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

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1. Policy Statement

Oregon Tech's Institutional Review Board (IRB) reviews research projects that involve human subjects, to protect the right and welfare of individuals recruited to participate in research activities conducted under the auspices of the Oregon Institute of Technology. All research conducted by any Oregon Tech faculty member, staff member, or student using human subjects must have prior approval from the Oregon Tech IRB before the research is initiated. Additionally, all human subjects research at Oregon Tech must comply with relevant federal guidelines and policies.

The IRB is a federally mandated body established under the US Department of Health and Human Services (DHHS) regulations for the protection of human subjects 45 CFR 46 (Protection of Human Subjects).

The Oregon Tech IRB shall oversee animal subject research protocols as well.

2. Reason for Policy/Purpose

- To ensure that all research conducted at Oregon Tech meets all federal, state, and institutional guidelines for human subjects research.
- To provide an organizational structure and establish basic operating procedures for an institutional review board (IRB).

3. Applicability/Scope

This policy applies to all [faculty, staff, and students] of the University.

4. Definitions

Research: "A systematic investigation designed to test hypotheses, evaluate programs, draw conclusions, or contribute to generalizable knowledge. Research is usually described in a formal protocol that sets forth objectives and a set of procedures designed to reach those objectives." (45 CFR 46.102(l))
Human Subjects: "Living individuals about whom investigators (professionals or students)

conducting research obtain (1) data through intervention or interaction with individuals, or (2) identifiable private information. Identifiable private information includes any acquired information via self-report, behavior, or observation in which the identity of research subjects is or may readily be ascertained by the investigators or be associated with the information." (45 CFR 46.102(e)) Animal Subjects: non-human vertebrate animals (fish, amphibians, birds and non-human mammals).

Minimal Risk: "[T]he probability and magnitude of harm or discomfort anticipated in the 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" (45 CFR 46.102(j)).

Informed Consent Process: "The requirement to obtain the legally effective [understandable] informed consent of individuals before involving them in research [...]. The informed consent process involves three key features: (1) disclosing to potential research subjects information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research [without coercion]" (45 CFR 46.116).

Obtained 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 [without coercion]. 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).

Vulnerable Populations: "[Persons] who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests." (The Council for International Organizations of Medical Sciences). Vulnerable populations can include children, pregnant women, human fetuses and neonates, prisoners, veterans, adults with diminished cognitive capacity or who are educationally disadvantaged, and employees or students under the authority/evaluative power of the study investigators.

5. Policy

Policy Details

The Provost is the signatory official who is legally authorized to represent Oregon Tech. The Provost appoints IRB members and is responsible for overseeing activities performed by the IRB in accordance with the Oregon Tech Federalwide Assurance and Section 45 Part 46 of the Code of Federal Regulations. The Vice Provost for Research and Academic Affairs serves as the Human Protections Administrator who is responsible for interface with the DHHS Office for Human Research Protections.

The IRB is authorized to revise and update this policy and associated IRB Procedures as needed to reflect new standards, regulations, and University Operating Policies.

IRB Membership: The IRB shall consist of at least five members, appointed by the President of Oregon Tech or by an individual designated by the President, in accordance with 45 CFR 46.107.

- "Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution" (45 CFR 46.107(a)).
- "Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas" (45 CFR 46.107(b)).
- "Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution." (45 CFR 46.107(c))
- "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB" (45 CFR 46.107(d)).
- "An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB" (45 CFR 46.107(e)).

Supervision and Terms of Service: All IRB 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 Provost for Research and Academic Affairs.

Review Authority: The IRB must review every research proposal submitted by an Oregon Tech faculty, staff, or student member that involves the use of human and/or animal subjects.

Failure of an Oregon Tech researcher to obtain IRB approval or to follow approved protocols may result in disciplinary action.

Process: All Oregon Tech faculty, staff, and students conducting human subjects research must submit a completed research protocol application to the IRB, using required Oregon Tech IRB forms and submission processes. The IRB determines the status of submitted studies based on the human participant risks involved and the nature of the study as indicated below:

- Exempt Status: Granted by the IRB to research projects that (a) pose little or no risks to participants; and (b) do not involve a sensitive topic (i.e., a topic which could cause a participant distress); and (c) do not involve vulnerable populations; and (d) collect anonymous information (i.e., no names or other identifying information will be collected or recorded) including research using questionnaires or surveys, research conducted in

educational settings involving normal curriculum (even if minors are involved), and research conducted using archival data.

- Expedited Status: Granted by the IRB to research projects that (a) involve minimal risks to the participants; and (b) do not involve sensitive topics; and (c) do not utilize vulnerable populations; and (d) include research using questionnaires, surveys, and interviews that are not anonymous (i.e., participants can be identified).

- Full Board Review Status: Granted by the IRB to research projects that (a) involve more than minimal risks to the participants, or (b) involve a sensitive topic, or (c) involve a vulnerable population.

Determination Status: Upon completing the review process, the IRB will make a determination for each research protocol application as indicated below:

- Incomplete or Not Ready for Review: materials submitted are incomplete or missing components for the IRB to make a determination (applicants are asked to revise and resubmit).
- Require Modifications to Secure Approval: materials submitted require additional details or clarification for the IRB to make a determination (applicants are asked to revise and resubmit).

- Approve: materials submitted address all required components, the IRB has determined the research protocol meets DHHS requirements for ethical conduct of research.

- Approve with Conditions: materials submitted address all required components, the IRB has determined the research protocol meets DHHS requirements for ethical conduct of research, but conditions are require before the researcher can begin the study (for example, a third-party permission letter is needed, such as from a medical facility, school district, or a partnering university IRB, to grant the researcher approval).

- Disapprove: materials submitted address all required components, the IRB has determined the research protocol does not meet DHHS requirements for ethical conduct of research.

IRB Amendment: If after receiving IRB approval, a researcher needs to amend the study protocol or timeline, the researcher must submit a completed IRB amendment request.

Animal Research: Research protocols shall be designed to minimize unnecessary utilization of animal subjects if other methods can yield the same or equivalent types of data. All animal research procedures will conform to the guidelines established by the American Veterinary Medical Association (AVMA) and published by the AVMA National Academies of Practice. Emphasis on the use of animals in research shall be on humane treatment and proper care and handling of animal subjects. All researchers using animal subjects must be instructed in their proper care. Responsibility to ensure training for animal maintenance staff and research workers lies with the principal investigator (PI) of the research project using the animals. Approval of a research protocol by the IRB requires the principal investigator to 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.

Responsibilities of Oregon Tech Researchers: All Oregon Tech faculty, staff, and students, on- and off-campus conducting research using human subjects must have prior approval from the Oregon Tech IRB before the research can begin. It is the responsibility of the researcher 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.

Sponsored Projects: Research protocols must be approved by the IRB regardless of whether outside grant funding is sought for the project. A sponsored project is subject to additional policies under Oregon Tech Sponsored Projects & Grants Administration.

IRB Training: All IRB members and Oregon Tech faculty, staff, and students must complete required IRB/Human Subjects Research training (and Animal Subjects Research training when applicable) in accordance with relevant federal, state, and University guidelines and policies.

6. Links to Related Procedures, Forms, or Information

Code of Federal Regulations; Part 46 - Protection of Human Subjects; Subpart A - Basic HHS Policy for Protection of Human Research Subjects

American Veterinary Medical Association – Policy; Use of Animals in Research, Testing, and Education

OIT IRB Forms and Information are maintained by the IRB on an OIT secured site: irb@oit.edu

7. Policy Review/Consultation

This policy was adopted pursuant to Oregon Tech's policy review and making process.

8. Policy Approval

Approved by the President on August 17, 2022.

Nagi G. Naganathan, Ph.D., ASME Fellow
President

Adoption Date
June 9, 2022

Supersedes, Renames, and Assigns Policy Number
Supersedes OIT-25-010, adopted January 21, 2003