

## Procedures for the Tennessee Board of Regents Institutional Review Board

Version: 4.0.  
Effective Date: 04/23/2024.

### I. Need

A. The need for a Tennessee Board of Regents (TBR) Institutional Review Board (IRB), hereinafter referred to as “TBR IRB”, is recognized as essential for the TBR System Office as well as for use by TBR institutions, if applicable, for research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency making these procedures applicable to such research. Researchers must be professional and adhere to their disciplinary ethical codes and those codes that govern research in general, i.e., the principles set forth in the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979) and the U.S. Department of Health and Human Services (HHS) regulations (45 CFR Part 46 Subpart A, also known as “the Common Rule”).

B. The TBR IRB may be used for the purpose of research involving human subjects in educational and social science-based research when conducted:

1. by employees or associates of the TBR System Office, including research conducted under a federal or state grant;
2. at TBR institutions without a local IRB and for ad-hoc research by employees of TBR institutions that do not have local IRBs;
3. by researchers affiliated with institutions or agencies without an IRB;
4. by a TBR institution that requests review by the TBR IRB in lieu of an external IRB;
6. at multiple TBR institutions; and
7. where otherwise required to comply with federal or state law.

In other situations and unless specifically requested by a TBR institution or directed by the TBR Chancellor or designee, the TBR IRB will not provide oversight or monitoring of any institution within the TBR System that has an institutional IRB. The TBR IRB will not review proposals for dissertation from external researchers. For institution-specific and dissertation proposal requests, approval from individual institutional IRBs must be sought, except for cases when there is no institutional IRB, which can be reviewed by the TBR IRB on an ad-hoc basis. All researchers and applicants will follow all procedures outlined below, unless there is a conflict with the applicable federal regulations, in which case the federal regulations will govern. (These procedures are designed to provide the TBR IRB a single source to review in the majority of situations, but occasional review of the federal regulations may be required.)

### II. Human Subjects Research to be Reviewed by the TBR IRB

A. Anyone who is proposing research involving human subjects for the purposes specified in section I.B. must submit an application to the TBR IRB before beginning recruitment of subjects or data collection. In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects, the research shall first be reviewed and approved by the TBR IRB. A checklist tool for helping determine whether a proposal may involve human subject research as defined by federal regulations is available at <https://policies.tbr.edu/guidelines/institutional-review-research>.

B. In keeping with the HHS definitions in Title 45, Code of Federal Regulations (CFR) Part 46, 45 CFR 46.102, for the purposes of these procedures:

1. **Research** is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition

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constitute research for purposes of these procedures, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

2. A **human subject** is a living individual about whom an investigator conducting research (a) obtains information or biospecimens through intervention or interaction with the individual, and uses studies, or analyzes the information or biospecimens; or (b) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

3. **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

4. **Interaction** includes communication or interpersonal contact between investigator and subject.

5. **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

C. In accordance with 45 CFR 46.108(a)(3) and (4), the TBR IRB establishes these written procedures for:

1. Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the TBR System Office;
2. Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous TBR IRB review;
3. Ensuring prompt reporting to the TBR IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the TBR IRB approval until any proposed changes have been reviewed and approved by the TBR IRB, except when necessary to eliminate apparent immediate hazards to the subjects;
4. Ensuring prompt reporting to the TBR IRB, TBR Chancellor or designee, and the Office for Human Research Protections (OHRP) of:
  - a. Any unanticipated problems involving risks to the subjects or others or any serious or continuing noncompliance with these procedures or the requirements or determinations of the TBR IRB; and
  - b. Any suspension or termination of TBR IRB approval.

### III. Federal Wide Assurance (FWA) Requirement

A. TBR Academic Affairs leadership will maintain a Federal Wide Assurance (FWA) to let federal agencies know of its intention to comply with regulations for the protection of human subjects.

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### IV. Structure of TBR IRB

A. The TBR IRB is a board tasked by the TBR Chancellor with rendering decisions, rather than recommendations about permission to conduct research, within the TBR system as specified in section I.B. and to review and conduct the periodic monitoring of such research involving human subjects. The TBR IRB assumes the responsibility for protecting the rights of human subjects.

#### B. Composition of the TBR IRB

1. Based on 45 CFR 46.107, the TBR IRB will:
  - a. have at least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the TBR System Office, or commonly proposed or conducted at TBR institutions. One member is designated to chair the TBR IRB; however, a Co-Chair structure may also be utilized upon approval of a majority of TBR IRB members;
  - b. be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects;
  - c. include members with knowledge about a variety of internal and external policies, resources, regulations, and applicable codes of professional conduct;
  - d. include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
  - e. include at least one member who is not otherwise affiliated with the TBR System Office or any TBR institution and who is not part of the immediate family of a person who is affiliated with the TBR System Office or any TBR institution; and
  - f. not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the TBR IRB.
2. The TBR IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the TBR IRB. These individuals may not vote with the TBR IRB.
3. The Chancellor or designee is responsible for appointing members from the System Office and members external to the TBR System. Presidents or designees are responsible for appointing members from colleges. The TBR IRB members, including alternate members, are appointed for three-year terms with renewable terms for an undefined period. The TBR IRB (co-)Chair and Secretary, collectively known as TBR IRB Officers, are elected by the TBR IRB for three-year terms with renewable terms for an undefined period. The TBR IRB members and Officers can resign at any time during their term with two months advance notice. The Executive Officer is an ex-officio member of the TBR IRB.

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### V. TBR IRB Requirements

- A. Research conducted through the TBR System Office and in TBR institutions is limited in nature to studies related to education, educational practices, and social science.
- B. The TBR IRB Chair is responsible for maintaining documentation for initial and continuing reviews as well as any action taken by the TBR IRB and any findings required under the HHS regulations regarding research conducted.
- C. The HHS regulations at 45 CFR 46.111, and which are incorporated into these procedures, set forth the criteria that must be satisfied in order for the TBR IRB to approve research. These criteria include, among other things, determinations by the TBR IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. In conducting the initial review of proposed research, the TBR IRB must obtain information in sufficient detail to make the determinations required under HHS regulations at 45 CFR 46.111.
- D. Investigators are responsible for fulfilling requirements associated with continuing review in time for the TBR IRB to carry out continuing review prior to the expiration date of the current IRB approval. Requests to renew IRB approval should be submitted at least four (4) weeks before the expiration date listed on the original Form A Cover Sheet. Requests to review proposed modifications should be submitted upon identification of the need for a proposed modification, and no later than eight (8) weeks before approval expires. In particular, investigators are responsible for submitting sufficient materials and information for the TBR IRB to meet its regulatory obligations and should follow the TBR System Office's procedures for continuing IRB review of research that are required by 45 CFR 46.108(a)(3) and 45 CFR 46.109(f)(1) and referenced in the TBR System Office's OHRP-approved Federalwide Assurance.

### VI. Levels and Criteria for Review

- A. Application levels of review are Exempt, Expedited Review, and Full Board Review.

**1. EXEMPT from Review.** To be classified as Exempt from Review, the research project must involve no more than minimal risk to the subject and must satisfy one or more of the following criteria:

- a. 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 [45 CFR 46.104(d)(1)];
- b. 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:

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- (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 the TBR IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7), which is that there must be adequate provisions for protecting privacy and maintaining confidentiality. [45 CFR 46.104(d)(2)];
- c. 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:
- (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 45 CFR 46.111(a)(7);
  - (iv) For the purpose of these procedures, benign behavioral interventions are defined as being 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;
  - (v) 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. [45 CFR 46.104(d)(3)].
- d. 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;

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(ii) 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 at 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.* [45 CFR 46.104(d)(4)]

**2. EXPEDITED Review.** A project that does not qualify for Exemption from Review may be classified for Expedited Review by the TBR IRB, if it meets one or more of the following criteria for Expedited Review established by federal guidelines:

a. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the TBR IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

b. The categories in this list apply regardless of the age of subjects, except as noted.

c. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

d. The expedited review procedure may not be used for classified research involving human subjects.

e. Relevant research categories that pertain to both initial and continuing TBR IRB review, unless the reviewer determines there is more than minimal risk:

1. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or

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diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

2. Collection of data from voice, video, digital, or image recordings made for research purposes. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

3. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

4. Continuing review of research previously approved by the convened IRB as follows:

- a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
- b. where no subjects have been enrolled and no additional risks have been identified; or
- c. where the remaining research activities are limited to data analysis.

5. Continuing review of research where categories one (1) through four (4) do not apply but the TBR IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

f. An expedited review procedure consists of a review of research involving human subjects by a subcommittee of three (3) TBR IRB members designated by the TBR IRB Chair from among members of the TBR IRB in accordance with the requirements set forth in 45 CFR 46.110.

**3. FULL BOARD REVIEW.** Any research project which does not satisfy criteria for Exemption or Expedited Review must undergo Full Board Review.

### B. Informed Consent

1. **General requirements for informed consent.** All participants in the research must be provided with the information listed below, and the Principal Investigators and Co-Principal Investigators must obtain legally effective informed consent from each participant, or consent from a legally authorized representative for the participant prior to involving a human subject in research covered by these procedures.

- a. Consent can only be received after the potential subject or subject representative has had sufficient time to consider whether or not to participate in the study.

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- b. The information about the study must be provided in language understandable to the participant or legally authorized representative.
- c. Informed consent must begin with a concise and focused presentation of the key information that is mostly likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
- d. Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
- e. An informed consent form or information sheet will not include a statement that the participant waives her/his legal rights or releases the Principal Investigators and Co-Principal Investigators, any sponsors, institutions, or organizations from liability for negligence.

**2. Basic elements of informed consent.** An Informed Consent Form should include the following elements:

- a. A statement that the study involves research;
- b. An explanation of the purposes of the research;
- c. The expected duration of the subject's participation;
- d. A description of the procedures to be followed;
- d. Identification of any procedures that are experimental;
- e. A description of any reasonably foreseeable risks or discomforts to the subject;
- f. A description of any benefits to the subject or to others which may reasonably be expected from the research;
- g. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- h. A statement addressing anonymity in the reporting of the findings;
- i. For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained;
- j. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;



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- k. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled;
- l. The approximate number of subjects involved in the study;
- m. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject, if applicable;
- n. Identification of any procedures that are experimental, if applicable;
- o. Any additional costs to the subject that may result from participation in the research, if applicable;
- p. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent, if applicable;
- q. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable, if applicable;
- r. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject, if applicable;
- s. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject, if applicable; and
- t. Any additional information the TBR IRB believes will be helpful to the participants.

3. **Types of informed consent.** Unless the TBR IRB waives the requirement for an investigator to obtain a signed informed consent form for reasons set out in these procedures, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy (including in an electronic format) shall be given to the person signing the informed consent form. The consent form may be either of the following:

- a. **Written Consent:** A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigators should give either the subject or the representative adequate opportunity to read it before it is signed.
- b. **Oral Consent:** A short form written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the TBR IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary,

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and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

4. **Waiver of requirement for signed informed consent form.** The TBR IRB can waive the requirement for the investigators to obtain a signed consent form for some or all subjects, if it finds either:

a. That the only record linking the subject and the research would be the consent document, and the **principal risk** would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

b. That the research presents **no more than minimal risk** of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the TBR IRB may require the investigators to provide subjects with a written statement regarding the research.

### VII. Procedures for TBR IRB

A. In order to approve research covered by these procedures, the TBR IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized:

a. By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and

b. Whenever appropriate and if applicable, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. 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. In evaluating risks and benefits, the TBR IRB should consider 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 TBR IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment, the TBR IRB should take into account the purposes of the research and the setting in which the research will be conducted. The TBR IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

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4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, these procedures.
  5. Informed consent will be appropriately documented or appropriately waived in accordance with these procedures.
  6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
  7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- B. The TBR IRB Chair, or TBR IRB members designated by the TBR IRB Chair, will determine the level of IRB review required for submitted research proposals (e.g., “exempt”, “expedited”, or “full” IRB review).
- C. No research covered by these procedures can begin until it has been formally approved by the TBR IRB. Except when an expedited review procedure is used, the TBR IRB must review proposed research at convened meetings at which a majority of the members of the TBR IRB are present, including at least one member whose primary concerns are in nonscientific areas. A majority of those present at the meeting must approve the research.
- D. Upon approval, only Principal Investigators and Co-Principal Investigators will be authorized to participate in the research process, have access to the participants and data collected, and disseminate any of the findings of the study.
- E. Review Documentation Procedures:
1. An “exempt” review requires the completion of Form A, Attachment to Form A, Form C, a copy of the interview protocol or survey, and a copy of the Informed Consent Form, as well as any letter(s) of permission to conduct research as needed. (The forms are available at <https://policies.tbr.edu/guidelines/institutional-review-research>). The complete application will be submitted to the TBR IRB Chair for review. If the TBR IRB Chair, or designated TBR IRB member, determines that the complete application meets the criteria for exemption, the application will be approved, and the applicant will be notified of the approval as well as provided with a copy of the approved application.
  2. An “expedited” review requires the completion of Form A, Form B, Form C, a copy of the interview protocol or survey, and a copy of the Informed Consent Form. (The forms are available at <https://policies.tbr.edu/guidelines/institutional-review-research>). Evidence of a valid certificate of completion of Human Subjects Training may be required by the TBR IRB Chair or grant awards. The complete application will be submitted to the TBR IRB Chair for review. Upon receiving the application, the TBR IRB Chair will confirm the completeness of the application and make a recommendation for expedited review. For applications recommended for expedited review, the TBR IRB Chair will identify a subcommittee of three (3) members of the TBR IRB to review and provide a recommendation to approve or not approve the application. The reviewers will have two weeks (14 days) from the date they receive the application to provide a recommendation to the TBR IRB Chair. Based upon the reviewers’ recommendations, the TBR IRB Chair will notify the applicant of the decision. If approved, the applicant will also receive a copy of the approved application with

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signatures of the TBR IRB Chair and the three IRB members who reviewed the application. If not approved, the TBR IRB Chair will provide instructions and recommendations for revising the application.

3. A “full board” review requires all the same application and submission process as an “expedited” review. Upon receiving the application, the TBR IRB Chair will confirm the completeness of the application and make a recommendation for a full board review. A full board review requires that all members of the TBR IRB review the application and provide a recommendation. The decision to approve the application requires a majority vote by the TBR IRB members. Full board reviews can take a substantial amount of time to establish a decision; therefore, a specific timeline for a decision cannot be provided.

If the application is approved, the applicant will also receive a copy of the approved application with signatures of the TBR IRB Chair and the IRB members who reviewed the application. If not approved, the IRB Chair will provide a rationale regarding the decision.

In the event all TBR IRB members are unavailable for the full board review, a quorum of IRB members, with at least one member with non-scientific interests, will review and vote on the application. A quorum is defined here as at least 51 percent of TBR IRB members including the TBR IRB Chair, but excluding alternate members and subject matter experts.

### F. Decision Categories.

1. **Approval.** The application meets all of the ethical standards for research involving human subjects. Upon written notification of approval, the research can begin.

2. **Not Approve/Modify; Revise and Resubmit.** The TBR IRB Chair or a designated subcommittee has identified aspects of the application that require additional information, clarity, or revision. The applicants will be notified of the decision in writing along with a list of requested modifications, revisions and recommendations necessary to obtain approval.

3. **Rejection.** If, after review and discussion, the majority vote of the board decides to reject the application, the TBR IRB Chair will provide the applicant with a detailed written explanation of issues identified and a justification for the decision and will provide the investigator an opportunity to respond either in person or in writing, at the TBR IRB’s discretion. Rejections would only be considered when the TBR IRB determines that the issues identified could not be resolved through modifications or revisions.

G. The TBR IRB Chair may solicit additional assistance in the case of complexity of problems or potential risk to participants for which the TBR IRB Chair or members of the TBR IRB itself desire additional expertise to make a determination. Individuals providing additional assistance may not vote with the TBR IRB.

H. The TBR IRB Meetings. The TBR IRB will meet biannually unless there is need to meet more frequently per the determination of the TBR IRB Chair. A quorum is defined as at least 51 percent of TBR IRB members, including the TBR IRB Chair, and excluding alternate members and subject matter experts. A quorum of TBR IRB members, with at least one member with non-scientific interests, can take action based on majority vote. If a quorum is not present, the TBR IRB may discuss business before the TBR IRB but may not take action.

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I. Applications approved with a full board review are valid for a period of time not to exceed twelve (12) months. The TBR IRB shall conduct continuing review of research requiring a full board IRB review at intervals appropriate to the degree of risk, but not less than once per year. Unless the TBR IRB determines otherwise and provided that no modifications have been made, continuing review is not required for studies approved through expedited review and studies that obtained full board review and progressed to the point that they involve only data analysis, including analysis of identifiable private information. For an application requiring continuing review, the Principal Investigator must submit a request, in writing, to the TBR IRB Chair for the renewal of the application, along with a copy of the approved TBR IRB application. See Form D at <https://policies.tbr.edu/guidelines/institutional-review-research>. Any proposed changes must fit within the original aims and scope of the study; otherwise, a new application must be submitted for TBR IRB approval. In the request, the Principal Investigator must outline any intended changes or modification to the research project. If no changes will be made to the original application, the Principal Investigator must state so in the request. A continuing review is subject to expedited review procedures, including only requiring approval of the TBR IRB Chair, if the criteria in Section VI.2.e.4 are met or unless the TBR IRB Chair determines that additional review is warranted.

J. The TBR IRB has the authority to suspend or terminate the approval of research that is not being conducted in accordance with the TBR IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the TBR IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Secretary of Health and Human Services (or head of any other appropriate federal department or agency).

### VIII. Researchers' Responsibilities

A. Research approved via a full board review and lasting longer than twelve (12) months from the initial date of approval by the TBR IRB must be resubmitted for the TBR IRB to approve sufficiently in advance of the expiration of approval.

B. Proposed changes to the research protocol must be forwarded to the TBR IRB Chair, who will review to determine if the proposed changes are substantive, thus requiring an additional review.

C. Any unanticipated problem or adverse event that poses either a risk to a human subject or constitutes an event of noncompliance with the approved protocol or these procedures must be reported by the Principal Investigator to the TBR IRB Chair and the Academic Affairs leadership immediately. See Form E at <https://policies.tbr.edu/guidelines/institutional-review-research>. The TBR Academic Affairs leadership shall inform the TBR Chancellor of any unanticipated problem or adverse event. The TBR IRB will determine whether any further action is necessary, including, but not limited to, modification to the study protocol or informed consent documents, suspension or termination of the research, or reporting to regulatory agencies.

D. Researchers should affirm that they have read *The Belmont Report*, the federal regulations for the protection of research subjects, and the history and ethics of research with human participants. The TBR IRB Chair or conditions of a grant may require that researchers complete training in the ethical conduct of research and compliance. The completion of sections 1 and 6 of the Online Research Ethics Course offered through the Office of Research Integrity at the Department of Health and Human Services ([https://ori.hhs.gov/education/products/montana\\_round1/research\\_ethics.html](https://ori.hhs.gov/education/products/montana_round1/research_ethics.html)) or Human Subject

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Research in Education and the Social Sciences training through the Collaborative Institutional Training Initiative (CITI) (<https://about.citiprogram.org>) or any other TBR IRB-approved training will be accepted as verification of training in ethical conduct of research and compliance. The TBR IRB Chair will make the final determination for educational compliance.

E. Researchers acknowledge that their primary responsibility is to safeguard the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of society and the research.

F. Researchers will obtain, document and maintain records of informed consent from each subject or participant as required by the HHS and stipulated in the TBR IRB procedures.

G. Researchers will not enroll subjects in research prior to the review and approval of the TBR IRB.

### IX. Record Keeping and Audit Readiness

A. The TBR Academic Affairs leadership will house electronic (and other, if applicable) documentation of TBR IRB activities for a period of not less than ten (10) years after the research is completed.

B. The following records must be maintained:

1. copies of all research proposals reviewed; scientific evaluations, if any, that accompany the proposals; approved sample consent forms; progress reports submitted by investigators; and reports of injuries to subjects;
2. minutes of the TBR IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the TBR IRB; the vote on those actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of the controverted issues and their resolution;
3. records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review described in § 46.109(f)(1);
4. copies of all correspondence between the TBR IRB and researchers, including emails;
5. list of the TBR IRB members, including degrees, areas they represent, relevant experience and association with the TBR System Office;
6. the TBR IRB procedures and forms, and evidence of training completed by the researchers as may be required by the TBR IRB Chair or grant awards;
7. statements of significant new findings provided to subjects, as required by § 46.116(c)(5);
8. the rationale for an expedited reviewer's determination that research appearing on the expedited review list in these procedures is more than minimal risk; and
9. documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with these procedures.

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C. In the event of an external audit, the TBR IRB Officers will promptly provide a comprehensive set of documents essential for audit readiness. These documents include, but are not limited to, the current IRB membership roster, minutes of IRB meetings, current and historical versions of IRB procedures and forms, approved research protocols, correspondence records, and detailed records of research activities from researchers. Additionally, documents such as continuing review records, modifications to approved studies, adverse events or unanticipated problems reports, conflict of interest disclosures, and training records will be provided as applicable. The detailed records of research activities comprise, but are not limited to, participant consent forms, recruitment records, data management plans, and explanations for study modifications as applicable. The TBR IRB Officers will commit to identifying and addressing any areas of potential concern prior to external review. Additionally, the TBR IRB will offer resources to researchers and IRB members to ensure a clear understanding of audit expectations and procedures.

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 Version: 4.0.  
 Approval Date: 04/23/2024.  
 Effective Date: 04/23/2024.  
 Approved By: Tennessee Board of Regents Institutional Review Board

**Approval Statement:**

These *Procedures for the Tennessee Board of Regents Institutional Review Board* (TBR IRB) have been reviewed and approved in accordance with TBR policies, federal regulations, and ethical principles governing human subject research.

Signature:  Date: 2024-04-25 | 1:32 PM CDT

Full Name/Position: Tabetha Garman, TBR IRB Chair

**Revision History \***

Version	Approval / Change Date	Section(s) Updated	Summary of Changes
1.0	04/28/2022	IX.A.	Extended required record-keeping period to 10 years (discussion of the proposed Procedures at the inaugural meeting).
2.0	04/06/2023	V.D., VII.E., VII.I., VIII.C., II.A., IV.B.3., VII.H.	Specified when to submit requests to renew approval and review modifications. Included links to the IRB forms and checklist for HSR determination. Included details on reporting unanticipated problems. Included details on appointment and duration of service of IRB members. Defined a quorum for the meetings.
3.0	10/24/2023	VII.I., VIII.A.	Limited the continuing review requirement to research requiring a full board review and lasting longer than 12 months (if not in data analysis stage already).
4.0	04/23/2024	All pages. IX.C. Approval page	Revised a header to include the version number and effective date. Added a section on audit readiness. Added the Approval Page.

\* More detailed *Log of Changes* for the TBR IRB procedures and forms is maintained by the IRB Officers.