Office of Sponsored Programs and Research
Webb Hall – 228B
Livingston, AL 35470
205-652-3403

UWA IRB – New Protocol Application Form

Instructions for all new research involving human participants

Step 1. Complete an **IRB – New Protocol Form**. All persons performing research with human subjects must fully complete this form.

Step 2. Include copies of the tools you may use in the project including participant recruitment materials, data collection instruments, or any other special approvals or permissions needed to conduct your research, such as letters of support or a statement from the head of the organization from which you are recruiting.

Step 3. Complete the **IRB – Informed Consent Form**
The informed consent document is a voluntary agreement to participate in research. This requirement applies to all adults age 19 and older (see Step 4 for participants under age 19). Informed consent is not simply a signed form, but a process in which the participant is informed about the study, including its purpose, procedures, and potential risks. According to the HHS Revised Common Rule, informed consent must begin with a *concise and focused presentation of key information* that will help potential participants decide whether they wish to take part. The information should be organized and presented in a way that promotes understanding and supports thoughtful decision-making. The goal of informed consent is to provide participants with the knowledge they need to make an informed choice about involvement in the study. This includes clearly communicating their rights and responsibilities. Participants must sign the form as confirmation of their agreement to participate.

Step 4. As needed, complete an **IRB – Waiver of Parental Consent and/or Child Assent Form**, **Parental Consent Form**, **Child Assent Form**
Individuals under the age of 19 are considered children and cannot legally provide informed consent to participate in research. Researchers must obtain parental consent and, when appropriate, child assent—the child's affirmative agreement to participate based on their age, maturity, and ability to understand the study. The IRB may grant a waiver of parental consent or child assent in certain circumstances, such as the research involves no more than minimal risk, obtaining parental permission or child assent is not practicable (e.g., anonymous surveys, online studies, or sensitive topics), the waiver will not adversely affect the rights or welfare of participants, or the research provides direct benefit to the child that is available only in the research context. If a waiver is not approved, researchers must obtain parental consent from the parent or legal guardian and, when appropriate, child assent for all research involving children, including exempt or expedited studies.

Step 5. Attach your **Collaborative Institutional Training Initiative (CITI) Certifications**
UWA subscribes to the CITI Program to provide required compliance training, ensuring that all researchers meet institutional and federal requirements. Certifications in the Human Subjects Research Course and the Responsible Conduct of Research Course are required.

Submission Information: All students will have the New Protocol Application signed by their faculty advisor (generally, the instructor for the class for which the research is due). Before submitting, make sure all steps have been completed. To submit your application and required additional documents, or if you have questions, email Caroline Stanton, Compliance and Research Officer, cstanton@uwa.edu.

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1. General Information

For all studies

1.1 **Project Title:**

1.2 **Principal Investigator (PI) Full Name:**

College/Division and Department/Unit:

Status: ☐ Undergraduate Student ☐ Graduate Student ☐ Postdoctoral Fellow

☐ Faculty ☐Staff ☐Other:

1.3 **Faculty Advisor Full Name:** (Required for student PIs):

1.4 **UWA research team members:**

Name (First Last)	College & Department

1.5 **Collaborations**

Will researchers from other institutions be involved in this project? ☐Yes ☐No

Has another IRB or ethics board reviewed the study, or will in the future? ☐Yes ☐No

If "Yes", provide details (name of IRB, approval date or estimated timing of future review, etc.). If already obtained, provide the approval letter when you submit this protocol application.

Non-UWA research team members:

Name (First Last)	Email	Affiliated Institution & Address

1.6 **Funding Information:**

Indicate if any part of your project is funded by a sponsor. Funding could be from a gift or a sponsored project.

☐ Funded ☐Pending Proposal ☐Not Funded

Funded projects or pending proposal, please provide:

a. Name of funding source (example, NIH, ED):

b. Award number (found on grant award) or funding opportunity number (found on the NOFO):

1.7 **Financial Conflict of Interest Disclosure**

Please see the UWA Policy on Financial Conflicts of Interest.

Have all UWA faculty listed on this protocol (including faculty advisor) disclosed their external commitments and financial interests as required by UWA policy, including any that are reasonably related to this research project? ☐Yes ☐No

For all personnel listed on this protocol: Do any of the personnel, their spouses/partners, or dependent children have any significant financial interests that are reasonably related to this research?
☐ Yes ☐No

For all personnel listed on this protocol: Do any of the personnel, their spouses/partners, or dependent children have any personal financial interest or commitment with any company or entity that sponsors, supports, or provides materials or data for this research? ☐Yes ☐No

1.8 **Project Description: Provide a summary of the project, including its purpose, objectives, research questions, hypothesis, and significance.**

1.9 **Benefits: Describe how this study will contribute to existing knowledge and explain any potential benefits, both to participants (individual or group) and to society or the scientific community.**

1.10 **Risks: Describe any potential risks to participants form study procedures or from a breach of confidentiality (e.g., anxiety, fear, discomfort), and how these risks will be minimized.**

1.11 **Research Design and Methodology: Describe the research design (e.g., qualitative, quantitative, or mixed methods). How will you perform your research and why do you expect it to be valid?**

1.12 **Study Procedures: Data collection tools (surveys, interviews, interventions, etc.) and locations of the study.**

1.13 **Participants:**

a. Describe participant groups and how they are fitting for the proposed research.

b. Target population (age, gender).

c. Inclusion/exclusion criteria.

d. Recruitment methods.

e. Anticipated number of participants.

f. Vulnerable groups that may be encountered in subject population (additional protections that will be put into place to ensure rights and welfare of such groups are protected).

1.14 **Data and Specimen Collection:**

Does your study involve active* collection of data, human biospecimens, or physiological data? ☐Yes ☐No

**Data collected by an investigator/agency for a specific purpose*

If "Yes", provide the needed information in Section 2 below.

Does your study involve secondary* use of data or human biospecimens? ☐Yes ☐No

**Data originally collected by someone else for another purpose but now being reused.*

If "Yes", provide the needed information in Section 3 below.

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2. Active Collection of Data, Human Biospecimens, or Physiological Data

2.1 **Describe what type of data, human biospecimens, or physiological data you will actively collect and how it will be collected.**

3. Secondary Use of Data or Human Biospecimens

3.1 **Explain where the data or specimens come from (e.g., medical records, prior studies, etc.) and how you will obtain them.**

3.2 **Provide confirmation that a data use agreement has or will be signed.**

3.3 **Provide any special permissions needed for access to or storage of data/biospecimens (e.g., letters of support, etc.).**

3.4 **Provide the date range of when the data/specimens were originally collected.**

3.5 **Clarify whether original consent included future use, or if a waiver of consent is being requested.**

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4. Privacy and Confidentiality Information and Procedures for All Studies

For all studies

4.1 **Select the identifiers that researchers will collect or record (Note: we recommend collecting/recording the minimum identifiable data needed for your research.)**

- ☐ Name
- ☐ Full date of birth
- ☐ Mailing or email address
- ☐ Phone or fax numbers
- ☐ Social Security number
- ☐ License or Vehicle ID
- ☐ IP address
- ☐ Biometric identifiers
- ☐ Photos/images/audio recordings
- ☐ Signatures, handwriting samples
- ☐ Medical records
- ☐ Other identifier

☐ No member of the research team will have access to any personal identifiers. (*Select this option only if you have not selected any of the others above.)* **If no identifiers are being collected or recorded, skip to Section 5: Investigator Attestation.**

4.2 **Describe why each identifier is required.**

4.3 **Data Security Practices: Select all that you will follow, if relevant and appropriate for your study:**

☐ Datasets will be de-identified. Data elements will be separated into a coded data set to be used for research purposes and a "key" to be kept under researcher's control.

☐ PI will maintain a list of individuals who have access to the data.

☐ Access to identifiable information will be controlled: all electronic devices used by the research team will be password protected, and data will not be saved on researcher's mobile devices.

☐ Any physical data/materials will be kept under lock and key (in locked cabinets or access-controlled offices).

☐ Identifiable data will only be saved in approved, encrypted file share locations (e.g., Dropbox, etc.).

☐ If data containing personal identifiers will be stored on a laptop or tablet, either the data or the whole device will be encrypted.

☐ Identifiable data will be encrypted if it is stored on a networked computer or device or stored on or transmitted via the web.

☐ Each authorized person will access research data using an account assigned for their own use, rather than shared or group accounts.

Please provide any additional information you would like to share about your data security plans:

4.4 **Describe how and where research data will be stored and accessed by the research team?**

4.5 **What do you plan to do with the research data? Select all that apply:**

☐ No plans to share the data with anyone outside the research team. Will securely keep the data under my control and destroy the data after any publications from this project are done.

☐ Store the data with identifiers for future research. (This will require additional consent – Broad Consent – from participants.)

☐ De-identify the data and store it for future research using security methods described here.

☐ Share data with identifiers with other UWA or non-UWA researchers or in a common data repository. (This will require additional consent – Broad Consent – from participants.)

☐ De-identify the data and share with other UWA or non-UWA researchers or in a common data repository.

☐ De-identify the data and make it publicly available to meet sponsor and publication requirements.

☐ Other (describe)

4.6 **Will names or other identifiers be used in publications or presentations?**

4.7 **If there is any other information to share about your study that you haven't provided, provide it here:**

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5. Investigator Attestation

For all studies. To be signed by the Principal Investigator (PI). If the PI is a student, the faculty supervisor must also sign.

Principal Investigator:

I certify that the information I provide in this application is correct and complete. I also pledge that I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the Institutional Review Board for Human Participants.

Printed name of PI:

Signature of PI:

Date:

The faculty supervisor must either sign this document or email the attestation below by email. For the latter, copy the attestation statement, include the student investigator's name and project title in the email, and send it to cstanton@uwa.edu

I have examined this completed form, and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of the research participants. I will take responsibility for providing supervision of the student; for informing her/him of the need for safekeeping of all raw data (e.g., surveys, questionnaires, interview notes, video/audio recordings, test protocols, etc.), as well as the signed consent forms, in a university office or computer file; and for overseeing all compliance with the IRB's policies and procedures.

Printed name of Faculty Supervisor:

Signature of Faculty Supervisor:

Date: