

Policy Title:	Research and Ethical Standards
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**A. Description**

This policy covers the following topics related to all research conducted under the auspices of Southern Oregon University:	
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This policy and associated procedures are intended to include requirements to assure SOU is in compliance with Federal Requirements, in US Public Health Service (PHS) sponsored research expectations as outlined in Code of Federal Regulations (CFR); where there are substantive differences between this policy and those requirements, those requirements shall take precedence. See Relevant Authority section of this Policy for specific CFR references.	

**B. Definition(s)**

**Research:** a systematic investigation, study, or experiment designed to contribute to generalizable knowledge. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

**Research Record:** any data, document, computer file, physical or cloud storage, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

**Principal Investigator (PI) or Project Director:** the leader of a team of investigators (research or project team) who has ultimate responsibility for the conduct of the research or service project.

**Faculty sponsor:** individual overseeing student research involving animal or human subjects

**Sponsored Research:** Projects or programs funded by grants or contracts from government or non-governmental agencies that carry stipulations on spending, reporting, or other aspects of the award.

**Researcher:** any individual who is responsible for the design, conduct, or reporting of sponsored research, or proposals for such funding. This term includes principal investigators, project directors, faculty sponsors, and their team members working on the project, such as co-PI, co-director, post-docs, graduate assistants, and undergraduates. The definition may also include collaborators or consultants, as appropriate.

**Researcher's Family:** any member of the Researcher's immediate family, specifically, domestic partner and any dependent children.

**Institutional Responsibilities:** the Researcher's professional responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

**Sponsored Programs/Grants and Contracts Office:** official SOU entity that manages pre- and post- award processes and supports Principal Investigators and Project Directors throughout the lifecycle of all grants or sponsored contracts.

**Informed Consent:** a basic ethical tenet of scientific research on human populations that guarantees participants are fully informed about their part in the research project, including any potential repercussions to them personally. The subject or their legally authorized representative freely, and without any undue influence or subtle pressure, gives their consent in writing to prior to participation.

**Financial Interest:** anything of monetary value received or held by a Researcher or an Researcher's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- salary, royalties, or other remuneration from Southern Oregon University;

- income from the authorship of academic or scholarly works;
- income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Researcher does not directly control the investment decisions made in these vehicles.

Financial Interest includes any reimbursed or sponsored travel undertaken by the Researcher and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Researcher as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

**Significant Financial Interest:** Financial Interest that reasonably appears to be related to the Researcher's Institutional Responsibilities, and:

- if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000; or
- if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds \$5,000; or
- if with a non-publicly-traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure; or
- is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through Southern Oregon University, or
- is reimbursed or sponsored travel related to their institutional responsibilities.

**Financial Conflict of Interest:** a significant financial interest (or, where the Associate Director of Faculty Scholarship and Research Compliance requires disclosure of other Financial Interests, a Financial Interest) that Southern Oregon University reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

**Research Misconduct or Misconduct in Science:** fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- a) Fabrication is making up data or results and recording or reporting them.
- b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- d) Research misconduct does not include honest error or differences of opinion.

**Allegation:** any written or oral statement or other indication of possible research misconduct made to an institutional official.

**Whistleblower:** a person who makes an allegation of scientific misconduct.

**Respondent:** the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

**Investigation,** the formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct.

**Inquiry:** the gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.

**Parties to an Investigation or Inquiry:** all individuals involved in an inquiry or investigation, including whistleblower(s), respondent(s), witnesses, and others participating in the inquiry or investigation procedure.

**Retaliation:** any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.

### C. Policy Statement

#### **1. Eligibility to serve as Principal Investigator or Project Director**

- a. Faculty holding the following academic appointments ARE eligible to serve as principal investigators, project directors, and/or faculty sponsors:
  - Professor
  - Associate Professor
  - Assistant Professor
  - Instructor
  - Senior Instructor I
  - Senior Instructor II
  - Adjunct or Affiliate faculty appointments, are only eligible with Provost's approval
- b. Staff with the following titles ARE eligible to serve as principal investigators and/or project directors:
  - President
  - Vice President
  - Provost

- Associate Provost
  - Directors
  - Others are only eligible with the University President's or a Vice President's approval
- c. Students are NOT permitted to serve as PI or project directors for grants, sponsored contracts, and research involving animal or human subjects. Graduate students may serve as co-PIs with School Director's approval.
- d. All student research must be supervised by a faculty member or sponsor. Furthermore, all student research projects involving animal or human subjects, including master's theses, must have a faculty sponsor or PI listed on the Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) submission.

## **2. General Provisions**

### *a. Procuring External Funding*

Principal investigators and Project Directors shall submit all proposals for grants and sponsored contracts through the Sponsored Programs/Grants and Contracts Office. As the legal applicant, Southern Oregon University assumes administrative responsibility for the project and ensures compliance with all policies and regulations pertaining to the award. Funded projects are subject to the same federal, state, and university policies governing other activities on campus.

### *b. Outside Employment*

SOU employees shall submit a Request for Approval for Outside Employment prior to considering any outside employment for research, consulting, or other activities that may substantially interfere with their duties while on contract at SOU. Approval must be granted before accepting such an opportunity.

### *c. Reporting on Research*

- 1) Principal investigators and project directors shall not conduct or participate in sponsored research that restricts the freedom of investigators to publish results of research.
- 2) Researchers shall disseminate their research findings except where unanticipated circumstances (e.g., the health of the researcher) or proprietary agreements with employers, contractors, or clients preclude such dissemination.
- 3) Consistent with the spirit of full disclosure of methods and analyses, once findings are publicly disseminated, researchers shall permit their open assessment and verification by other responsible researchers with appropriate safeguards, where applicable, to protect the anonymity of research participants.
- 4) In the case of human subject research, researchers shall share data in a manner that is consistent with research subjects' interests and protection of confidentiality of the information they have been given. They maintain the confidentiality of data, whether legally required or not; remove personal identifiers before data are shared; and if necessary, use other disclosure avoidance techniques.

### **3. *Requirements for Research Involving Animals***

Research projects involving vertebrate animals must be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) prior to any work beginning to assure SOU complies with all applicable provisions of the Animal Welfare Act and other applicable Federal statutes and regulations relating to animals.

### **4. *Requirements for Research Involving Human Subjects***

Research projects involving human subjects must be reviewed and approved by the Institutional Review Board (IRB) prior to any work beginning to assure SOU complies with all applicable Federal Regulations and other restrictions required by sponsor. Some categories of minimal risk research qualify for exemption from the Federal regulations and do not require additional oversight by the IRB; however, these studies require review by SOU's IRB to determine eligibility for this exemption.

### **5. *Significant Financial Conflict of Interest and Disclosure Responsibilities***

#### *a. Disclosure*

All researchers on externally funded sponsored programs shall disclose significant financial interests that are related to the Researcher's institutional responsibilities to the Southern Oregon University, through the Associate Director of Faculty Scholarship and Research Compliance or designee prior to the acceptance of a sponsored award and annually thereafter until there is no external funding.

The Associate Director of Faculty Scholarship and Research Compliance shall be responsible for the distribution, receipt, processing, review and retention of disclosure forms, as well as reporting financial conflicts or non-compliance to the US Public Health Service (PHS) in accordance with PHS regulations.

#### *b. Training*

The Associate Director of Faculty Scholarship and Research Compliance shall provide training to all researchers on this policy and their responsibilities regarding disclosure and the conflict-of-interest regulations, and maintain records of training to assure all researchers are updated on any changes and complete training at least every four years.

#### *c. Suspension of Activities*

All relevant activities may be suspended until a financial conflict of interest is resolved or appropriate protections are implemented. A researcher's failure to comply with this policy may also constitute cause for disciplinary or other administrative action pursuant to Southern Oregon University policy.

#### *d. Records Retention*

The Associate Director of Faculty Scholarship and Research Compliance shall retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted, unless any litigation, claim, financial management review, or audit is started before the expiration of the three-year period, the records shall be retained until

all litigation, claims or audit findings involving the records have been resolved and final action taken.

*e. Confidentiality*

To the extent permitted by law, all disclosure forms, conflict management plans, and related information shall be confidential. However, Southern Oregon University may be required to make such information available to the sponsor. If Southern Oregon University is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Researcher will be informed of this disclosure.

*f. Public Accessibility*

Prior to the expenditure of funds, Southern Oregon University will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- 1) the Significant Financial Interest was disclosed and is still held by the senior and key personnel;
- 2) a determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- 3) a determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS regulation.

**6. Research Misconduct Reporting**

*a. Responsibilities*

- 1) All researchers shall guard against research misconduct by themselves, their colleagues and collaborators, and the people they teach or supervise.
- 2) All SOU employees shall report any research misconduct to the Associate Director of Faculty Scholarship and Research Compliance as soon as possible after becoming aware of an incident.

If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may consult the Associate Director of Faculty Scholarship and Research Compliance informally to determine whether the incident appears to meet the definition of research misconduct. The Associate Director of Faculty Scholarship and Research Compliance may refer the individual or allegation to other offices or officials, if appropriate.

- 3) All SOU employees and students shall cooperate with a research misconduct inquiry or investigation, and shall provide relevant evidence in the course of any research misconduct proceedings.

*b. Protections*

- 1) Inquiries and investigations shall be conducted in a respectful manner that will ensure fair treatment of all parties.

- 2) Respondent(s) will be informed of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of counsel.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of research misconduct, s/he has the right to receive institutional assistance in restoring her or his reputation.

- 3) Institutional employees accused of research misconduct may consult with non-lawyer personal advisor (who is not a principal or witness in the case) or legal counsel to seek advice and may bring the personal advisor or counsel to interviews or meetings on the case but they may not speak during the inquiry or investigation meetings.
- 4) As requested, the Associate Director of Faculty Scholarship and Research Compliance and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of respondents against whom no finding of research misconduct is made.
- 5) No person may retaliate in any way against any parties to the inquiry or investigation. The Associate Director of Faculty Scholarship and Research Compliance shall investigate reports of alleged or apparent retaliation and recommend appropriate actions to the Provost or designee.

*c. Confidentiality*

- 1) All research misconduct investigations shall protect the confidentiality of all parties to the greatest extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation.

The Associate Director of Faculty Scholarship and Research Compliance shall:

- a) Limit disclosure of the identity of respondents, complainants, and witnesses to those who need to know in order to carry out a thorough, competent, objective, and fair research misconduct proceeding; and
  - b) Except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding.
- 2) The Associate Director of Faculty Scholarship and Research Compliance shall use written confidentiality agreements or other mechanisms when appropriate to ensure that the recipient does not make any further disclosure of identifying information. If the complainant requests anonymity, the University will strive to honor the request within the limits set by applicable policy and law.
  - 3) The Provost or designee may communicate about research misconduct allegations and proceedings with other persons as required by law or as necessary to protect public health or safety, the integrity of research, fundamental fairness to the respondent or other parties, or an overriding interest of the University.



*d. Conflicts of Interest*

- 1) At all stages of research misconduct proceedings, all persons involved shall identify and disclose to the Associate Director of Faculty Scholarship and Research Compliance, Provost, or University President, as appropriate, any potential conflict of interest, i.e., real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.
- 2) If such conflicts are present, the individual shall recuse himself or herself from any investigative or decisional role in the case.
  - a) If any prospective committee member at any point in the process presents a conflict of interest, that committee member shall be replaced by the Associate Director of Faculty Scholarship and Research.
  - b) If the Associate Director of Faculty Scholarship and Research has a conflict of interest, the Provost shall name a replacement to carry out his/her responsibilities as noted in this Policy, section 6, and functions in the Research Misconduct Procedures for the particular matter.
  - c) If the Provost has a conflict of interest, the University President shall name a designee to carry out the Provost designee's responsibilities under this Policy, section 6, and functions in the Research Misconduct Procedures for the particular matter.
  - d) Conflicts of interest on the part of Deans, Directors, or Department Chairs shall be dealt with by the Provost or designee.
- 3) If it becomes necessary to appoint any replacement during the course of the process, the new appointee shall be fully informed regarding earlier procedures and evidence secured, but the process shall not commence anew.
- 4) The Provost or designee is responsible for resolving disagreements over what constitutes a conflict of interest, except in the case of alleged conflicts involving the Provost, in which case the designee appointed by the University President is responsible.

*e. Process and Standards of Review*

- 1) Review of an allegation shall follow the Research Misconduct Procedure, which shall assure that all allegations move through the following three stages:
  - a) Preliminary assessment stage determines if the allegation provides sufficient clarity and detail to suggest an inquiry may find evidence of potential misconduct.
  - b) If sufficient clarity and detail, proceeds to an inquiry stage that consists of information gathering and preliminary fact finding to determine whether there is sufficient evidence of possible misconduct to recommend further investigation.
  - c) If there is sufficient evidence of possible misconduct, proceeds to an investigation stage that is a formal examination of all relevant facts and concludes with of their findings and recommendations to the Provost or designee for further action.

In addition, for sponsored research, the Associate Director of Faculty Scholarship and Research Compliance shall augment the Research Misconduct Procedure with any additional

requirements of that sponsor to assure SOU complies with those requirements as well.

- 2) A finding of research misconduct requires that:
  - a) There be a significant departure from accepted practices of the relevant research community; and
  - b) The respondent committed the research misconduct intentionally, knowingly, or recklessly.
- 3) Allegations of research misconduct must be proven by a preponderance of the evidence.
- 4) The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct when the University establishes by a preponderance of the evidence that:
  - a) The respondent:
    - i. Had research records and intentionally, knowingly, or recklessly destroyed them;
    - ii. Had the opportunity to maintain the records but did not do so; or
    - iii. Maintained the records and failed to produce them in a timely manner; and that
  - b) The respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

*f. Factual Findings*

The factual findings of the Investigation Committee shall be conclusive and binding on any later University proceeding convened for other purposes (e.g., grievances relating to sanctions imposed).

*g. Limitation of Actions*

Allegations must be raised within six (6) years of the date on which the alleged research misconduct occurred unless:

- 1) The respondent continues or renews any incident of alleged research misconduct that occurred before the 6-year limitation through the citation, republication, or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized; or
- 2) The Provost or designee, following consultation with Office of Research Integrity within the US Department of Health and Human Services (DHHS) [or other appropriate Federal Office], determines that the alleged misconduct could reasonably have a substantial adverse effect on the health or safety of the public.

This policy may be revised at any time without notice. All revisions supersede prior policy and are effective immediately upon approval.

D. Relevant Authority

This policy implements the requirements of [9 CFR Part 2, Subpart 3 \(Animal Welfare\)](#), [42 CFR Part 50, Subpart F \(Objectivity in Research\)](#), [42 CFR Part 93, Subpart C \(Research Misconduct\)](#), [45 CFR Part 46 \(Protection of Human Subjects\)](#), and [45 CFR 94 \(Financial Conflict of Interest\)](#).

E. Other Information

[Southern Oregon University's Institutional Review Board \(IRB\)](#)

Southern Oregon University's Institutional Animal Care and Use Committee (IACUC)

[Sponsored Programs at SOU/Grants and Sponsored Contracts](#)

Researchers Financial Conflict of Interest Disclosure and Review Procedure

Research Misconduct Procedure

[Request for Approval for Outside Employment Form](#)

The Policy Contact, defined above, will write and maintain the procedures related to this policy and these procedures will be made available within the Custodial Office.