

**POLICIES GOVERNING PROCEDURES FOR THE USE OF ANIMALS
IN RESEARCH AND TEACHING AT WESTERN WASHINGTON
UNIVERSITY**
and
REVIEW OF HUMAN SUBJECT RESEARCH

INTRODUCTION

It is the policy of Western Washington University to provide the best possible care for animals used in research or teaching both for humane reasons and because such animals make for high quality research. Accordingly, all animals owned, cared for, or handled by the University are covered by these policies. In every instance, Western's policies specifically meet or exceed accepted guidelines as well as all applicable federal, state, and local legislation.

To achieve these goals, the University follows the guidelines established by the Public Health Service in its publication, PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS. Standards for laboratory animal husbandry, veterinary care, and physical plant (animal facilities and environments) meet those described by the ANIMAL WELFARE ACT administered by the U.S. Department of Agriculture and THE GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS published by the U.S. Department of Health and Human Services. The latest editions of these publications are available for inspection at the Bureau of Faculty Research (Old Main 430).

Although all University employees and students are responsible for adherence to these policies, the University has established the Animal Care and Use Committee to monitor and enforce these guidelines.

DUTIES OF THE ANIMAL CARE AND USE COMMITTEE (ACUC)

All experiments or procedures involving live vertebrate animals must be approved in advance by the Animal Care and Use Committee. The appropriate forms are available at the Bureau for Faculty Research, which coordinates the activities of the Committee. Investigators should allow sufficient time for the Committee to review applications because no experimental procedures may be initiated without Committee clearance.

Specific responsibilities of the ACUC include the following:

1. Review at least once every six months the University's program for humane care and use of animals.
2. Inspect at least once every six months the University's animal facilities and ensure that proper external reviews are conducted as needed.
3. Make recommendations and prepare reports regarding any aspect of the institution's animal program and facilities.
4. Review the training procedures for university employees charged with the care and use of animals at the University.
5. Review, approve, suggest modifications, or disapprove of activities relating to the care and use of animals.
6. Immediately recommend to the supervising senior administrator the suspension of inappropriate activity involving animals.
7. Generate and maintain administrative procedures that will facilitate the discharge of these duties.

GENERAL GUIDELINES FOR USE OF LABORATORY ANIMALS

The educational and research use of laboratory animals is and has been of enormous value to our world, and for this reason, Western sponsors animal research. In our laboratories and classrooms, the educational goal or the research objective will determine the most appropriate use of laboratory animals. In all instances, the researcher and the committee will employ all available techniques for reducing pain and stress within the parameters of the experiment. The kinds and numbers shall be carefully matched with the specific aims of the research proposal. When more than one species can be satisfactorily used, a major consideration shall be to choose the lowest species on the phylogenetic scale and the least sentient. Higher order animals should be used only in situations especially well matched with a teaching or research aim.

A. DUTIES AND OBLIGATIONS OF UNIVERSITY PERSONNEL

1. Investigators, instructors, and colony supervisors have a moral obligation to abide by the humanitarian dictate that experimental animals are not to be subjected to unnecessary pain or distress.
2. Use of live, vertebrate animals and the procurement of tissues from living animals for research or teaching must be performed by, or under the appropriate supervision of, a qualified biological, behavioral, or medical scientist approved by the ACUC.
3. The housing, care, and feeding of all animals must be supervised by a scientist approved by the ACUC.
4. Investigators, instructors, and colony supervisors are responsible for instructing personnel in the humane care and use of animals.
5. The principal investigator, instructor, and/or colony supervisor shall be responsible for the monitoring of animals for compliance with this policy.

B. RESEARCH AND INSTRUCTIONAL USE

1. The research project or educational use should demonstrate a reasonable expectation of yielding fruitful results for the good of society or to advance knowledge.
2. Experimental use of animals should be so designed that the anticipated results will justify the procedure.
3. Statistical analysis, mathematical models or in vitro biological systems should be used when appropriate to complement or replace animal use and to assure that the numbers of animals used are matched with the aim(s) of the project.
4. Animals used for demonstration, development of student skills, or other instructional objectives will be cared for consistent with the guidelines.

5. Animals maintained in a colony and which have not been assigned or distributed to an investigator or instructor will be cared for in a manner consistent with the guidelines.

C. TREATMENT OF ANIMALS

1. POST-EXPERIMENTAL CARE

Post-experimental care of animals must minimize discomfort and the consequences of any disability resulting from the experiment in accordance with acceptable practices in veterinary medicine.

2. RESTRAINT

Prolonged physical restraint procedures which result in distress or ill effects should be used only after alternative procedures have been considered and found inadequate.

3. BEHAVIORAL REINFORCEMENT

Experiments studying behavioral responses to noxious stimuli such as shock, heat or cold stress should be designed to use a level of stimulus as low as possible consistent with obtaining reliable responses.

4. PAIN

Operationally, pain can be defined as discomfort exceeding that associated with the administration of an anesthetic. The experiment should be conducted so as to avoid all unnecessary suffering and injury to the animal. If pain or distress is a necessary concomitant of the experiment, these should be minimized both in intensity and duration. An animal that is observed to be in a state of severe pain which cannot be alleviated should be immediately destroyed, using a humane, acceptable method for euthanasia. In any study the degree of pain involved should never exceed that determined by the humanitarian or scientific importance of the problem.

5. SURGERY

Multiple major surgical procedures at different times on an individual animal solely for the instruction of students or for the demonstration of established scientific knowledge cannot be justified.

6. ANESTHESIA

If the experiment or procedure is likely to cause greater discomfort than that attending anesthetization, anesthetic or analgesic drugs should be used until the experiment or procedure is ended. Exceptions to this guideline should be made only where the anesthetization would defeat the purpose of the experiment and data cannot be obtained by any other humane procedure.

7. ENVIRONMENTAL ENHANCEMENT

As required by the Animal Welfare Act, the University developed a program to ensure the psychological well being of all nonhuman primates maintained by the University. The program includes social groupings and the enrichment of the animals' physical environment. (See WWU Policy for Environmental Enhancement of Nonhuman Primates.)

8. EUTHANASIA

When it is necessary to kill an experimental animal, the animal must be killed in a humane manner, in such a way as to ensure immediate death, and in accordance with approved procedures. (For approved procedures see. "Report of the AVMA Panel on Euthanasia," JOURNAL OF THE AMERICAN VETERINARY MEDICAL ASSOCIATION, January 15, 1993.) No animal shall be discarded until dead and shall be disposed of by an acceptable method.

9. CONVEYANCE TO THIRD PARTIES

It is the policy of the University not to supply animals to individuals or organizations for use in experiments, as pets, or for other purposes except as approved by the ACUC.

POLICIES & PROCEDURES FOR THE REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS

INTRODUCTION

All research done at Western Washington University is guided by codes of ethical principles developed by the scientific community.

The manner in which these ethical principles are to be applied (through a peer review process) is established in the Code of Federal Regulations, Title 45, Part 46 (commonly referred to as 45 CFR 46) published in 1981 and last amended in 1991. Failure to comply with these regulations may result in loss of funding for the research involving human subjects to the investigator and to the institution.

THE HUMAN SUBJECTS REVIEW COMMITTEE (HSRC)

Western Washington University has an internal review board charged with reviewing all research conducted at the University for conformity to 45 CFR 46. At this University, the Human Subjects Review Committee is the designated administrative body.

Western Washington University is responsible for the protection of the rights and welfare of human subjects used in research by, or under the supervision of, faculty and staff members of the University, when such research is carried out as part of their duties as teacher, investigator, thesis advisor or graduate student, or other academic activities. The responsibility is delegated to the Human Subjects Review Committee (HSRC). The Committee shall determine for all activities, as planned and conducted, whether the rights and welfare of all subjects will be adequately protected.

To meet this responsibility, the Committee will review all proposed research projects involving human subjects conducted by faculty members, University staff, or graduate students, whether funded or not, when facilities, services, or personnel of the University are used. The HSRC is chaired by the Vice Provost for Research and includes five full-time members of the general faculty of Western Washington University, and one community representative. The Committee seeks external consultation whenever questions beyond its competency or specialized expertise arise. The Committee meets at the call of its chairperson to consider questions of policy and the individual research proposals which require full-committee review.

CRITERIA FOR APPROVAL

The task of the HSRC is to work with individuals conducting research to assure that all research involving human subjects meets the following criteria and thus can be approved:

1. Risks to human subjects are minimized;
2. Risks to subjects are reasonable in relation to anticipated benefits to subjects, if any, and the importance of knowledge that may reasonably be expected to result;
3. Selection of subjects is appropriate;
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative;
5. The informed consent will be appropriately documented;
6. Where appropriate, adequate provision is made for monitoring the data collected and the data collection process to ensure the safety of the subjects;
7. Where appropriate, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data;
8. Where subjects are likely to be vulnerable to coercion or undue influence, appropriate safeguards have been included in the study to protect the rights and welfare of the subjects.

All research involving human subjects whether unfunded or funded from any source must be reviewed and must meet the above criteria. Training projects with a research component must be reviewed. (46.111)

DEFINITIONS

RESEARCH means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (46.102d)

A HUMAN SUBJECT is any living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (46.102f). This includes the use of written private information such as that contained in records.

MINIMAL RISK means that the probability and the magnitude of harm or discomfort anticipated in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (46.102.l).

WAIVER OF REVIEW (“Exempted” research)

Exempted from all HSRC review at this University is research which is a recognized part of the course content of undergraduate and graduate courses, unless such research is federally funded and provided that such research consists of survey procedures, interview procedures, or observation of public behavior, and data are collected in such a way that human subjects cannot be identified, directly or through identifiers linked to the subjects. The responsibility for review of research proposals required as a standard part of course content lies with the faculty member/instructor teaching that course. The protection of human subjects in this instance is accomplished through departmental review of course content and review by the course instructor of individual research projects.

Research conducted as part of an independent study, or thesis or dissertation, is not exempted, but waiver may be requested if the research falls in one or more of the categories listed below.

Research activities in which the only involvement of human subjects will be in one or more of the following categories is reviewed by the chairperson of the HSRC or a designated member and may be *waived* from either expedited or full committee review. *THE DECISION TO WAIVE REVIEW IS MADE BY THE CHAIRPERSON OR A DESIGNATED MEMBER OF THE HSRC.*

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular or special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place these subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under exemption 2 above if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

At Western Washington University the chair of the HSRC or a designated member decides whether the full (46.101b) or expedited review of research is waived.

PROTOCOL REVIEW

The full review process shall be carried out at convened meetings in which a majority of the members of the HSRC are present, including one member whose primary concerns are non-scientific areas. The chairperson shall have a vote. For a protocol to be approved, it shall receive the approval of a majority of members.. At the discretion of the chairperson, committee review may be conducted by mail. Should any member request a meeting to review one or more of the mailed protocols, a meeting shall be called. The HSRC considers the following factors:

1. **RISK OF INJURY:** The risk to subjects must be minimized, by using procedures which are consistent with sound research design and which do not unnecessarily expose subject to risk, and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

2. **APPROPRIATE SELECTION OF SUBJECTS:** The HSRC will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, HSRC will require that additional safeguards be included in the study to protect the rights and welfare of these subjects.
3. **VOLUNTARY AND INFORMED CONSENT:** All subjects, adults or children, must be fully informed in advance of the degree of risk involved in their participation and, insofar as possible, given an explanation of the nature and consequences of the proposed research. Methods of securing cooperation of subjects should be specified in advance as clearly as possible. No coercion may be used to obtain or maintain cooperation. Adult subjects or their legal representatives consent to participate must be given in writing (see Model Informed Consent Form in the application packet). If a subject is under the age of 18, informed consent must be obtained in writing from the subject's parent or legal guardian. Subjects over seven years of age must give their consent as well. All subjects, adults and children alike, must be assured that they may choose to withdraw from the research program at any time without penalty.
4. **CONFIDENTIALITY AND PRIVACY:** All information provided by a human subject, including responses to questionnaires, tests, and interviews, must be kept confidential to those performing the research and, when feasible, anonymous. Published accounts of such data must not reveal the identity of the subject.
5. **ADEQUATE PROVISION TO ENSURE THE SAFETY OF THE SUBJECTS:** The HSRC will stress risks to subjects in their review of research projects to ensure that the provision for physical and psychological safety is adequate and the risk involved in each study is as minimal as possible. The research plan must make adequate provision for monitoring the data collected and the data collection process to ensure the safety of the subjects.
6. **RESEARCH DESIGN:** In situations of risk to subjects, the Committee may return to the applicant, without action, proposals involving human subjects which it feels are unlikely, through faulty design, to yield accurate and scientifically meaningful data.

7. **CODES AND STANDARDS:** In its review process, the Committee will consider the degree to which proposed research conforms to the prevailing social codes and moral standards of the community or cultural group involved.

On occasion, an application is submitted accompanied by a review of the project from another institution. If the other institution has primary responsibility in the project and if the Institutional Review Board adheres to federal guidelines and uses similar criteria to those of WWU in their review, the forms of the primary institution may be used.

EXPEDITED REVIEW

Under certain conditions specified in federal regulations (45 CFR 46.101), and at the discretion of the HSRC Chair, a protocol may be considered under an expedited review process. Under expedited review, a protocol is reviewed by the chair or one or two members of the committee designated by the chair. All protocols approved under expedited review should be reported to the HSRC.

PROCEDURE FOR APPLICATION

Understanding the importance of the protection of human subjects in research, recognizing the role of the HSRC, and having mastered complex definitions so that you understand where your research “fits”, you now need to know how to go about obtaining HSRC approval allowing you to proceed with your research.

Be aware that whether or not your research is federally funded, and whether or not you think it may be exempt from review, you need HSRC approval to proceed if your research involves *data that has been or will be collected from human* subjects. Activity review forms for the use of human subjects in research are available in the Bureau for Faculty Research office, complete with instructions for information required. The questions are straightforward, but they may present some issues you have not considered. Do not hesitate to ask the Chairperson or any HSRC member to help you complete the form.

The completed form is submitted to the Bureau for Faculty Research, Old Main 430. It will be reviewed to determine exempt status, may receive expedited review, or may require review by the full committee. Full committee review will usually take one to two months; other reviews take less time.

You will receive written communication from the HSRC indicating either approval of your proposal, or setting conditions which must be met before the proposal will be approved. DATA COLLECTION INVOLVING HUMAN SUBJECTS MAY NOT BEGIN BEFORE THE HSRC APPROVAL IS RECEIVED.

EVEN AFTER APPROVAL, IT WILL BE NECESSARY TO NOTIFY THE HSRC OF ANY CHANGES IN YOUR RESEARCH PLANS. IF THE DURATION OF YOUR STUDY IS LONGER THAN A YEAR, YOU WILL BE REQUIRED TO SUBMIT A BRIEF PROGRESS REPORT ANNUALLY, AND TO RECEIVE HSRC APPROVAL ANNUALLY.