Application for Use of Human Subjects in Research at Walla Walla University

Walla Walla University (WWU) is dedicated to the protection of human participants in all research conducted by faculty, staff and students. This dedication includes the protection of the right to privacy, the protection of confidentiality, the protection of informed consent, and the protection from physical, psychological, spiritual, and social harm for any individual or group participating in qualified research.

The aim of the Ethics in Research Committee (EIRC) is to ensure the protection of the rights of human subjects participating in research project conducted by WWU faculty, staff, and students. This is accomplished through the review and approval process of all research activities that involves the use of human subjects.

There are three levels of review (exempt, expedited, full) for EIRC applications determined based on the amount of risk to the participants in accordance with university policy. Students that are participating research projects as part of a class assignment where the project is not intended for public presentation at professional conferences or publication nor involves the use of human participants will work directly with your instructor to review the suitability of the research and as needed refer the project for EIRC review. This level of review is not intended for theses or dissertations.

Investigators may not solicit subject participation or begin data collection until they have received EIRC approval.

Application forms are available on the internet at EIRC.wallawalla.edu. The form may be downloaded and completed but must be submitted in electronic copy. If you have questions about the EIRC application form or about the review process, contact:

Kari Firestone, PhD, RN, CNS
Chair, Ethics in Research Committee
Phone: 509-527-2462/Email: kari.firestone@wallawalla.edu

To apply for review, submit an electronic copy of the completed application and project proposal to the chair of the EIRC. Complete all application questions and provide an electronic signature. To ensure that your application submission is complete, please also submit (only PDF and Word files are accepted):

• Study proposal
• Any research instruments (tests, surveys, questionnaires, protocols, or any form used to collect data)
• All informed consent documents
• Copies of any recruiting materials (flyers, text of E-mail, or web-based solicitations)
Part I: Administrative Information

Principal Investigator Information

Name:
Email Address:
Phone #:
Department:

Role at WWU:
☐ Faculty ☐ Staff ☐ Undergraduate Student ☐ Graduate Student ☐ N/A, specify:

Students only – Name of Supervising Faculty:

Study Overview

Title of Research Project:

Proposed Start Date (month/date/year):

Anticipated Completion Date (month/date/year):

Indicate the intended use of your data? Check all that apply.

☐ Publication/journal article
☐ Class report
☐ Professional Conference
☐ Student conference
☐ Thesis or dissertation
☐ Results released to agency or organization.
☐ Other (explain below)

Project abstract (200 words or less):
Funding Information

Has funding been already awarded for this project? ☐ Yes ☐ No

Will funding be requested for this project? ☐ Yes ☐ No

Source of funding (if applicable):

  Internal funding: ☐ Yes ☐ No

  Source: ☐ Department funds ☐ Personal funds ☐ Other (describe below)

  External funding: ☐ Yes ☐ No If yes, list funding source:

Review Category

Please check the box that indicates the review category that you believe your research study fits into (final determination made by EIRC):

☐ Exempt: Proposals for research that pose no risk to participants. Very few proposals will fall under this category. These studies include educational research (i.e. evaluating the use of accepted or revised standardized tests, testing or comparing a curriculum or lesson).

☐ Expedited: Expedited review is intended for projects that pose minimal physical, psychological, economic, and social risks to the participant and comply with the standards of informed consent, privacy and confidentiality, and appropriate balance of risks and benefits. These studies involve the use of secondary research data (i.e. data collected by someone else as part of medical or school records, information gathered from an existing database, or data that someone else has already collected via survey, test, etc.).

☐ Full: This is the default procedure for all research projects involving human participants. Proposals for research involving more than minimal risk are subject to a full review. These studies include projects involving any moderate to serious physical, emotional, psychological, legal, social or economic risk to participants. Projects involving sensitive questions or invasive procedures. Projects involving vulnerable populations where a disparity in power exists between the research and the participants, or the participants capacity to consent may be affected (e.g. individuals with cognitive or intellectual disabilities, children, the elderly). Projects where there is a potential for coercion (e.g. studies involving “captive” groups such as employees, students, prisoners, etc.)
Provide a brief, one paragraph, background and rationale for the study.

In layman terms, state the research question to be answered by this study.

**Description of Research Sample & Recruitment:**

Indicate the total number of subjects you require, and your sampling procedure:

Describe the group to be studied including: age range, gender, ethnic background, and source of subjects required (e.g. psychology classes, patients at a hospital, single parents that are members of a community group, etc.):

Method of recruitment. How will potential subjects be identified and selected (attach any recruiting materials you plan to use such as flyers, text of E-mail, or web-based solicitations). Select all that apply:

- [ ] Postings, Flyers
- [ ] Radio, TV
- [ ] E-mail solicitation, how were addressed obtained:
- [ ] Web-based solicitation, indicate site(s):
- [ ] Other, please specify:

Provide an estimate of the amount of time that will be required from each person that participates in this research study (e.g. number of sessions, amount of time per session, and duration of time over which the study will take place):
Please select the best answer:

☐ Yes  ☐ No  Will any subjects be minors (18 years or less in age)? If yes, please attach a Child’s Assent Form.

☐ Yes  ☐ No  Will any subjects be prison inmates?

☐ Yes  ☐ No  Will any subjects be physically, cognitively or intellectually disabled?

☐ Yes  ☐ No  Will any subjects be unable to make informed decisions about participation?

☐ Yes  ☐ No  Will any subjects be from another vulnerable or at-risk group not previously noted (e.g. students, pregnant women, economically disadvantaged persons, substance abuse population)?

☐ Yes  ☐ No  Will any ethnic group or gender be excluded?

☐ Yes  ☐ No  Will any subjects not be fluent in the use of the English language?

☐ Yes  ☐ No  Will any subjects be compensated (e.g. money, t-shirt, extra credit, etc.) for the study? If yes, what is the amount and type of compensation:

☐ Yes  ☐ No  Does the proposed research require that you deceive subjects in any way? If yes, explain why deception is necessary and how participants will be debriefed about the deception after the completion of their participation in the study:

☐ Yes  ☐ No  Will there be any cost to the subjects? If yes, please explain:

Study Methods

Briefly discuss the research methods and/or procedures that involve the use of human subjects. How will these methods allow the investigator to address the study purpose/research questions?

If actively collecting data, please select ALL planned methods of data collection:

☐ In-person individual interviews
☐ In-person surveys
☐ Paper mail surveys
☐ Telephone surveys
☐ Internet surveys
☐ Use of social networking sites
☐ Data collected using other electronic devices (e.g. cell phones, text, etc.)
☐ Direct observation
☐ Cognitive or behavioral measures including daily diaries
☐ Focus groups
☐ Audio/video recording
☐ Anthropometric measures (e.g. height, weight, waist circumference, BMI, etc.)
☐ Self-health monitoring (e.g. pedometers, food diaries, etc.)
☐ Examination of archived data and/or records (e.g. academic, medical, legal, etc.)
☐ Other activities or interventions. Please describe:
Part III: Risks and Benefits Assessment

Does your research address culturally or socially sensitive issues?  ☐ Yes ☐ No

Are there any risks involved with this study?  ☐ Yes ☐ No

Describe any risks (physical, psychological, social, legal, etc.) that the research subject may encounter by participating in this study. Also describe how you plan to minimize these risks (e.g. stress, discomfort, embarrassment, invasion of privacy, legal risks, side-effects):

In the event of that any of these potential risks occur, how will it be handled? (e.g. compensation, counseling)?

Will this study interfere with any of the subjects’ normal routines?  ☐ Yes ☐ No  If yes, explain:

Describe any anticipated benefits of this study to the individual subject, to society, and/or academic knowledge:

Part IV: Privacy, Confidentiality and Informed Consent

Describe how (oral or written) and when voluntary consent will be obtained from participants. Include who will be responsible for obtaining consent from participants and who will be providing consent (e.g. the participant, a parent, guardian, etc.):

☐ Yes ☐ No  Will personal identifiers be collected?
☐ Yes ☐ No  Will identifiers be translated to a code, separated or removed from the data?
☐ Yes ☐ No  Will recordings be made (audio, video)?
☐ Yes ☐ No  Will the results of this research be made available to the subjects involved?

Data collected will remain (select one): ☐ anonymous ☐ confidential ☐ intentionally identified, please explain:

*Note: If individually identifiable information such as images (video or photos), audio recordings, names or notable descriptions of participants will be published, shared or otherwise disseminated, the consent form must make this explicit to the participant.
Describe how and where the data will be kept so that the data remains confidential and secure:

List who will have access to the data:

How will the data be destroyed (e.g. erasure of tapes, shredding of data) and at what point in time:

Attach copies of all written consent forms and/or the script language for oral consent. Please use the consent templates available.

The informed consent (written forms or script language for oral consent) must include:

- Title of study (title should match the title listed on this form – if not, explain why)
- The purpose of the research
- A description of the research procedure
- Location where the research will take place
- Length of time the participant is expected to participate
- A description of any potential risks to the subject, including physical, psychological, social harm, discomfort, or inconvenience
- Whether identifying information will be collected, and if so, how it will be kept confidential
- Benefits of the research to society and/or to the individual
- How confidentiality of records identifying the participant will be maintained (including where the data is stored, who has access to the data and how long the data will be kept)
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled
- A statement that the subject may withdraw from the study at any time without penalty
- Who to contact for answers to questions about the study, their rights as research subjects or in the event of a research-related injury or emergency (e.g. PI, Faculty Sponsor)
Principle 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 EIRC.

Signature of the Principle Investigator

Date

Faculty Sponsor Approval (required for all students): I affirm the accuracy of this application and I accept responsibility for the conduct of this research, supervision of human subjects, and maintenance of informed consent documents.

Signature of the Faculty Sponsor

Date

Attachments Included Check List (as appropriate):

☐ Project proposal
☐ Data collection instruments (tests, surveys, questionnaires, protocols, focus group guides or any form used to collect data)
☐ All informed consent documents
☐ Copies of any recruiting materials (flyers, text of E-mail, or web-based solicitations)

This box is for Walla Walla University’s – EIRC Office Use Only

Date Received: ______________________  ☐ Exempt  ☐ Expedited  ☐ Full Review

Date Approval Sent: ______________________

EIRC Committee Chair Signature: ___________________________________________________