APPLICATION FOR RESEARCH INVOLVING HUMAN SUBJECTS

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

Project Title: Click or tap here to enter text. **Principal Investigator (PI):** ***Department:*** (If PI is *not* TTU student, staff, or faculty, provide institutional affiliation:) ***Email:*** **Is the PI an Undergraduate or Graduate Student?** Yes ☐ No ☐ If ***Yes*** (or if PI *and all* Co-PIs are not TTU students, staff, or faculty), complete the following: ***Faculty Supervisor:*** ***Department:*** ***Email:***	**For IRB Use Only:** **Application #:** _____

GENERAL INSTRUCTIONS:
This form must be approved by the IRB prior to conducting research. Subject recruitment and data collection/analysis *cannot* begin until the project receives formal approval from the TTU IRB.

Handwritten forms will not be accepted. Complete the document in MS Word. Please check spelling, grammar, and punctuation prior to submission.

PARTS A-C must be completed by the **Principal Investigator (PI)**. **PART D** must be signed by the **PI** and, if the PI is a student (or if the PI *and all* Co-PIs are *not* students, staff, or faculty at TTU), the **Faculty Supervisor**.

PART E must be completed and signed by a certified **Departmental Reviewer**. (To identify the certified Departmental Reviewer[s] in your department, please see Certified Departmental Reviewers for IRB Applications.)

For Expedited Reviews, **PART F** will be completed and signed by a subcommittee of IRB members.

For Full Board Reviews, **PART G** will be completed and signed by the IRB Chairperson.

Note: Approvals for applications receiving Expedited and Full Board Review are granted for no more than 12 months. Multi-year research will require a Request For Continuation/Change Form submitted at least two weeks prior to IRB 12-month expiration date.

Submission Process: Applications can be submitted in hardcopy or electronic form. However, *all signatures must be original; no scanned or copy/pasted signatures will be accepted.*

For hardcopy submissions*:* Do not staple documents. Submit the complete application directly to the Office of Research (Derryberry Hall, Room 433) or via campus mail at Box 5164.

For electronic submissions*:* Scan entire application with all necessary signatures into a single document and email to IRB@tntech.edu).

For additional information, please visit the TTU Human Subjects Research website or email the IRB Chairperson, Chad Rezsnyak (crezsnyak@tntech.edu).

Technical Notes**:** (1) Please download a new application from the website for each new research project, as the application is updated periodically to resolve minor formatting issues. (2) When printing an application, please use grayscale (i.e., black text). Color printing might affect the visibility of the checkmarks in Parts A and B.

PART A. CHECKLISTS

1. Pre-Application Checklist

As the PI, please confirm, by checking the following boxes, that you have done the following prior to completing the IRB application:

- ☐ Reviewed the TTU IRB "Getting Started" page
- ☐ Reviewed the TTU IRB "Definitions" page
- ☐ Reviewed the TTU IRB "IRB Review Process" page
- ☐ Reviewed the Research/Review Category Decision Trees
- ☐ Reviewed the requirements for Informed Consent
- ☐ Completed the following CITI Training courses:
  - **Human Subjects Research (including privacy) | All student & faculty researchers & Fac. Supervisor**
  - **Social and Behavioral Responsible Conduct of Research**
  - **Researchers including all student investigators and faculty acting as an investigator (PI/Co-PI) (**also known as the IPS or Information Privacy Security course)
- ☐ Biomedical researchers must also complete the **"Biomedical Researchers including all students and faculty acting as an Investigator (PI-co-PI)"** course in addition to the 3 courses listed above. Does this IRB application involve biomedical research? Yes ☐ No ☐
- ☐ Reviewed the TTU Conflict of Interest Policy
- ☐ Reviewed the TTU Responsible Conduct of Research Policy

2. Application Documentation Checklist

Please confirm by checking the appropriate boxes that **all** of the required documents are included with the application and included in the following order:

- ☐ A completed **Application for Research Involving Human Subjects** signed by ***PI***, ***Faculty Supervisor*** (if applicable), and a ***certified Departmental Reviewer***
- ☐ Certificates of Completion of CITI training for the ***PI*** and ***all Co-PIs***. (Faculty Supervisors must also have CITI Training Certificate of Completion on file in the Office of Research.)
- ☐ Copy of ***all*** instruments, surveys, and questions to be used
- ☐ Copy of ***all*** informed consent form(s)
- ☐ Copy of recruitment materials (emails, posters, advertisements, etc.), ***if applicable***
- ☐ Copy of letter(s) of permission to conduct research, ***if applicable***

PART B. GENERAL INFORMATION

1. Projected Start Date of Study: ☐ Upon approval or ☐ Specify Date: mm/dd/yyyy

2. TTU Co-Investigators (If needed, list additional investigators on page #3)

Name	Department/Unit	Check if Student
		☐
		☐
		☐

***Note**: **Only** the PI and Co-PIs listed here will be authorized to collect and analyze data, to have access to the data, and to disseminate the data in any way or form.*

3. Multi-Institutional Research: Are all PIs faculty, staff, or students at TTU? Yes ☐ No ☐

***If No**, please list the names and affiliations of all Co-PIs who are not faculty, staff, or students at TTU below. (If needed, list additional investigators on page #3.)*

Name	Affiliation	Check if Student
		☐
		☐
		☐

4. Funding Status: ☐ Not Funded

☐ Pending Funding Source:

☐ Funded Grant Proposal/ Index #:

5. Data Collection Method(s) to be used:

☐ Survey/Questionnaire ☐ In-Depth Interviews ☐ Observations ☐ Experimental
☐ Focus Groups ☐ Psychological Testing ☐ Educational Testing ☐ *Secondary Data**
☐ *Internet/Social Media*‡ ☐ Other (Explain:)

6. Medium for Data Collection:

☐ Written Notes ☐ Voice Recorder ☐ Photograph
☐ Field Journal ☐ *Secondary Data** ☐ Video Recorder
☐ Web-based Survey ☐ *Internet/Social Media*‡ ☐ Other (Explain:)

7.a. *Secondary Data:** If "Secondary Data" was selected in #5 or #6, select the appropriate description of the data:

☐ Data are publicly available.
☐ Data include private/restricted information but no identifying information.
(***Note:*** *Attach documentation indicating authorization to access the data.*)
☐ Data includes private/restricted information ***and*** identifiers.
(***Note:*** *Attach documentation indicating the authorization to access the data. Expedited or Full Board Review required.)*

7.b. *Internet/Social Media Data*‡: If "Internet/Social Media" was selected in #5 or #6, please complete this section:
Is a username and password required to view the data being collected?
Yes ☐ No ☐
If Yes*, Expedited or Full Board Review is required.*

8. Approximate number of human participants anticipated:

9. Target Population (Check all that apply): *Items in shaded box require Expedited or Full Board Review.*

☐ Adults (18+ years)	☐ Students (Explain:)
☐ Children under 18 ***in an educational setting***	
☐ Children under 18 ***outside*** of an educational setting	☐ Prisoners
☐ Cognitively impaired or economically, educationally, or medically disadvantaged	☐ Institutionalized persons
☐ Pregnant women	☐ Non-English-speaking persons
☐ Infants, Neonates, or Human Fetuses	☐ Other Protected Population (Explain:)

10. Will reported data include any private information (e.g., social security numbers, contact information) or identifying information (e.g., actual names, specific employers, specific job titles) of the participants?
Yes ☐ No ☐
If Yes*, Expedited or Full Board Review is required.*

11. Will the researchers obtain informed consent from participants? ☐ Yes ☐ No ☐ Not Applicable
If Yes*, how will you obtain consent?* ☐ Written ☐ Electronic ☐ Other: (Explain:)
If No*, Expedited or Full Board Review is required.*

12. Will subject(s) be involved in deception or incomplete disclosure *without prospective agreement (See Exempt Category #3)*? ☐ Yes ☐ No
If Yes*, Expedited or Full Board Review is required.*

13. Potential Risk of Harm: *Items in shaded box require Expedited or Full Board Review.*
☐ None ☐ Physical ☐ Psychological ☐ Economic ☐ Legal ☐ Social
☐ Other (Explain:)

(#2, cont.) Additional TTU Co-Investigators:
Please state first & last name and department, and if this is a student, for each additional Co-PI.

(#3, cont.) Additional Non-TTU Co-Investigators:
Please state first & last name, institutional affiliation, and if this is a student, for each additional Co-PI.

PART C. DETAILED DESCRIPTION OF PROPOSED RESEARCH

Instructions: Please type narrative responses in the shaded boxes, and be as descriptive and reflective as possible in your responses. Do not leave any boxes blank. *Address all of the requested information*.

1. STATEMENT OF PURPOSE & BACKGROUND: Address **all** of the following:

a. Explain the purpose of the research.
b. Present all research questions that will be explored and/or all hypotheses that will be tested through the research.
c. Provide relevant background information to provide a rationale for the proposed research.
d. Provide justification for the use of humans in the research, if the project could conceivably use some other source of data.
e. Explain how the findings will be used.
f. Provide citations for relevant references as necessary.

2. RESEARCH DESIGN & METHODS

2.a. Methods & Methodology: Address **all** of the following:

1. Discuss *all* of the methods for collecting data *and* the medium/media used for collecting data.
2. Address the general methodology for the study.
3. Address the number of participants.
4. Explain the location(s), setting(s), and/or medium/media where data will be collected.
5. Address any special considerations that could affect participants or that would minimize the potential of harm to participants as the result of the research.
6. *If applicable,* identify any medical devices or equipment that will be used in the study, and describe any intervention(s), groups to which participants will be assigned, or experimental manipulations.

2.b. Role of Participants: Address **all** of the following:

1. Describe, specifically, what the participants are required to do.
2. Explain the amount of time required for each activity.
3. Estimate the total time commitment for a participant.

2.c. Deception or Incomplete Disclosure: Address **all** of the following:

*If **Yes** to #12 under PART B* was selected and deception *will* be used,

1. explain, in detail, how deception or incomplete disclosure will be used in the research;
2. provide extensive justification for the use of deception or incomplete disclosure; and
3. describe the debriefing procedures.

*If **No** to #12 under PART B was selected* and deception *will not* be used, simply type, "No deception or incomplete disclosure strategies will be used."

3. PARTICIPANTS

3.a. Characteristics of the Target Population: Address **all** of the following:

1. Elaborate upon the characteristics of the target population listed for #9 under Part B.
2. Provide justification for selecting this target population.
3. *If **any** shaded characteristics were selected for #9 under PART B*, the target population is considered a special or vulnerable population where ability to provide informed consent may be limited; therefore, address the following:
    a. provide a rationale for including such a population and
    b. explain the steps taken for gaining access to this population

3.b. Recruitment Procedures: Address **all** of the following:

1. Describe the *recruitment procedures* (e.g., email invitation, word-of-mouth, fliers, advertisements).

2. Provide justification for the *recruitment procedures*.
3. From those responding to the *recruitment procedures*, provide a list of the *selection criteria* that will be used for determining who will be included or excluded from the study.
4. Provide a justification for the *selection criteria* and explain who makes the decision to include or exclude participants.
5. Explain the *method(s) of recruitment*, or sampling technique, which must include explaining whether participants are randomly selected or non-randomly selected.
6. Explain how the recruitment and selection procedures will ensure voluntary participation and not single out or embarrass individuals who choose to participate or choose not to participate.
7. Describe what procedures you will follow if a participant decides to withdraw his/her consent.
8. If applicable, identify the institutions or organizations from which you will recruit participants, and explain how permission was granted for recruitment.

3.c. Costs, Compensations, & Incentives: Address **all** of the following:
1. Describe any costs that the subject may incur as a result of participation (charges for tests, travel, lost work time, missed classroom activities, et cetera).
2. Explain whether compensation or incentives are offered to participants. *If planning to offer extra credit to TTU students*, please review Policy for Extra Credit as Incentive/Compensation.
3. If compensation and/or incentives are offered,
    a. provide details of the nature of the compensation/incentives;
    b. explain the conditions for receiving the compensation/incentives; and
    c. explain how the compensation/incentives are distributed.

4. RISKS, RISK MANAGEMENT, & RISKS-BENEFITS ASSESSMENT
4.a. Risks & Potential Problems: Address **all** of the following:
1. Identify potential or known physical, psychological, social, and economic or legal risks of harm that might be associated with participation in the research.
2. Explain the extent of the potential of harm as a result of the study.
3. Explain why these risks are essential to the study.
4. *If **any** shaded characteristics were selected for #9 under PART B*, the target population is considered a special or vulnerable population where ability to provide informed consent may be limited; therefore, specifically address the following:
    a. explain the risks of harm to the participants from this vulnerable population.
    b. explain why the risks of harm to these protected participants are necessary for the study.

4.b. Management of Risks: Address **all** of the following:
1. Explain, in detail, all of the precautions, safeguards, procedures, or other steps incorporated into the research activity to reduce or limit the severity or likelihood of harm.
2. *If **any** shaded characteristics were selected for #9 under PART B*, the target population is considered a special or vulnerable population where ability to provide informed consent may be limited; therefore, address *all* of the following:
    a. Explain how voluntary participation is guaranteed;
    b. Explain how participation will be carefully monitored to guarantee the protection of the vulnerable population.
    c. Explain the procedures in place to guarantee that guardians and/or legal representatives are properly informed about the progress of the study and the participation of those under their protection.

4.c. Risks-Benefits Assessment: Address **all** of the following:
1. Describe the anticipated benefits to (a) the subjects, (b) the target population from which the subject is drawn, and (c) society/science expected to result from this research.

2. Provide detailed assessment of whether the potential risks of harm to the participants outweigh the benefits of the study.

5. PROTECTIONS

5.a. Confidentiality, Anonymity, & Privacy: Address **all** of the following:

1. Describe procedures for maintain confidentiality of data, *during data collection.*
2. Explain the procedures for protecting the privacy of the participants, *during data collection*.
3. Explain who will have access to the collected data.
4. Address where, how, and how long the collected data will it be stored.
5. Explain the step taken to guarantee anonymity of participants in the *reporting of the findings*.
6. *If **Yes** for #10 under PART B was selected*, and identifiable information will be reported in the findings, provide the following:
    a. an explanation of the specific identifiable information will be used in the findings;
    b. an explanation of how the identifiable data will be disseminated;
    c. extensive justification for reporting identifiable information;
    d. a thorough explanation of how participants will be protected; and
    e. an explanation of the procedures for informing participants of how the identifiable information they provide will be used.

5.b. Informed Consent Process: Address **all** of the following:

*If **Yes** was selected for #11 under PART B* and informed consent *will be* required,

1. describe who will make the initial contact with potential participants;
2. explain the procedures for reviewing the research and their rights as participants;
3. address the procedure for assessing the potential participants' understanding of what will be asked of them as well as steps taken to ensure that they understand the voluntary nature of their participation; and
4. explain how informed consent will be documented for all participants.
5. *If **any** shaded characteristics were selected for #9 under PART B*, the target population is considered a special or vulnerable population where ability to provide informed consent may be limited; therefore, specifically address the following:
    a. explain who will be granting permission for the protected subjects to participate in the study; and
    b. explain how the protected subjects will provide informed, voluntary consent.

*If **No** was selected for #11 under Part B* and informed consent *will not* be required,

1. provide assurance that the research involves *no more than minimal risk to the subjects*;
2. provide extensive justification for not requiring informed consent, and explain how the research could not practicably be carried out without the waiver of informed consent;
3. explain how the waiver of informed consent will not adversely affect the rights and welfare of the subjects.
4. explain how participants will be informed about the nature of the study, their rights as participants, and who to contact if they have questions; and
5. address the procedure for assessing the potential participants' understanding of what will be asked of them as well as steps taken to ensure that they understand the voluntary nature of their participation.

*If **Not Applicable** was selected for #11 under Part B* and informed consent *is not applicable* to this study, provide a thorough explanation for why it is not applicable.

6. SECONDARY DATA: **(***Complete **only** if #7.a. under PART B was completed* and secondary data will be used.**)**
Address **all** of the following:

a. Describe the dataset or database that will be used in the study, including the owner and/or grantor. *If planning to use TTU student data*, please review the IRB Requirements for Using Tennessee Tech Student Data.

b. Explain the reason for using this dataset/database.
c. Explain the procedure for acquiring the dataset/database.
d. Explain the specific type of information from the dataset/database that will be used for this study.
e. *If dataset is restricted (with or without identifying information about the subjects)*, describe the steps taken to protect the data.
f. *If data includes identifying information about the subjects*, describe how identifiers will be removed.

7. DATA COLLECTED FROM INTERNET/SOCIAL MEDIA: **(***Complete **only** if "Internet/Social Media" was selected under #5 under PART B*.**)** Address **all** of the following:
a. Explain from what online website(s) or social media platform(s) will data be collected.
b. Explain what specific data will be collected.
c. Explain specifically how the data will be collected.
d. Are the data anonymous? If not, explain exactly how the data will be deidentified.

*If **Yes** was selected for B.7.b.*, please answer the following:
a. Explain the process for getting permission to collect data on the platform or within the website.
- A letter of permission from an administrator with authority for approving data collection must be included with this application.
- Informed consent from each participant is required. Complete 5.b. above.

PART D. PRINCIPAL INVESTIGATOR/ FACULTY SUPERVISOR ASSURANCE
1. Principal Investigator Assurance:

In signing this, I certify that the information in this application is accurate and the research outlined in this application will be conducted ***only*** in accordance with the approved application.

I understand that, as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human participants and the ethical conduct of the research outlined in this application.

I agree to comply with all Tennessee Tech University policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human participants in research, and agree to the following assurances:

- I assure that all personnel working with human participants described in this application are technically competent for their role in the project and have completed the required CITI training modules for working with human participants.
- If funded by an extramural source, I assure that this application accurately reflects all procedures involving human participants as described in the grant/contract proposal to the funding agency. I also assure that I will notify the IRB, Office of Research, and the funding/contract entity if there are modifications or changes made to the protocol after the initial submission to the funding agency.
- I understand that it is the responsibility of the TTU IRB to perform continuing reviews of human participants research as necessary. I also understand that as continuing reviews are conducted, it is my responsibility to provide timely and accurate review or update information when requested, to include notification of the IRB when my study is changed.
- I assure that I have accurately described (in this application) any potential financial, social, professional, or any other Conflict(s) of Interest that my collaborators, the University, or I may have in association with this proposed research activity that could significantly impair my (our) objectivity, could create an unfair competitive advantage for any other person or organization, or could bias the review of this application.
- I guarantee that the project will be performed by qualified personnel according to the research protocol.
- I will maintain a copy of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets completed or collected from the human participants.
- I will promptly submit any deviation or proposed modification from the procedures detailed herein to the IRB, and await approval by the TTU prior to implementation.
- I will promptly report any ***unanticipated*** problems and/or ***adverse events*** involving risks to participants or others that involve the protocol as approved that occur during the course of conducting the research to the TTU IRB within 10 business days of the date of occurrence.

*For Internet/social media data collection **only** (if "Internet/Social Media" was selected under B.5. or B.6.):*
_____ (PI Initials) I have reviewed the policy or policies of the owner or owners of the online medium/media/platform from or through which data will be collected regarding data collected for research purposes and confirm that this application adheres to this policy or policies.

Principal Investigator's Signature:

Print Name: _____

Signature: _____

Date: _____/ _____/ 20_____

2. Faculty Supervisor Assurance:
(Required [a] if the PI is a Student OR [b] if PI and all Co-PIs are not TTU students, staff, or faculty)

By my signature as Faculty Supervisor on this IRB application, I certify that the Principal Investigator and Co-Principal Investigator(s) are knowledgeable about the TTU and federal regulations and policies governing research with human participants and have sufficient training and experience to conduct this particular study in accord with the approved IRB application.

- I have ***thoroughly*** read this application prior to it being submitted to the Departmental Reviewer for initial review.
- I agree to meet with the Principal Investigator listed above on a regular basis to monitor study progress.
- I agree to be available, personally, to supervise the principal investigator in solving problems arising during the course of the study.
- I understand that as the Faculty Supervisor, I will be responsible for the performance of this research project.

*For Internet/social media data collection **only** (if "Internet/Social Media" was selected under B.5.or B.6.):*
_____ (FS Initials) I have confirmed that the PI's research outlined in this application adheres to the policy or policies of the company or companies that own the online medium/media/platform through which data will be collected.

Faculty Supervisor's Signature:

Print Name: _____

Signature: _____

Department/Unit: _____

Date: _____/ _____/ 20_____

PART E. DEPARTMENTAL REVIEWER EVALUATION

This Section to be Completed by a Certified Departmental Reviewer

Review Category: Exempt* ☐ Expedited ☐ Full Board ☐

**If Exempt*, Specify Category for Exempt Research (Check One):

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐

(See Levels of Review and Criteria)

By signing this, I confirm that I have ***thoroughly*** reviewed the application to determine the appropriate level of review and that the application in compliance with 45CFR46.

Print Name: _____

Department/Unit: _____

Signature: _____

Date: _____ / _____ / 20_____

PART F. EXPEDITED REVIEW DECISION

This Section is to be Completed by the TTU IRB Subcommittee

Category (or Categories) for Expedited Review (if applicable): _____

This Application Has Been Approved by an Expedited Review:

Approved By: _____
Name / Signature / Date

Approved By: _____
Name / Signature / Date

Approved By: _____
Name / Signature / Date

This Application Requires a Full Board Review:

Lead Reviewer: _____
Name / Signature / Date

IRB Chairperson: _____
Name / Signature / Date

PART G. FULL BOARD REVIEW DECISION

This Section is to be Completed by the TTU IRB Chairperson

Full Board Review Convened on _____, 20_____.

Number of participating IRB Members: _____

_____ **This application has been approved by the TTU IRB.**

_____ **This application has been approved by the TTU IRB <u>with requested modifications</u>.** (See attached explanation.)

_____ **This application has *<u>not</u>* been approved by the TTU IRB.** (See attached explanation.)

IRB Chairperson: _____
Name / Signature / Date