**IRB DEPARTMENTAL REVIEWER GUIDEBOOK**

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***Tennessee Tech University Institutional Review Board for the Protection of Human Subjects***

***3rd Edition***

***Revised April 2, 2019***

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**PART I: THE TENNESSEE TECH INSTITUTIONAL REVIEW BOARD**

In accordance with Code of Federal Regulations 45CFR46, Tennessee Tech University (TTU) is required to have an Institutional Review Board (IRB) for reviewing and approving all research involving human subjects conducted by TTU faculty, staff, and students. The mission of the IRB is to ensure the ethical treatment of participants within the study, as outlined in the Belmont Report. Therefore, the IRB is responsible for making sure that any research involving human subjects meets all professional and ethical standards and that processes are in place within the studies that minimizes the potential for harm to the participant as a result of their participation in the study.

The TTU IRB consists of 16 members, 14 who are faculty with scientific interests from various departments, two who are members of the community with non-scientific interests, and one Executive Officer, Dr. Francis Otuonye, Associate Vice President of Research. The IRB is housed within the Office of Research, and all IRB applications are processed therein. The current chairperson is Dr. Steven Seiler, who is an Associate Professor in the Department of Sociology and Political Science.

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| --- | --- | --- |
| **Current Board Members** |  |  |
| **Name** | **Classification** | **Department** | **Email** |
| Dr. Francis Otuonye | Executive Officer | Office of Research & Economic Development | FOtuonye@tntech.edu |
| Dr. Steven Seiler | Chair, F, SI | Sociology & Political Science | sseiler@tntech.edu |
| Dr. Melinda Anderson | F, SI | Agriculture & Human Ecology | manderson@tntech.edu |
| Dr. Meral Anitsal | F, SI | Business | manitsal@tntech.edu |
| Dr. Megan Atkinson | F, SI | Library | matkinson@tntech.edu |
| Dr. Chris Burgin | F, SI | Counseling & Psychology | cburgin@tntech.edu |
| Dr. Michael Clark | CM, NSI  | NA | mclark@tntech.edu |
| Dr. Jann Cupp | F, SI | Counseling & Psychology | jcupp@tntech.edu |
| Dr. Paula Engelhardt | F, SI | Physics | engelhar@tntech.edu |
| Dr. Steven Frye | F, SI | Interdisciplinary Studies | sfrye@tntech.edu |
| Dr. Paula Greathouse | F, SI | Curriculum & Instruction | pgreathouse@tntech.edu |
| Dr. Terry Guo | F, SI | Manufacturing  | nguo@tntech.edu |
| Dr. Seth King | F, SI | Curriculum & Instruction | saking@tntech.edu |
| Dr. Sue Piras  | F, SI | Nursing | spiras@tntech.edu |
| Dr. Chad Rezsnyak | F, SI | Chemistry | crezsnyak@tntech.edu |
| Dr. James Rogers | CM, NSI | NA | jsmyrna@smyrnachurchofchrist-ckvl.org |
|  |  |  |  |
| *Non-Voting/ Resource* |  |  |
| Mr. Greg Holt |  | Compliance Office | gholt@tntech.edu |

Key:

CM: Community Member NSI: Non-Scientific Interest

F: Faculty SI: Scientific Interest

**Contact information**

|  |  |  |  |
| --- | --- | --- | --- |
| IRB Questions | Dr. Steven Seiler | x3171 | sseiler@tntech.edu  |
| Application Status | Ms. Amy Hill | x3464 | amyhill@tntech.edu  |

**Useful Links:**

[TTU IRB](https://www.tntech.edu/research/committees/humansubjects/index.php)

[Federal Code of Regulations](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)

[Belmont Report](http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/)

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**PART II: PURPOSE, ROLE, AND RESPONSIBILITIES OF THE DEPARTMENTAL REVIEWER**

***Purpose of Departmental Reviewers:***

The overwhelming majority of IRB applications fall within Exempt Status or Expedited Review. With Departmental Reviewers, the approval process for a satisfactory application classified as Exempt Status can take between 24 and 48 hours. The Expedited Review process for a satisfactory application takes three weeks or less. Without the Departmental Reviewers, an application requesting Exempt Status could take upwards of a month for approval, and an Expedited Review could take a couple of months.

***Role & Responsibilities of Departmental Reviewers:***

To ensure the most efficient review process for IRB applications, Departmental Reviewers serve as the first step in the process. They are responsible for (a) making sure the Application for Research Involving Human Subjects has the necessary signatures, (b) making sure all of the necessary forms and documents are included in the application, (c) making sure all forms are filled out correctly, (d) evaluating the potential of harm to the participants as a result of the study, and (e) either confirming that the application meets the criteria for Exempt Status or recommending the application for Expedited or Full Board Review.

Departmental Reviewers are appointed by the Department Chairperson. Each department or unit should have at least one Departmental Reviewer; however, the IRB recommends establishing a Departmental Review Committee of two or more certified Departmental Reviewers. Having at least two Departmental Reviewers is especially useful for occasions in which one Reviewer needs to submit an IRB application. A Departmental Reviewer cannot review applications in which she or he is listed as the Principal Investigator.

***Required Training for Departmental Reviewers:***

Once appointed, in order to be certified as a Departmental Reviewer, the candidate must complete training in the responsible conduct of research, ethics in human subject research training, and training specific to Departmental Reviewers. This is an exclusively online training through the Collaborative Institutional Training Initiative (CITI), which is housed at Miami University.

TTU Policy 730 (Institutional Review Board) requires all researchers (Principal Investigator & Co-Principal Investigators), Faculty Supervisors, Departmental Reviewers, and IRB Members to complete human subjects training. TTU Policy 750 (Responsible Conduct of Research) requires all researchers and board members to complete training in the responsible conduct of research.

In the CITI training website, the required training courses include:

* “SBE Researchers including all students and faculty acting as an Investigator (PI-co-PI)”
* “Departmental Reviewer”
* “Social and Behavioral Responsible Conduct of Research”

Each training course has a number of modules. Each module should take about an hour to complete; however, an entire course does not need to be completed in one sitting. Each course consists of 13-16 brief modules, and, at the end of each module, you will need to complete a two- to five-question quiz. The courses must be passed with an 80 or higher.

\* Please note that the Departmental Reviewer training has only three additional modules than the Co-PI/PI training course. Once a module is complete, it fulfills the requirements for all courses that require it.)

*Step-by-Step Instructions for the Departmental Reviewer CITI Training:*

1. Go to <https://www.citiprogram.org/>.
2. Create an account through the “Register” link.

Step One:

🡪 Under “Select Your Organizational Affiliation,” select “Tennessee Technological University.”

🡪 Check “I AGREE to terms…”

🡪 Continue to Step #2

Step Two:

 🡪 Provide name and TTU email address.

 🡪 Continue to Step #3

Step Three:

 🡪 Select a username & password

 🡪 Continue to Step #4

Step Four:

 🡪 Select country of residence

 🡪 Continue to Step #5

Step Five:

 🡪 Select “No” and “No”

 🡪 Continue to Step #6

Step Six:

 🡪 Provide required information

 🡪 Under “Role in Research,” select “Principal Investigator.”

 🡪 Continue to Step #7

Step Seven:

🡪 Under “Question #1,” select “SBE Researchers including all students and faculty acting as an Investigator [PI-co-PI].”

🡪 Under “Question #2,” select the “Social and Behavioral Responsible Conduct of Research.”

🡪 Under “Question #3,” select “Not at this time.”

🡪 Skip “Question #4.”

🡪 Under “Question #5,” select “I’m not required to complete IPS training at this time.”

 🡪 Click “Submit”

 🡪 Finalize Registration

Step Eight:

 🡪 On the “Courses” page, scroll to bottom of the page and select “Add a Course.”

Step Nine:

🡪 Under “Question #1,” select “Departmental Review Coordinator.”

🡪 Under “Question #2,” select the “Not at this time.”

🡪 Under “Question #3,” select “Not at this time.”

🡪 Skip “Question #4.”

🡪 Under “Question #5,” select “I’m not required to complete IPS training at this time.”

 🡪 Click “Submit”

🡪 You’re now ready to complete the required training courses. All of your required courses should appear on the “Courses page.”

3. Once you have completed the training, please download and email the Certificate of Completion to Amy Hill (AmyHill@tntech.edu) in the Office of Research.

**SBE Researchers including all students and faculty acting as an Investigator [PI-co-PI] Modules:**

Research and HIPAA Privacy Protections (ID: 14)

History and Ethical Principles - SBE (ID: 490)

Defining Research with Human Subjects - SBE (ID: 491)

The Federal Regulations - SBE (ID: 502)

Assessing Risk - SBE (ID: 503)

Informed Consent - SBE (ID: 504)

Privacy and Confidentiality - SBE (ID: 505)

Research with Prisoners - SBE (ID: 506)

Research with Children - SBE (ID: 507)

Research in Public Elementary and Secondary Schools - SBE (ID: 508)

International Research - SBE (ID: 509)

Internet-Based Research - SBE (ID: 510)

Belmont Report and Its Principles (ID: 1127)

Students in Research (ID: 1321)

Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928)

Conflicts of Interest in Human Subjects Research (ID: 17464)

Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)

Basics of Health Privacy (ID: 1417)

Health Privacy Issues for Researchers (ID: 1419)

FERPA: An Introduction (ID: 17407)

FERPA for Researchers (ID: 17410)

Data and Safety Monitoring in Human Subjects Research (ID:17433)

**Departmental Reviewer Modules:**

Research and HIPAA Privacy Protections (ID: 14)\*

History and Ethical Principles - SBE (ID: 490)\*

Defining Research with Human Subjects - SBE (ID: 491)\*

The Federal Regulations - SBE (ID: 502)\*

Assessing Risk - SBE (ID: 503)\*

Informed Consent - SBE (ID: 504)\*

Privacy and Confidentiality - SBE (ID: 505)\*

Research with Prisoners - SBE (ID: 506)\*

Research with Children - SBE (ID: 507)\*

Research in Public Elementary and Secondary Schools - SBE (ID: 508)\*

International Research - SBE (ID: 509)\*

Internet-Based Research - SBE (ID: 510)\*

Belmont Report and Its Principles (ID: 1127)\*

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Health Privacy Issues for Researchers (ID: 1419)\*

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FERPA for Researchers (ID: 17410)\*

Data and Safety Monitoring in Human Subjects Research (ID:17433)\*

The IRB Member Module - 'What Every New IRB Member Needs to Know' (ID: 816)

Cultural Competence in Research (ID: 15166)

International Studies (ID: 971)

\* Modules count toward both PI/Co-PI and Departmental Reviewer courses.

**Social & Behavioral Responsible Conduct of Research Modules:**

Introduction to RCR (RCR-Basic) (ID: 17009)

Authorship (RCR-Basic) (ID: 16597)

Collaborative Research (RCR-Basic) (ID: 16598)

Conflicts of Interest (RCR-Basic) (ID: 16599)

Data Management (RCR-Basic) (ID: 16600)

Mentoring (RCR-Basic) (ID: 16602)

Peer Review (RCR-Basic) (ID: 16603)

Research Misconduct (RCR-Basic) (ID: 16604)

Research Involving Human Subjects (RCR-Basic) (ID: 13566)

Plagiarism (RCR-Basic) (ID: 15156)

 **PART III: DETERMINING RESEARCH/ LEVEL OF REVIEW FOR RESEARCH**

The IRB has three classifications for applications: (1) Exempt Status, (2) Expedited Review, and (3) Full Board Review. However, not all activities (including some that we might call “research”) always meet the definition of “research” in the Federal Code of Regulation. These Decision Trees should help you in determining if an activity is “research” and, if so, what classification it falls within.

**Undergraduate/Graduate Students:** Begin on this page (page #11)

**Faculty/Staff:** Begin on page #12

**Undergraduate/ Graduate Student (Only) Decision Tree:**

**IRB Application is Not Required**

No

Does the Study involve Human Subjects?

Yes

**Go to Decision Tree on Page #12: Research Decision Tree**

No

Is the study being completed as a requirement for a class?

Yes

Restricted only the professor and/or students in this specific class

Will the findings be distributed beyond the classroom e.g., Research Day, an undergraduate or professional conference, publication, distributed or presented through any other media within the public domain **OR** will the findings be restricted only to the classroom, e.g., only submitted to the professor for a grade, presented to the students within the classroom.

Distributed beyond the classroom

**IRB Application is Not Required.**

**An IRB Application is Required**

See **Page #14** for definitions and **Page #17** for explanations of Student Activities and recommended guidelines.

**Continue to Page #12:**

**IRB Category of Review Decision Tree**

**Research Decision Tree:**

Yes

No

Does the Study involve Human Subjects?

**IRB Application is Not Required**

Will you be systematically collecting data to test hypotheses, contributing to general theories or principles **OR** will you be collecting data for internal management purposes (e.g., program evaluation, quality assurance, quality improvement, or fiscal or program audits, marketing studies)?

Internal Management

Test hypotheses, contributing to general theories or principles

Will the findings be used in a professional presentation, publication, or professional conference or distributed or presented through any other media within the public domain **OR** will the findings be used solely for internal management purposes and not distributed beyond the department, unit, or organization subject to the review or evaluation?

For internal management purposes **and** will not be distributed beyond the department, unit, or organization subject to the review or evaluation

For presentation, publication, professional conference, or will be distributed or presented through another medium within the public domain

**An IRB Application is Required**

**Continue to Page #13:**

**IRB Category of Review Decision Tree**

**IRB Category of Review Decision Tree:**

Yes

Yes

Yes

Are children subjects in the research?

No

Are the research subjects competent adults?

No

**Submit application for Full Board Review**

**Submit application for Expedited Review**

No

**Submit application for Exempt Status**

Yes

Yes

Does the research involve deception?

No

Yes

Does the research present a clear risk of harm for or potential of serious harm to research subjects?

No

Do the procedures meet the criteria for any Exempt category (1-6)? (See **page #19**)

Are the research subjects legally restricted or incarcerated?

No

***Definitions.***

***Research:*** a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. *Activities which meet this definition constitute research for purposes of this policy, 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.*

***Human subject:*** a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

***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.

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

***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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

A ***systematic*** study occurs when a researcher implements or uses commonly accepted scientific methods of data collection and analysis. This collection and analysis allow for the researcher to methodically and objectively interpret the results to explore answers to predetermined questions or testing predetermined hypotheses. The approach to a study alone does not determine the need for IRB review. In many cases, people conduct interviews or draw blood for reasons that have nothing to do with research.

The statement ***“designed to develop or contribute”*** is interpreted as a study that produces results that are intended for dissemination outside of the University via poster presentations, professional or student conferences, any form of publication, or in any online media.

***Generalizable knowledge*** is results intended to (1) have predictive value, (2) provide scientific clarity, and (3) be applied to a larger population in order to further scientific knowledge or inform policy. Generalizable knowledge would be applicable to a scientific community beyond the classroom and beyond the participants in the study.

Additional useful definitions:

***Risk***is the probability of harm or injury (economic, legal, physical, psychological, social) occurring as a result of participation in a research study.

***Minimal risk*** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

***Existing or secondary data*** are information in the form of data, documents, records, pathological specimens, or diagnostic specimens collected by someone else for research (e.g., survey data, interview transcriptions) or non-research purposes (e.g., results of blood work, mental health diagnoses, students' academic progress). Common examples of secondary data are medical records, student records, data collected for a previous study, or audio/video recordings collected for other purposes. For information to be considered "existing," it must have been collected at an earlier data for purposes other than the currently intended use.

*Public data:* Data collected by an organization with the intention of being, or otherwise authorized approval to be, released to the general public (e.g., U.S. Census data, General Social Survey datasets, PEW Research Center datasets). Such data do not include identifying information about the participants/subjects.

*Restricted or private data:* Data collected by a person or organization that is not available to the general public.

*De-identified data*: An existing dataset that has been stripped of all identifying information, *by the owner of the dataset*, in a manner that would guarantee that the data cannot be linked back to the subjects from whom it was originally collected.

*Identifiers*: Information within an existing dataset that links to specific individual subjects either directly or indirectly. Examples of direct identifiers are names, addresses, student T#s, phone numbers, social security numbers, patient ID numbers. Indirect identifiers are (a) information that, by using a single indicator or a combination of indicators, a reasonably knowledgeable person could ascertain the identities of the subjects by individual indicators (e.g., place of employment, job title, gender, age, ethnicity) or (b) information coded within the dataset linked that is linked to a key with identifying information about the subjects.

***Vulnerable populations*** are particular classes of research participants who are likely to be vulnerable (or susceptible) to coercion or undue influence or who full agency in their decision-making capacities.

Examples of “vulnerable populations” are, but are not limited to, children (people under the age of 18), prisoners (i.e., individuals involuntarily confined or detained in a penal institution), pregnant women, human fetuses, neonates, people with cognitive, mental, or physical disabilities, people who are economically or educationally disadvantaged, or people with terminal illnesses.

From [TTU IRB "Definitions"](https://www.tntech.edu/research/committees/humansubjects/definitions.php)

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***Student Activities Involving Human Subjects.***

The IRB has identified three categories of student activities involving human subjects:

1. ***Student Research***
	1. “Student research” is defined as an activity undertaken by undergraduate or graduate students which meets the DHHS definition of research: “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” “Student research” can take place in a class or as a faculty-directed independent study.
	2. “Student research” meets the DHHS criteria for research; therefore, it is subject to IRB review at the appropriate level.
2. ***The Classroom Project***
	1. The “classroom project” is a class project of significant length and scope that is included in the course syllabus. The “classroom project” may involve systematic data collection and analysis and may be referred to as “research,” but does not meet the DHHS definition of “research,” as it is not intended to contribute to generalizable knowledge. (See I.A.1).
	2. The purpose of the “classroom project” is to function as a learning tool designed to facilitate the student’s mastery of research theory and practice. The purpose is NOT to “develop or contribute to generalizable knowledge,” which places it outside of the definition of "research." Results of the “classroom project” may not be presented outside of the department in which the activity takes place, including publication, inclusion in theses, dissertations, or presentations in public fora.
3. ***The Student Assignment***
	1. The "student assignment" is a required out-of-class activity involving interviews or surveys and is one component of many in a given course. The assignment is completed and submitted for a grade in the course. It is not typically a systematic investigation, and it is not designed to contribute to generalizable knowledge.
	2. Results of the “student assignment” may not be presented outside of the department in which the activity takes place, including publication, inclusion in theses, dissertations, or presentations in public fora.

*Suggested Guidelines for Student Activities with Human Subjects*

1. “Student Assignments” and “Classroom Projects,” are activities involving human subjects that do not meet the OHRP and IRB definitions of "research." These activities, therefore, are not subject to IRB review. Such activities are identified and monitored by the Department Review Committee in the department in which the activities take place.
2. It is recommended that all faculty members and students who participate in the conduct of Student Assignments and Classroom Projects, as defined by the IRB, be familiar with the IRB definitions of these activities, and with the definition of “research” adopted by the OHRP and the TTU IRB.
3. It is recommended that all faculty members and students who participate in the conduct of Student Assignments and Classroom Activities complete CITI training for activities with human subjects, at the level suggested by the IRB. (See website training page.)
4. A [Determination Form for Human Subjects Activities](https://www.tntech.edu/assets/usermedia/cas/18732/Determination_Form_for_Student_Activities_involving_Human_Subjects.docx)  (DFHSA) is offered for use or adaptation at the departmental level to identify a project as belonging to the category of Student Assignment or Classroom Project. Neither the use nor the submission of this form is required by the IRB. This form may, however, be adapted for use within the department, at its discretion, and procedures for the use of the form determined by the department chair or departmental review committee.
5. Please note that any proposed student activity involving human subjects which does not meet all of the requirements and qualifications for Student Assignment or Classroom Project is considered to be “research,” under the OHRP definition, and “Student Research,” as defined by the IRB. The proposal for such a project must be submitted to the IRB for approval at the appropriate level of review, prior to commencement of contact with human subjects.
6. The class instructor or project supervisor should report to the Office of Research any suspected adverse events or effects involving human subjects that take place during, or as a result of, the conduct of the project or assignment.
7. Unless unavoidable, we discourage the use of human subjects that are under the age of 18 or are members of “vulnerable populations,” such as pregnant women, people with mental or physical disabilities, or prisoners. Moreover, we discourage any activities that present more than minimal risk for the participants, involve participation in illegal activities, involve the collection of sensitive private information, or involve the use of deception.
8. If the class instructor or supervisor feels that the use of human subjects under the age of 18 or from a “vulnerable” population or that activities involving elevated risk for the participants, illegal behavior, collection of sensitive information, or deception are necessary to fulfill the learning objective for the classroom project or student assignment, we strongly encourage them to consult with their department chairperson and other faculty within the department or college to establish internal guidelines for overseeing the activities and ensuring the safety of the human subjects and that they are treated ethically and professionally.
9. The course instructor or supervisor is solely responsible for all aspects of classroom projects and student activities. Anyone conducting any type of non-research activities should work closely with their departmental chairpersons and departmental faculty to maintain the highest professional and ethical standards."

See [Student Activities Involving Human Subjects](https://www.tntech.edu/research/committees/humansubjects/irb-student-activities.php)

***Categories of Exempt Status.***

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

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. [45 CFR 46.104(d)(1)]
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; or (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. PLEASE NOTE: An exemption cannot be used when children are involved for research involving survey or interview procedures or observations of public behavior, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed. [45 CFR 46.104(d)(2)]
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: (a) 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 or (b) 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. 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. PLEASE NOTE: 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)]
4. 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: (a) The identifiable private information or identifiable biospecimens are publicly available; (b) 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; (c) 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 non-research 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)]
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. [45 CFR 46.104(d)(5)]
6. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed, or (b) if 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. [45 CFR 46.101(b)(6)]

PLEASE NOTE: Exemption from IRB review does not mean an IRB application is unnecessary. Research that falls under one of the aforementioned exempt categories still requires review by a Departmental Reviewer. In accordance with OHRP’s recommendations, investigators do not have the authority to make an independent determination that a research project involving human subjects is exempt.

Based upon [CFR 45.46.101.b.1-6](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html).

***Requirements for Expedited Review.***

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

**Applicability**

1. 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 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.
2. The categories in this list apply regardless of the age of subjects, except as noted.
3. 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.
4. The expedited review procedure may not be used for classified research involving human subjects.
5. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

**Criteria**

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
a.  Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
b.  Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
a.  from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
b.  from other adults and children2, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
*Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.*
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
*Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.*
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or 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.)
6. Collection of information from voice, video, digital, or image recordings made for research purposes that are not exempt under 45 CFR 46.104(d).
7. 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.)
8. 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.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the 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.

***Requirements for Full Board Review.***

Any project that is (a) not covered by one of the exempt or expedited categories or (b) involves a vulnerable population requires Full Board Review.

***SKIP***

***Policy for Use of TTU Student Data in Research.***

Proposed projects using TTU student data (i.e., data from students’ educational records) for research purposes must comply with Tennessee Tech IRB policies and Tennessee Tech Family Educational Rights and Family Act (FERPA) policies.

Examples of TTU student data are as follows:

* GPA (TTU, High School, Other College/University)
* Standardized Test Scores (e.g, ACT, GRE, TOFEL)
* Attendance reports
* Advising records
* Graded assignments within a class or classes
* Exam Grades within a class or classes

Although Administrators, Faculty, and Staff (e.g., professors, advisors, chairpersons, mentors, deans) have access to Tennessee Tech student records, and although faculty have records of students’ graded work (e.g., assignments, quizzes, exams, papers) within their classes, they are not authorized to share such data for research purposes. Only the Tennessee Tech FERPA Officer, Brandi Hill, is authorized to release data from student records for research purposes. Therefore, the use of such data for research purposes requires, first, IRB approval and, second, authorization from the University FERPA Officer.

The procedures for proposed projects that will use data from Tennessee Tech student records are as follows:

1. Complete and submit an IRB application to a Certified Departmental Reviewer.
2. The Departmental Reviewer will recommend the application for Expedited Review.
3. Once the IRB approves the application through an Expedited Review, the approval will be sent to the PI with the FERPA Officer copied to the email. Although the IRB can approve an application using student records, the data will only be released to the PI by the FERPA Officer.

IRB approval does not require the FERPA Officer to provide the data to the PI or guarantee that the FERPA Officer will provide the requested data. Additionally, an IRB approval does not stipulate any timeframe for the FERPA Officer to provide the PI with the requested data. Therefore, IRB approval, alone, is insufficient for accessing student records for research purposes.

FERPA policies and IRB policies are separate policies under federal law and at Tennessee Tech. Therefore, each are enforced and monitored independently. The IRB and the FERPA Officer will work together to assist PIs in their research. However, the IRB does not have any jurisdiction over FERPA, and the IRB supports the FERPA Officer's ultimate decision whether or not to provide data from student records to PIs.

FERPA requires that students grant permission to access their student records whenever possible. IRB requires that students provide informed consent whenever it is possible to do so. However, in some research studies, it is not possible or otherwise reasonable to get permission or informed consent from students. In these cases, a waiver of informed consent must be requested from IRB. The application must provide a strong justification for such waivers in order to be approved by the IRB.

Per Tennessee Tech Policy 1206: Confidentiality of Student Records and FERPA Compliance, the following information is considered personally identifiable:

"Personally Identifiable Information—information including, but not limited to:

1. The student's name;
2. The name of the student's parent or other family members;
3. The address of the student or student's family;
4. A personal identifier, such as the student's social security number, student number, or biometric record;
5. Other indirect identifiers, such as the student's date of birth, place of birth, and mother's maiden name;
6. Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty; or
7. Information requested by a person who Tennessee Tech reasonably believes knows the identity of the student to whom the education record relates."

For questions related to using Tennessee Tech student records for research purposes, please contact the IRB Chairperson, sseiler@tntech.edu.

For questions related to FERPA policies, please contact the Tennessee Tech FERPA Officer, Brandi Hill, bhill@tntech.edu.

PLEASE NOTE: The procedures outlined here apply only to proposed projects that intend to use data from Tennessee Tech student records. For proposed projects that intend to use student data from any other educational institution, written permission must be provided by authorized personnel at the institution.

**PART IV: APPLICATION PROCESS FOR EXEMPT STATUS, EXPEDITED REVIEW, AND FULL BOARD REVIEW**

**Exempt Status:**

**1.** **Principal Investigator**

- Complete the [Application for Research Involving Human Subjects](https://www.tntech.edu/research/files/irb_forms_ss/IRB_Application_for_Research_Involving_Human_Subjects_4_1_19.docx) and include CITI Training Certificate(s) for PI and all Co-PIs, Informed Consent Form, copy of instrument (e.g., survey, interview protocol), and any necessary supporting documents.

- PI must sign under **Part D** within the Application.

- **If PI is an undergraduate or graduate student,** a ***Faculty Supervisor*** must review and sign **Part D** within the Application as well.

**2.** **Departmental Reviewer**

- The PI must submit the complete application with signature(s) to a Certified Departmental Reviewer.

- The Departmental Reviewer reviews the application in accordance with the criteria outlined in Part V of this guidebook.

- If the Departmental Reviewer feels the application meets the criteria for Exempt Status, she or he will select “Exempt,” select the appropriate “[Category of Exempt Research](https://www.tntech.edu/research/committees/humansubjects/levels-of-review.php),” and sign under **Part E** of the Application.

**3. Research Office**

- The Departmental Reviewer or the PI submits the entire application to Amy Hill in the Office of Research.

**4. Official Approval**

- Once Ms. Hill receives and processes the application, she will send the PI an email with official approval of the application.

**5. Begin Research**

- Once the PI receives the official approval, she or he can begin the research process.

**Expedited Review:**

**1.** **Principal Investigator**

- Complete [Application for Research Involving Human Subjects](https://www.tntech.edu/research/files/irb_forms_ss/IRB_Application_for_Research_Involving_Human_Subjects_4_1_19.docx) and include CITI Training Certificate(s) for PI and all Co-PIs, Informed Consent Form, copy of instrument (e.g., survey, interview protocol), and any necessary supporting documents.

- PI must sign under **Part D** within the Application.

- **If PI is an undergraduate or graduate student,** a ***Faculty Supervisor*** must review and sign **Part D** within the Application as well.

**2.** **Departmental Reviewer**

- The PI must submit the complete application with signature(s) to a Certified Departmental Reviewer.

- The Departmental Reviewer reviews the application in accordance with the criteria outlined in Part V of this guidebook.

- If the Departmental Reviewer feels the application requires Expedited Review, she or he will select “Expedited” and sign under **Part E** of the Application.

**3. Research Office**

- The Departmental Reviewer submits the complete application with signatures to Amy Hill in the Office of Research.

**4. IRB Chairperson**

- Once Ms. Hill processes the application, she will then submit the application to the IRB Chairperson.

- The IRB Chair will confirm that the application requires an Expedited Review, and then identifies a subcommittee of Board Members (one Lead Reviewer and two Secondary Reviewers) to review the application.

**5. IRB Subcommittee**

- The Lead Reviewer of the IRB subcommittee will contact the PI with a decision within 14 days from the day the subcommittee received the application.

- If the decision is to approve, the Lead Reviewer will send the PI an official approval of the application.

- If revisions are necessary, the Lead Reviewer (or the IRB chairperson) will notify the PI of the decision, provide a list of requested revisions, and provide resubmission instructions.

**6. Begin Research**

- Once PI receives the official approval from the Lead Reviewer, she or he can begin the research process.

\* NOTE: If the study involves TTU student data, Brandi Hill will be included on the official approval email. At that point, she will determine whether or not she can release the requested data to the PI. (See page #25 for details.)

**Full Board Review:**

**1.-3. Identical to Expedited Review**

**4. IRB Chairperson**

- The IRB Chair will confirm that the application requires a Full Board Review, and then the application will be added to the agenda for the next IRB meeting.

**5. Full IRB Review**

- All of the IRB members will receive the application in advance of the next scheduled meeting.

- At the meeting, the board members will discuss the application and vote on a decision to approve, defer (i.e., request revisions), or disapprove the application.

- Chairperson will notify the PI of the Board’s decision shortly after the meeting.

- If revisions are necessary, the PI will outline the necessary revision and provide instructions for resubmitting the application.

- Once the revised application is received, it will be added to the next IRB meeting agenda.

**6. Begin Research**

- Once PI receives the official approval from the IRB chairperson, she or he can begin the research process.

**IRB Application Workflow**

**jh**

**Office of** **Research**

**Office of Research**

**Faculty Supervisor**

**Undergraduate/ Graduate Student**

**Principal Investigator**

**Faculty/Staff Principal Investigator**

**Departmental Reviewer**

**IRB Chairperson**

**Expedited Review:**

3-IRB member subcommittee

**Full Board Review:**

Review by entire IRB at scheduled meeting

Certify for Exempt Status

Recommend for Expedited or Full Board Review

**PART V: REQUIRED APPLICATION DOCUMENTS**

**Required Documents for Applications for Exempt Status, Expedited Review, & Full Board Review.**

Application for Research Involving Human Subjects

CITI Training Completion Certificates for the PI, all Co-PIs, and, if applicable, Faculty Supervisor certifying completion of the following courses:

* 1. “Social and Behavioral Responsible Conduct of Research”
	2. “SBE Researchers including all students and faculty acting as an Investigator (PI-co-PI)”

Copy of the Research Instrument(s) (e.g., survey, interview protocol)

Copy of the Informed Consent Form

Any Other Applicable Documents (e.g., gatekeeper letters/ letters of permission, recruitment materials)

**qwe**

**PART VI. ETHICAL PRINCIPLES AND APPLICATION**

The [Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) outlines three ethical principles for research involving human subjects: (1) respect for persons, (2) beneficence, and (3) justice. These ethical principles should be at the forefront of your mind when reviewing IRB applications. These principles, as well as how these principles should be applied, are as follows:[[1]](#footnote-1)

**Principle I: Respect for Persons**

Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and, second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

***Application:***

***Informed Consent.*** Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

*1. Information.*Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common understanding does not exist. Another standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care. It may be that a standard of "the reasonable volunteer" should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that **(1)** incomplete disclosure is truly necessary to accomplish the goals of the research, **(2)** there are no undisclosed risks to subjects that are more than minimal, and **(3)** there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

*2. Comprehension.*The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

Special provision may need to be made when comprehension is severely limited -- for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disable patients, the terminally ill and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

*3. Voluntariness.*An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.

**Principle II: Beneficence**

Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In [the Belmont Report], beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.

The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children -- even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

***Application*:**

***Assessment of Risks and Benefits.***The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.

***The Nature and Scope of Risks and Benefits.***The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term "risk" refers to a possibility that harm may occur. However, when expressions such as "small risk" or "high risk" are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

The term "benefit" is used in the research context to refer to something of positive value related to health or welfare. Unlike, "risk," "benefit" is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and Federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects' rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.

***The Systematic Assessment of Risks and Benefits.***It is commonly said that benefits and risks must be "balanced" and shown to be "in a favorable ratio." The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, non-arbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Finally, assessment of the justifiability of research should reflect at least the following considerations: **(i)**Brutal or inhumane treatment of human subjects is never morally justified. **(ii)** Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures. **(iii)** When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject -- or, in some rare cases, to the manifest voluntariness of the participation). **(iv)** When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits. **(v)** Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

**Principle III: Justice**

Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are **(1)** to each person an equal share, **(2)** to each person according to individual need, **(3)** to each person according to individual effort, **(4)** to each person according to societal contribution, and **(5)** to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

***Application:***

***Selection of Subjects.***Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only "undesirable" persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

**PART VII. CONSIDERATIONS DURING REVIEW**

The substance of concern for research involving human subjects lies in the criteria by which the IRB evaluates proposals. The following are major considerations when reviewing an application:

1. Risks to Subject: To what extent does the proposed research present potential of harm to the participants of the study ***as a result of the study***? Risk of harm can be associated with the recruitment process, the research design, the research instrument, any interactions between the participants and the research team and among participants, the data analysis process, the reporting of the findings, the procedures related to the securing and maintaining the data, and confidentiality of the data collected. What steps will the PI take to minimize the risks of harm to the participants? What processes are in place for handling any harm that possibly occurs?
2. Risks vs. Benefits: Risks to the subject are reasonable in relation to anticipated benefits, if any, to subject, and to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, consider only those risks and benefits that may result from the research (as distinguished from the risks and benefits of therapies or services that subjects would receive even if they do not participate in the research).
3. Subject Selection: The selection of subjects must be equitable. In making this assessment, take into account the purposes of the research, the setting in which the research will be conducted, and the population from which the subjects will be recruited.
4. Informed Consent: Informed consent must be sought from each prospective subject or the subject's legally authorized representative and will be legally documented. If a waiver of informed consent is requested, very strong justification must be provided. (If a waiver of informed consent is requested, the application must be submitted for either expedited or full board review.)
5. Confidentiality, Privacy, and Anonymity: The PI must have a stated plan for monitoring the data collected to ensure the subjects' privacy and the confidentiality of the data. Moreover, it must include an explanation about protecting the identities of participants in the dissemination of the findings (e.g., though publications, presentations, research announcements, research briefs).
6. Other Considerations: Consider also the acceptability of the research project in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and special vulnerabilities of the subjects.

**PART VIII. REVIEW CHECKLISTS**

**Checklist for the Application for Research Involving Human Subjects:**

**Cover Page:**

**If the PI is a student, is a Faculty Supervisor in your department listed?** If not, return application to PI.

**Is all of the requested information filled out?** If not, return application to PI.

**Part A:**

**Did the applicant check all of the boxes under the Pre-Application Checklist?** If not, return to PI or consult with the PI to make sure all she or he has reviewed all of the necessary policies and subsequently check the boxes on the PI’s behalf.

**Did the applicant check all of the boxes under the Application Documentation Checklist?** If not, return to PI or consult with the PI to make sure all of the necessary documentation is enclosed in the application and subsequently check the boxes on the PI’s behalf.

**Part B:**

 **Is the application handwritten?** If it is, return to PI. All forms must be typed.

**Is every item in Part B filled out?** If not, return application to PI.

**Are any Co-PIs affiliated with other institutions?** If “yes,” an IRB Authorization Agreement must be established with all non-TTU institutions for which the Co-PIs are affiliated. Contact the IRB Chairperson for details.

**Are any items selected within any blue-shaded boxes?** If yes, the application can not be classified as Exempt Status. It will have to be recommended for Expedited or Full Board Review.

**Under #7, if either “Data include private/restricted information but no identifying information” or “Data includes private/restricted information *and* identifiers” is selected, is additional documentation indicating authorization to access the data enclosed with the application?** If not, return the application to the PI and request that formal authorization documentation is enclosed with the application.

**NOTE: IF THE APPLICATION INVOLVES THE USE OF STUDENT DATA OF ANY SORT, IT MUST BE RECOMMENDED FOR EXPEDITED REVIEW. (See Page 26)**

**Does the research require informed consent?** If no is selected, the application can not be classified as Exempt Status. It will have to be recommended for Expedited/Full Board Review.

**Is “Other” checked for items #12 or #15 on page 2?** If either is checked, make sure a document is enclosed for each that elaborates. It will have to be recommended for Expedited/Full Board Review.

**Part C**

Close attention needs to be paid to every element of Part C. Rather than explaining each item on Part C, you just need to make sure all part of this section are adequately answered. An adequate answer is one that has enough information for you to assess the treatment of human subjects in the research process. To certify for exempt status, you will need enough information to confirm that the study falls clearly into one of the six exempt categories. To recommend an application for expedited or full board, you will need to make sure that the applicant has provided sufficient information that would allow the IRB to properly assess the treatment of human subjects in the research process.

**Please do not accept “NA” as a response for 1-5.** “NA” would only be an appropriate answer for 6 for studies that will not be using secondary data.

**NOTE: IF THE APPLICATION INVOLVES THE USE OF STUDENT DATA OF ANY SORT, IT MUST BE RECOMMENDED FOR EXPEDITED REVIEW. (See Page 26)**

**Part D**

 **Did the PI write her or his name, sign, and date the application?** If not, return to PI for signature.

**If the PI is a student, did the Faculty Supervisor from your department write her or his name, sign, and date the application?**  If not, return application to Faculty Supervisor for signature.

**CITI Completion Reports:**

Make sure that a copy of the CITI Completion Report or Certificate for “Responsible Conduct of Research” and “SBE Researchers including all students and faculty acting as an Investigator [PI-co-PI]” are included for (1) the PI and (2) each Co-PI. If not, return the application to the PI.

(NOTE: The Faculty Supervisor must also be certified through CITI; however, a copy of the CITI Training Certificate does not need to be included for her or him. Once the application is submitted to the Office of Research, Ms. Hill will confirm the certification of the Faculty Supervisor.)

**Research Instrument:**

Make sure the application includes a complete copy of the actual survey questions or interview questions that will be used for the study. If the comprehensive copy is not included, return the application to the PI.

Are all of the questions appropriate to answer the research question or test the hypotheses? If not, return to PI for revisions.

Do any questions ask information that could be incriminating, personal, or trigger an emotional reaction or episode? If yes, the study will require an Expedited Review or Full Board Review.

NOTE: IF THE APPLICATION INVOLVES THE USE OF STUDENT DATA OF ANY SORT, IT MUST BE RECOMMENDED FOR EXPEDITED REVIEW. (See Page 25)

**Informed Consent Form:**

Make sure the Informed Consent form has all of the following items:

A statement that participants must by at least 18 years of age in order participate in this study.

The PI’s name and contact information.

The purpose/objective of the study.

An explanation of the information the PI obtain be used for.

A statement explaining the methods that will be used and about what will be required of the participants.

A statement about any risks, hazards or inconveniences the subject may endure.

A statement about any benefits the subject might expect from participation.

A statement about any conditions they must meet in order to participate.

A statement of a guarantee of anonymity or confidentiality.

A statement that the participants may discontinue participation at any time without any penalty.

A signature line (or, for online surveys, a prompt) for the participant to acknowledge that they understand and agree with the terms of the study and that they want to participate.

If the informed consent form does not have all of these items, return the application to the PI to request revisions. Indicate what items are missing.

Here are just some additional questions that you can reflect upon as you review an IRB application.

**1. The proposed research design is scientifically sound and will not unnecessarily expose subjects to risk.**

a) Is the use of human subjects necessary to answer the research question(s) being asked or test the hypothesis (hypotheses) stated?

b) Is the research adequately described? Does the research use procedures consistent with sound research design?

c) Are the objectives clearly stated, with valid measurements and analysis proposed? Can the research be reasonably expected to answer its proposed questions?

d) Does the investigator have access to a population that will allow recruitment of the necessary number of participants?

**2. Risks to subjects are minimized.**

a) What are the risks of the research? Consider physical, psychological, social, economic, and legal risks.

b) Is the study designed to minimize risk? If not, would an alternative scientific design reduce the likelihood or magnitude of harm but still answer the scientific question?

c) Is the proposed participant population the most appropriate to minimize risk? If not, would an alternative population reduce the likelihood or magnitude of harm but still answer the scientific question? Would the use of fewer subjects answer the scientific question?

d) Whenever possible, are procedures proposed that are already being performed for diagnostic or treatment purposes?

e) Would alternative procedures reduce the likelihood or magnitude of harm but still answer the scientific question? Would the use of fewer procedures answer the scientific question?

f) Are medical or psychological resources available that participants might require as a consequence of the research? Will appropriate debriefing be provided?

**3. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.**

a) How do possible harms or discomforts that will be faced by subjects as a consequence of research participation compare to those experienced in normal daily life or during routine physical or psychological examinations or tests?

b) What is the nature of the harms or discomforts (e.g., physical, social, economic, psychological, or legal) and their potential seriousness? What are the chances that they will occur and the effect on participants or their families if these were to happen?

c) Are measures included to prevent or decrease the likelihood of harm or discomfort?

**4. Risks to subjects are reasonable in relation to anticipated benefits to subjects, if any, and the importance of knowledge that may be reasonably expected to result.**

a) What are the risks of the research? (Consider physical, psychological, social, economic, and legal risks.)

b) What are the anticipated benefits of the research? Are there any benefits to participants?

c) What is the importance of the knowledge expected to result from this research? Does it justify exposing participants to risk?

**5. Selection of subjects is equitable.**

a) Who is to be enrolled? Is the rationale for inclusion/exclusion clear?

b) Is the proposed participant population appropriate, considering the purposes and setting of the research?

c) Will proposed recruitment processes, advertisements, or participation arrangements result in the equitable selection of participants? Will payments or other incentives inappropriately influence equitable selection?

d) Are proposed recruitment processes, advertisements, and participation arrangements free from misleading, inaccurate, exculpatory, coercive, or unduly influential methods and language?

e) Are the burdens and benefits of research equitably distributed?

f) Are any potential participants vulnerable to coercion or undue influence? If so, are recruitment processes, advertisements, and participation arrangements designed to minimize the possibility of coercion or undue influence?

**6. Additional safeguards have been included to protect subjects likely to be vulnerable to coercion or undue influence.**

a) Are some or all potential participants likely to be vulnerable to coercion or undue influence? If so, have additional safeguards been included to eliminate or minimize coercion and/or undue influence?

b) Are appropriate protections in place for vulnerable participants, such as children, prisoners, pregnant women, fetuses, neonates, educationally- or economically-disadvantaged persons, or adults unable to consent?

c) For adults unable to consent is assent a requirement? If so, is the plan for assent adequate? For greater than minimal risk research presenting the prospect of direct benefit, is comparison of the risk to the benefit at least as favorable as that presented by the alternatives? For greater than minimal risk research without the prospect of direct benefit but likely to yield generalizable knowledge about the individual’s disorder or condition, is the risk no more than a minor increase over minimal risk?

d) Are safeguards in place for other potentially vulnerable populations (e.g., students, employees, terminally ill persons, or homeless persons)?

e) Are students recruited by investigator(s) from whom they receive direct instruction? If so, are procedures in place to ensure voluntary participation? For greater than minimal risk research, is the prospect of direct benefit possible? For “student pools” are incentives and alternatives to participation reasonable?

f) Are employees recruited by investigator(s) to whom they directly report? If so, are procedures in place to ensure voluntary participation? For greater than minimal risk research, is the prospect of direct benefit possible?

**7. Legally effective informed consent is obtained from subjects or their legally authorized representatives. (NOTE: If informed consent is not being required, skip to question 9.)**

a) Have the nature and circumstances of the consent process been adequately described? Who will conduct the consent interview? What is the timing of obtaining informed consent?

b) Who will provide consent? Will the participant be able to understand the facts, appreciate the implications, and be able to communicate a decision? If there are questions regarding the participants’ capacity to make a decision, is the plan for assessment of capacity to consent adequate? For greater than minimal risk research, is an independent assessment of capacity proposed?

c) If a legally authorized representative will provide consent, is it clear who can serve as a legally authorized representative for the research?

d) Is the process culturally and linguistically appropriate to the research population? What language(s) do potential participants or representatives speak? Is the consent discussion in language understandable to the participant or representative? Can the research team communicate directly with participants? If not, are translation arrangements appropriate?

e) How much time will be devoted to the consent discussion? Does the consent process provide sufficient opportunity for participants to consider whether to participate? Is there any waiting period between informing participants and obtaining consent?

f) Does the consent process minimize the possibility of coercion or undue influence? Is there a power differential to be considered? Is the process free from excessive motivating factors? Are recruitment processes, advertisements, and payment arrangements acceptable?

g) Is the discussion free of exculpatory language? Is information provided to participants in a way that does not waive or appear to waive any of the participants’ legal rights or release or appear to release the investigator, sponsor, or institution from liability for negligence?

h) Should a subject advocate or observation or monitoring of the consent process be considered?

**8. Informed consent will be documented by a written consent form signed by subjects or their legally authorized representatives.**

a) Does the consent document include the basic and appropriate additional elements of consent?

b) Who will sign the consent document? Will a copy of the consent document be given to the person signing? If the research is FDA- regulated, will the participant or representative sign and date the consent form?

c) Is the consent document written in language understandable to the participant or representative?

d) How much time is allotted for signing the consent document? Is adequate opportunity provided for participants or their legally authorized representatives to read consent forms before they are signed?

e) Is the consent form free of exculpatory language? Is the consent document free of language that waives or appears to waive any of the participants’ legal rights or releases or appears to release the investigator, sponsor, or institution from liability for negligence?

f) When using the short form, does the consent document state that the elements of disclosure required by regulations have been presented orally to the participant? Does the written summary include the basic and appropriate additional elements of consent?

g) When using the short form, will there be a witness to the oral presentation? Is the witness conversant in both English and the language of the participant? Will the witness sign both the short form and a copy of the summary?

h) When using the short form, will the participant or representative sign the consent document? Will a copy of the consent form be given to the person signing? If the research is FDA-regulated, will the participant or representative sign and date the consent form?

i) When using the short form, will the person obtaining consent sign a copy of the summary? Will a copy of the summary be given to the participant or legally authorized representative?

**9. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects (for greater than minimal risk research).**

a) Is an appropriate data safety and monitoring plan included? Does the plan specify what information will be evaluated, study endpoints, timing of monitoring, and decisions to be made by the monitoring process?

b) What will monitoring include – comparison of actual harms (nature, incidence, and severity) and benefits to those expected, causality of unexpected harms, etc.?

c) When will monitoring occur – at specific points in time, after a specific number of participants have been enrolled, or upon recognition of harm?

d) Who will perform the monitoring – the investigator, sponsor (e.g., medical monitor, safety monitoring committee), or independent monitor or monitoring board?

e) Would use of a data safety monitoring board or other research oversight process enhance participant safety?

**10. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**

a) Will participants have an expectation of privacy?

b) How will the investigator access private information from or about participants? Will participants think that the information sought is any of the researcher’s business?

c) Will participants be comfortable in the research setting? Will participants be comfortable with the research procedures?

d) Will confidentiality be pledged? Are there legal/ethical requirements affecting confidentiality? Will data release cause risk of harm?

e) How will confidentiality of identifiable data be protected? Are there adequate controls on storage, access, handling, and sharing of data?

f) Are any special privacy and confidentiality issues properly addressed (e.g., access to and use of genetic information)?

g) Is a certificate of confidentiality needed to maintain the confidentiality of identifiable data?

h) Will personally identifiable protected health information be accessed or used? Has the investigator provided a HIPAA authorization form or waiver request?

**11. There is an adequate plan to manage information obtained in multi-center research that is relevant to the protection of subjects.**

a) Is the investigator the lead investigator of a multi-center study or is the organization the lead site in a multi-center study? If so, is there an adequate plan proposed to manage relevant study information?

b) How are unanticipated problems involving risks to subjects or others reported? To whom are these reported?

c) How will amendments be handled? How will sites be informed when approval has been obtained? How will the investigator be informed of other sites’ approval?

d) Are there plans for sharing interim results? How will sites be informed of study suspension or premature closure?

e) How will participating sites be informed of study completion?

**12. Other questions or concerns regarding the proposed research.**

a) Are there any ethical issues posed by the proposed study design or methods?

b) Does the research uphold the Belmont principles of respect for persons, beneficence, and justice?

c) Are there any other questions or concerns regarding the proposed research?

sdf

# APPENDIX: GENERAL IRB PROCEDURES

(Available on the Tennessee Tech website, [Comprehensive IRB Procedures](https://www.tntech.edu/research/pdf/irb_forms_ss/REVISED_General_IRB_Procedures_4_1_19.pdf).)

# GENERAL IRB PROCEDURES

Tennessee Tech University, per DHHS - [45 CFR 46.103(b)(4) and (5)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.103)

## 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](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html), 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](https://www.tntech.edu/research/files/researchcompliance/IRB_Application_for_Research_Involving_Human_Subjects_4_13_18_2_LinksB.docx), a copy of [CITI training](https://www.tntech.edu/research/committees/humansubjects/training-req.php) 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](https://www.tntech.edu/research/committees/humansubjects/certified-reviewers.php)). The Departmental Reviewer will confirm the research is compliant with [45 CFR 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) 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](https://www.tntech.edu/research/files/researchcompliance/IRB_Application_for_Research_Involving_Human_Subjects_4_13_18_2_LinksB.docx). 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](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101):

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](https://www.tntech.edu/research/files/researchcompliance/NEW_FORM_IRB_Request_for_Continuation_Change_Form_11_13_17_Links.docx)

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](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101). 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](#_APPENDIX_A:_DECISION).

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](https://www.tntech.edu/research/files/researchcompliance/NEW_FORM_IRB_Request_for_Continuation_Change_Form_11_13_17_Links.docx) 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](https://www.tntech.edu/research/files/researchcompliance/NEW_FORM_IRB_Request_for_Continuation_Change_Form_11_13_17_Links.docx), 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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)

[Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html)

[Tennessee Tech Office of Research & Economic Development](https://www.tntech.edu/research/index.php)

[Tennessee Tech IRB, Procedural Overview](https://www.tntech.edu/https%3A/www.tntech.edu/research/committees/humansubjects/getting-started.php)

[Tennessee Tech IRB, Definitions](https://www.tntech.edu/research/committees/humansubjects/definitions.php)

[Tennessee Tech IRB Forms](https://www.tntech.edu/research/committees/humansubjects/irb-forms.php)

[Tennessee Tech IRB Training Requirements](https://www.tntech.edu/research/committees/humansubjects/training-req.php)

[Tennessee Tech Certified Departmental Reviewers for the IRB](https://www.tntech.edu/research/committees/humansubjects/certified-reviewers.php)

# 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***)

1. Directly quoted from Part B & C of the Belmont Report (<https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>). Reorganized for original source for clarity and conciseness. [↑](#footnote-ref-1)