Appendix M. Ethics In Research Policy

WALLA WALLA UNIVERSITY
ETHICS IN RESEARCH POLICY

Preamble
Walla Walla University is a community of both faith and inquiry. As a community of faith we hold that all life is a gift of the Creator and is to be treated with care and respect. As a community of inquiry we believe that research and discovery are important for the enhancement of life. Some research cannot be accomplished without the use of living organisms. The following policy is intended to ensure that such research will demonstrate the care and respect for life and human dignity that our belief demands.

Procedure
The university will establish a standing committee known as the Ethics Review Board. It will be chaired by the VPAA and will consist of representatives from each academic department involved in research on animal or human subjects, faculty members at large who teach in the area of philosophy and ethics, and one or two community members from outside the university representing areas such as ethics, medicine, and/or law. This Review Board will:

1. Establish principles, polices, and procedures for ethics in research which will be followed by each department as it approves, conducts, and reviews research.

2. Serve as the appeal board when decisions made at the department level are contested.

3. Review all research proposals that have a level of risk that exceeds the protocols under which the departmental research review process functions.

4. Regularly and randomly assess the research review processes and decisions at the departmental level.

5. Prepare standard material for use by departments, such as forms for securing informed consent.

6. Prepare an annual report assessing the institution's compliance with this policy.

Principles of Research on Human Subjects
The basic principles that will guide all research on human subjects are those found in The Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. 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. The following applications are derived from these principles:

1. 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.

2. Assessment of Risks and Benefits. No research will be justified that involves brutal or inhumane treatment of subjects. Risks should be reduced to those necessary to achieve the research objective and must be carefully justified. All risks must be clearly communicated to the subjects.

3. 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).

Each department will review and approve research proposals according to these guidelines. The department will also determine if the research is conducted in an academically sound manner by investigators who have adequate background in research methods and the content area of the research. When there is significant risk, deception, or when the research involves subjects, such as children or prisoners, whose ability to give fully informed consent is questionable, departments will take the research proposal to the Review Board.
Principles of Research on Animal Subjects
The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever WWU departments develop requirements for testing, research, or educational procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these departments actually perform or sponsor such procedures, the Review Board shall ensure that these principles are adhered to:

1. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7, U.S.C. 2131 et. seq.) and other applicable Federal laws, guidelines, and policies.

2. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

3. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.

4. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain, when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

5. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

6. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

7. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals must be directed by a scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. Veterinary care shall be provided as needed.

8. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

9. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle 2, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

In addition, animal research will be carried out with reference to the OPRR "Public Health Service Policy on Humane Care and Use of Laboratory Animals" and the U.S. Department of Health and Human Services "Guide for the Care and Use of Laboratory Animals."
M.1. Sample Informed Consent Form

The following is a sample informed consent form.


RESPONSIBLE INVESTIGATOR:

TITLE OF PROTOCOL:

TITLE OF CONSENT FORM:

I have been asked to participate in a research study that is investigating (describe purpose of study). In participating in this study I agree to (describe briefly and in lay terms procedures to which subject is consenting).

I understand that:

a. The possible risks of this procedure include (list known risks or side effects; if none, so state). Alternative treatments include (list alternative treatments and briefly describe advantages and disadvantages of each; if none, so state).

b. The possible benefits of this study to me are (enumerate; if none, so state).

c. Any questions I have concerning my participation in this study will be answered by (list names and degrees of people who will be available to answer questions).

d. I may withdraw from this study at any time without prejudice.

e. The results of this study may be published, but my name or identity will not be revealed and my records will remain confidential unless disclosure of my identity is required by law.

f. My consent is given voluntarily without being coerced or forced.

g. In the event of physical injury resulting from the study, medical care and treatment will be available at: (list name and address of facility).

Date

Subject or Responsible Party

Subject's Social Security Number

Auditor/Witness

Investigator