

Ethics in Research Committee (EIRC) Human Subjects in Research Policy

Policy Statement 2020

Walla Walla University 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 EIRC is guided by the ethical principles regarding the use of human participants in research as established in the April 18, 1979, report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" commonly known as The Belmont Report. These include (1) respect for persons as autonomous agents, (2) beneficence, or the effort to assure the well-being of the subject, and (3) justice or fairness in distribution.

Purpose: The purpose of the Ethics in Research Committee is to oversee and review all research involving the use of human subjects associated with WWU.

The EIRC seeks to ensure the protection of the rights of human subjects participating in research projects, conducted by WWU faculty, staff and students. This is accomplished through the review of all research that involves the use of human subjects. Therefore, the purpose of the Ethics in Research Committee is to facilitate ethical academic research conducted by faculty, staff and students that protects research participants from unintended harm, especially in the areas of informed consent and confidentiality. This protection is assured by the consideration of the following:

- **Informed Consent.** Subjects will be given full information concerning possible benefits and risks in a comprehensible manner that assures voluntary participation. No coercion will be used, and subjects will be free to withdraw.
- **Assessment of Risks and Benefits.** An appropriate balance between potential benefits of research to the individual or society and the risks assumed by the subjects should be assessed. Risks should be minimized to those necessary to achieve the research objective and must be carefully justified. All potential risks must be clearly communicated to the subjects.
- **Selection of Subjects.** Care will be given to the selection of subjects to assure fairness, so that benefits and risks are not distributed unevenly to a particular social group. In addition, extreme care must be exercised in using children as subjects. Consent must come from both the parent and the child (as appropriate to its age).
- **Valid Scientific Methods.** Research that is not scientifically valid may expose the participant to risks of harm without the possibility of benefit from findings.

Responsibility: The WWU EIRC was established by and answers to the Vice President for Academic Administration.

Accountability:

The WWU EIRC is directly accountable to the Associate Vice President for Graduate Studies.

Assumptions and Functions:

- All research involving the use of human subjects is to be evaluated reviewed and approved at some level prior to its being conducted participant recruitment and data collection.
- If the topic is a deemed sensitive one (such as one regarding sexual activity, use of illicit drugs, heretical theological views, etc.), the proposal should may be reviewed by both the EIRC and the President's Cabinet as well.
- If not, it should be reviewed by the sponsoring department. Research conducted under the student research and class project level of review may be subject to review by the EIRC. However, if not, the course faculty assumes responsibility for the ethical treatment of participants in accordance with WWU's dedication to the protection of human participants.
- If the study Research that is likely to result in public presentation or peer-reviewed publication, even as part of a class assignment, it will be reviewed by the EIRC.
- Research in which the identity of the participants is not recorded or stored by the researcher and is using archival data only, does not need approval by the EIRC.
- If a WWU faculty member is collaborating with a member of a different institution on a research project, and that project has received IRB approval from the other institution, the WWU faculty member may submit the IRB approval to the EIRC for expedited review.
- Internal or departmental surveys used for self-study, and are not for public dissemination do not require EIRC approval.
- All research data collected must be recorded in a manner that the human subjects cannot be identified directly or indirectly.
- The confidentiality of all personally identifiable data must be managed throughout the research and thereafter.

Functions:

Review all research proposals to determine the level of review required for approval. Levels of review used for the approval of human participant research is as follows:

- **Exempt:** Proposals for research that pose no risk to participants. Very few proposals will fall under this category. Exempt review typically takes 1-2 weeks from the time the application is received.

Exempt categories include the following:

- 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. Expedited review typically takes 2-3 weeks from the time the application is received.

Expedited review is intended for projects that:

- Involve secondary use of research data (no EIRC review is required for the use of previously collected, publicly available, anonymously collected data)
- **Full Review:** 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. A full review typically takes 4 weeks from the time the application is received.

The following are examples of research that may require a full EIRC review:

- 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).
- Projects where there is a potential for coercion (e.g. studies involving “captive” groups such as employees, students, prisoners, etc.)
- **Student Research and Class Projects:** This level of review is intended for students that are participating in research projects in order to learn the research process to ensure that these assignments consider ethical and procedural concerns associated with research. The criteria for projects that would fall under this level of review is as follows:
 - The purpose of the assignment or project is to learn about the research process.
 - The project is eligible for exempt or expedited review.
 - The project is part of a course and the research project is conducted under faculty supervision.

Note: If the project is intended to add to the generalized body of knowledge for the discipline (i.e. public presentation at professional conferences or publication) and involves human participants the project is subject to an ethics review. This level of review is not intended for theses or dissertations.

Faculty operating within the EIRC standards who elect to use the Student Research and Class Projects level of review must:

- Submit the **Student Research and Class Projects** form once the students project/research has been identified.
- This form must be approved by the EIRC prior to proceeding with the research project(s). All

- projects for the identified course may be submitted on the same form.
- Students are required to submit the EIRC application and research proposal to the professor for approval instead of the EIRC.

Process Application and Review Process:

1. An application for the use of human subjects in research is available from the Office of Academic Administration and from the chair of the EIRC. All forms are available on the EIRC webpage.
2. Electronic submission of EIRC application and the project proposal is required.
3. The application must be complete before the EIRC chair will review it.
4. There will be one application deadline per term (Fall, Winter, Spring) designated. If an application is received during summer term, an ad-hoc meeting may be called. Exemptions to this deadline will be granted as necessary by the committee chair.
5. Upon receipt of a proposal, the chair of the EIRC will electronically distribute it to the EIRC members.
Upon submission of application and project proposal, the EIRC chair will review the application and determine if the application qualifies for exempt, expedited or full committee review.
6. Once the level of review is identified, the chair of the EIRC will distribute the proposal to the EIRC members as designated by the level of review.
 - For student research and class projects, the committee chair and 1-2 EIRC committee members will review these materials.
 - For expedited review, the committee chair and 1-2 EIRC committee members will review these materials.
 - For full review, the full EIRC committee will review these materials.
7. The EIRC members will be given 3-4 weeks to review these materials. The EIRC committee will meet in person approximately 1-2 weeks after the application deadline each term to review submitted proposals.
8. Usually the committee members will review the proposal and electronically submit a vote of approval, denial, or request to meet as a group about the study proposal by the end of this period. The committee members review the proposal and submit a vote of approval, denial, request for additional information, clarification or request a change to the application.
9. If any one of the EIRC members wishes further discussion of the proposal, a meeting is called by the EIRC chair for further consideration before an official vote is taken.
10. If additional information is requested by the committee, the EIRC chair will notify the principle investigator in writing of the committees request for additional information, clarification or requested changes to the application.
11. The principal investigator must then address a response and/or revise the application in order to continue the review and obtain approval.
12. Following and in harmony with a majority vote by the committee, a letter of announcement is sent out to the applicant a majority vote by the committee, the EIRC chair a letter of announcement is electronically sent out to the principal investigator.
13. The results of each review and copies of the research proposal are kept in a secure electronic location for a period of five years.

14. Copies of current policies and the application form will be kept by the VPAA and the EIRC chair.

Conditions of Approval:

EIRC approval is valid for one year. At the end of that year, the principle investigator must submit **Form A** indicating project termination, completion or request a renewal.

Modifications to the Project:

If major changes are planned, the principle investigator must submit a new EIRC application for review.

Minor changes (e.g. minimal changes in the wording of a survey instrument, changes in sample size, etc.) must be approved by a submission of **Form A**. This form must be submitted and approved prior to making any of the changes. Once the EIRC reviews these changes, the principle investigator will be notified if approved or deemed not acceptable.