OREGON INSTITUTE OF TECHNOLOGY

Institutional Review Board for Use of Human and Animal Subjects in Research
OIT-25-010

Introduction

"No person in the United States should be enrolled in research without the twin protections of informed consent by an authorized persons and independent review of the risks and benefits of research." – The National Bioethics Advisory Commission, 1997.

In order to study and learn about a variety of subjects of a sociological, medical, or biological nature, it is often necessary to conduct research on living subjects. Although these investigations may provide valuable information for society and toward the advancement of knowledge, the research often does not provide direct or indirect benefits to the human subjects who participate. In some cases there may be a significant risk of harm associated with participating. For investigations utilizing animals, the benefits to the subjects are usually negligible or nonexistent. It is important to ask if research using human and other animal subjects is an ethically justifiable activity and whether the procedures utilized ensure maximum protection for the subjects. This protection includes physical, mental, and sociological aspects of well being.

Federal law (45 CFR Part 46, effective August 19, 1991) governs the use of human subjects in research.

Purpose of Policy

1. To establish an ethical rationale for supervising research activities at the Oregon Institute of Technology (OIT) that involves human and animal subjects. Animal subjects are defined as non-human vertebrates. For human subjects, this policy emphasizes that all participants must be informed volunteers.

2. To provide for an organizational structure and establish basic operating procedures for an institutional review board (IRB). Research proposals, using human or animal subjects, conducted at OIT or by the faculty, staff and students of OIT must be submitted to the IRB.

3. To propose the IRB as a standing oversight committee to review and collate departmental research manuals, procedures, and protocols.

Ethical Considerations

The scientific method is an established protocol for observing phenomena and gathering data to obtain answers to questions. Hypotheses can be either supported or rejected when information is obtained in a systematic manner. Research on biological and sociological questions often requires the participation of human or other animal subjects.

For humans, informed consent is the key to soliciting and incorporating subjects into a research study. Individuals have a fundamental right to be informed, in advance of participation, on:

1. the benefits, if any, of participating in the proposed research;
2. the risks, if any, of participating in the proposed research;
3. the uses and distribution of data, findings, or materials derived from the subject's participation.

Consent should be explicit and limited. A consent form should be easy to read, the terms of participation clearly defined, and the uses of the data and findings from the research should be explained in non-technical language. If tissue or biological products (e.g., blood, urine, sputum) are obtained from the subject, their use and subsequent disposal must be clearly defined and agreed to by the subject as part of the consent form.

> *Informed Consent* – "A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence." (45 CFR 46.116; 21 CFR 50.20 and 50.25)

A model consent form is attached to this policy (Exhibit A). The Principal Investigator must attach a copy of the consent form to be used in the prospective study when it is submitted for review by the IRB.

For other vertebrate animals (fish, amphibians, birds and non-human mammals), ethical considerations include the following:

1. Research protocols shall be designed to minimize unnecessary utilization of animal subjects if other methods can yield the same or equivalent types of data.

2. All research procedures will conform to the guidelines established by the American Veterinary Medical Association (AVMA) and published by the AVMA National Academies of practice. A copy of these guidelines will be maintained by the OIT IRB. All research proposals involving animal subjects must conform to these principles.

3. Emphasis on the use of animals in research shall be on humane treatment and proper care and handling of subjects. All individuals using animal subjects will be instructed in their proper care. Responsibility to insure training for animal maintenance staff and research workers lies with the principal investigator of the research project using the animals.

4. Approval of a research protocol by the IRB requires the principal investigator submit a plan to address humane treatment and maintenance requirements of animal subjects. The plan must also include provisions for training research staff to comply with AVMA guidelines.

Institutional Review Board (IRB)

1. Structure. The IRB shall consist of five members, appointed by the President of OIT or by an individual designated by the President. The members shall be drawn from and represent the following interests; 1) an administrator, faculty or staff member with oversight expertise or experience in human or animal research; 2) a faculty member from the department of Natural Sciences; 3) a faculty member from the department of Humanities and Social Sciences; 4) a staff member representing student or administrative services at OIT; and 5) a knowledgeable member appointed from the community. The external member of the IRB shall not be directly affiliated with OIT or be an immediate family member of someone who is affiliated with OIT, in compliance with 45 CFR 46.107 (d).

2. Supervision and terms of service. All members will be appointed for three-year terms, with dates of appointment staggered so that not more than two members are replaced in any year. Initial appointments for three of the members may be for less than three years. Reappointments for consecutive terms are permissible. The IRB reports to the Vice President for Academic Affairs (Provost).

3. Review authority. The IRB must review every research proposal submitted by an OIT faculty, staff or student member that involves the use of human and/or

animal subjects. All proposals reviewed by the IRB will be submitted to the Provost if additional authorization of academic expenditures is required. Use of non-academic facilities may also need to be approved by the Vice President of Finance and Administration of the Vice President of Student Affairs as appropriate.

Expedited Studies

The IRB may expedite the review of research proposals in the following categories by using an accelerated process that does not require a meeting of the entire IRB. All other studies must be reviewed by the full membership of the IRB.

1. Naturalistic observations (ethology). Studies in which the investigator is only observing the behavior of humans or animals in their environment, whether natural or man-made. Such studies do not involve experimental manipulation of either the environment or the subjects. Data collection will be demographic and no human subject will be specifically identified by name or other than descriptive designation.

2. Student laboratory exercises in medical imaging, dental hygiene, health sciences, and biology in which examinations of anatomy, dental practices, bacterial culture, or blood and body fluid analyses are performed for educational purposes under the supervision of a faculty member. Procedures involving blood sampling (capillary puncture, arterial or venipuncture) need only a simple classroom consent form will be signed by each student subject (Exhibit B). Clients in the dental clinics and in programs using clinical or emergency care facilities are required to complete consent forms appropriate to those clinics.

3. Anonymous demographic surveys in which no identifying subject information is collected.

Responsibility

It is the responsibility of the principal investigator to establish that the proposed research meets the guidelines for studies involving human or animal subjects. Failure to meet the guidelines will result in denial of the proposal by the IRB.

Research protocols must be approved by the IRB regardless of whether outside grant funding is sought for the project. A Grant and Development Cover Sheet (Exhibit C) must be attached to all proposals involving external sources of support.

The overriding guideline is that no harm or risk of harm shall be unnecessarily imposed on an animal or human research subject. For humans, all risks and potential risks will be carefully explained and that consent to participate will be based on full disclosure or risks and benefits of the research.

Departmental Research Manuals, Procedures, and Protocols

Rather than provide a lengthy and detailed protocol manual to fit the many diverse types of research that might be conducted at OIT, this policy refers to the specific protocols and procedures that would be appropriate for a specific department or organizational unit. Therefore, the departmental research manuals, by definition, are considered addenda to this policy. Each manual and protocol shall be submitted by a department or unit wishing to conduct research on human or non-human animal subjects. These manuals and subsequent revisions hereto shall be reviewed by the IRB before authorization to conduct research is granted.

Addenda:

1. Forms

    a. Exhibit A. Model Consent Form

    b. Exhibit B. Classroom Consent Form

    c. Exhibit C. Grants and Development Cover Sheet

    d. Exhibit D. Human or Animal Subject Review Sheet

2. List and location of departmental research manuals

    a. Psychological and Sociological Studies Research Subject Manual
    Applied Psychology Program
    Office of the Chair, Department of Humanities and Social Sciences

    b. Natural Sciences Studies Research Subject Manual
    Office of the Chair, Department of Natural Sciences

3. Additional sources of information

    a. Oregon State University, Human Subjects Handbook. September 2000. Chairperson of the OIT IRB

    b. National Bioethics Advisory Commission. Ethical and Policy Issues in Research Involving Human Participants. Bethesda, Maryland, August 2001. Chairperson of the OIT IRB

Recommended by:

Administrative Council – January 21, 2003
Faculty Senate – November 7, 2002
President's Council – May 14, 2002

Approved: /s/ Martha Anne Dow
Martha Anne Dow, President

Date: January 21, 2003

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Model Consent Form

Date of Consent _____

Research Project Title _____

Principal Investigator _____ Phone No. _____

Briefly describe project (attach additional information if necessary):

_____

_____

_____

Benefits, if any, to subject (attach additional information if necessary):

_____

_____

_____

Risks, if any, to subject (attach additional information if necessary):

_____

_____

_____

_____
Typed or printed name of subject

_____ _____
Signature of subject Date

_____ _____
Signature of witness Date

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Classroom Consent Form

Date of Consent _____

Course Title _____ CRN _____

Instructor or Staff Member in Charge _____

Briefly describe activity (attach additional information if necessary):

_____

_____

_____

Benefits, if any, to subject (attach additional information if necessary):

_____

_____

_____

Risks, if any, to subject (attach additional information if necessary):

_____

_____

_____

_____

Typed or printed name of subject

_____ _____

Signature of subject Date

_____ _____

Signature of witness Date

OREGON INSTITUTE OF TECHNOLOGY
Institutional Review Board Review Sheet
Human and Animal Subjects Used in Research

IRB# _____ Date _____

Title of Project _____

Submitted by Investigator Department

_____ _____

_____ _____

_____ _____

Research project will use: _____ human subjects _____ animal subjects

The proposed research includes (check all that apply):
____ survey or questionnaire only
____ naturalistic (non-interventional) observations
____ experimental (involves subject manipulation) observations
____ invasive procedures (requires medical or veterinary review)

Describe project in terms of subject use (attach additional sheets if necessary):

Describe any real or potential dangers to human or animal health, including potential mental and social effects as a result of research participation:

If human use, describe means to obtain informed consent:

Describe provisions for collecting and maintaining research data, including storage and access to confidential data, if appropriate.

Are special facilities required to either maintain animals or to conduct the research? ____
If so, please describe:

Signature of Principal Investigator _____

Signature of Department Chair _____

_____

Review Board

Reviewed on _____

_____ Approved as submitted

_____ Approval subject to conditions (letter attached)

_____ Proposal denied as written (letter attached)

Signature of Chair of OIT IRB _____
Date