

Central Washington University

University Research Ethics and Conflicts of Interest Policy

I. RELATION TO UNIVERSITY MISSION

Central Washington University, as one of the six state-supported institutions offering baccalaureate and graduate degrees, is committed to serving as an intellectual resource to assist central Washington, the region, and the state in solving human and environmental problems. To this end, one of the University's goals is to build mutually beneficial partnerships with the public sector, industry, professional groups, institutions, and the communities surrounding our campuses. The University is equally committed to the state's economic development, competitiveness, and technological leadership. The University thus supports the active engagement of its faculty in basic and applied research, technology transfer, and related approved consulting activities to assist in the development, application, or commercialization of its intellectual resources for the mutual benefit of the University and Washington State.

II. PRINCIPLES FOR CONDUCTING RESEARCH AT THE UNIVERSITY

The University is a public institution and has a duty to the public to perform research and to apply its intellectual resources in a manner that conforms to the highest ethical standards and that complies with applicable state and federal laws. Research investigators, including faculty, staff, students, and associated entities, must either avoid conflicts of interest or must disclose any actual or potential conflicts that may arise so that the University can work with the investigator to manage, reduce, or eliminate those conflicts. Since such management helps ensure that the research is conducted in a way that will withstand public scrutiny and is consistent with ethical standards, University research investigators must fully cooperate with the University's management of any actual or potential conflicts of interest.

Any financial interest of an investigator that may affect the design, conduct, or reporting of University research, or which may compromise the University's duty to the public or to the University's students or employees, must be disclosed so that conflict(s) can be managed, reduced, or eliminated. The Central Washington University Research Foundation maintains a separate but compatible conflict of interest policy that must also be followed when performing research under the auspices of that organization.

III. DEFINITIONS USED IN THIS POLICY

- A. **Clinical Trial:** Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between an intervention (e.g., medical or psychological) and an outcome (e.g., health or behavioral). “Intervention” means any intervention used to modify a health or behavioral outcome. The definition includes drugs, medical procedures or devices, behavioral treatments, process-of-care changes, and the like.
- B. **Conflict of Interest (COI):** The existence of an interest which may reasonably be determined to affect or appear to affect the design, conduct, or reporting of research. COI is not limited to financial interests but may consist of other personal interests of a non-financial nature.
- C. **Conflict of Interest Review Committee (COIC):** The University committee which reviews all pertinent documentation, including COI resolution plans, relating to potential or actual financial COI cases based on federal and state law and University policy. The COIC has the responsibility and authority to (1) assess whether a potential conflict exists, (2) assess the extent of the conflict, and (3) manage, reduce, or eliminate the conflict before approving the research or applied project.
- D. **Ethics Safe Harbor Provisions:** Disclosure of COIs is required for research employees to be protected within the “safe harbor” provisions of the Ethics in Public Service Act, RCW 42.52, relating to university research employees. Research employees must disclose and refer to the COIC any actual or potential COIs on the part of persons responsible for the design, conduct, or reporting of research and any significant financial interest in the conduct or outcome of the research. The COIC is then responsible for managing, reducing, or eliminating the conflict before approving the research or applied project.
- E. **Equity Interest:** Stocks, stock options, ownership, partnership or limited liability company, or other ownership interests. Equity interest does not include interest in a mutual fund or other stock management not under the individual’s control, but does include interest held in a deferred compensation plan that is under the individual’s control.
- F. **Family:** The investigator or research employee, the investigator’s or research employee’s spouse/domestic partner, and dependent children and other dependent relatives living in the investigator’s or research employee’s household (investigator’s or research employee’s financial interest includes the aggregate financial interest of the family).
- G. **Financial Interest:** Financial interest is defined in accordance with applicable federal or state law and includes but is not limited to monetary and equity interests.

- H. **Gift:** Anything of value to the extent that adequate consideration is not received. A gift of greater than \$50 from an outside entity is a significant financial interest and must be disclosed if it is from an entity that may be affected by the investigator's or research employee's applied research or technology transfer activities.
- I. **Investigator:** Any individual responsible for the design, conduct, and reporting of research, basic or applied, including the principal investigator, a co-principal investigator, a collaborator, or the applied project's director.
- J. **Research:** A systematic scientific investigation designed to develop, apply, or contribute to generalizable knowledge, including basic and applied research as well as associated instruction, scholarly, creative, public service, product development, and extension activities.
- K. **PHS Awarding Component:** A division of the Public Health Service (PHS), such as CDC, NIH, NIMH, etc., which is sponsoring the research.
- L. **Research Employee:** The university research safe harbor provisions of the Ethics in Public Service Act apply only to research employees engaged in basic or applied research, technology transfer, or approved consulting activities related to research and technology transfers, or other incidental activities. The University defines research employees as individuals who are:
 - a. Faculty with appointments in the professorial ranks whose terms of employment and advancement include contributions via scholarly research.
 - b. Any other University employees, including research scientists, postdoctoral research associates, professional staff, and graduate students, who are responsible for the design, conduct, or reporting of research.
 - c. Appointees who are not formally employed by the University, but who are obligated to follow applicable faculty and University policies and procedures. This may include visiting scientists.
 - d. Faculty or administrative staff who directly manage the application or transfer of technology process on behalf of the University, including the Provost and the Dean of Graduate Studies and Research.
- M. **SBIR/SBTT:** Small Business Innovation Research (SBIR) and Small Business Technology Transfer (SBTT) Programs.
- N. **Significant Financial Interest** exists whenever:
 - a. The investigator, research employee, or member of his/her family, is a manager, officer, trustee, or employee of an external entity whose financial interest would reasonably appear to be affected by the outcome of the research;

- b. The investigator or research employee, and/or member of his/her family, receives aggregate (1) fees for consulting, (2) gifts, and/or (3) honoraria in excess of \$1,000 in any 12-month period within the past 24 months from an external entity whose financial interest would reasonably appear to be affected by the outcome of the research;
- c. The investigator, research employee, or family member has ANY financial interest that would reasonably appear to be affected by the outcome of research that involves clinical trials of human subjects or other human subject research requiring the review of the full Institutional Review Board; or
- d. The investigator, research employee, and/or family member has an interest in an external entity that exceeds \$10,000 in fair market value, an ownership interest in any single entity in excess of 5%, compensation from an external entity in excess of \$10,000 during a calendar year, or intellectual property rights and royalties from such rights in excess of \$10,000 per year. A significant financial interest does not exist if such interest exists due to ownership of stock through diversified investments such as mutual funds in which the research employee does not control investment decisions.

The above thresholds apply to the aggregate financial interests of **both** the investigator/research employee **and** the investigator/research employee's family member(s). Included in the aggregate is anything of monetary value, consisting of but not limited to salary, consulting fees, honoraria, gifts, equity interests, ownership interests, and royalty income. Not included are wages or salary from the University, income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities, or income from service on advisory committees or review panels for public or nonprofit entities.

- O. **Sponsor:** The entity which has or will provide financial support for the research, which may include corporate sponsors, state agencies, the University, or agencies of the federal government, including the Public Health Service (PHS) and the National Science Foundation (NSF).
- P. **Technology Transfer or Application:** The efforts of University research employees that transfer and/or apply intellectual property and technology to or on behalf of a third party, including a private enterprise. For federally sponsored research, the Bayh-Dole Act requires the University to transfer resulting inventions and technology into the economy through commercialization whenever possible. The transfer and/or application of technology may often include interaction with and investment in external entities which may create actual or potential COI.

IV. PURPOSE OF THIS POLICY

- A. Protect investigators, research employees, and students from the risk of COI or appearance of conflict and to ensure that such COI does not create doubt about the integrity of the research resulting in possible federal and state sanctions or the tainting of professional reputations.
- B. Protect research subjects from risks related to the investigator's and research employee's COI.
- C. Ensure the integrity of research conducted by University investigators, project directors, and research employees, and ensure that all projects and research are free from bias by reducing, managing, or eliminating COI when necessary.
- D. Facilitate the responsible transfer and/or application of University technology and the provision of applied research to the public and industry for the benefit of society.
- E. Meet the University's obligations to the sponsors of University research and projects, including federal sponsors, to adopt and enforce a COI policy which is effective in practice.
- F. Provide investigators, project directors, and research employees guidance on requirements and processes for identifying and disclosing COI.
- G. Provide University administrators and the COIC guidance on requirements and processes for managing COI.
- H. Guide investigators, project directors, and research employees in making informed decisions on when and how to engage in technology transfer, applied research, and/or outside professional activities to avoid compromising the integrity of their research or their responsibilities to the University and to the public.

V. APPLICATION

This policy applies to all University investigators, project directors, and research employees and to all University research or its application regardless of the source of funds, including federal and non-federal funds, state funds, gifts, CWU Research Foundation funds, and any University fund.

Federal funding provisions:

If Public Health Service (PHS) funds University research, this policy applies to all entities involved in the research project, including subcontractors, sub-grantees, and collaborators, to the extent required by 42 CFR Part 50, Subpart F, and/or 45 CFR Part 94..

The University must report any COI to PHS for all research sponsored by PHS. Conflicts must first be reported prior to expending any PHS funds. Any subsequently arising conflict must be reported within 60 days of being identified. The University must provide information on conflicts of interest to the Department of Health and Human Services (HHS) upon request.

When the University intends to collaborate with another institution on PHS and/or National Science Foundation (NSF) sponsored projects, the University must receive written assurance that the collaborating institution has a COI policy which complies with the federal sponsor's regulations.

VI. APPLIED RESEARCH/TECHNOLOGY TRANSFER ACTIVITIES BY RESEARCH EMPLOYEES

Research employees' professional relationships with private industry, nonprofit institutions, and other government entities can facilitate the transfer and/or application of technology or the provision of applied research, thus stimulating economic growth while providing investigators, research employees, faculty, and students with a rich environment in which to teach, learn, and conduct research.

- A. Travel to promote the University's applied research/technology transfer activities:
 - a. The University can usually provide investigators and research employees with funds for travel, including related meals and lodging expenses, to meet with representatives from external entities when pursuing research collaborations through sponsored research agreements and when exploring opportunities for University transfer and/or application of technology through intellectual property licensing. Travel must be justified and reimbursed following University travel policies, including the University's policy on travel paid by third parties.
 - b. Investigators, project directors, and research employees must avoid accepting gifts from external entities (not including gifts from friends and relatives that may have an interest in external entities as long as the gifts are not related to the working relationships). This is particularly true if the external entity's financial interest would reasonably appear to be affected by the outcome of University research. However, travel, meals and lodging expenses can be provided by external entities and be exempt from the gift designation if the external entity's payment of the travel expenses will qualify under Internal Revenue Service rules as a bona fide business expense of the investigator, project director, or research employee. Travel reimbursed by an external entity must be justified by the University traveler as a legitimate applied research or technology transfer activity or an outside professional activity related to the traveler's scholarly expertise.
- B. Applied research/technology transfer through outside professional activities and consulting:

- a. Outside professional activity related to an investigator's, project director's, or research employee's field or discipline is a critically important method of applied research and technology transfer. Faculty members may perform such outside activity under the provisions of applicable CWU policies or the Collective Bargaining Agreement (CBA) between the United Faculty of Central and Central Washington University. Other employees should consult the terms of their employment to determine what activities are allowable.
- b. To avoid actual or perceived COIs, investigators, project directors, and research employees must disclose all outside professional activities in their field or discipline beyond the employee's University duties and obtain approval from the appropriate department chair or other supervisor within five working days of the commencement of the activity. Such disclosure and approval must occur prior to receiving any wage, fee for services, honoraria, or other compensation.
- c. Investigators, project directors, and research employees need not disclose scholarly activities, including publications, journal article reviews, grant applications, panel reviews, presentations, seminars and lectures unless they are aware of an actual or perceived COI. Scholarly activities are not generally considered "consulting" or "outside employment." Such activities need only conform to the standards of applicable CWU policies or the CBA between the United Faculty of Central and Central Washington University or for non-faculty investigators, project directors, or research employees, their contract of employment, when applicable, employment letter, Washington Administration Code or the respective collective bargaining agreement.
- d. Outside consulting agreements are personal employment agreements, regardless of whether compensation is provided for the activities. The research employee may wish to seek personal legal advice prior to signing any such agreement. Although consulting agreements may require the consultant to assign all patentable discoveries to the external entity, the University research employee cannot transfer intellectual property to an outside entity if the University has ownership rights in that intellectual property. Thus, it is essential that care is taken by University research employees who are presented with such agreements to not violate the employment contract with the University, as articulated in applicable CWU policies or the CBA between the United Faculty of Central and Central Washington University, or other conditions of employment.
- e. If the employee anticipates that University facilities, personnel, equipment, land, or other resources will be used in an outside professional activity, such use must be declared and approved in advance. When facilitating applied research and technology commercialization activities, use of University resources is conditionally allowed under this policy. Approval for such activities would typically take the form of an approved sponsored research agreement. Such agreements must clearly justify why the work is being conducted as a

consultancy rather than an agreement between the sponsor and the University and must articulate how the work advances applied research and/or technology commercialization. Such an agreement between the University and the employee engaged in the outside professional activity must be executed prior to the use of University resources for private activities. It is anticipated that the employee engaged in the outside professional activity will pay full charges paid by others, including appropriate F&A fees, for the use of such resources. Agreements between the University and the employee to use resources for outside professional activities are considered a conflict only when the resources are those which the research employee normally uses in the course of his or her employment with the University or over which the research employee or a member of his or her family has direct input in determining the availability of a resource.

- f. In addition to disclosure and approval, the research employee is expected to perform his or her University duties and the outside professional activity ethically, legally, and professionally. Care must be taken by the research employee to minimize the potential that the outside professional activity will damage the University's academic integrity, mission, or interests.
- g. A research employee must update his or her COI information annually.
- h. The COI disclosure form must be completed and forwarded to the research employee's chair or supervisor prior to engagement in an activity with potential for COI. The research employee's chair or supervisor must review the information on the COI disclosure form and decide whether the outside activity is an actual or perceived conflict with the research employee's duty to the University or the research in which the research employee is engaged. If such review leads the chair or supervisor to believe that an actual or perceived conflict exists, the chair or supervisor must immediately convey the disclosure to the Provost on behalf of the COIC, with a copy to the appropriate dean and a copy to the Dean of Graduate Studies and Research, to avoid undue delay in starting the research.
- i. If the research employee disagrees with the chair or supervisor's referral of the activity to the COIC, the research employee may ask that the Dean of Graduate Studies and Research review the decision. If a determination is made that imposing conditions or restrictions will be either ineffective or inequitable, and that the potential negative impacts that may arise from a potential COI are outweighed by interests of the applied research, the application or transfer of technology, or the public health or welfare, then, when permitted by applicable regulations, the Dean of Graduate Studies and Research may allow the research to go forward without referring the disclosure to the COIC.

- j. Any COIs that arise during the course of a research project must be disclosed. For PHS-funded research, the University must report any conflicting interest to the PHS awarding component that issued the award prior to expending any funds, AND any interest identified as conflicting subsequent to the initial report within 60 days of that identification. Upon request, the University will make information available to the HHS about all actual or perceived conflicting interests and how those interests are managed, reduced, or eliminated.
 - k. The University, via the provost or deans, relevant department chair/director, and research employee, must maintain records, identifiable to each research project, for each disclosure of COI, including the determinations by the COIC and the research employee's actions in managing the conflict. These records must be maintained at least three years beyond the termination or completion of the research. This requirement complies with PHS regulation, 45 CFR 74.53(b). If a federal or state agency is reviewing the history of the conflict management, the records must be maintained for three years beyond such review.
- C. Applied research and/or technology transfer through research employee private enterprise involvement, including start-up companies:
- a. Research employee start-up companies that are founded by or have a close relationship with University research employees are a valuable method of promoting economic development through applied research or the transfer of University-created knowledge and technology.
 - b. Companies started by others also encourage and foster applied research and the transfer of technologies from the University to private enterprise. Such companies may engage research employees in a variety of ways, including technical advising.
 - c. When engaged in applied research and/or technology transfer activities through the formation of start-up companies, the research employee must disclose actual or perceived COI to her/his chair or supervisor using the COI disclosure form. The chair or supervisor will forward copies of the disclosure information to the appropriate dean and to the Dean of Graduate Studies and Research, and will refer the situation to the COIC for management via a copy to the Provost.

The University will:

- i. Ensure that the provost, appropriate dean, Dean of Graduate Studies and Research, and relevant department chair/director are aware of the research employee's enterprise;

- ii. Manage any COI through the COIC and through the provost, appropriate dean, Dean of Graduate Studies and Research, and appropriate chair/director;
- iii. Manage all intellectual property disclosed to the Intellectual Property Committee or assign the intellectual property to the Central Washington University Research Foundation (CWURF) for management.
- iv. Not take equity ownership in the private start-up enterprise that utilizes University intellectual property.

The research employee will:

- v. Fully disclose any significant financial interest or other potential, actual, or perceived COI to the research employee's supervisor, chair, or when appropriate, to the Dean of Graduate Studies and Research, provost, appropriate dean, or director.
- vi. Comply with all applicable University policies, including employment, intellectual property, and COI policies.
- vii. Fully disclose her/his relationship to any start-up company to anyone working on his/her research or related research, including co-investigators, research assistants, trainees, fellows, or students, and to subcontractors working on related research.
- viii. Not allow her/his relationship to the start-up company to impair the rights of any graduate or undergraduate student or University employee. A research employee must never allow outside interests to impair a student's best interests including right to publish, progress toward degree, or opportunities for related training and experience.
- ix. Never compromise the safety and health of a research subject based on the research employee's outside interests. Any outside COI related to research involving human subjects must be disclosed to the Institutional Review Board (IRB) for their consideration in the IRB review and management of research protocols, as well as to the COIC.
- x. Disclose any potential COI's to the COIC. The research employee, in collaboration with the COIC, must develop a suitable management strategy for an identified COI.

D. Approved private use of University resources:

The Ethics in Public Service Act (RCW 42.52) was revised in 2005 with respect to University-approved research, researcher consulting, and technology transfer. A new section (safe harbor provisions) of RCW 42.52 provides that the University may have an administrative process to allow approved private use of University facilities, equipment, and staff time to advance the University's research and technology transfer mission. The University costs must either be *de minimis* or the activity must be a pre-approved outside professional activity. The University must be reimbursed for all costs which are more than *de minimis* pursuant to a contract with the University for use of facilities or resources. If the contract only utilizes existing University resources, a facility use agreement may be used. If the contract includes deliverables such as experimental design or data analysis, a contractual, sponsored program agreement, which includes a description of expectation and deliverables, should be utilized. In no instance may a philanthropic donation be used to reimburse the University for the costs of providing such facilities or resources.

University policy will conditionally allow the private use of University facilities for applied research and technology transfer activities, provided that:

- a. Appropriate University offices, including the Office of Graduate Studies and Research, the Intellectual Properties Committee, the Office of Business Affairs, and the Office of the Provost, as well as the CWU Research Foundation as appropriate, shall work closely to collectively determine that private use is acceptable under tax law and does not conflict with grant requirements or existing University obligations. Such offices will consult, as appropriate, with the University's legal counsel.
- b. All projects which include a potential COI must have COIC assurance that a COI does not exist or that the COI can be appropriately managed prior to facility use.
- c. All projects are subject to approval by the appropriate dean and/or provost using established University approval mechanisms. As noted above, such activities may not be supported by philanthropic donations.
- d. All projects must comply with and not interfere with state and federal research projects underway in the research employee's lab.
- e. If any employee(s) of a start-up company or other private entity wishes to be included as named participants on any research contract with the private entity, the request will be referred to the COIC. The COIC will determine whether the integrity of the research will be compromised by the proposal and if the COI can be managed, reduced, or eliminated.
- f. Except to the extent provided by other applicable University intellectual property policies and/or contracts, all inventions arising from University research are owned by the University and subject to an option to negotiate additional licenses. Joint

ownership may be possible if private entity employees separately contribute to the invention.

- g. Students (including employed graduate research assistants) in the research employee's lab will not be permitted to function as employees of a private entity in which the research employee has an interest without obtaining prior permission from the chair/director, dean (as appropriate), and Provost. The students must be free to pursue publication, advance in their line of study, and publish their thesis without restriction.

VII. GUIDANCE FOR DE MINIMIS AND CONTRACTED USE OF UNIVERSITY RESOURCES IN APPLIED RESEARCH AND/OR TECHNOLOGY TRANSFER ACTIVITIES

- A. The revised Ethics in Public Service Act, RCW 42.52, recognizes that limited private use of University resources by University research employees for applied research and/or technology transfer activities will not undermine public trust and confidence and can advance the mission of the University.

If the applied research/technology transfer activity and the planned use of University resources has prior approval by the supervising department chair and dean, a research employee may use his or her personally-assigned offices, telephones, computer, e-mail account, internet connections, and comparable types of personally-assigned equipment to conduct outside applied research/transfer technology activities if:

- a. There is little or no additional cost to the University;
- b. Any use is reasonable in duration and frequency and is the most effective use of time or resources;
- c. The use does not interfere with the performance of the official duties of either the University research employee, other University employees, or students;
- d. The use does not disrupt or distract from the conduct of University business due to volume or frequency;
- e. The use does not disrupt other University employees and does not obligate other University employees to make unauthorized uses of University resources; and
- f. The use does not compromise the security or integrity of University property, information, or IT network.

- g. The use is otherwise consistent with this and other applicable University policies and with the standards under 42 CFR Part 50, Subpart F, relating to the promotion of objectivity in research.
- B. The following resources may not be used for outside applied research and/or technology transfer activities unless a sponsored research agreement between the outside entity and the University has been approved to use the stipulated University resources for the contractual purpose.
 - a. Long-distance or other toll calls or use of a University cell phone.
 - b. Paper and other University consumables.
 - c. Time of other University employees during the employee's assigned work.
 - d. Assistance of a graduate student.
 - e. University laboratories, laboratory supplies, or hardware.
 - f. University research support including but not limited to grant and sponsored project administration.
 - g. Equipment that is assigned to another University employee or student.
 - h. University-owned intellectual property.

VIII. FAILURE TO COMPLY WITH UNIVERSITY COI POLICY – SANCTIONS

- A. Any university employee shall report to the Dean of Graduate Studies and Research any investigator or research employee who he or she believes has:
 - a. Failed to file a required report.
 - b. Knowingly filed a false or misleading report.
 - c. Refused to cooperate with the COIC or compliance officer in implementing this policy.
 - d. Substantially and knowingly failed to observe the terms of a conflict management plan adopted by the COIC.
 - e. Knowingly failed to report a COI.

- f. Used University resources for outside applied research and/or technology activities in a manner that did not comply with this policy, which includes breach of a contract between the research employee and the University for use of resources.
- B. The Dean of Graduate Studies and Research, in consultation with the COIC, shall review the report and attempt to resolve the matter. If a resolution is not achieved, and if the Dean determines that a violation of University rules may have occurred, he or she may initiate such corrective action or disciplinary proceedings as may be indicated after consultation with human resources or faculty relations, whichever is applicable.

Failure to comply with this policy may result in action under federal or state law against the investigator or research employee. If the COI involves a research project administered by the University, any action legally required by the funding agency will also be taken.

- C. For PHS-funded research: In accordance with 42 CFR Part 50, Subpart F, if the investigator's or research employee's failure to follow conflict of interest policy has biased the research, the University is required to promptly notify the PHS-awarding component of the corrective action taken or to be taken.
- D. If HHS determines that a PHS-funded project to evaluate a drug, medical device, or treatment was conducted by an investigator or research employee with a conflict that was not disclosed or managed, the University requires the investigator or research employee to disclose the conflict in each public presentation of the results of the research.