GENERAL IRB PROCEDURES
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

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

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

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.

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***)