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Policy Information

Effective Date:

May 12, 2021

Last Revised Date:

December, 2021

Reference:

University Handbook for Appointed Personnel 2.06.08

Classified Staff Manual 413.0

University Staff Manual

Responsible Unit:

Office for Responsible Outside Interests

Email:

COI@email.arizona.edu [1]

Purpose and Summary

This Policy is intended to protect the integrity and reputation of the University of Arizona (University) by ensuring conflicts of interest and commitment are appropriately eliminated or managed and by promoting objectivity in research.

Scope

All University Employees, including faculty, staff, graduate and undergraduate student employees, and temporary employees; all University affiliates and associates, including Designated Campus Colleagues who Conduct Research at or under the auspices of the University; and Research Subrecipients and External Consultants (collectively “Covered Individuals”) are subject to this Policy.

Definitions

Conducting Research includes the design, development, testing, evaluation, conduct, reporting, review, and oversight of a program of scientific inquiry.

Conflict Official means an individual who reviews conflict disclosures and facilitates conflict management, including individuals in the Office for Responsible Outside Interests, individuals in the office of Procurement and Contracting Services, and designees of those units.

Covered Individual means all University Employees (including undergraduate and graduate student employees), Designated Campus Colleagues, External Consultants, and Research Subrecipients.

Designated Campus Colleagues includes affiliates, associates, volunteers, and interns who contribute their time, services, and expertise to help the University accomplish its missions of teaching, research, and service.

External Consultant means an individual or firm that provides professional advice or services on a sponsored project for a fee, but is not a University Employee.

Institutional Financial Interests means:

1. A University Administrator's Significant Financial Interest;
2. A University Administrator's Significant Personal Interest;
3. A loan of any amount between a non-publicly traded entity and a University Administrator or their family member;
4. The University's equity or similar interest in a publicly traded entity valued at more than \$100,000 or any amount in a non-publicly traded for-profit entity;
5. Substantial gifts, including in-kind gifts, received from an actual or potential commercial research sponsor or an individual or entity that owns or controls products being studied or tested as part of the Research;
6. Gifts totaling \$1 million or more, cumulatively, and other gifts determined by the University's Conflict of Interest Program to be substantial;
7. Any agreement with an external entity that includes the right for the University or a University Administrator or their family member to receive payments, royalties or other income from the commercial development or sale of an investigational product that is the subject of University Research;
8. Ownership by the Arizona Board of Regents (ABOR), on behalf of the University, of a patent and/or other intellectual property right in or sponsorship of an investigational new drug (IND) or device (IDE) application with respect to any drug or device for which human subject Research will be conducted;
9. Donation and sponsorship funds.

Investigator means any person who shares the responsibility of Conducting Research. This includes, but is not limited to, the Principal Investigator (PI), Co-PI, Co-Investigator, Project Director (PD), Co-PD, Senior/Key Personnel, and any other person, regardless of title or position, who is responsible for Conducting Research performed by or under the auspices of the University.

Outside Commitments: (1) are professional and other activities that are related to a University Employee's professional expertise, outside of their University duties and responsibilities; (2) are for the benefit of an external entity or individual and are not covered by a fully executed written

agreement between the University and the external entity; and (3) require a time commitment. Outside Commitments include Outside Employment, independent contracts for consulting services, private consulting groups comprised of University Employees, volunteer/pro bono work, appointments at postsecondary educational institutions, and foreign components, as that term may be updated by the University's Office for Responsible Outside Interests.

Outside Employment refers to any employment relationship outside of the University requiring a time commitment.

Outside Interests means a person's (or that person's family members'), Significant Financial Interests (SFI), Significant Personal Interests (SPI) and Foreign Interests, as those terms are updated by the Office for Responsible Outside Interests.

Research and **Research Project** mean any organized program of scientific inquiry that involves a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge that is performed at or under the auspices of the University. Research includes non-sponsored research, research fellowship and training programs, and research-related activities in undergraduate, graduate, and postdoctoral education.

Research Subrecipient is a party that receives a subaward or subcontract from the University under a University-sponsored project and is accountable to the University for the use of the funds provided by the subaward.

Substantial Interest is any nonspeculative pecuniary or proprietary interest, either direct or indirect, other than a remote interest. Remote interest is defined in A.R.S. § 38-502(10) [2].

University Administrator is any University Employee in a position of administrative leadership of a college, academic department, business, or other administrative unit, where a regular job requirement is to make institutional decisions on behalf of the University of Arizona. The role of a University Administrator includes, but is not limited to, the following positions (whether such positions are staffed on an interim, full-time, or part-time basis):

- University Senior/Associate/Assistant Vice Presidents
- University Provost
- University Senior/Associate/Assistant Vice Provosts
- University Deans
- University Vice/Deputy/Associate/Assistant Deans
- University Directors
- University Department Heads/Chairs
- University Business Officers/Managers
- University Division Chiefs, Center Heads/Directors
- University Employees with the authority to sign agreements on behalf of the University of Arizona or Arizona Board of Regents
- University Employees whose duties and responsibilities include contracting or services related to Research administration, Research contracting, Research compliance, responsible conduct of Research, sponsored projects services, or technology transfer and who are in a position to influence decisions or commit University resources in the performance of the University Employee's duties and responsibilities.
- Individuals who serve as Chairs on the University's Institutional Review Board committees, regardless of whether such individuals are University Employees.

University Employees means all University employees, including faculty, staff, graduate and

undergraduate student employees, and temporary employees.

Policy

All Covered Individuals must:

1. In accordance with the table below, timely disclose through the University eDisclosure system, all Outside Interests, Outside Employment, Outside Commitments, Institutional Financial Interests, and Substantial Interests;

Covered Individual Category	Areas of Required Disclosure
All University Employees	Outside Employment, Outside Commitments, Substantial Interests
University Administrators	Institutional Financial Interests, Outside Employment, Outside Commitments, Substantial Interests
Investigators*	Significant Financial Interests, Significant Personal Interests, Foreign Interests, Outside Employment, Outside Commitments, Substantial Interests

** Note: Investigators who are University Administrators are responsible for all areas of required disclosure.*

2. Adhere to any requirements deemed necessary by the University's Conflict Official or the University Employee's supervisor to comply with a directive or request from an external agency, or to manage or eliminate conflicts;
3. Ensure institutional responsibilities receive full effort, attention, and commitment, and obtain written approval from the Covered Individual's supervisor prior to engaging in Outside Employment or Outside Commitments;
4. Comply with training requirements established by the Office for Responsible Outside Interests;
5. Disclose all sponsored and non-sponsored Research Projects to the Office for Responsible Outside Interests prior to Conducting Research if the individual is an Investigator;
6. Fully cooperate in any investigation or review of activities and comply with all directives or recommendations made by the University's Conflict Official or the Covered Individual's supervisor to correct, eliminate, or manage a conflict.

Potential sanctions for violations of this Policy may include, but are not limited to:

- Additional training requirements or management terms;
- Suspension of an individual's funding or research privileges;
- Discipline, up to and including termination of employment or University affiliation.

Compliance and Responsibilities

All Covered Individuals to whom this Policy applies are responsible for becoming familiar with and following this Policy. The Office for Responsible Outside Interests and Covered Individual's supervisors are responsible for promoting and understanding this Policy.

The Office for Responsible Outside Interests, Conflict Officials, and Covered Individual's supervisors

are responsible for taking appropriate steps to help ensure compliance with this Policy.

Frequently Asked Questions*

Why do I have to disclose my Outside Employment and Outside Commitments to the Office for Responsible Outside Interests?

The University requires that full-time (0.50 FTE or greater) employees disclose their Outside Activities for review of conflicts of commitment because the University has a fiduciary responsibility to ensure that inappropriate external influences outside the course and scope of one's University employment do not affect the performance of one's primary duties to the University. Outside Activities raise important questions related to time and energy allocation, University resource allocation, intellectual property protection and potential for conflicts of interest.

What happens if someone who is participating in a Research Project funded by the PHS/NIH does not comply with this Policy?

In accord with PHS/NIH policy (42 CFR § 50.605(3)), a retrospective review will be conducted if the Office for Responsible Outside Interests determines that an Investigator participating in any University project funded by the PHS/NIH (excluding Phase I SBIR/STTR grants) has not (a) complied with this Policy; or (b) complied with a required FCOI management plan; or (c) disclosed a SFI or SPI in a timely manner to allow appropriate review and management. Consistent with PHS/NIH grants policy 42 CFR § 50.606(c), "in any case in which a determination is made that a PHS/NIH-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required, the Investigator will be required to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations."

Does the public have access to conflict of interest information?

For Research Projects funded by PHS/NIH agencies, excluding Phase I SBIR/STTR grants, the University is required to respond within five (5) business days of receipt of a written request from a member of the public for information regarding determination of an FCOI of senior/key personnel for the funded project. Such public requests must comply with the requirements of 42 CFR § 50.605(a)(5) and 45 CFR § 94.5(a)(5) of the NIH grants policy.

Pursuant to A.R.S. § 38-509, all disclosures of Substantial Interests, as defined by A.R.S. § 38-502, are available for public inspection.

Sources*

Federal Laws and Regulations Applicable to Conflicts of Interest

Public Health Service (PHS) Regulations

- Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (**42 C.F.R. Part 50, Subpart F** [3])
- Responsible Prospective Contractors (**45 C.F.R. Part 94** [4]) (Note: this link opens a PDF document.)
- **FDA rules on Investigator Conflict of Interest: 21 CFR 54.4** [5]

National Science Foundation (NSF) Regulations

- **Award and Administration Guide Chapter IV, Part A. Conflict of Interest Policies** [6]

State Law Applicable to Conflicts of Interest

- **Arizona Revised Statutes § 38-503** [7]

Related Information*

Definitions can be found on the Office for Responsible Outside Interests' **Definitions webpage** [8].

The Office for Responsible Outside Interests is here to serve you. If you have any questions or feel the need to anonymously report an issue, you can reach out through the University Ethics & Compliance Hotline, (866) 364-1908 or hotline.arizona.edu [9].

Arizona Revised Statutes §§ 38-503-38-511 [10]

- Any contract entered into in violation of Arizona Revised Statutes §§ 38-503 - 38-511 is voidable or subject to cancellation at the option of the Arizona Board of Regents and the University. A violation of Arizona Revised Statutes §§ 38-503 - 38-511 may result in criminal penalties.

ABOR Policy 3-901 Conflict of Interest [11]

ABOR Policy 6-705 Outside Employment [12]

The following policies remain in effect: UHAP 2.6.06 (Consulting or Other Outside Employment [13]); Gifts to the University: Solicitation and Receipt [14]; Political Activity and Lobbying [15]; and the College of Medicine Policy and Guidelines for Interactions between the University of Arizona College of Medicine and Commercial Interests ("Industry") [16].

Revision History*

07/27/2022: added University Staff Manual as reference under Policy Information. [non-substantive revision]

02/02/2022: corrected responsible department name in the Outside Interests defined term.

12/2021: This Policy incorporates and replaces the following policies:

1. Conflict of Commitment Policy
2. Conflict of Interest (UHAP) Policy
3. Conflict of Interest in Purchasing Policy
4. Individual Conflict of Interest in Research Policy
5. Institutional Conflict of Interest Policy

Source URL:<https://policy.arizona.edu/ethics-and-conduct/conflicts-interest-commitment-policy>

Links

[1] <mailto:COI@email.arizona.edu> [2]
<https://www.azleg.gov/viewdocument/?docName=https://www.azleg.gov/ars/38/00502.htm> [3]
<http://www.ecfr.gov/cgi-bin/text-idx?SID=429a459cf86b74ba9fc8049689c50603&mc=true&node=pt42.1.50&rgn=div5#sp42.1.50.f> [4]
<http://www.gpo.gov/fdsys/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec94-4.pdf> [5]
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=54.4> [6]
https://www.nsf.gov/pubs/policydocs/pappguide/nsf15001/aag_4.jsp [7]
<https://www.azleg.gov/viewdocument/?docName=http://www.azleg.gov/ars/38/00503.htm> [8]
<https://research.arizona.edu/compliance/office-responsible-outside-interests/disclosure-requirements/definitions> [9] <https://www.lighthouse-services.com/arizona/LHILandingPage-arizona.asp> [10]
<https://www.azleg.gov/arsDetail/?title=38> [11]
<https://public.powerdms.com/ABOR/documents/1491882> [12]
<https://public.powerdms.com/ABOR/documents/1499298> [13]
<https://policy.arizona.edu/employment-human-resources/consulting-or-other-outside-employment> [14] <https://policy.arizona.edu/employment-human-resources/gifts-university-solicitation-and-receipt> [15] <https://policy.arizona.edu/ethics-and-conduct/political-activity-and-lobbying-policy-interim> [16]
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