Submission Type: Initial Date: 6-12-2026

IRB #: IRB-FY2026-377
Title: Application Template
Creation Date: 6-12-2026
Status: Unsubmitted
Principal Investigator:

1- Basic Information

Preparing and Completing the Application

You do not have to finish the application in one sitting; just make sure you save frequently. As you complete the various sections of the application new sections relevant to the type of research being conducted will appear on the left; therefore, not all numbered sections may appear. You may go to another section using the menu on the left or the arrows at the bottom of each page. When adding attachments, each attachment button will allow you to add multiple documents and most common file types can be uploaded, including .pdf, .docx, and images.

Additional help information has been added throughout the form for guidance and clarity. That additional information can be found by clicking the question mark it the top-right corner of various questions. You are strongly encouraged to use this feature. Once you have answered all required sections (indicated with a red asterisk), a checkmark will appear for that section. **After all required sections are marked as complete, the option to submit the application will appear at the bottom left underneath all of the sections.**

For more information about the TWU IRB submission process, IRB tracking, and Cayuse IRB Tasks, please refer to the TWU IRB Procedures, TWU IRB website, and Cayuse help features.

*required

TWU Campus

Note: If you are a student on a different campus than your faculty advisor, your faculty advisor's campus IRB will be the reviewing IRB.

✓ Denton

Houston

*required

Is this activity research?

Research is a systematic investigation designed to test hypotheses, evaluate programs, draw conclusions, or contribute to generalizable knowledge. Research is usually described in a formal protocol that sets forth objectives and a set of procedures designed to reach those objectives.

✓ Yes

No

Unsure

*required

Does this research involve human subjects?

Does research involve a living individual about whom a researcher obtains information or biospecimens through intervention or interaction with the individual OR does the research involve data that comes from a living individual about whom the researcher obtains, uses, studies, or generates identifiable private information or biospecimens?

✓ Yes

No

2- Research & Review Type

*required

Type of Project

Select the type of project (Check all that apply).

- Thesis
- Professional paper
- Dissertation
- Class project
- Faculty research
- Pilot
- Other

*required

Study Review Category

Indicate the level of review for this study.

- Exempt
- Expedited
- Full

Drugs, Biologics, and Devices

Will the study involve administering/investigating any of the following outside of the FDA-approved use? Check all that apply.

- Drug/Supplements

Biologics

Devices

None of the above

Funding Source

Have you already received funding for this research project?

Yes

No

*required

Study Dates

Provide an estimated start and end date for this study.

*required

Estimated Start Date

This is an estimated start date. You may NOT start your study until you receive IRB approval.

*required

Estimated End Date

We will use the estimated end date you provide here as a basis for your expiration date.

*required

Does this study involve working with more than one institution's IRB?

Yes

✓ No

3- Study Personnel Information

*required

What is the Principal Investigator's status at TWU?

Faculty

Student

Staff

Other

Study Personnel

Note: If you cannot find a person in the people finder, please contact the IRB Office: irb@twu.edu.

*required

Principal Investigator

Provide the name of the Principal Investigator of this study.

*required

Primary Contact

Provide the name of the Primary Contact of this study.

Co-Principal Investigator(s)

Provide the name(s) of Investigator(s) for this study.

Other TWU Research Team Members

Provide the name(s) of other TWU research team members for this study. Note: If you cannot find a person in the people finder, please contact the IRB Office.

Human Subjects Training Certificates

If a research team member has not completed the CITI human subjects training but has a current certificate from another program (must be less than 3 years old), please attach it here.

Other Non-TWU Research Team Members

Provide the name(s), email address(es) and the role(s) of other Non-TWU research team members for this study.

*required

Please attach a human subjects training certificate for each non-TWU research team member listed.

Note: If the Non-TWU research team member has not completed the CITI human subjects training but has a current certificate from another program (must be less than 3 years old), please attach it here.

Other Research Personnel

Provide the name(s) of any other research personnel who will have access to study data (e.g., transcriber of recorded interviews, transcription agencies, phlebotomist, translator, survey analyst, etc.), but will not be included as part of the research team.

*required

Attach signed confidentiality agreement *form for each person listed.*

*required

Conflict of Interest

Do you or any research team member(s) participating in this study have a financial interest related to this research project?

Yes

No

4- Study Purpose & Research Questions/Hypotheses/Objectives

*required

Is this study a clinical trial?

- ✓ Yes
- No

*required

Type of Clinical Trial

Select the type of clinical trial below. Check all that apply.

- Randomized
- Non-Randomized
- Placebo
- Blinded
- Other

*required

Clinical Trial Phase(s)

Select the phase of the clinical trial. Check all that apply for this study.

- Pilot Study
- Phase I
- Phase II
- Phase III
- Phase IV

N/A

*required

Study Purpose

Describe the purpose of the study and/or the rationale for conducting this study.

*required

Research Questions/Hypotheses/Objectives

Provide the research question(s), study hypotheses and/or study objectives.

5- Subject Information

*required

Subjects to be Enrolled

Provide a description of the subjects in this study.

*required

Approximate Number of Subjects to be Enrolled

Please enter the estimated total number of subjects to be enrolled in this study. If your study involves different parts/phases, provide the total for each part/phase, then the estimated total for the entire study.

*required

Vulnerable Populations

Select below any population(s) that you will specifically recruit for this study. Check all that apply. If no vulnerable populations will be recruited, check "None of the Above."

- Pregnant women
- Fetuses
- ✓ Minors
- Prisoners
- Individuals with Impaired Decision-Making Capacity
- Other
- None of the Above

If you are recruiting any vulnerable populations for this study, explain the necessity of using these particular groups.

*required

Necessity of Inclusion

*required

Age (or age range)

Provide the age or age range of study subjects.

*required

Provide a rationale for the inclusion/exclusion based on age.

*required

Sex of Study Subjects

Select the sex of the subjects that will be enrolled in this study.

Female

Male

Both

*required

Ethnicity of Subjects

Will subjects be included/excluded based on ethnicity?

Yes

No

Additional/ Other Inclusion Criteria

List any other inclusion criteria to be considered for participation in the study. Provide a rationale for all inclusion criteria listed.

Additional/Other Exclusion Criteria

List any other exclusion criteria to be considered for participation. Provide a rationale for all exclusion criteria listed.

6- Subject Recruitment

*required

Secondary Data Analysis

*Will this study **ONLY** utilize secondary data for which consent is not required?*

- Yes
- ✓ No

*required

Recruitment Process

Describe subject recruitment process in detail. Include information on how potential participants will receive information about the study.

*required

Recruitment Documents/Materials

Attach all study recruitment materials you will use in this section. This includes (but is not limited to) flyers, email/phone/verbal scripts, social media posts, letters, advertisements, etc.

*required

Eligibility Screening/Testing

Will the study utilize screening/eligibility questionnaires, tests, forms to be completed by or administered to the subject?

- ✓ Yes

Explain the process for screening subjects.

*required

Attach the screening/eligibility questionnaire link(s) and/or document(s).

If uploading a survey/questionnaire link, please also upload a pdf version for IRB records.

**Note: You may only ask screening questions that will be used to determine eligibility. All other questions need to be asked after obtaining informed consent.*

No

*required

Will the subjects be told about the intent of the study prior to participating?

Yes

No

7- Study Procedures

*required

Research Procedures

Describe the research procedures in detail. (See the question mark on the right side for information that should be included here.)

*required

Will Audio/Video Recording be used in this study?

- Audio Only
- Video Only
- ✓ Both Audio and Video
- No

*required

What device will you use to audio/video record?

*required

What is the purpose of the audio/video recording?

*required

Who will have access to the audio/video recording?

*required

Is internet/email a part of the study?

Yes

No

*required

Apps, Programs, Software, etc.

Please list all apps/programs/software, etc., that you will use to manage, gather, process, or use with participant data.
(This includes, but is not limited to programs/apps such as Google Forms, Qualtrics, Zoom, Otter.ai, etc.)

*required

Artificial Intelligence (AI)

Do any of the apps/programs/software you listed above use AI?

✓ Yes

Since your study uses AI software, you must explicitly explain in your consent form that you will use Artificial Intelligence software with their data. You must also inform participants what the AI software will do with their data. You will need to look into the software's policies to see what they will do with any data loaded into their system, and inform participants of that in the consent form. The participants need to be informed that once the AI software has access to their data, there is no guarantee that the data will be protected.

---

*required

Non-TWU Study Site

Will any direct recruitment or research activity occur at a specific Non-TWU agency, institution, or organization location/site? (This does not apply to online studies.)

✓ Yes

*required

Name and location of the site(s)?

*required

Affiliation of the **Principal Investigator** to this site(s)?

If the PI has no affiliation to the site, state, "None."

*required

Affiliation of the **Subjects** to this site(s)?

Agency Approval Letter(s)

Agency approval letters are required by the IRB before data can be collected at a site. Indicate whether or not you have obtained an agency approval letter.

Yes

No

No

*required

Location/Setting of the Study

Where will the study take place? Describe the physical and privacy aspects of this location.

*required

Time Commitment

What is the time commitment for the subjects? Include the number of sessions/visits, maximum time commitment per session, and the maximum total time commitment.

*required

Subject Data, Specimens, and Records

Does this project involve the collection or use of materials (data or specimens) recorded in a manner that could identify the individuals who provided the materials, either directly or through identifiers linked to these individuals?

Yes

No

8- Informed Consent Process

*required

Questions about the Study

Subjects should be provided the opportunity to ask the researchers questions about the study at any time before, during and after the completion of the study. Describe how subjects can contact the researchers if they have questions about the study.

*required

Does this study require documented (handwritten or digitally signed) informed consent?

This is intended for studies where consent is documented with the participant's signature or typed name on a consent form.

✓ Yes

*required

Signed Informed Consent

Describe in detail the process for obtaining written/documented informed consent.

*required

Consent Form(s) Documents

Attach the study consent form(s).

No

*required

Assent of Minors

What is your process for obtaining assent?

Explain how you will obtain assent from minors even if you do not use an assent from.

*required

Assent Form

Does this study use an assent form?

✓ Yes

*required

Attach the assent form for this study.

No

9- Study Instruments & Other Attachments

*required

Study Instruments

Will any data collection instruments (e.g., data collection forms, surveys, questionnaires, interview guides, focus group discussion guides, etc.) be used in the study?

Yes

No

*required

Will the survey, interview, or other instruments ask any questions where the participant's response(s) can identify them?

Yes

No

Other Attachments

Are there other attachments (Standard Operating Procedures, Supplementary Documents, References, Device/App brochures, etc.) that you need to upload?

10- Risks & Benefits

*required

Potential Risks and the Steps to Minimize the Risks

*required

List all the potential risks to the human subjects involved in this research. All risks must be identified and listed on the consent form as well.

Please ONLY list the risks here. Descriptions and steps to minimize will be requested below.

*required

Describe how each risk will be minimized.

Make sure all steps listed here match the steps listed in the consent form.

*required

Benefits/Remuneration

*required

What direct benefits will participants receive for participating in the study?
This includes incentives (gift cards/cash), free services, access to information, and access to an intervention. If there are none, state below that there are no direct benefits to the subjects.

*required

What are the generalizable benefits of this study?

(i.e., contribution to knowledge in a particular field)

*required

Will you provide results of the study to the subjects after the completion of the study?

✓ Yes

*required

Explain how *(e.g., mail, email, posting online, etc.)* you will provide the results of the study to the subjects.

No

11- Protecting the Confidentiality of Subjects

*required

Identifiable Private Information to be Collected

List all documents, consent forms, recordings, electronic data, health records, biospecimens, etc., that contain identifiable private information to be collected in this study.

*required

Will you analyze the identifiable data listed above?

- ✓ Yes. Data analysis will be conducted on identifiable data.
- No. Data analysis will only be conducted after the data are de-identified.

*required

What software/application/program, etc. will you use to analyze the identifiable data?

(e.g., Atlas.ti, NVivo, SPSS, etc.)

*required

Storage Location of Identifiable Private Information/Data/Specimens

Where will the identifiable private information or data be stored? Describe the security measures you will take to protect the stored data.
(e.g., in a locked file cabinet with limited access, or a password protected computer.)

Storage of Signed Consent Forms

Where will signed consent form will be stored? Note, signed consent forms must be stored for a minimum of 3 years after the close of the study. They must be stored separately from the data/information listed in the section above.

*required

Electronic Transmission of Identifiable Private Information

Will the identifiable private information be transmitted electronically? (This includes, but is not limited to downloading, emailing, transferring from cloud storage to computer/hard drive/flash drive, and/or video conferencing .)

✓ Yes

*required

Explain how data will be protected during transmission.

Provide the steps/security measures you will take to protect the data during transmission.

No

*required

Identifiable Private Information Destruction Timeline

Will the documents containing Identifiable Private Information be destroyed?

✓ Yes

*required

Timeline for the Destruction

Provide a time frame for when the documents containing identifiable private information will be destroyed. (e.g., 5 years after the completion of the study.)

*required

Method(s) of Destruction

Identify specific ways that the documents containing identifiable private information will be destroyed at the end of this period of time.

No