ATTACHMENT B Submission Type: Initial Date:

IRB #:
Title:
Creation Date:
Status:
Principal Investigator:

1 - Basic Information

Preparing and Completing the Application

You do not have to finish the application in one sitting; the information will be saved and you may continue at a later time. As you complete the various sections of the application new sections relevant to the type of research being conducted will appear on the left-hand side; 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 comer of each section. You are strongly encouraged to use this feature! Once you have answered all required sections (indicated with a red asterisk), a green check mark will appear for that section (in the menu to the left). 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.

TWU Campus

Please select your campus. Note that if you are a student, you should select your faculty advisor's campus.

- ☐ Dallas
- ☐ Denton
- ☐ Houston

Is this activity research?

- ☐ Yes
- ☐ No
- ☐ Unsure
  If your activity falls under one of the following categories, it may not qualify as human subjects research, and will not need IRB review.
  - o Quality improvement (Internal program evaluation with no intent of external application or generalizability)
  - o Course related Activities/Class projects (For educational purposes only)
  - o Oral History (Non investigative and non-generalizable)
  - o Case Study (Retrospective analysis and no more than three clinical cases)

Does this research involve human subjects?

- ☐ Yes
- ☐ No
  Since this study involves no human subjects, it does not require IRB review.

2 - Research & Review Type

Type of Project

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

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

Investigator response here

Study Review Category

Indicate the level of review for this study.

- ☐ Exempt

Please check from the following list the category(ies) for which you are claiming exempt status:

- o Category 1 - Education research (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.)
- o Category 2 - Interactions (Education tests, surveys, observation of public behavior)
- o Category 3 - Benign behavioral interventions (This exemption category may not be used for research involving children.)
- o Category 4 - Secondary research for which consent is not required (Research involving the study of existing data)
- o Category 5 - Federal Research and Demonstration projects
- o Category 6 - Taste Testing and Food Quality

- ☐ Expedited
- ☐ Full

Drug, Devices, and Biologics

Will the study involve administering any of the following? Check all that apply.

- ☐ Drug/Supplements
  Please describe:

Investigator response here

- ☐ Biologics
  Please describe:

Investigator response here

- ☐ Devices
  Please describe:

  Investigator response here

- ☐ None of the above

Funding Source

Have you already received funding for this research project?

- ☐ Yes
  List the funding agency/sponsor:

  Investigator response here

- ☐ No

Study Dates

Provide an estimated start and end date for this study.

Start Date

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

End Date

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

Does this study require IRB review by more than one institution?

- ☐ Yes
- ☐ No

Will the study utilize an Institutional Authorization Agreement (IAA)?

- ☐ Yes, TWU will rely on the other institution's IRB for the review and approval of the protocol. The other institution's IRB will serve as the IRB of Record.
- ☐ Yes, the other institution will rely on the TWU IRB for the review and approval of the protocol. The TWU IRB will serve as the IRB of record.
- ☐ No, each institution will conduct its own IRB review.

Institutional Authorization Agreement (IAA): Non-TWU IRB is the IRB of Record / Non-TWU IRB Information

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Provide the information and documents requested below.

Non-TWU IRB of Record / What is the name of the other institution?
Provide the name of the Non-TWU /RB (or IRB of record)

Investigator response here

Provide name and title of the PI on the Non-TWU IRB application (If different from TWU PI).

Investigator response here

For IAAs only

Non-TWU IRB contact information:
Provide Non-TWU IRB contact information:
Federalwide Assurance #:
IRB Contact Name:
IRB Contact Number:
IRB Contact Email:
Study Protocol:

Attach the study application that was reviewed and approved by the Non-TWU IRB

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Status of the Non-TWU IRB Review

- ☐ Approved
  Attach the IRB approval notification from the Non-TWU IRB.

  ATTACH

- ☐ Approval Pending

3 - Study Personnel Information

What is the Principal Investigator's status at TWU?

- ☐ Faculty
- ☐ Student
  - o Undergraduate student
  - o Graduate student
- ☐ Staff
- ☐ Other
  Please explain

  Investigator response here

Study Personnel

Note: If you cannot find a person in the people finder, please contact the /RB Office.

Principal Investigator

Provide the name of the Principal Investigator of this study.

Name:
Organization:
Address:
Phone:
Email:

Primary Contact

Provide the name ofthe Primary Contact of this study.

Name:
Organization:
Address:
Phone:
Email:

Faculty Advisor (If PI is student)

Provide the name of your faculty advisor. This person must have a faculty appointment. Graduate Teaching Assistants may not supervise IRB protocols as the faculty advisor.

Name:
Organization:
Address:
Phone:
Email:

Co-Principal investigator(s)

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

Name:
Organization:

Address:
Phone:
Email:

**Can add multiple people as Co-PIs*

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.

Name:
Organization:
Address:
Phone:
Email:

**Can add multiple people*

Human Subjects Training Certificates

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

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Other Non-lWU Research Team Members

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

Name:
Email:

**Can add multiple people*

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 CIT/ human subjects training but has a current NIH certificate (must be less than 3 years old), please attach it here.

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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.

Name:

**Can add multiple people*

Attach signed confidentiality agreement form for each person listed.

ATTACH

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
  Provide the name(s) of the person(s) with financial interests to disclose and briefly explain their financial interest to this research project.

  Investigator response here

- ☐ No

4 - Study Design & Methodology

Is this study a clinical trial?

- ☐ Yes
- ☐ No

Type of Clinical Trial

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

- ☐ Randomized
  Describe how the randomization will be completed for this study.
  Investigator response here
- ☐ Non-Randomized
- ☐ Placebo
  Provide a rationale for using a placebo.
  Investigator response here
- ☐ Blinded
  Single-blind or Double-blind?
  - o Single-blind
  - o Double-blind
- ☐ Other
  Please describe.
  Investigator response here

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*

Study Purpose

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

Investigator response here

Research Questions/Hypotheses/Objectives

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

Investigator response here

5 - Subject Information

Subject Enrollment

Provide a description of the subjects in this study.

Investigator response here

Approximate Number of Subjects to be Enrolled

Please enter the estimated total number of subjects to be enrolled in this study.

Investigator response here

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."

- ☐ Fetuses
- ☐ Minors
- ☐ Prisoners
- ☐ Individuals with Impaired Decision-Making Capacity
- ☐ Other
  Please describe
- ☐ None of the above

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

Investigator response here

Age (or age range)

Provide the age or age range of study subjects.

Investigator response here

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

Investigator response here

Sex of Study Subjects

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

- ☐ Female
  If only females will be recruited, provide the rational for this inclusion criterion.

  Investigator response here

- ☐ Male
  If only males will be recruited, provide the rational for this inclusion criterion.

  Investigator response here

- ☐ Both

Ethnicity of Subjects

Will subjects be included/excluded based on ethnicity?

- ☐ Yes
  Describe the inclusion/exclusion criteria, and provide a rationale for inclusion/exclusion of subjects based on ethnicity.

  Investigator response here

- ☐ 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.

Investigator response here

Additional/Other Exclusion Criteria

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

Investigator response here

6 - Subject Recruitment

Subject Recruitment

Will this study ONLYutilize secondary data (is this a retrospective study)?

- ☐ Yes
  - *Explain how you will obtain the study data.*

    Investigator response here

  - *Will the secondary data be identifiable?*
    - Yes
    - No
- ☐ No

Eligibility Screening/Testing

Willthestudy utilizescreening/eligibilityquestionnaires,tests,formstobecompletedbyor administered to thesubject?

- ☐ Yes

  Please explain the process for screening subjects.

  Investigator response here

  - *Attach any screening/eligibility testing documents*.

    ATTACH
- ☐ No

Recruitment Process

Describe subject recruitment process in detail.

Investigator response here

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.*

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

- ☐ Yes
- ☐ No

  Deception Justification

  Provide an explanation of why deception is necessary and the debriefing method to be used to fully inform subjects of the study's intent.

  Investigator response here

7 - Study Procedures

Research Procedures

Describe the research procedures in detail.

Investigator response here

Is video recording a part of this study?

- ☐ Yes
  Describe the purpose of the video recording, and specify who will have access to these recordings.

  Investigator response here

- ☐ No

Is audio recording a part of the study?

- ☐ Yes
  Describe the purpose of the audio recording, and specify who will have access to these recordings.

  Investigator response here

- ☐ No

Is internet/email a part of the study?

- ☐ Yes
  Describe how the internet and/or email will be used.

  Investigator response here

- ☐ No

Non-TWU Study Site

Will the subjects be affiliated with a specific non-TWU agency, institution, or organization?

- ☐ Yes
  - o Name of the site(s)?

    Investigator response here

- Affiliation of the Principal Investigator to this site(s)?
  If the PI has no affiliation to the site, state, "None."

  Investigator response here

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

  Investigator response here

- 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
    Attach the signed agency approval letter/s on letterhead from each agency or written documentation of the agency's approval.

    ATTACH
  - No
    If agency approval cannot be obtained prior to submitting the IRB application, explain here.

    Investigator response here

☐ No

Location/Setting of the Study

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

Investigator response here

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.

Investigator response here

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

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 you if they have questions about the study.

Investigator response here

Does this study use signed informed consent?

This includes obtaining a signature (including electronic) on a consent form

- ☐ Yes
  - o Signed Informed Consent
    Describe in detail the process for obtaining written informed consent.

    Investigator response here
  - o Signed Consent Form Storage
    Describe where you will securely store signed consent forms (must be in a secure location). Explain how long the consent forms will be kept (must be maintained for a minimum of three years from the study close date). Describe howyou will destroy the signed consent forms after this period. Note that copies of signed consent forms must be submitted to the /RB when you submit your study close request.

    Investigator response here
  - o Consent Form(s)
    Attach the study consent form(s).

    ATTACH
- ☐ No
  - o Other Consenting Procedures
    If you will not use a signed consent form provide a detailed rationale, and describe the process for obtaining informed consent.

    Investigator response here
  - o Consent Information Document
    Attach the informational document to which participants can access in order to provide informed consent.

    ATTACH

Assent of Minors

Does this study use an assent form?

☐ Yes

Attach the assent form for this study.

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☐ No

Provide a rationale (if applicable) for not using an assent form.

Investigator response here

9 - Study Instruments

Study Instruments

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

- ☐ Yes

  Please attach all data collection instruments here.

  ATTACH

- ☐ No

Will these instruments record any information that can identify the subjects?

- ☐ Yes

  Please justify why the instruments need to record identifiable information.

  Investigator response here

- ☐ No

10 - Risks & Benefits

Potential Risks and the Steps to Minimize the Risks

List all the potential risks to the human subjects involved in this research. All risks must be identified and listed on the consent form (if applicable).

Investigator response here

Describe how each risk will be minimized.

Investigator response here

Benefits/Remuneration

What will the subject receive for participating in the study?
(i.e., financial remuneration, free services, access to information, and access to an intervention) If there are none, state below that there are no direct benefits to the subject.)

Investigator response here

What are the generalizable benefits of this study? (i.e., contribution to knowledge in a particular field)

Investigator response here

Study Results

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

- ☐ Yes

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

  Investigator response here

- ☐ No

11- Protecting the Confidentiality of Subjects

Identifiable Private information to be Collected

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

Investigator response here

Storage Location and Protection of Identifiable Private Information

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.)

Investigator response here

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

  Explain how data will be protected during transmission.
  Provide the steps/security measures you will take to protect the data during transmission.

  Investigator response here

- ☐ No

Identifiable Private Information Destruction Timeline

Will the documents containing Identifiable Private Information be destroyed?

- ☐ Yes

  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.)

  Investigator response here

  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

  Investigator response here

- ☐ No

  Indefinite Storage
  If the documents containing identifiable private information will be stored for an indefinite period of time, please explain.

  Investigator response here