

University of Arizona Interim Policy on Investigator Conflict of Interest in Research (Effective August 24, 2012)

INTRODUCTION

- A. Investigator Requirement: Training on Conflict of Interest
- B. Investigator Requirement: Disclosures of Significant Financial Interests
- C. Investigator Requirement: Compliance
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- Institutional Responsibilities
- Institutional Review Committee (IRC)
- Relatedness to Institutional Responsibilities
- Relatedness to a specific research project
- Significant Financial Interest
- Exclusions from Significant Financial Interest
- Financial Conflict of Interest (FCOI)
- Public Health Service (PHS)

POLICY REQUIREMENTS

INTRODUCTION

The University of Arizona (“University”) is dedicated to research integrity. This means that in its performance of research the University is committed to ethical conduct, upholding the principles of transparency and accountability, free and unbiased inquiry, the transfer of ideas and technologies for the benefit of the public, sound stewardship of the resources entrusted to it, and compliance with all applicable state and federal laws and terms of relevant contracts and grants.

The University recognizes that faculty and other employees engage in many relationships with external entities, some of which could have a direct relevance to University research. These interrelationships are increasingly common and are not only sometimes unavoidable but often arise as part of conscious 21st Century national public policies fostering public-private partnerships and interactions in research and development. The University is committed to facilitating technology transfer activity that moves University-developed knowledge into practical applications, the creation of new businesses, and general economic development for the benefit of the people of Arizona.

Because the intersection of individuals’ personal financial interests with University research creates both possibility and perception of potential for bias in research, the University recognizes its obligation to protect the reasonable expectation that the design, conduct and reporting of University research is free from bias generated by Investigators’ financial conflict of interest. Commitment to the following principles guides this University research policy:

- Objectivity, integrity and credibility in the University’s research activities and related institutional research review processes;
- The safety and welfare of participants in University research;
- The public’s trust in the University and its research;
- Full compliance with applicable federal and state laws and regulations and sponsor agreements for research funding;

Nothing in this Policy is intended to restrict faculty members from choosing the subject matter of their research, scholarly work or other activities.

(NOTE: The first occurrence of **bolded words or phrases** in this policy refers to terms listed in the ‘Definitions’ section.)

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A. Investigator Requirement: Training on Conflict of Interest

1. Who must complete this course
Every **Investigator** (see ‘Definitions’).
2. Timing of required course completion
 - a. Prior to engaging in any Public Health Service (PHS, including NIH) funded project begun on or after August 24, 2012 (excluding Phase I SBIR/STTR grants); and
 - b. Prior to January 1, 2013, for all University of Arizona Investigators; and
 - c. At least every four years; and
 - d. As directed by the University when one of the following applies:
 - (i) the University revises the requirements for Investigators pursuant to this policy;
 - (ii) the Investigator is new to the University;
 - (iii) the Investigator is found not to be in compliance with this policy or a University management plan for the Investigator’s **financial conflict of interest** [42 CFR 50.604(b)]:
(http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf).
3. Link to the course
Course information: <http://orcr.arizona.edu/coi/training>

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B. Investigator Requirement: Disclosures of Significant Financial Interests

1. Who must disclose and what must be disclosed

Investigators must disclose all **significant financial interests** that can reasonably be deemed related to any of the Investigator's **institutional responsibilities**, including areas of professional activity or expertise broadly.

This “**relatedness**” is not a judgment on whether the employee would deliberately within his/her exercise of institutional responsibilities make choices for the purpose of affecting the value of her/his significant financial value. “Relatedness” is the condition in which it may reasonably appear that choices directly and significantly affecting the value of the significant financial interest could be made.

See the ‘Definitions’ section of this policy for more information on “relatedness” of significant financial interests.

2. When and how required disclosures are made

Investigators must file an initial disclosure of significant financial interests or update previously filed disclosures. Each Investigator is required to recertify their disclosure:

- a. Annually; and
- b. Within 30 days of acquisition of a new significant financial interest not previously disclosed; and
- c. As may be required by the University’s Human Subjects Protection Program for new or continuing IRB review applications; and
- d. For projects that have received from PHS (including NIH) on or after August 24, 2012, a Notice of Award or noncompeting continuation with funding (excluding Phase I SBIR/STTR grants):
 - (1) For new awards, at least 45 days prior to access to funds; and
 - (2) For ongoing projects, at least 105 days before the start of the new budget period; and
 - (3) For Investigators newly joining an existing sponsored project, no later than 45 days in advance of their first day of participation as an Investigator in the project.

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3. Link to disclosure

The required form and instructions for disclosing significant financial interests are online at <http://orcr.arizona.edu/coi/forms>.

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C. Investigator Requirement: Compliance

Investigators are required to comply with the provisions of this policy including all management plans and administrative directives issued to them as a result of the University's evaluation of their significant financial interests, which process is described below.

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D. Institutional Obligations: Review, Assessment, Management and Reporting of Financial Interests

1. Institutional Review Committee (“IRC”)

Evaluations of Financial Conflict of Interest and determination of any management plan are performed by the **IRC** with the support of the University’s Conflict of Interest Program staff. More detail is provided in the “Procedures for the University of Arizona Policy on Investigator Conflict of Interest in Research” (<http://orcr.arizona.edu/coi/procedures/investigator>).

2. Evaluation of Financial Conflict of Interest (“FCOI”)

The first step is an evaluation to determine whether the significant financial interest constitutes an **FCOI**. An FCOI is a significant financial interest that is deemed to have potential to *directly and significantly* affect the design, conduct, or reporting of research.

3. Determination of management plan

If an FCOI is identified, the second step is an evaluation to determine whether the FCOI is permissible with a management plan. More detail is provided in the “Procedures for the University of Arizona Policy on Investigator Conflict of Interest in Research” (<http://orcr.arizona.edu/coi/procedures/investigator>).

4. IRC report to Investigator, supervisor, involved offices

If the IRC determines that there is an FCOI, the IRC will report that determination and any IRC-specified management plan to the Investigator and the Investigator’s immediate supervisor as well as to the University’s Human Subjects Protection Program if the project is human subjects research. The IRC-specified management plan will also be reported to any other offices that have a role in the plan.

5. Investigator certification of commitment to management plans

If the Investigator certifies his or her commitment to the IRC’s management plan, then the affected research will be permitted to proceed, subject to any IRB approval that may be separately required pursuant to human subjects research regulations.

6. University reports FCOI to research sponsors as required

The University will make FCOI identification and management reports to research sponsors with the timing and format required

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under the terms and conditions of the relevant sponsorship rules and agreements.

For PHS/NIH-funded projects, initial, annual and revised FCOI reports will be made to the NIH in accord with following NIH requirements:

- a. Prior to the initial expenditure of PHS funds;
- b. Within sixty (60) days of new or newly-identified significant financial interest;
- c. At least annually, at the time of an extension or the annual progress report;
- d. Within 120 days for a retrospective review pursuant to F.2 below.

7. Public access to FCOI information for PHS-funded studies

For projects that have received from PHS (including NIH) on or after August 24, 2012, a Notice of Award or noncompeting continuation with funding (excluding Phase I SBIR/STTR grants), the University is required to respond within five (5) business days of receipt of a request from a member of the public for information about identified financial conflicts of interest of **senior/key personnel** in a specific PHS-funded project by providing: the senior/key personnel name, title and role in the research project, the name of entity in which the financial conflict of interest is held by the senior/key personnel, the nature of the financial conflict of interest and its approximate dollar value [42 CFR 50.605(a)(5) and 45 CFR 94.5(a)(5)]: (http://grants.nih.gov/grants/policy/loi/fcoi_final_rule.pdf).

The procedure and form for making such a request is posted online at <http://orcr.arizona.edu/loi/public>.

8. IRC additional actions

As part of the IRC's review, the IRC may determine that disclosed significant financial interests do not constitute FCOI for the design, conduct or reporting of a research project but may require administrative direction to the disclosing Investigator pursuant to the University's commitment to financial interest transparency, to student/trainee protection, or to other relevant policies on financial interests. The IRC may respond with a letter of administrative direction to the Investigator, copying the department head and dean; it may refer the matter to another

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University office or review group (such as the Executive Review Committee) with relevant responsibilities; or it may submit recommendations to the Senior Vice President for Research, who will make the final determination regarding specific actions on a case-by-case basis.

9. Link to detailed procedures

The details of the procedures for these evaluations and reports are provided in the “Procedures for the University of Arizona Policy on Investigator Conflict of Interest in Research” (<http://orcr.arizona.edu/coi/procedures/investigator>).

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E. Subrecipients

For any subcontract pursuant to a PHS award to the University of funding (initial or noncompeting continuation) on or after August 24, 2012 (excluding Phase I SBIR/STTR grants), one of the following two options will be established in the subrecipient contract [42 CFR 50.604(c)]:

http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf.

1. Option 1

The subrecipient shall certify that it has a PHS-compliant COI policy and process and shall agree to apply its PHS-compliant COI policy to all of its investigators performing under the PHS-supported subrecipient contract and that it will be responsible for its investigators' compliance under its policy and pursuant to the subcontract.

2. Option 2

The subrecipient shall agree that all of its investigators participating in the subcontracted work will be subject to the University's COI Policy and processes, and that it will be responsible for its investigators' compliance under the University's policy and pursuant to the subcontract.

3. Link to detailed procedures

The University's relevant procedures are described in greater detail in the "Procedures for the University of Arizona Policy on Investigator Conflict of Interest in Research"
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F. Noncompliance

1. Inquiries to determine facts

In the event that the University becomes aware through its active monitoring processes or otherwise that one or more requirements of this policy may not have been complied with, the University will make appropriate inquiries to determine the facts.

2. Retrospective review

For any University project that has received on or after August 24, 2012, from PHS (including NIH) a Notice of Award or noncompeting continuation with funding (excluding Phase I SBIR/STTR grants), if the University determines (a) that there has been noncompliance with this policy or (b) that there has been noncompliance with a required FCOI management plan, or (c) that a significant financial interest related to the project has not been timely reported and reviewed and managed:

- a. The IRC will complete a review within sixty (60) days to assess (a) whether there is an FCOI, in which case the University will immediately implement an interim management plan, and (b) if so, within 120 days the University will complete a retrospective review to determine whether the FCOI, and/or any noncompliance with this policy or with an FCOI management plan, has biased the design, conduct or reporting of the research and (c) how any identified bias may be mitigated [42 CFR 50.605 (3)]: http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf.

3. Required reports to PHS

If the IRC retrospective review described above has identified FCOI, the University will timely make the required reports to the PHS [42 CFR 50.605 (3)(B)(9)(iii)]: http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf.

4. Additional sanctions or administrative actions

In cases of noncompliance with this policy, the University may apply employee sanctions or administrative actions as it deems appropriate to the case and in accord with relevant employment policies.

5. Sponsor requirements for corrective action

Research sponsors may make their own determinations regarding the adequacy of the University's corrective responses

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and may also direct specific different or additional corrective actions, for example: “In any case in which the HHS determines that a PHS-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 a financial conflict of interest that was not managed or reported by the Institution as required by this part, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.” [42 CFR 50.606(c)]: (http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf).

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- **NIH 42 CFR Part 50 and 45 CFR Part 94** “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors” (DHHS Final Rule August 25, 2011): <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>
- **NIH FAQs on COI Rules:** http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- **CFR Part 54** (US Food and Drug Administration “Financial Disclosure by Clinical Investigators”): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>
- **FDA:** <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm>
- **NSF:** http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp
- **NSF:** <http://www.iecjournal.org/iec/2011/10/nsf-conflict-of-interest-issues.html>
- **AAMC:** <https://www.aamc.org/initiatives/coi/>

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Investigator(s): The Project Director or Principal Investigator or Co-Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research performed by the University. This may include students, trainees, collaborators, and consultants. This term includes only persons who have some degree of independence in performing some aspect of design, conduct or reporting of the research and does not include persons whose performance within the research activities is purely ancillary or solely under immediate supervision.

With respect to clinical research this term includes all persons who are directly involved in the research intervention or consenting or evaluation of human research subjects, but it does not include hospital staff or office staff who only provide ancillary or intermittent care and who do not make direct and significant contributions to the data.

Senior/key personnel: The Principal Investigator, the Project Director and any other person identified as senior/key personnel in the grant application, contract proposal and contract, progress report, or any other report submitted to the sponsor by the University. “Zero percent” or “as needed” is not an acceptable level of involvement for senior/key personnel.

Institutional Responsibilities: An Investigator’s activities in performance as a University employee, as a collaborator with or consultant to the University, or related to activities involving the Investigator’s professional expertise, such as: teaching, administrative duties, clinical activities, research (sponsored or unsponsored), PHS-sponsored project activities, service on University committees, professional participation on panels and review boards including data and safety monitoring boards, creation and presentation of scholarly work, etc., regardless of when and where the activities occur.

Institutional Review Committee (IRC): A University-wide committee, consisting of at least 10 voting members who are appointed by the Senior Vice President for Research: 3 faculty from the Health Sciences; 1 faculty from the College of Engineering; 2 faculty from the College of Science; 4 faculty from other academic units. Members should be active researchers with an understanding of their respective disciplines’ research practices and activities. The committee also includes non-voting, ex-officio members as necessary: the Assistant Vice President for Research Compliance and Policy; Director of Technology Transfer; Director of Office of Research Contracts and

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Analysis; a representative from Sponsored Projects; the Human Subjects Protection Program; Procurement and Purchasing. Office of the General Counsel shall provide legal advice to the committee. The committee may invite other non-voting, ad hoc members to assist in discussions and decisions as needed.

Relatedness to Institutional Responsibilities: When applied to a significant financial interest and institutional responsibilities, “relatedness” means that the value of the significant financial interest may reasonably appear to have potential to be significantly and directly affected by the Investigator’s performance of his or her institutional responsibilities.

This relatedness is not a judgment on whether the Investigator would deliberately within his/her exercise of institutional responsibilities make choices for the purpose of affecting the value of her/his significant financial value. Relatedness is the condition in which it may reasonably appear that choices directly and significantly affecting the value of the significant financial interest could be made.

Following are a few nonexclusive examples of appearance of relatedness to institutional responsibilities:

- One’s professional activities include presentations on topics that are directly and significantly material to one’s own significant financial interests.
- One’s clinical practice includes professional choices that could benefit one’s own significant financial interests.
- One’s professional or administrative responsibilities include potential to influence University research, business, or purchase decisions (1) with a company in which one has equity; (2) regarding real property one owns or regarding intellectual property from which one earns royalties paid outside the University; (3) with a company for which one is an officer or a board member.

Relatedness to a specific research project: When applied to a significant financial interest and any of the investigator’s research projects, “relatedness” means that the value of the significant financial interest may reasonably appear to have potential to be significantly and directly affected by the employee’s performance in the design, conduct or reporting of the research.

This relatedness may be to: services for which an investigator has received external compensation or equity; or to the best interests of the

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entity from which the investigator has received external compensation or equity; or to the intellectual property that is evaluated or used in the research; or to more than one of these interfaces.

This relatedness is not a judgment on whether the investigator would deliberately make choices within design, conduct or reporting of the research for the purpose of affecting the value of her/his significant financial value. Relatedness is the condition in which it may reasonably appear that choices directly and significantly affecting the value of the significant financial interest could be made.

Following are a few nonexclusive examples of appearance of relatedness to a research project:

- The research evaluates or uses drugs, devices, assays, biologics, software, equipment, or other products, procedures or materials in which the investigator has a significant financial interest.
- The research evaluates or uses drugs, devices, assays, biologics, procedures, software, equipment, or other products, procedures or materials owned by, or with significant potential impact on, an entity in which the investigator has a significant financial interest.
- The research evaluates or uses intellectual property that is a direct competitor to intellectual property in which the investigator has a significant financial interest.

Significant Financial Interest: A financial interest consisting of one or more of the following interests of the Investigator, *and those of the Investigator's spouse or domestic partner, and dependent children*, that reasonably appear to be related to the Investigator's institutional responsibilities (see definition of Institutional Responsibilities above):

- With regard to any *publicly traded entity*, a significant financial interest is:
 - an *aggregated value of \$5,000 or more composed* of any remuneration received from the entity in the twelve months preceding the disclosure plus the value of any equity interest in the entity as of the date of disclosure plus the value of any loans between the Investigator and the publicly traded entity.
 - For purposes of this definition, *remuneration* includes salary and also any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).
 - For purposes of this definition *equity* interest includes any stock, stock option, or other ownership interest. Value of equity

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interests is determined through reference to public prices or other reasonable measures of fair market value.

- With regard to any *non-publicly traded entity*, a significant financial interest is:
 - any remuneration received from the entity that exceeds \$5,000 in aggregate in the twelve months preceding the disclosure.
 - any equity interest at all, regardless of value (e.g., any stock, stock option, or other ownership interest);
 - any loan of any amount between the Investigator and the non-publicly traded entity.
- Any intellectual property right or interest (e.g., patent, copyright, license) for which income related to such right or interest has been received, unless the intellectual property rights have been assigned to the University and income received is per a royalty-sharing agreement with the University.
- Position as an official, advisory board member, or other board member in a for-profit entity, whether or not compensated.
- ***Travel-related*** significant financial interest:

Investigators in projects that have received from the U.S. Department of Health and Human Services (“Public Health Service” or “PHS” or NIH) on or after August 24, 2012 (excluding Phase I SBIR/STTR grants), a notice of award (initial or noncompeting continuation) with funding, must disclose to the University all travel related to institutional responsibilities (see definition of “institutional responsibilities”) that is reimbursed or sponsored by an entity other than a U.S. Federal, state, or local government agency, a U.S. Institution of higher education as defined at 20 U.S.C. 2 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education (note that this exclusion does not encompass all nonprofit entities) [42 CFR 50.603 (2) under “Significant financial interest means...”]:
http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf.
- **Exclusions from Significant Financial Interest:**

The following types of financial interests are not considered significant financial interests even if related to the Investigator’s institutional responsibilities:

 - salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or

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- otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share with the University in royalties related to such rights;
- income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made by the investment managers within these mutual funds or retirement accounts;
 - income from seminars, lectures, teaching engagements or service on advisory committees or review panels sponsored by a U.S. Federal, state, or local government agency, a U.S. Institution of higher education as defined at 20 U.S.C. 1001(a), a U.S. academic teaching hospital, medical center, or a research institute that is affiliated with a U.S. institution of higher education (note that this exclusion does not encompass all nonprofit entities);
 - for Investigators in PHS-funded research required to report sponsored or reimbursed travel as noted above, excluded from this reporting requirement is travel sponsored or reimbursed by a U.S. federal, state, or local government agency, a U.S. institution of higher education as defined at 20 U.S.C. 2 1001(a), or an academic teaching hospital, medical center, or research institute that is affiliated with a U.S. institution of higher education (note that this exclusion does not encompass all nonprofit entities).

Financial Conflict of Interest (FCOI): A significant financial interest that is deemed to have potential to *directly and significantly* affect the design, conduct, or reporting of research. This policy requires that Investigators report significant financial interests to the University. The University is responsible for determining whether any of the significant financial interests constitutes an **FCOI**.

Public Health Service (PHS): The U.S. Department of Health and Human Services (DHHS), and any components of the PHS to which the authority involved may be delegated, including the NIH.