Purpose and Summary

The University of Arizona ("University") recognizes that public-private collaborations play a key role in advancing scientific frontiers, enhancing the University’s research and educational mission, and enabling the commercial development of University discoveries with potential for improving the human condition and developing Arizona’s economy (together, "Missions"). The benefits to the University from such public-private interactions may include revenues from the commercialization of University-owned research results or intellectual property, sponsorship of research, funding for educational programs and charitable donations.

This Policy is managed by the Conflict of Interest Program, a unit of Research Compliance Services, and applies to those University Administrators who have authority over the Conduct of Research, as well as to University Administrators with decision-making authority in the University’s research administration and Tech Transfer Arrangements, including but not limited to Sponsored Projects Services (SPS), Contracting and Research Services (CRS), Technology Launch Arizona (TLA), and Procurement and Contracting Services (PACS).

While acknowledging and supporting appropriate interactions between the University and the private sector, the goal of this Policy is to protect the credibility and integrity of the University, through the identification, review, and management of actual or potential Institutional Conflict of Interest. Left unaddressed, Institutional Conflict of Interest could undermine public trust and
support of the University and its Missions. Particular attention is paid under this Policy to those circumstances in which Institutional Conflict of Interest may affect, or appear to affect, the safety or welfare of human research participants.

An Institutional Conflict of Interest, for purposes of this Policy, describes a situation in which the financial interests of the University, or of individuals in a position to make decisions with University-wide implications, may affect or appear to affect decisions made on behalf of the institution in connection with its Missions. Careful balancing and management of the University’s competing interests becomes necessary when Significant Financial Interests[1] of the University or of a University Administrator have the potential to influence or appear to influence decisions made by or on behalf of the University.

- For example, when a University Administrator with direct authority over the Conduct of Research holds a Significant Financial Interest in an entity that sponsors University research, such interest must be disclosed, reviewed and, if an Institutional Conflict of Interest is determined to exist, the external interest must be managed appropriately or eliminated. This is necessary to avoid the appearance of undue outside influence on the University’s decisions affecting the Conduct of Research.
- Similarly, if a University Administrator with direct authority over the Conduct of Research participates materially in a procurement decision involving a Major Institutional Purchase from a research sponsor or company whose investigational product is the subject of University research, an Institutional Conflict of Interest may exist under this Policy regardless of whether or not the University Administrator has a personal financial interest in the External Entity.
- In addition, substantial gifts received by the University[2] from a commercial research sponsor or entity that owns an investigational product that is the subject of University research may give rise to an Institutional Conflict of Interest under this Policy.

This Policy establishes guidelines for the identification and management of potential Institutional Conflict of Interest that may arise in each of the above listed areas.

[1] Capitalized terms not otherwise defined in the text have the meanings set forth in "Definitions," below.

[2] Decision-making with respect to the Conduct of Research at or under the auspices of the University research activities is managed separately from the University’s financial affairs and technology transfer operations. Gifts from external entities or persons in all cases are made to The University of Arizona Foundation, or to the University’s Development Offices and administered by The University of Arizona Research Foundation, pursuant to the UA Financial Services Manual Policy 8.12. Gifts [2].

**Definitions**

**A. Conduct of Research**: Any organized program of scientific inquiry that involves a systematic investigation designed to develop or contribute to generalizable knowledge that is performed at, or under the auspices of, the University of Arizona, and includes the design, development, testing, evaluation, conduct, reporting, review, or oversight of such program of scientific inquiry.
Research includes, but is not limited to, basic and applied research, clinical research, research fellowships and training programs, and research-related activities in undergraduate and graduate education.

B. Excluded Interests: The following financial interests are not considered to be Significant Financial Interests, and do not need to be disclosed for purposes of this policy:

1. Salary, royalties, or other Remuneration paid by the University to a University Administrator currently employed or otherwise appointed by the University;
2. Income from investment vehicles such as mutual funds and retirement accounts, so long as the University Administrator does not directly control the investment decisions made by the investment managers within these funds or accounts;
3. 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 or a U.S. institution of higher education or affiliated academic teaching hospital, medical center, or research institute (this does not exclude all nonprofit entities);
4. Clinical care income and tuition income.

C. External Entity: Any group, organization or legal entity (e.g., partnership, firm, trust, joint venture, corporation, etc.) that is not part of the University of Arizona or the Arizona Board of Regents (ABOR).

D. Family Member: A University Administrator’s spouse and dependent children. For purposes of this Policy, a “spouse” includes a person to whom one is married, or a person with whom one lives together in the same residence and where each person shares responsibility for the other’s welfare and financial obligations.

E. Fiduciary Role: One’s legal and/or ethical obligation to act in the best interests (e.g., the financial and/or operating success) of another person or entity, other than any nonprofit educational institution or other nonprofit organization that is not affiliated with a for-profit research sponsor, whether such role is compensated or uncompensated. Examples of Fiduciary Roles include but are not limited to membership on a board of directors or board of advisors, or a management role in a company or other entity (e.g., as corporate officer, LLC member, general partner, and governing board member of a professional association).

F. Human Subjects Research: This term is used as defined by the Department of Health and Human Services (HHS) and the Office for Human Research Protections (OHRP) in applicable federal laws and regulations as amended from time to time (including, without limitation, 45 CFR Part 46 and 21 CFR Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulation.

G. Institution: The University of Arizona in its entirety, including but not limited to colleges, departments, centers, and administrative offices.

H. Institutional Financial Interests: Collectively, the “Significant Financial Interests of the University” and “Significant Financial Interests of University Administrators” (as defined in N and O, below).

I. Institutional Responsibilities: Means (1) all activities performed in the course and scope of one’s responsibilities as a University employee; and (2) activities performed on behalf of the University by any agent of, collaborator with, or consultant to the University.
J. Oversight of the Conduct of Research: Direct responsibility for the supervision of faculty and staff participating in research conducted at or under the auspices of the University (e.g., evaluation and management of promotion, tenure, pay raises, and the assignment of job responsibilities).

K. Relative: Relative has the definition set forth in ARS § 38-502 as amended from time to time.[1] For purposes of this Policy, a “spouse” includes a person to whom one is married, or a person with whom one lives together in the same residence and where each person shares responsibility for the other’s welfare and financial obligations.

L. Remuneration: Receipt of money, financial interests, intellectual property rights, title or interest, or any other thing of value, including but not limited to, loans, salary, fees, royalties, milestone payments, payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship), value of equity or other ownership interests, or entitlement to an ownership interest (e.g., stocks, LLC membership, partnership, stock options, warrants, etc.).

M. Significant Financial Interests of a University Administrator: Any of the following interests of a University Administrator or his/her Family Member or Relative (other than “Excluded Interests” as defined above) is considered to be a Significant Financial Interest under this Policy:

1. Intellectual property rights, title, or interests (e.g., patent, copyright) where the University Administrator with Oversight of the Conduct of Research has received income related thereto (e.g., as owner of a patent or copyright or as an assignee or licensee of such rights).

2. When, with regard to a specific Human Subjects Research project to be conducted at or under the auspices of the University, a University Administrator with direct oversight of the Conduct of Research either

   a. Holds a Significant Financial Interest (as defined in this section) in an External Entity that sponsors the Research, or that owns the investigational product that is the subject of, such research; or

   b. Holds ownership, licensing or other interests in intellectual property rights that are the subject of such Human Subjects research, and has received, or has the potential to receive, significant milestone payments, royalties, or other income from the sales of an investigational product that is the subject of such research (e.g., as owner, licensee, or assignee of a patent or copyright or as an assignee of such rights).

3. Any Fiduciary Role in an External Entity, whether or not compensated.

4. With respect to any publicly traded for-profit External Entity, or any nonprofit External Entity, receipt, by a University Administrator (or Family Member or Relative) in the twelve (12) months preceding disclosure, of Remuneration with an aggregated value of $5,000 or more.

5. With regard to any non-publicly traded, for-profit External Entity, a Significant Financial Interest exists when a University Administrator or his/her Family Member or Relative holds or receives one or more of the following:

   a. Any ownership interest, or entitlement to receive an ownership interest, in such entity,
regardless of value (e.g., stocks, stock options, warrants, partnership, LLC membership, etc.); and/or

b. Any loan of any amount between such entity and the University Administrator or his/her Family Member or Relative; and/or

c. Any other Remuneration received from such entity that exceeds $5,000 in aggregate in the twelve (12) months preceding the disclosure.

N. Significant Financial Interests of the University: Means interests or assets held by the University that meet any of the following criteria:

1. Equity or similar interests in an External Entity[2] (including but not limited to stock options, warrants, partnership, or membership in an LLC) that meet the following threshold valuations (but not including Excluded Interests, as defined above):
   a. Valued at more than $100,000 in any publicly traded, for-profit organization; or
   b. Any such interest, regardless of value, in a for-profit organization that is not publicly traded.

2. Gifts. Substantial gifts (including gifts in kind) received from an actual or potential commercial sponsor of research, or from an individual or entity that owns or controls products being studied or tested.
   a. Gifts that total $1 million or more, cumulatively, received from a for-profit External Entity (or from an individual or philanthropic unit affiliated with such entity) are deemed to constitute a Significant Financial Interest of the University.
   b. In addition, as contemplated in Section A.3 of the Policy Section above, the Conflict of Interest Program will develop criteria for identifying substantial gifts that may not meet the $1 million threshold. Such criteria are included in the Procedures for this Policy, which are posted on the Conflict of Interest web page [3].

3. Intellectual Property Ownership or Interests.
   a. Any agreement with an External Entity that includes the right for the University or a University Administrator or his/her Family Member or Relative to receive Remuneration from the commercial development or sale of an investigational product that is the subject of University research, and that utilizes intellectual property or technologies in which ABOR claims an ownership interest under ABOR Policy 6-908 Intellectual Property; and/or
   b. Ownership by ABOR, on behalf of the University, of a patent and/or other intellectual property rights in, or sponsorship of an investigational new drug (“IND”) application with respect to any drug or device for which Human Subject Research will be conducted at or under the auspices of the University.

O. Supervisor: The individual who is directly responsible for oversight, performance evaluations, and promotion recommendations related to such University Administrator.

P. Tech Transfer Arrangements: All University transactions and arrangements handled through Tech Launch Arizona/Tech Transfer Arizona (TLA/TTA) that involve Institutional Financial Interests, including but not limited to, proposed technology transfer licensing transactions or other arrangements that require the approval of the University President or ABOR under applicable policies, laws, or regulations then in effect.
Q. University Administrator: Any individual in a position of administrative leadership of a recognized University 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 Vice/Associate/Assistant Presidents
- University Provost
- University Vice/Associate/Assistant Provosts
- University Deans
- University Vice/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
- Individuals who serve as Chairs on the University’s Institutional Review Board committees, regardless of whether such individuals are employees of the University

[1] As of the original issue date of this Policy, ARS § 38-502 defines “Relative” as an individual’s spouse, child, grandchild, parent, grandparent, brother or sister of the whole or half blood, and his/her spouse, and the parent, brother, sister, or child of a spouse.

[2] Nothing in this Policy should be interpreted to suggest, condone, or authorize any violation of the Arizona Constitution Article 9, Section 7.

Policy

A. Identification of Institutional Conflicts of Interest

1. Existence of Institutional Conflict of Interest. For purposes of this Policy, an Institutional Conflict of Interest exists whenever Institutional Financial Interests (as defined above) influence, or may reasonably appear to influence, (a) the Conduct of Research; or (b) business or administrative decisions made by University Administrators on behalf of the University that are related to the University’s Missions, including but not limited to the Conduct of Research. Particularly close attention must be paid to situations that involve Human Subjects Research.[1]

2. Institutional Financial Interests That Involve Human Subjects Research. In reviewing Institutional Financial Interests that relate to Human Subjects Research, the protection of the safety and welfare of the Individuals who are the subjects of such research is of heightened concern. Therefore, the Executive Review Committee (as defined below) will apply, at minimum, the following criteria in evaluating Institutional Financial Interest related to Human Subjects Research. Additional considerations may be deemed necessary on a case-by-case basis. Appropriate criteria consistent with these guidelines are included in the procedures [4] for this Policy.

   a. Each disclosure of an Institutional Financial Interest that is related to Human Subjects Research, and that involves more than minimal risk to human subjects, requires strict scrutiny by the Executive Review Committee. In such cases, the Conflict of Interest
(“COI”) Program Office, in coordination with the Executive Review Committee Chair and the University’s Human Subjects Protection Program Office, will invite an Institutional Review Board (“IRB”) Chair, Co-Chair or Member to participate in the Executive Review Committee’s review, in an advisory role.

b. In its review of disclosed Institutional Financial Interests related to Human Subjects Research, the Executive Review Committee shall apply a rebuttable presumption that, absent compelling circumstances (based on criteria included in the procedures document cited above), the research to which the disclosure is related should not be conducted at or under the auspices of the University.

i. The rebuttable presumption may be challenged and overturned if the Executive Review Committee determines that compelling circumstances exist and a management plan is developed to effectively manage or eliminate the Institutional Conflict of Interest. The determination of whether compelling circumstances exist will be made by the Executive Review Committee on a case-by-case basis, as outlined in the procedures for this Policy.

3. Administration of Institutional Conflict of Interest Policy. The University’s Conflict of Interest Program, a unit of the Research Compliance Services that reports to the Senior Vice President for Research, is responsible for the administration of this Policy. The Conflict of Interest Program will work in coordination with the Executive Review Committee, which is appointed by and is advisory to the University President (see section B.1 below).

4. Disclosure of Institutional Financial Interests. The Conflict of Interest Program will maintain a record of disclosures made by each University Administrator and by the directors and department heads of administrative units affected by this Policy. Forms and training materials referenced in this Policy are available on the Conflict of Interest Program web page.

a. Significant Financial Interests of University Administrators. University Administrators must disclose their Significant Financial Interests to the Conflict of Interest Program at the time of initial appointment, and thereafter annually during the month of reappointment, and within thirty (30) days of the existence of any new Significant Financial Interest of such University Administrator.[2]

b. Significant Financial Interests of the University. All University Administrators are responsible for disclosing Significant Financial Interests of the University of which they become aware, and will affirm that this disclosure obligation has been fulfilled by completion of certification to the Conflict of Interest Program as outlined in the Procedures for this Policy, which are posted on the Conflict of Interest website. Disclosures will be coordinated with the Conflict of Interest Program pursuant to section A.5 below. These disclosures will include, but are not limited to, the following areas:

i. Substantial Gifts from Research Sponsors. The University recognizes the generosity of donors and their importance in helping the University to achieve its core research, educational, and public service missions. It is not the intent of this Policy to discourage donations; however, in order to identify and manage a potential Institutional Conflict of Interest that may result from gifts, the Conflict of Interest Program will work with the University of Arizona Foundation and University Development Offices to identify substantial gifts from research sponsors that may constitute Significant Financial Interests of the University that are subject to review under this Policy.

ii. Major Institutional Purchases. The Conflict of Interest Program will work with Procurement and Contracting Services to identify major purchases from and non-routine supply contracts with any commercial External Entity that sponsors research at or under the auspices of the University, or whose drug or device is the subject of such research.

iii. Technology Transfer Arrangements. The Conflict of Interest Program will work
with Tech Launch Arizona to identify technology transfer transactions that include Institutional Financial Interests of the University, as more fully described in section A.4 below. These disclosures will include, but are not limited to, all proposed technology transfer licensing transactions and other arrangements that require the approval of the University President or ABOR.[3]

iv. Sponsored Research Agreements and Service Agreements. The Conflict of Interest Program will work with SPS and CRS to identify private or sponsored research agreements and service agreements that give rise to Institutional Financial Interests of the University.

5. Reporting of Institutional Conflict of Interest Concerns. Any individual who has concerns regarding a possible Institutional Conflict of Interest should contact the Conflict of Interest Program or submit information confidentially through the University’s Ethics Hotline.[4] The Conflict of Interest Program, in coordination with the Executive Review Committee, will promptly review concerns that it receives and will ensure timely consideration of and responses to such concerns, including appropriate corrective action as necessary.

B. Review of Institutional Financial Interest Disclosures

1. The Executive Review Committee: The Executive Review Committee is responsible for reviewing disclosures of Institutional Financial Interests under this Policy, and for the determination and management of Institutional Conflict of Interest. The Executive Review Committee is advisory to the University President, and will submit for approval by the President, or the President’s designee, written Institutional Conflict of Interest determinations and management plans.

   a. The Executive Review Committee will consist of at least seven (7) voting members with sufficient seniority and ability to exercise independent judgment. Executive Review Committee Members will be appointed by the University President for staggered, three-year terms. The Executive Review Committee will include representatives from University Internal Audit, the Senior Vice President for Research, Tech Launch Arizona, Procurement and Contracting Services, the Office of the Senior Vice President for Business Affairs, Risk Management, the Chair or Co-Chair of the Institutional Review Committee, and senior faculty (deans and/or department heads). At the discretion of the University President, or the President’s designee, voting members of the Executive Review Committee may include a community representative who is not employed by the University, and emeriti faculty.

   b. Non-voting, ex officio representatives may be invited to participate in Executive Review Committee meetings at the discretion of the Executive Review Committee Chair, to provide expertise as necessary and appropriate to reviews and determinations, including representatives from the University IRB, the Office of the Vice President for Legal Affairs and General Counsel, and Research Compliance Services. The Conflict of Interest Officer manages the administrative matters of the Executive Review Committee and attends each meeting.

2. Review Procedures. The Executive Review Committee will review disclosures and make determinations following the procedures for this Policy, which are posted on the Conflict of Interest website.

   a. Management Plans. Based on its review of disclosed Institutional Financial Interests, the Executive Review Committee will determine whether an Institutional Conflict of Interest exists and make written recommendations to the University President, or designee, as to whether a management plan is appropriate and necessary. If management is determined to be necessary and appropriate, the Executive Review Committee will work with the Conflict of Interest Program, the individual University Administrator(s) involved and the
applicable Supervisor, to develop a plan that will reasonably manage or eliminate the
Institutional Conflict of Interest. All management plans will include provisions for post-
approval monitoring (see Section A.2 under “Compliance and Responsibilities” below).

b. Conflicts of Interest Involving Human Subjects Research. The Conflict of Interest
Program, in coordination with the Human Subjects Protection Program, will
communicate to the IRB relevant portions of determinations and management plans
related to Human Subjects Research. The Executive Review Committee’s
recommendations for the management of such research will not preclude the IRB from
recommending additional or more stringent safeguards as part of its review of the
research protocol under applicable human subjects laws and regulations. The Executive
Review Committee will give deference to the Institutional Review Board’s
recommendations in such cases, and any differences of opinion will be resolved through
written mutual agreement in discussions between the Executive Review Committee
Chair and relevant Institutional Review Board Chair(s), coordinated through the Conflict
of Interest Program and the Human Subjects Protection Program. Unresolved disputes
will be subject to the decision of the University President or the President’s designee.
Management plans for Institutional Conflicts of Interest related to Human Subjects
Research must be approved by the University President, or the President’s designee, the
applicable University Administrator(s), and his/her dean and department head (or other
comparable supervisors for non-faculty University Administrators), prior to final IRB
approval of the related research protocol.

c. Institutional Conflict of Interest Review Involving University President. If the potential
conflict involves a Significant Financial Interest of the University President, the matter
will be governed by applicable Arizona Board of Regents conflict of interest policies.

d. Reporting. The Executive Review Committee, through the Conflict of Interest Program,
will report final determinations and management plans to other appropriate University
offices and personnel and/or to the University of Arizona Foundation, as appropriate, for
the implementation and continued compliance with the required actions of the
management plan.

C. Documentation

The Conflict of Interest Program will maintain documentation of all disclosures made, all Executive
Review Committee reviews, determinations, recommendations, and all management plans for a
period of six (6) years following elimination of the Institutional Financial Interest or the completion
of all related University research, whichever is later.

D. Appeals

University Administrator(s) may appeal the Executive Review Committee’s determinations by
following the appeal process outlined in the procedures for this Policy, which are posted on the
Conflict of Interest Program webpage. University Administrator(s) must first appeal the Executive
Review Committee’s decision to the Executive Review Committee members by providing written
notification to the Conflict of Interest Program.

E. Compliance Reviews and Post-Approval Monitoring

The Conflict of Interest Program is responsible for monitoring compliance with this policy and for
ensuring compliance with management plans pursuant to this policy.

1. Compliance Reviews. The Conflict of Interest Program will conduct annual reviews of the
University community’s compliance with this policy. Such reviews will include, at minimum,
random selection of University departments and University Administrator(s) to conduct a review of disclosures and random selection of submitted disclosures to ensure accuracy.

2. **Post-Approval Monitoring.** The Conflict of Interest Program, in conjunction with the applicable University Administrator(s), their deans and departments heads (or comparable supervisory personnel for non-faculty University Administrators), will be responsible for implementing and monitoring post-approval compliance with actions required by Institutional Conflict of Interest management plans. All Institutional Conflict of Interest management plans will include provisions for post-approval monitoring at least twice per year.

**F. Noncompliance**

1. **Noncompliance with Disclosure Requirements.** In cases in which the Executive Review Committee determines that there has been noncompliance with the disclosure requirements of this Policy the Conflict of Interest Program will contact the University Administrator(s) found to be noncompliant and attempt to remedy the noncompliance. After two (2) attempts have been made by the Conflict of Interest Program the matter will be forwarded to the individual’s Supervisor for attention.

2. **Noncompliance with a Management Plan.** In cases in which the Executive Review Committee determines that there has been noncompliance with the terms of any management plan issued under this Policy, the Executive Review Committee will endeavor to work with the individual(s) to find an appropriate remedy. The Executive Review Committee may elect to recommend:
   a. Revision of the existing management plan to apply more stringent requirements or external monitoring;
   b. Revocation of Executive Review Committee approval of the conflicted activity, including possible cancelation of research or activities related to identified Institutional Conflict of Interest;
   c. Removal of noncompliant individual(s) from research or activities related to the Institutional Conflict of Interest; and/or
   d. Other corrective actions, as appropriate.

In the event that the Executive Review Committee’s attempt to remedy noncompliance is not successful, the Executive Review Committee will report the matter to the University President, or the President’s designee, for consideration of whether employee sanctions or other administrative actions are appropriate, in accord with relevant Arizona Board of Regents and University policies and procedures, and applicable laws and regulations.

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[1] This Policy supplements but does not replace other conflict of interest policies of the University. All University Administrators who are subject to this Policy are also expected to be aware of and to comply with those requirements. (Guidance on each of these policies and procedures is available at the Conflict of Interest Program page on the Office for the Responsible Conduct of Research website [5]). Other University policies that require the disclosure and management of specific types of conflicts include Managing Individual Conflicts of Interest; Conflict of Commitment Policy; Purchasing Policy Manual; College of Medicine Policy on Interactions with Commercial Interests; Policy on Conflicts of Interest arising from Interpersonal Relationships. Procedures for accepting gifts for the benefit of the University, including guidance about what is and what is not a gift, are detailed in Financial Services policy 812 [2].

[2] Disclosure forms can be found on the Conflict of Interest Program website or by contacting the Conflict of Interest Program.
Related Information*

Arizona Board of Regents Policy 3-901. Conflict of Interest [6]


Arizona State Constitution, Const. Art. 9, Section 7 [8]

Arizona Revised Statutes (A.R.S.) § 15-1635.01 [9]

Arizona Revised Statutes (A.R.S.) § 38-502. Definitions (of Conflict of Interest of Officers and Employees) [10]


UA Conflict of Interest web page [3]

UA Conflict of Interest procedures [4]


Source URL: http://policy.arizona.edu/research/institutional-conflict-interest-policy

Links
[1] mailto:ORCR-COI@email.arizona.edu