Policy Title: Human Research Protection Program

Policy Number: TBD

Reason for Policy:

To articulate the University of Oregon's guiding principles and program elements for the ethical conduct of research involving human subjects/participants.

Entities Affected by this Policy:

Employees, officials, students, and agents of the university, and anyone else while using University facilities or resources, engaging in the conduct of research involving human subjects/participants.

Responsible Office:

For questions about this policy, contact the Office of the Vice President for Research and Innovation's Research Compliance Services unit at 541-346-2510 or researchcompliance@uoregon.edu.

Enactment & Revision History: TBD

Policy:

The University of Oregon (the University) is committed to ensuring the safety, rights, and welfare of all human subjects/participants in research conducted at or by the University. All research, funded or not funded, involving human subjects/participants conducted by members of the University community (employees, officials, students, and agents) or using University facilities or resources, will be governed by the Human Research Protection Program (HRPP). The HRPP is guided by the ethical principles of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the "Belmont Report"), applicable professional and ethical standards and codes, and carried out in compliance with applicable federal laws, state laws, University policies or procedures.

The University defines research involving human subjects/participants using current *Department of Health and Human* Services and/or *Food and Drug Administration* definitions. The current definitions are as follows, with citations to the relevant code of federal regulations (CFR):

- *Human subjects/participants* include any individuals who meet either of the following definitions:
    - A living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (45 CFR 46.102(e)(1));
    - An individual who is or becomes a participant in research, either as a recipient of the test article (e.g., drugs or devices) or as a control. A subject may be either a healthy human or a patient (21 CFR 50.3(g)).
- *Research* includes any effort that meets either of the following definitions:

- A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes (45 CFR 46.102(l));
- *Clinical investigation* which means any experiment that involves a test article (e.g., drugs or devices) and one or more human subjects/participants and fits the definition of research under Food and Drug Administration regulations. The terms *research, clinical research, clinical study, study,* and *clinical investigation* are deemed synonymous for purposes of this policy (21 CFR 56.102 (c)).

The Vice President for Research and Innovation (VPRI) is responsible for the Human Research Protection Program (HRPP). The HRPP is the core ethical, regulatory, and administrative organizational umbrella under which all aspects of the University's human subjects/participants protection activities are directed and managed. The HRPP implements policies and practices to ensure the adequate protection of human subjects/participants in order to be compliant with relevant laws, regulations, professional and ethical standards, and to support and enhance researchers' endeavors.

The HRPP includes the following elements:

- Oversight for all human subjects/participants research conducted by or at the University. No research involving human subjects/participants may be conducted without review and oversight by the Institutional Review Board (IRB) or other entities designated by the HRPP to ensure the protection of human subjects/ participants in accordance with the HRPP Plan.
- A University designated Institutional Official (IO), who is legally authorized to act for and on behalf of the University in matters related to human subjects/participants research and the protection of human subjects/participants. The IO is responsible for ensuring the HRPP is adequately resourced to protect the rights and welfare of human subjects/participants and functions in compliance with requirements applicable to research involving human subjects/ participants.
- A written HRPP Plan specifying procedures governing the conduct of human research to promote institutional and individual compliance with applicable regulatory, legal, external sponsor, and ethical standards. The HRPP Plan may include definitions, functions of the IRBs, integration of research integrity standards, steps for quality assurance and compliance monitoring, and processes for reviewing ethics concerns. The HRPP Plan will document procedures for determining when activities are overseen by the HRPP. The HRPP Plan is subject to the approval of the IO. Unless necessary to immediately protect the rights and welfare of human research participants, significant changes to the HRPP Plan which divert from regulatory standards will be executed with appropriate consultation from stakeholders.
- Institutional Review Boards (IRBs) with independent authority to review, approve, suspend, terminate, and monitor research involving human subjects/participants.
- Maintaining any federal, state, and other registrations and/or assurances.
- Mechanisms for education, training, and support to investigators.
- Processes to seek input from stakeholders and support continuous improvement in the HRPP.

Resources:

Policies related to this policy:

Allegations of Research Misconduct

Conflict of Interest, Conflict of Commitment, and Outside Activities

Inventions, License Agreements, Educational & Professional Materials Development, Patents & Copyrights

Proprietary Research

Research: Classified Research

Research: Financial Conflict of Interest in