GENERAL IRB PROCEDURES
Tennessee Tech University Institutional Review Board
for the Protection of Human Subjects

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Tennessee Tech University, per DHHS - 45 CFR 46.103(b)(4) and (5)

I. Overview
The Tennessee Tech Institutional Review Board for the Protection of Human Subjects (IRB) is responsible for reviewing all research conducted by Tennessee Tech faculty, staff, and students, in accordance with 45 CFR 46, to ensure the ethical treatment of participants within such studies. The board consists of Tennessee Tech faculty/staff with and without scientific interests and members of the community, and it is formally registered with the federal government (IRB00005901; FWA00011357). The IRB has two meetings during the fall semester and two during the spring semester that are published in the University's online calendar.

A complete IRB application consists of an Application of Research Involving Human Subjects, a copy of CITI training Certificate of Completion for the Principal Investigator (PI) and each Co-Principal Investigator (Co-PI), a copy of the Informed Consent Form, all research instruments, and any additional pertinent documents and/or permissions.

II. General Approval Procedures
The IRB may approve an application only when its decision is based on consideration of the following:

- Risks to subjects are minimized (i) by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result and involve only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within its purview.

- Selection of subjects is equitable. In assessing this, the IRB should consider the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative and documented in accordance with, and to the extent required, by federal regulation.

- When appropriate, the research plan adequately provides for monitoring the data

collected to ensure the safety of subjects.

- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain data confidentiality.

Approval of a project by the IRB signifies only that the procedures adequately protect the rights and welfare of the subjects and do not indicate University approval to conduct research. Approval of a project by the IRB applies only to the procedures submitted in the application. The investigator must secure prior approval from the IRB for any changes in the procedures that will affect the use of human subjects. The investigator must also report to the IRB any problems that arise in connection with the use of human subjects. If an approval is granted with contingencies, those contingencies must be satisfied (reviewed and approved) prior to beginning the project. Approval for projects is valid only until the expiration date.

All applications received by the Office of Research are recorded in a database. At convened IRB meetings, the Executive Officer (i.e., Associate Vice President of Research) and the IRB members receive a report detailing all new IRB applications submitted for expedited review or full board review as well as the status of the applications.

III. Procedures for Conducting Initial Review of Research
Three (3) levels of review are utilized for approval of research involving human subjects: **exempt status**, **expedited review**, and **full board review**. For each level of review, an IRB-certified Departmental Reviewer within the PI's department/unit conducts the initial review of the application materials (See Certified Departmental Reviewers). The Departmental Reviewer will confirm the research is compliant with 45 CFR 46 and either confirm that the application qualifies for **exempt status** or recommend the application for **expedited review** or **full board review**, through a signed endorsement under Part E of the Application for Research Involving Human Subjects. After this review, the IRB application is submitted to the Office of Research for processing and further dissemination as outlined below.

A. Exempt Status
A project is eligible for exempt status if it falls within one or more of the exempt categories outlined in 45 CFR 46.101b:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human

subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45CFR46.111(a)(7).

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45CFR46.111(a)(7).

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (i) information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined in 45 CFR 164.501 or for "public

health activities and purposes" as described under 45 CFR 164.512(b); or (iv) the research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies if (i) wholesome foods without additives are consumed, or (ii) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45CFR46.111(a)(8).

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) broad consent for the storage, maintenance, and

secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45CFR46.116(a)(1) through (4), (a)(6), and (d); (ii) documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45CFR46.117; (iii) an IRB conducts a limited IRB review and makes the determination required by 45CFR46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) the investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

If, after a thorough review of the application, a certified Departmental Reviewer determines the project falls within one or more of the exempt categories, she/he will certify the application as exempt and submit the complete application to the Office of Research for verification of all required items and recording within the IRB database. By definition, the IRB does not conduct any further review of the application; therefore, the Departmental Reviewer is responsible for guaranteeing the application is eligible for exempt status. Once a staff member in the Office of Research confirms the application is complete and has been approved by a certified Departmental Reviewer for exempt status, she/he will notify the PI, via email, that the application has been approved. Once the PI receives the approval email from the Office of Research, data collection can begin.

While continuing review is not required in this category, any changes in the approved project must be submitted to and approved by the IRB Chairperson via a Request for Continuation/Change Form

B. Expedited Review & Full Board Review

An **expedited review** is required for studies involving more than minimal risk of harm to participants, involves a protected population, or otherwise does not adhere to the exempt categories outlined in 45CFR 46.101b. An expedited review consists of a formal review of the application by a subcommittee of three IRB members. A **full board review** is required for applications that do not fit within the purview of the exempt status or expedited review categories and involves a review of proposed research by a quorum of IRB board members, including at least one member whose primary concerns are non-scientific and one community member, that will occur at a convened meeting. The decision categories for expedited review and full board review are detailed in Appendix A.

After the initial review in which the Departmental Reviewer recommends the application for expedited review or full board review, the PI submits the completed application with all appropriate signatures and necessary documents to the Office of Research. Staff within the Office of Research will review the application to make sure it is complete, including all signatures and documentation. If the application is incomplete, the Office of Research will notify the PI, via email, that the application cannot be processed. For completed applications, the Office of Research will record it in the database and forward the application to the IRB Chairperson for either assignment to a subcommittee of IRB board members for expedited review or dissemination to the entire IRB board in preparation for a full board review.

Expedited Review Procedures. An application a Departmental Reviewer recommends for **expedited review** must be further reviewed and approved by a subcommittee of IRB members, consisting of a Lead Reviewer and two Secondary Reviewers, which are assigned by the IRB Chairperson. The IRB Chairperson prepares a memo and forwards the memo along with the IRB application to each of the reviewers. The Office of Research staff member is also copied on this email. If an IRB member on the email has indicated that she/he would prefer a paper copy of the application materials, one is sent from the Office of Research. The reviewers will then follow the procedures outlined below:

1. Subcommittee Review. Within two weeks, reviewers send their overall assessment, concerns, and—if appropriate—revision recommendations to the Lead Reviewer via email. Each of the three reviewers independently evaluates the application according to IRB standards and guidelines.

2. Lead Reviewer's Determination. The Lead Reviewer will make a decision based upon feedback from the two other reviewers and her/his review of the application. If the application cannot be "approved," the Lead Reviewer will prepare a summary of all the responses that justify the decision. The summary will clearly and specifically describe any concerns and suggested revisions.

A decision within the two-week window must be made based on feedback from both reviewers and the Lead Reviewer's evaluation. If a reviewer fails to contact the Lead Reviewer within the two-week review window, the Lead Reviewer will send a friendly reminder to the reviewer via email. If the reviewer does not reply within three days, the decision can be based upon feedback from one reviewer and the Lead Reviewer's evaluation.

3. Decision Notification. Within two weeks, the Lead Reviewer will notify the PI of the decision via email. If the decision is anything other than "approved," a summary of the reviewers' feedback will be included. For applications that cannot be "approved," the summary provided to the PI will address human subjects-related concerns that frequently include lack of clarity, insufficient risk assessment or management, and/or insufficient procedures of informed consent as well as recommendations for resolving such concerns. In addition to the PI, the decision email will be copied to the IRB Chairperson, Office of Research, and, if applicable, the faculty supervisor. It will be blind copied to each of the two other co-reviewers.

4. If Revisions are Required. If the application requires "Minor Editorial Revisions," the Lead Reviewer will ask the PI to send the revised documents directly to her/him, rather than sending the revised documents to the Office of Research, within 30 days from the decision notification date.

If the verdict is "Revise & Resubmit," the Lead Reviewer will ask the PI to submit one copy of the entire revised application to the Office of Research within six months from the decision notification date. Once the PI resubmits the revised application, the Office of Research will process the application and send it to the IRB Chairperson for assignment to

a subcommittee. The revised application will be reviewed by the same subcommittee who previously reviewed the application, if possible. If the PI does not submit the revised application within six months from the date she or he was notified of the decision, the application and associated decision will expired, and the PI will be required to submit a new application for the project.

An IRB subcommittee does not have the authority to reject an application. If the subcommittee does not feel the study outlined within the application could be approved through a revision process, the application will be "Referred to Full Board Review." In such an instance, the IRB Chairperson will notify the PI that the application requires full board review and that it has been added to the agenda for the next scheduled IRB meeting. (See "Full Board Review" below for procedural details).

5. Official Approval. The email with a decision "approved" from the Lead Reviewer signifies the official approval of the application. Upon receipt of this email, the PI can begin collecting data. The subcommittee members (for expedited review) or the IRB Chairperson (for full board review) who approved the application will sign the approved application at the next IRB meeting.

Full Board Review. An IRB application recommended by the Departmental Reviewer for **full board review** should be submitted to the Office of Research. After confirming the application is complete and has all necessary signatures, staff in the Office of Research will disseminate the complete application to each member of the IRB and add the application to the agenda for the next scheduled IRB meeting. To be added to the meeting agenda, the application must be received at least two weeks prior to the scheduled meeting to allow board members time to review the application. At the convened meeting, each board member can discuss the IRB application after which the board will vote on the application. The possible decisions are "approved" or "disapproved;" however, prior to the formal vote, a board member can make a motion to "table the vote," which means that revisions are necessary to approve or properly evaluate the application.

The PI will have the option of attending the meeting to answer questions the board might have prior to rendering a decision on the application. The question and answer period will be limited to no more than 45 minutes, unless the IRB Chairperson, in consultation with the board members, determines that additional time is necessary. If the PI would like to be attend the meeting for a possible question and answer period, she or will must notify the IRB Chairperson one week prior to the scheduled meeting.

The PI cannot be present while the board discusses the application or during the vote on the application. The board reserves the right, but is not required to, recall the PI to the meeting immediately after the vote in order to discuss the decision and/or actions that they would like the PI to take to revise the application.

The IRB Chairperson will communicate the decision directly to the PI. If the board votes to approve the application, the PI can begin collecting data immediately upon receipt of the approval email.

If the board votes to disapprove the application, the IRB Chairperson will provide a detailed explanation justifying the board's decision. Please note that an application can only be disapproved if, through full board review, the majority of board members feels the benefits of the study do not outweigh the potential harm to participants, and concerns pertaining to the risk of harm to participants could not be resolved without altering the core features, scope, or objectives of the study. The PI will not be allowed to proceed with data collection.

If the board votes to table the vote to a future meeting, the IRB Chairperson will notify the PI of the decision and provide detailed feedback justifying the decision and directing the PI in steps she/he should take to revise the application. In such an instance, the application will not automatically be added to a future meeting agenda, but will only be added to a future meeting if the revised application has been received by the Office of Research within six months from the date the PI was notified of the decision.

IV. Procedures for Continuing Review of Research

The IRB reviews research projects at intervals appropriate to the degree of risk but not less than once a year to ensure compliance with federal regulations. If the project has also been or will be submitted for consideration of external funding, the effective start date for the 12-month approval is the date indicated on the approved IRB application. For research involving no more than minimal risk, the approval period is 12 months. For research involving greater than minimal risk as determined at the time of approval, the IRB will determine the appropriate approval period. The approval letter from the Office of Research will indicate the expiration date.

For projects that continue for more than 12 months, the PI must submit a Request for Continuation/Change Form to the Office of Research for review by the IRB Chairperson and approval of project continuation. The form must be submitted not later than two weeks prior to the expiration of the previous 12-month approval. The form references the earlier approved project and requires information confirming continued compliance by the investigators with procedures outlined in their approved IRB application. Specifically, required details are as follows:

- The extent to which all procedures described in the current project are being/have been followed.
- Total number of subjects involved in the project to date or, if existing or secondary data are used, the number of individuals whose records have been obtained.
- List of any adverse events or unanticipated problems.
- The number of subjects who withdrew and the reason(s) (if known) for withdrawal.
- List of any complaints regarding the project.
- Discussion of any new information (such as recent literature, interim findings, etc.) since the last IRB approval that may affect the assessment of the risks or benefits or possibly

impact any participant's willingness to continue to take part in the research.

- Description of all amendments or modifications made to the project since the last IRB review.

- Discussion of any changes to the project that have been implemented without being approved by the IRB.

- Statement regarding whether data are still being collected.

- Information about any activities in the original application that have not yet been completed.

- Indication of whether any approvals of changes or additions are being requested. If so, an explanation of the type(s) of modifications being requested must be stated.

Formal approval from the IRB Chairperson must be attained to continue the research beyond the current expiration date. After the expiration date, per Federal Regulations, all research on the project must halt until the necessary IRB approval has been secured. Reminders will be sent to the PI three weeks prior to the expiration date.

V. Procedures for Determining which Projects Require Review More than Annually
The IRB must conduct continuing reviews of protocols at intervals appropriate to the degree of risk, but not less than once per year after the previous IRB review, even though the research activity may not begin until some time after the IRB has given approval. All human subjects research activities are subject to audit at any time by the IRB. In determining the appropriate interval for the continuing review of a protocol, the IRB will consider the level of risk involved in the study, as well as the risk/benefit ratio. If the application requires full board review, this recommendation will be considered during the review. The terms of the protocol approval include the interval for continuing review and will be communicated to the investigator in writing in the study approval letter. During a continuing review, the IRB considers the information provided by the researcher in the Continuing Review Request (see item IV), the report of findings to date, and the current informed consent document (if applicable), as well as any other requested information, to determine whether to extend approval for another year (or any other portion of time up to a year).

VI. Procedures for Requesting and Approving Changes to an Approved IRB Application
If the PI desires to change any aspect of a project previously approved by the IRB, the PI must submit a formal request, via a Request for Continuation/Change Form, to the Office of Research. All changes must be outlined and justified within the form, and any additional and/or revised instruments, informed consent forms, or letters of permission, CITI Training Certificates for any additional Co-PIs, and all other support material must be included with the form. Additionally, in accordance with federal guidelines, all requests for changes must also address the following:

- The extent to which all procedures described in the approved project are being/have been followed

- The total number of subjects involved in the project to date or, if existing data study, the number of individuals whose records have been obtained

- Any adverse events or unanticipated problems

- The number of subjects who withdrew and the reason(s) (if known) for withdrawal

- Any complaints regarding the project

- Any new information (such as recent literature, interim findings, etc.) since IRB approval that may affect the assessment of the risks or benefits or possibly impact any participant's willingness to continue to take part in the research

- Any changes to the project that have been implemented without being approved by the IRB.

- The status of data collection

- Any activities in the original application that have not yet been completed

Once processed, the form will be sent by the Office of Research, via email, to the IRB Chairperson for review who will either approve the request, request revisions from the PI, or reclassify the application for expedited review or full board review.

All changes in a previously approved project must receive IRB approval before implementation. If the decision is to approve the request, the PI can begin research associated with the approved changes upon receipt of the approval email from the IRB Chairperson. If the application cannot be approved in its current form, the IRB Chairperson will either provide feedback to the PI with explanation of why the application cannot be approved in its current form and request revisions or designate the application for expedited review or full board review. If revisions are requested, the PI will submit the requested revisions directly to the IRB Chairperson. If the IRB Chairperson feels the changes have substantial implications for potential risk of harm to participants or fundamentally changes the scope or objectives of the project, she/he will notify the PI via email of the decision to upgrade the change request to an expedited review or full board review and will follow the appropriate procedures for expedited review or full board review outlined in III.b above.

Approval of a request for change will not automatically change the expiration date of the project. If a continuation of the project beyond the initial expiration date is required, refer to the continuing review of research procedure in this document.

All changes to a previously approved project that deviate from the original application must be approved by the IRB prior to implementation, except when necessary to eliminate apparent

immediate hazards to the subjects. In the event emergency changes are made to eliminate apparent hazards to the subjects, the PI must notify the Office of Research of the hazards the subjects were, or could have been, exposed to; the change(s) that were implemented to remediate any hazards (or potential hazards); and the results of the change(s) implemented.

VII. Audit Procedures
The IRB Chairperson and Executive Officer oversee audits, and they can be conducted randomly to ensure ongoing compliance with federal IRB guidelines or upon request based on compliance concerns. The findings of audits will be reported in summary form and stripped of all information that could directly or indirectly identify actual or potential participants of the study. Reports of the findings of an audit will be on file within the Office of Research, and they will be available for review upon request, per federal guidelines.

VIII. Conditions for Seeking Outside Counsel for Compliance Verification
The IRB may, at its discretion, determine that information is needed from sources other than the PI to verify that no material changes have occurred since the previous IRB review. The IRB may request verification from sources other than the researcher that no material changes have occurred since the initial or previous continuing review if: (i) the study is complex, involving unusual levels or types of risk to the subjects; (ii) the researcher has failed previously to comply with the IRB's requirements or 45 CFR 46; or (iii) there exist reasons for concern about possible material changes occurring without IRB approval.

IX. Procedures for Reporting Noncompliance
Any unanticipated, serious, or continuing problems encountered regarding risks to subjects must be reported to the IRB by the PI immediately, but not later than 10 days, following the event.

Deviation from the previously approved protocol, failure to fully disclose information relevant to the IRB review, or conducting human subjects research prior to IRB approval are examples of non-compliance. If non-compliance is suspected or reported, an audit will be initiated by the IRB Chairperson. The IRB Chairperson and IRB Executive Officer will meet to examine the allegations. The PI will subsequently be notified of the allegations and be given ample time to respond. The IRB Chairperson will conduct an investigation, and, in consultation with the IRB Executive Officer, will make a determination regarding non-compliance. When non-compliance is found, the IRB will take appropriate action including, but not limited to, halting the research; assuring remedial action regarding any breach of regulatory or institutional human subject protection requirements; and addressing the question of the PI's and, if applicable, Co-PI's or Co-PIs' fitness to conduct human subject research. Upon the conclusion of the investigation, the IRB Chairperson will submit a report summarizing the allegations, the findings of the investigation, and the action to be taken based upon the findings to the IRB Executive Officer for review and approval. Upon approval from the IRB Executive Officer, the report will be emailed to the PI and—as applicable and appropriate—the Faculty Supervisor, Department/Unit Head, any Tennessee Tech regulatory bodies or University Administrators, and state or federal office. The report will be available for review, in accordance with federal guidelines, within the Office of Research.

Please contact the IRB Chairperson with any questions about interpreting or applying the standards and guidelines.

X. References
Federal IRB Guidelines (45 CFR 46)

Belmont Report

Tennessee Tech Office of Research & Economic Development

Tennessee Tech IRB, Procedural Overview

Tennessee Tech IRB, Definitions

Tennessee Tech IRB Forms

Tennessee Tech IRB Training Requirements

Tennessee Tech Certified Departmental Reviewers for the IRB

APPENDIX A: EXPEDITED/FULL BOARD REVIEW DECISION CATEGORIES

The official decision categories for expedited review and full board review are as follows:

1. Approved. Proposal meets all IRB standards; no revision necessary; ready for subcommittee reviewers' signatures.

2. Minor Editorial Revisions Required. Proposal could meet IRB standards with one or more ***minor editorial changes*** to an application that otherwise meets all of the requirements for approval.

3. Revise and Resubmit. The proposal requires more than minor modifications to the described research. It requires ***modification(s) to the described research*** to address serious issues regarding the treatment of human subjects in the research process and/or ***substantial editorial changes*** resulting from a lack of ***critical details or documentation*** necessary to evaluate the treatment of human subjects in the research process.

4. Referred to Full Board Review. One of the previous three actions are not sufficient for approval. (1) The proposal presents serious risks of harm to participants; (2) the proposal presents serious risk of harm to the participants without justification; and/or (3) the subcommittee believes, for any reason, the application requires a Full Board Review.

5. Disapproved. One or more criterion for approval cannot be met; research cannot be approved in its current form. (***Full Board Review only***)