ST. EDWARD'S UNIVERSITY

Institutional Review Board

** INACTIVE FORM **
SEU IRB Expedited or Full Board Review Application

This document can be used as a ***planning guide***, but it is no longer used for IRB proposal submissions. Instead, complete the online IRB Expedited or Full Board Review Application. You may copy/paste these answers into the online form. Contact IRB@stedwards.edu with any questions.

Student Researchers: Your faculty advisor will be required to review and approve this application and its supporting materials prior to IRB review.

Full Name of Principal Investigator:

SEU Email:

Phone number:

Mailing Address:

SEU Status: ___ Faculty ___ Staff ___ Student

Faculty Advisor Name (if applicable):
SEU students conducting human subjects research must have a faculty advisor who has endorsed the proposed research.

Faculty Advisor Email (if applicable):

Course ID and Semester/Year (if applicable):

Is this project for a dissertation? ___ Yes ___ No

Name(s) of co-investigators and their affiliations (if applicable):

PROJECT INFORMATION

1. **Project Title:**

Will this project extend beyond one (1) year?
__ Yes __ No

Do you anticipate funding for this research?
__ Yes __ No

If yes, which program or organization will provide funding (SEU or external)? How will the funding be allocated? What is the duration of the funding?

Please also explain any financial relationship and/or position of authority you might have with the funding agency. If not applicable, type N/A.

HYPOTHESIS AND PURPOSE

2. **What is this study about?**
   State the primary research question(s) of the study. What is the hypothesis, purpose, and/or goals of the proposed research?

3. **Why is this study important?**
   Describe the background and significance of the work. Use appropriate scholarly references to demonstrate the value of the proposed research.

THE HUMAN PARTICIPANTS INVOLVED IN THIS RESEARCH

You will need to prepare & submit Recruitment materials (advertising fliers, emails, etc.) and the Consent Form(s) (hard-copies and working links, if applicable). Any document that will be given to or seen by participants must be reviewed by the IRB.

4. **Do your participants include any of the following?** Select all that apply:
   __ Students enrolled in a course that you teach or supervise
   __ Children (under 18)
   __ Pregnant women
   __ Prisoners
   __ Individuals with diminished decision-making capacity
   __People living in a small, narrow, or rural community
   __People with precarious legal status
   __ No special populations included

5. **Who will be the participants?**
   Describe the **eligibility** requirements for participation. Is there any criteria for **exclusion**? List the **sources for the participant pool** and **how many** you intend to recruit. If they are students, list from which institutions you will be recruiting:

6. **What is the estimated reading level of the participants?**
   If you are recruiting adults, consider that the reading level might need to be stated as "18+ years old." Make sure your Recruitment & Consent documents are written at the appropriate level.

7. **How will you select / recruit the participants?**
   Describe your steps. Be specific about the methods & platforms used (email, social media, etc). How will you access personal information if needed for targeted recruiting? Recruitment documents must be attached to the bottom of the online application (email wording, advertising flyers, etc.).

8. **How will you obtain informed consent from participants?**
   Consent may be collected in a number of ways. Below are a few options:

   - Written signature in person.
   - Written signature through the researcher's SEU email account.
   - E-signature software (must specify which software and how the form will be securely transmitted).
   - Digital consent via a YES/NO option through a secure online platform (i.e. SEU Qualtrics).

   Consider if your protocols require a **non-English Consent Form** (If participants don't speak English) or an **Assent Form** (if participants are minors).

   Prepare the Consent Form(s) to attach to the online application. If collecting consent online, submit both a hard-copy (.docx or .pdf) and a working link. See the Forms and Templates web page for Consent Form Templates.

   Describe in detail how you will obtain informed consent:

9. **What is expected of participants?**
   Describe what participants will have to complete across the study and provide a concrete timeline. For multiple points of contact, explain what will happen in order and include a schedule.

   For all measures, describe if **in-person or online** and **how long each should take**.

   Prepare copies of these documents as .docx or .pdf files. For online surveys, you will need to submit both the working link and the list of questions as an attachment.

10. **Will you collect any of the following personally-identifiable information from subjects?** Select all that apply.
   __Names (First and/or Last)
   __E-mail addresses
   __Phone numbers or mailing addresses
   __ID numbers (student ID, social security, driver's license, etc.)
   __Audio-visual recordings or photographs
   __Bio samples, biometric, or genetic data (saliva, fingerprints, DNA, etc.)
   __Other
   __No personally-identifiable information will be collected

   NOTE: If you plan to take AV recordings of your subjects, remember to prepare and attach a completed Release of Recordings form.

11. **How will researchers protect participants' anonymity or confidentiality?**

    - "Anonymous" means participants are unidentifiable, even to the researcher. If you collect any personally-identifiable data from subjects, the research is not anonymous..

- "Confidential" means the protocols require the collection of personally-identifiable information (i.e. names, email addresses, AV recordings) and therefore must be protected from accidental disclosure.

IMPORTANT: If subjects include those in small, narrow, or rural populations, or those with precarious legal status, there might be greater need to protect confidentiality. Acknowledge and address this risk if necessary.

Describe your safeguards for each measure:

12. Will AI be used in any of your protocols?

__ Yes __ No

If YES, you are required to provide additional details below about the AI model, how it will be used, and how it handles and protects data. If you have a Consent Form, consider that any AI use and relevant data protections must be disclosed to your subjects.

a. What is the name and version of the AI tool?

b. Is this a paid license? Yes / No

c. Will the data be used for training purposes? Yes / No / Unsure

d. Please provide a link to any data security documentation or privacy disclosures provided by the AI vendor:

e. What is the purpose of using this AI tool in your research? (Check all that apply.)

___ Drafting the data collection instrument(s) and/or the consent form
___ Deidentifying data
___ Cleaning data for analysis
___ Qualitative analysis
___ Quantitative analysis
___ Revising research reports
___ Other: _____

f. For each use listed above, provide details and explain why it is important for you to use the AI tool in this way.

g. What type(s) of data will the AI process from your research protocols (e.g. personal, sensitive, public)?

h. How will data be collected, stored, and used by the AI? (The vendor should disclose how data is used by the AI tool.)

i. Describe any privacy or security risks that could arise from the AI's data handling. ("Minimal risk" must be acknowledged here.)

j. How will you ensure the data used by the AI tool is protected? (e.g. Will the data be anonymized or de-identified before being processed by the AI?)

k. How will participants be informed of the use of AI in the study and the relevant data protections? (Modify your Consent Form as needed.)

13. **Will the participants receive remuneration?** (e.g. raffle entry, gift cards, cash, snacks, merchandise, etc. in exchange for participation.)

___ Yes ___ No

If yes, explain below:

- What type of remuneration and how much?
- What are the requirements to receive it?
- How will it be distributed fairly and equally?
- What happens if subjects drop out early?
- How will you protect any personally-identifiable information connected to its distribution?

14. **Are any of the researchers (including the Faculty Advisor if relevant) in any position(s) of authority over the participants?** (e.g. participants being taught/coached, employees being supervised, etc.)

___ Yes ___ No

If yes, please explain the nature of the position of authority and what will be done to guarantee that 1) subjects' participation will still be voluntary (they will not feel pressured or coerced), and 2) there will be no consequences if subjects decline to participate.

15. **Are any non-SEU institutions/agencies involved? If yes, please explain below. If no, type N/A.**
(e.g. recruitment or funding from external colleges/universities, agencies, businesses, etc.)

- State the name(s) of the external organization(s).
- Explain how it is involved in your research.
- Explain if you have a working relationship or a position of authority within the organization(s).

Please attach official Letter(s) of Permission or Support (on the agency's official letterhead, or an email with title/headers) for your research to be recruited or conducted at all external sites.

<u>THE RESEARCH PROCEDURES</u>

Please note that you will need to include copies of all data collection instruments (tests, questionnaires, interview questions, surveys, etc.) along with this form.

16. **What is the research methodology for this study?**
Describe the research methodology you are using in this study. (e.g. qualitative, quantitative, mixed methods, etc.) Explain the grounding framework, the themes that will be analyzed, and your rationale for choosing this methodology.

17. **In what ways will you collect data?**
Summarize the data collection methods for the study. Prepare copies of all data collection instruments (tests, questionnaires, interview questions, surveys etc.)

For online surveys, submit a copy of the full list of questions in .docx or .pdf format. Please also include a working link to the survey, either here, in Q9, or attached as a separate document.

18. **Will you collect any sensitive information from subjects?**
Sensitive information includes private behavior, economic status, religious beliefs, employee on-the-job experiences, and anything which, if made public, might:

- damage subjects' self-esteem or reputation
- damage financial standing or employability
- put subjects at risk of criminal or civil liability

Examples include—but are not limited to—mental health challenges, substance abuse, sexual behavior (excluding sexual orientation and gender identity), and illegal activity.

___ Yes ___ No

If yes, this study might pose a greater than a minimal risk to participants. Please describe in detail the type of sensitive data you will collect and how that data will be protected:

19. **Describe how you will protect and secure all data during the research?**
Where will you store each data element? Who will have access to the raw data? How will it be secured?

IMPORTANT: The SEU cloud servers (Google Drive and Box) are IRB-approved for the secure storage of research data. Digital folders must have restricted access to only the research team members. **Personal laptops/computers, external hard drives, and flash drives are not accepted.**

Research emails must be conducted using the researcher's SEU email address, not a personal account; Zoom recordings must be conducted using the SEU MyHilltop VPN with participants' names hidden or de-identified with a pseudonym.

Outline your project's security details in the response below.

20. **Does your study involve deception?**

___ Yes ___ No

If yes, please describe:

- How is deception used in the protocols?
- Why is it necessary?
- Your procedures for debriefing the participants; include specific and appropriate resources, if necessary.

Prepare the Debrief to submit with the online application.

21. Are there prospective participants who, if selected, would be especially vulnerable to risk because of the study procedures?

___ Yes ___ No

If yes, describe the process that you will use to screen and/or eliminate all such vulnerable participants from your study.

22. Does your study involve procedures or ask questions that might distress your participants physically, emotionally, or psychologically, beyond what they might experience during an average day?

IMPORTANT NOTE: Researchers are expected to be competent and mindful regarding potential distress of subjects in their study. For student researchers, additional training or oversight might be required, depending on the protocols.

___ Yes ___ No

If yes, describe how you will identify and mitigate distress. Include the specific and appropriate resources you will provide to participants on the Consent Form and/or Debrief.

Attach a Debrief form to the bottom of this application, if necessary.

23. Briefly summarize the risks and benefits of the proposed project. Keep in mind that no study involving living human subjects is completely risk-free, but risks can be described as minimal.

- What are the risks to participants?
- What are the benefits to participants, if any?
- What are the potential benefits to your field of study?
- Do the benefits outweigh the risks?

24. Describe how the data will be analyzed.

Include names of anyone who will assist in the data analysis. Attach valid CITI(s) as needed.

25. **What is the long-term, secure-storage plan for each data element?** (e.g. surveys, notes, drafts, participant lists, AV recordings etc.)
Where will each data element be stored? How long will you retain the data? What is your plan for the data if/when it is no longer needed?

IMPORTANT**: By law, research data must be retained for a minimum of (3) years after study closure. Researchers may retain data for as long as it may be useful.* ***Personal laptops, computers, and external hard drives are not accepted as secure storage methods. *If data is not retained indefinitely, include your plan for destruction.*

26. **How will you share the data results?**
Please list all the potential ways in which your research results will be communicated, both inside and outside of SEU. (i.e. Honor's Symposium, dissertation defense, published journal articles, presentation at conferences, etc.):

CITI ONLINE RESEARCH ETHICS TRAINING

This project cannot be approved until CITI certificates for all investigators and faculty advisors have been received by the IRB. Please refer to the Steps To CITI Ethics Certification for instructions on using your SEU email. Please note: the average new learner spends several hours on this training.

Have all investigators and faculty advisors, including all those with access to data, completed the CITI (Collaborative Institutional Training Initiative) course as required?

__ Yes __ No

If no, please explain why:

Name(s) and CITI Expiration Date(s):

Required files to email to IRB@stedwards.edu as attachments:

1. CITI training certificates for all investigators and faculty advisors. **Please save as "CITI" [Last name]**.
2. Any recruitment materials (advertising flyers, emails, etc.) in .DOC or .PDF format. **Please save as "Recruitment" [Last name of PI]**.
3. A copy of your Consent Form. It is strongly recommended that you use one of the SEU templates at the bottom of the IRB web page. **Please save as "Consent Form" [Last name of PI]**

4. A Release of Recordings form, if any audio-visual data will be collected. **Please save as "Release of Recordings" [Last name of PI]**.

5. Copies of all data collection instruments (tests, questionnaires, interview questions, surveys etc) in .DOC or .PDF format. Note: If using Qualtrics, please submit a working link AND a copy of all questions that will be administered. **Please save as [Type of instrument] [Last name of PI]**.

6. Documentation—on official letterhead or from an official email—from institutions or agencies involved granting research permissions. (For example, a Letter of Permission to recruit students from a different university.) **Please save as [Name of Institution] "Permission Letter" [Last name of PI]**.

7. Any additional or supplementary materials for review, which could include debriefing forms, description of compensation, other materials related to the study. **Please save as [Name of Document][Last name of PI]**.