changes in leadership or personnel occur. In addition, the portal will serve as a resource for IRB members in addressing special conditions or challenges if they occur.

UTTC IRB Management of Special Problems

I. COMPLAINTS OR GRIEVANCES, AND ALLEGATIONS OF NON-COMPLIANCE

The IRB will respond within five (5) working days to complaints or grievances by participant[s] or others about the research, and to allegations of researcher non-compliance. The IRB will observe legal due process, and will comply with federal regulations and UTTC requirements.

II. PROBLEMS, DEVIATIONS, VIOLATIONS AND ADVERSE EVENTS

The IRB will respond within five (5) working days to problems, deviations, or violations of the approved protocol, and to serious adverse events. The IRB will observe legal due process, and will comply with federal regulations and UTTC requirements.

III. SUSPENSION OR TERMINATION OF PRIOR IRB APPROVAL

The UTTC IRB has the authority to suspend or terminate “for cause” a prior IRB approval of an active research project. In that case, the IRB will first, investigate the alleged cause, then, determine if there was/is a problem, and (if any problem) its severity, and finally, decide IRB action, if any. The IRB will observe legal due process, and will comply with federal regulations and UTTC requirements. The decision to *permanently* suspend or terminate prior approval of research activities will be made by only a convened IRB meeting with quorum.

IV. REPORT SUSPENSION OR TERMINATION OF PRIOR IRB APPROVAL

The IRB will report within five (5) working days to the researcher, and to specific applicable federal, funding, tribal, and UTTC officials if the IRB suspends or terminates prior IRB approval of an active research project.

A. LAPSE OF IRB APPROVAL OF RESEARCH DUE TO FAILURE TO RENEW

The IRB’s approval of a research project ends on the date of the next periodic review deadline, and no more than 365 days since last approval, whichever comes first. The IRB will quickly provide technical assistance to the PI to minimize both potential harms and disruption of the research and to maximize potential benefits of the research. The IRB will observe legal due process, and will comply with federal regulations and UTTC requirements.

B. APPEAL OF IRB DECISIONS

A researcher may appeal a UTTC IRB’s decision to the UTTC IRB. The UTTC IRB will consult with an appropriate resource person before and while responding to the appeal.