Office of Sponsored Programs and Research
Research Integrity Program
Webb Hall –Station 47
Livingston, AL 35470
Ph. 205-652-5392

UWA IRB – New Protocol Application Form

Instructions

Use this form for **all new research projects involving human participants,** regardless of the anticipated level of IRB review (i.e., exempt, expedited, or full board).

Form Organization: Different sections apply to different types of studies; follow the instructions on the section headings.

About the submission process:

- Submit the completed form to the IRB office via email (rgranec@uwa.edu).
- Include the following materials:
  - CITI Responsible Conduct of Research training certification
  - Project Description
  - Informed Consent
  - Study Procedures, including copies of the tools you may use in the project
  - Waiver of Parental Consent, if necessary
- For your information, IRB policies, guidance documents, and consent form templates can be found on the OSPR website.
- To avoid delays in the time it takes to process protocols, please ensure that PIs and everyone on a research team has completed online responsible conduct of research training. CITI certifications are valid for three years.
- If you have questions about the process, contact the IRB office (rgranec@uwa.edu), 205-652-5392.

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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 ☐ Not Funded ☐ Pending Proposal

If the project has been funded or there is a pending proposal:

Name of funding source:.

OSPR Number*:

*OSPR number is the UWA tracking number for sponsored projects. If you are unsure of the OSPR number, contact your sponsored programs office.

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 **Brief lay summary of purpose, research questions, and hypothesis:**

1.9 **How will this study contribute to existing knowledge?**

1.10 **Type of Study:**

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", answer the questions 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", answer the questions in Section 3 below.

2 Active collection of data, human biospecimens, or physiological data

3 Secondary use of data or human biospecimens

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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: Documentation Checklist.**

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 researchers' 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 publically 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 Documentation Checklist

For all studies

This is a list of the additional documentation that you may need to submit alongside the completed protocol application form:

For active data/biospecimens collection:

- Project Description
- Informed Consent
- Participant Recruitment Materials
- Data Collection Instruments
- Other IRB/ethics board approval letters
- Any other special approvals or permissions needed to conduct your research
    - Letters of Support
    - Head of organization that your or studying or from which you are recruiting

For secondary use of data/biospecimens:

- Confirmation that a data use agreement has or will be signed
- Any special permissions needed for access to or storage of data/biospecimens (e.g., letters of support, etc.)

For all types of research:

- Documentation of human participants' ethics training for any non-UWA research team members. UWA personnel training will be checked directly through CITI.

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6 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 send the attestation below by email. For the latter, copy and paste the attestation statement, include the student investigator's name and project title in the email, and send it to rgranec@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: