Tennessee
TECH

Tennessee Tech University Institutional Review Board

Departmental Review Overview

Overview

- TTU IRB Team
- Background
- TTU IRB Review Process
- TTU IRB Application
- After Approval

IRB Leadership Team

IRB Chair - Dr. Chad Rezsnyak

IRB Vice Chair – Dr. Michael Adduci

IRB Resource Team

Director – Research Integrity and Compliance

Charmian Leong

Contract Compliance Specialist

Ryan Edwards

Belmont Report

- Established ethical principles for human subjects research
  - Justice – Equality in recruitment
    - Risks and rewards shared equally
  - Beneficence – Minimize risk and maximize benefit
  - Respect for Persons – Protecting autonomy
    - Informed consent

Common Rule

- 45 CFR 46
  - Originally 1991, updated 2018
- Additional regulations for vulnerable populations:
  - Pregnant women, fetuses, neonates
  - Prisoners
  - Children

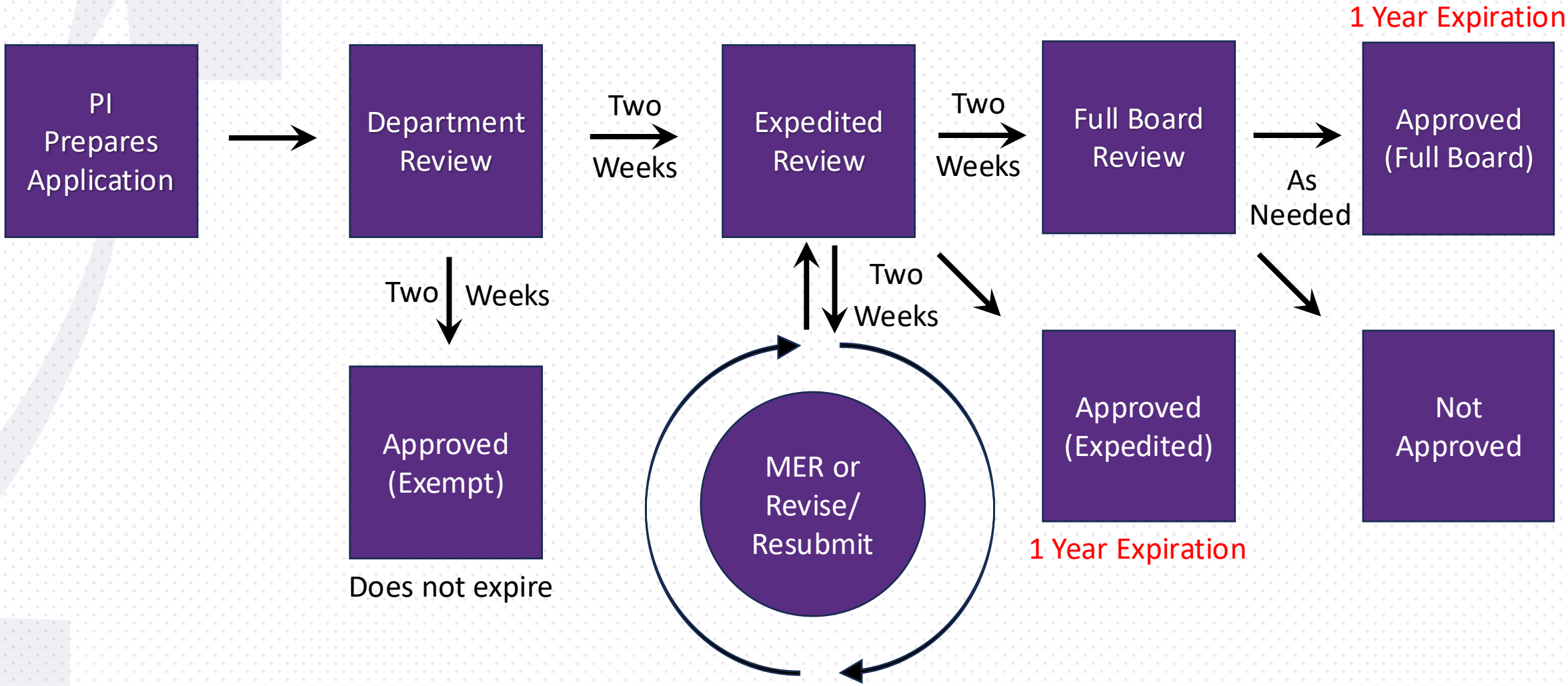
TTU IRB Role & Responsibilities

- Maintain compliance with federal law
- Protect human subjects
- Protect researchers
- Facilitate human subjects research

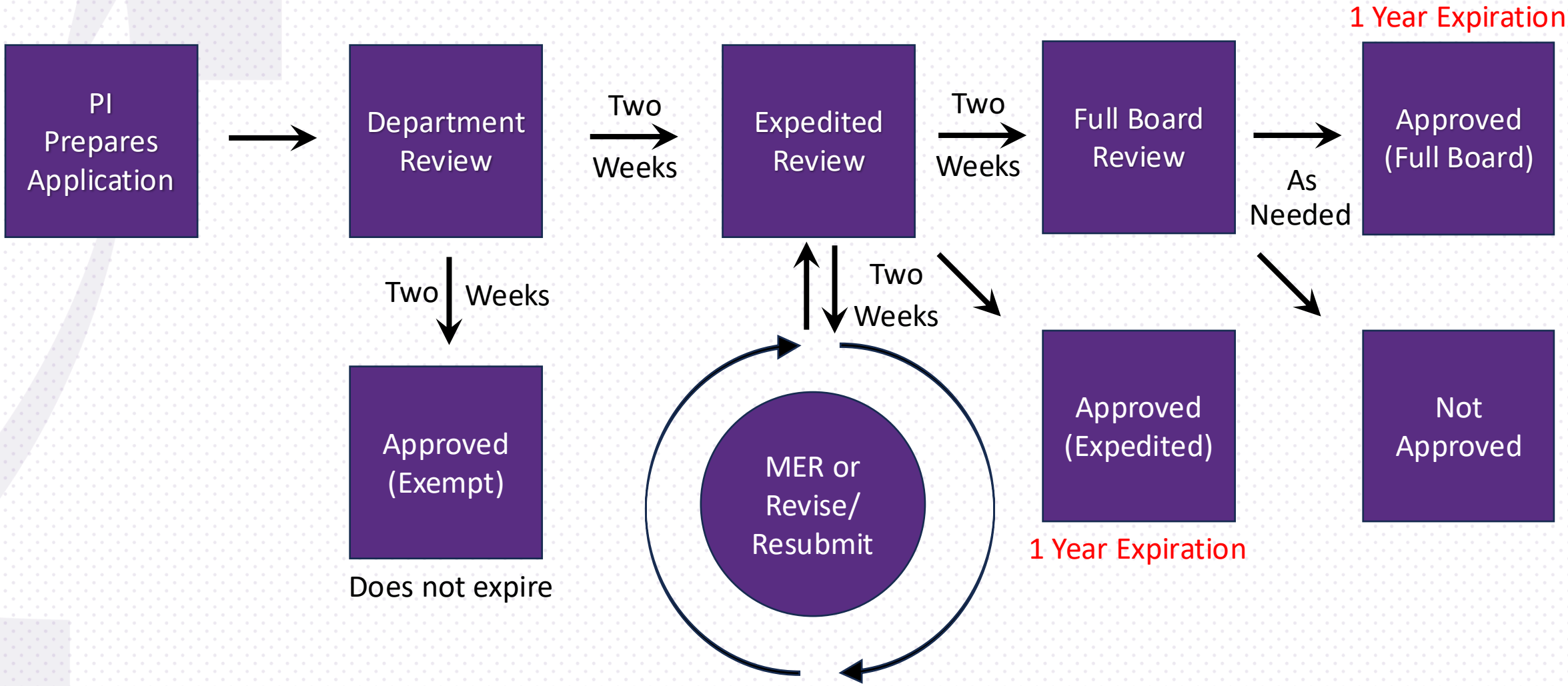
Scope of IRB Review

- Human subjects research
  - Human subjects as participants
  - Intended to **contribute to generalizable knowledge**
- Specifically excludes:
  - Classroom projects
    - **Results cannot leave the class**
  - Secondary data with approved public data sets
    - Data obtained previously now being used for research purposes.

TTU IRB Review Flowchart



TTU IRB Review Flowchart



Departmental Review

- Completed applications sent to certified departmental reviewer
- No conflict of interest
  - Has to be certified by someone other than PI
- Determine level of review
  - Exempt: “Exempt from further review”
  - Expedited: Subcommittee of three IRB members

(Some) Exempt Categories

- 1: Educational strategies in educational settings
- 2: Surveys/interviews if identities are not recorded or disclosure is not harmful
- 3: Benign behavioral interventions with adults if identities are not recorded or disclosure is not harmful
- 4: Secondary research where consent is not required

Factors Forcing Expedited/Full Review

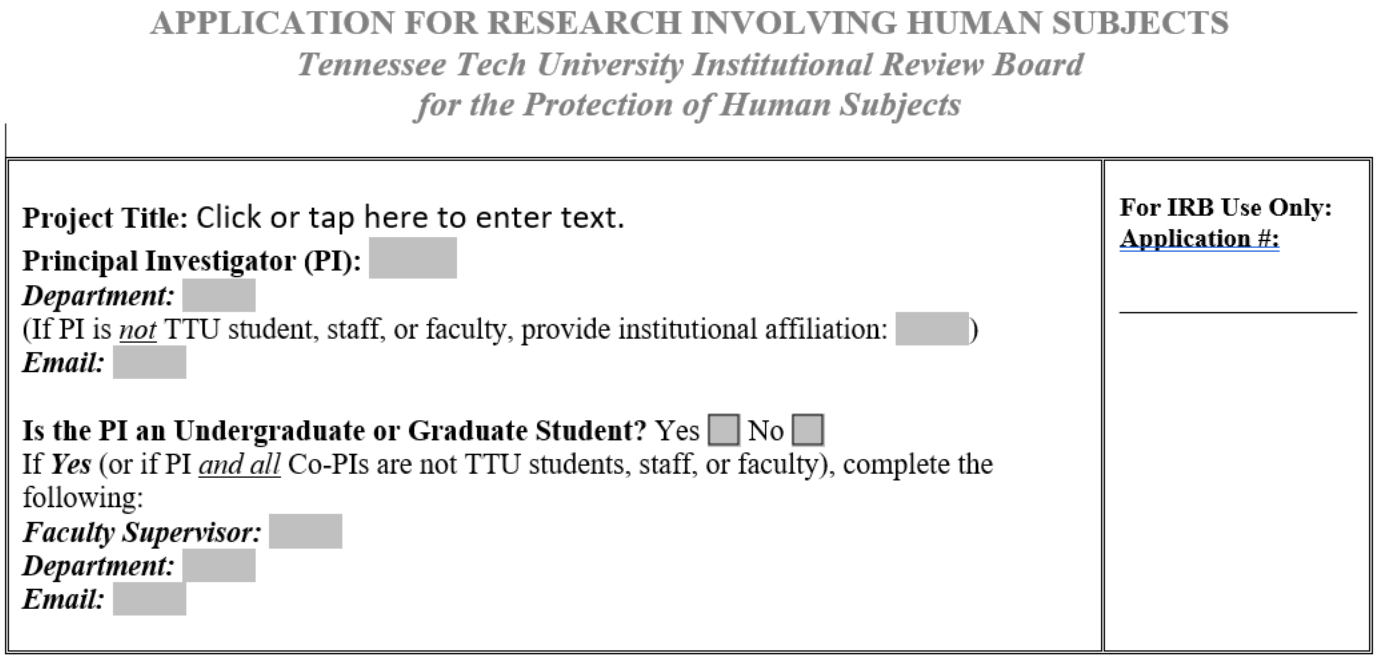
- More than minimal risk
- Protected populations
  - Children (under 18)
  - Pregnant women
  - Prisoners
- Alteration/waiver of informed consent
- Incomplete disclosure/deception

Research Design

- Design for principles & ethics, not for level of review
  - Identify research questions
  - Develop protocol to (ethically) investigate
  - Minimize risk

TTU IRB Application

- Download and complete digital fillable application from TTU IRB website.



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 #:

Application Best Practices

- Be thorough
  - Complete all appropriate fields
  - Answer each prompt
    - Identify your response to each (e.g., C.1.a.2: [response])
  - Include as much information as possible
- Be precise

A.1: Pre-Application 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

CITI Training

- Training Requirements & Access on IRB website
  - All PI's and Co-PI's
  - External collaborators need TTU-equivalent training
  - Additional training for biomedical

A.2: Documentation

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***

B: General Information

- Selections in blue trigger expedited review.
- Note: "Web-based Survey" distinct from "Internet/Social Media"

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:)

C.1: Purpose & Background

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.

C.2: Design & Methods

- First encounter with the protocol
- Time is cost

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."

C.3: Participants

- C.3.a: Characteristics
- C.3.b: Recruitment
  - Justify why only target population can participate
  - Voluntary participation – don’t single people out
  - Withdrawing consent – tricky for anonymous studies
- C.3.c: Cost & Compensation
  - Compensation/incentives need justification

C.4: Risk

- C.4.a: Risks & Potential Problems
  - Minimal risk = what would be encountered in everyday life
  - “No more than minimal risk” is ideal.
- C.4.b: Management of Risks
- C.4.c: Risk-Benefit Assessment

C.5.a: Protections

- Confidentiality – Maintaining security of data obtained from participants.
- Privacy – Participant control of access to themselves.
- Anonymity – Preventing identification of subjects & responses.
  - Remove identifiers/assign pseudonyms, report in aggregate, etc.

C.5.b: Informed Consent

- Template available on TTU IRB website.
- Must be written in language & level understandable to audience.
  - Children can provide assent; guardians provide consent.

C.6: Secondary Data

- If using student data, must be approved by university FERPA officer (Registrar)
  - Provide specific title of project and the exact data that will be requested.
  - Include letter of approval in IRB application.

C.7: Internet & Social Media

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.

After Approval

- Contact irb@tntech.edu if problems occur.
- Continuation/Change form:
  - Renew expedited/full board reviews annually if necessary.
  - Changes to protocol (e.g., participants, recruitment, etc.).

Questions?

- Contact irb@tntech.edu!

Resources

- TNTech IRB Website
- OHRP Human Subjects Protection Training
  - Decision Charts