I. Purpose:

This policy establishes principles and procedures designed to protect the actual and perceived integrity of University of Arizona research and to enhance the protection of human subjects in research without untoward influence resulting from either the University’s financial investments or holdings or the personal financial interests or holdings of key University Administrators.

In developing this policy and related procedures, the University has taken into account the issues identified and discussed in “Protecting Patients, Preserving Integrity, Advancing Health: Accelerating Implementation of COI Policies in Human Subjects Research,” published in 2008 by the Association of American Medical Colleges (AAMC) and the Association of American Universities (AAU).

II. Definitions

A. Executive Review Committee (ERC)

The ERC, appointed by the President of the University, is charged with reviewing and evaluating potential institutional conflicts of interest, developing and assisting with the enforcement of management plans, reviewing information related to post-approval implementation of management plans, and serving as a resource for the Institutional Review Committee, the General Counsel, and other members of the University community. The ERC is comprised of at least seven voting members, including representatives from the senior faculty (Deans and/or Department Heads), Internal Audit, Senior Vice President for Research, Office of Technology Transfer, Procurement and Contracting Services, Vice President for Business Affairs, and Risk Management. If the potential conflict involves the Provost or the President, the matter will be referred for review to the Office of the Senior Vice President and General Counsel of the Arizona Board of Regents.

B. Fiduciary Role

A fiduciary role refers to a legal and/or ethical obligation on the part of a covered party to act in the best interests (i.e., the financial and operational success) of another. Examples of fiduciary roles include, but are not limited to membership on a board of directors and management role in a company or partnership.
C. Human Subject Research
Human subjects research includes all research meeting the definition of "research" performed with "human subjects" as defined in the Federal Common Rule (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. In the event that the Common Rule definitions of "human subject" or "research" are modified through rulemaking, any such revisions shall apply for the purposes of this Policy.

D. Institution
Institution means The University of Arizona (UA) in its entirety, including but not limited to colleges, departments, and administrative offices.

E. University Administrator
For purposes of this Policy, University Administrators (previously referred to as Institutional Officials) include those administrators, faculty, and staff who are in a position to make or significantly influence decisions on behalf of the University involving the following:
1) the conduct of research;
2) the use of University resources, including decisions involving expenditures, purchasing, investments, equity, and technology transfer;
3) the execution of contracts and grants; or
4) the licensing of University intellectual property to external parties.

Based on the foregoing, University Administrators include but are not limited to:
• University President
• University Provost and Vice/Associate/Assistant Provosts
• University Vice Presidents and Associate/Assistant Vice Presidents
• Deans and Vice/Associate/Assistant Deans
• Directors, Department Heads and Chairs, and other senior administrators, as determined by the University.

F. Research/Conducting Research
"Research" shall mean any organized program of scientific inquiry. "Conducting Research" includes designing research, directing or serving as an investigator, performing laboratory experiments, having a role in soliciting consent from research subjects or making decisions related to eligibility of patients to participate in research, analyzing or reporting research data, or submitting manuscripts or abstracts concerning the research for publication. Examples include, but are not limited to, projects for which outside support is requested and projects for which approval of an Institutional Review Board is required. For purposes of this Policy, the determination of what constitutes research and what constitutes the conduct of research shall be made by the appropriate ICOI committee.
III. Reporting Requirements

Reporting requirements for specific categories of financial and fiduciary interests are outlined below. These are not necessarily prohibited arrangements but do trigger reporting requirements to allow for the review and management of potential institutional conflicts.

A. Reporting of UA Financial Interests
The following financial interests of the UA must be reported to the ERC:

- Equity and ownership interests acquired through technology licensing activity or related investments worth more than $100,000 in any publicly-traded, for-profit organization;¹
- Equity and ownership interests of any amount in any for-profit organization that is not publicly traded;
- Gifts of $1 million or more from any for-profit organization or philanthropic unit associated with a for-profit organization; and
- Payments, including royalty payments, resulting from technology transfer, licensing, and business activities such as Institutional consulting or service agreements that, for each arrangement, exceed $100,000 per year.
- Clinical care income and tuition income are not included as institutional interests.

The senior staff member responsible for the arrangement (e.g., technology license, gift, Institutional consulting agreement) must make the report to the ERC at least annually and at the time a new arrangement involving a UA Financial Interest as defined in this policy is proposed. The senior staff member must provide sufficient detail (e.g., number of shares or percentage of ownership; amount of gift; magnitude and timing of payments, royalty, and consulting fees) for a thorough initial review of potential ICOIs, and the ERC may request additional information.

Employees or other University affiliates concerned about possible conflicts of interest may report their concerns to the ERC or through the Whistleblower Hotline.

B. Reporting of University Administrators' Financial Interests
The following financial interests of University Administrators must be reported to the ERC:

- Equity and/or ownership interests in publicly-traded for-profit organizations

¹ Nothing in this policy should be interpreted to suggest any violation of A.R.S. Const. Art. 9 § 7.
of an amount exceeding $25,000 in the value of its stock. Not included are (a) equity or ownership interests in mutual funds for which the individual has no control over the investment decisions of the fund, and (b) equity or stock holdings for which the University Administrator has no role or influence over trading decisions. For example, if an University Administrator attests in writing that his/her equity investments are managed under contract with a professional asset manager (who is not a member of his/her immediate family) and that he does not participate in (e.g., direct, recommend, influence, or control) the purchase or sale of specific stocks, the requirement to disclose holdings of publicly traded stock subject to such an arrangement will be waived.

- Any equity (including stock, options, warrants, and the like), ownership, or founders' interests in non-publicly traded companies;
- Any Fiduciary Role, such as service on the board of directors of a for-profit organization.
- Income, including royalty, equity, consulting fees, or other payments from for-profit organizations that, in the aggregate, exceeds $25,000 per year from each organization.

Potential conflicts of interest may also be identified when deans, directors, and department heads sign off on Proposal Routing Forms and Human Subjects/Animal Subjects applications. Following the Interim Policy on Investigator Conflict of Interest in Research, deans, directors, and department heads should report any significant financial interests (as defined in the Individual policy) in the entity sponsoring or otherwise involved in the research or teaching activity.

Current University Administrators must submit a report to the ERC regarding existing and prospective Financial Interests within 60 days of the effective date of this Policy. Newly appointed University Administrators must submit a report to the ERC of all existing and prospective Financial Interests within 30 days of hire or appointment. Thereafter, prospective Financial Interests must be reported prior to ownership or receipts of such Financial Interests. Finally, all University Administrators must make an annual report regardless of whether they hold or will hold Financial Interests in the coming year. In the annual report, University Administrators will be required to certify that they are in compliance with all applicable conflict of interest policies. This requirement does not affect reporting and other obligations as applicable under each division's policy on individual conflict of interest or reporting in connection with separate policies, such as those addressing intermediate sanctions.

Additionally, employees or other individuals concerned about possible conflicts of interest may report their concerns to the ERC or through the Whistleblower Hotline.
Divisional procedures may establish a more stringent reporting standard for their University Administrators.

IV. Review of Possible Institutional Conflicts of Interest

The ERC will review all submitted reports and advise the President, Provost, Senior Vice President for Business Affairs, and Senior Vice President for Research of potential institutional conflicts and will provide an annual update on all approved and disapproved situations.

1) Potential conflicts of interest will be identified when University Administrators report significant financial interests in an entity conducting business with the University in an area over which that University Official has direct supervision or decision-making responsibilities. University Officials may report their interests directly to the ERC or the Institutional Review Committee (which will refer the report to the ERC).

2) The ERC will review the report of financial interests and determine whether a management plan is appropriate and necessary.

3) The ERC will implement and monitor post-approval compliance with its determination.

4) The ERC will report all reports of financial interests to the President, Provost, and Senior Vice President for Research on a semi-annual basis.

V. Review Criteria

ERC reviews must consider whether the financial or fiduciary interests disclosed in accordance with this policy affect or may potentially affect any of the following:

- Safety of human research subjects;
- Safety of patients;
- Integrity of research;
- Appropriate allocation of resources;
- Objectivity and independence of educational activities, including undergraduate, graduate, post-graduate, and continuing education;
- Independence of clinical care or other professional practice judgment; and/or
- Objectivity in business and contracting decisions

The same standards will apply to the review of the financial interests of the University and all University Administrators.
VI. ERC Recommendation Process

The ERC review of a specific case may result in one of the following recommendations:

A. No Institutional Conflict
   In cases resulting in a finding that there is no significant actual, potential, or perceived institutional conflict, the ERC committee must communicate its decision to the appropriate individual responsible for the activity and any University Administrator whose interest was at issue.

B. Manageable Institutional Conflict
   In cases that the ERC considers manageable, it will recommend one or more management measures. These may include, but are not limited to: (1) effective recusal from decision-making regarding the proposed arrangement by the financially interested University Administrator and disclosure of the recusal to the appropriate individuals to implement the recusal; (2) reduction in the magnitude of the financial interest (generally to below the thresholds outlined above); (3) disclosure of the financial interest in relevant publications, presentations, human subject consent forms, clinical procedure or other consent forms, educational material, etc., (4) oversight by a disinterested senior individual or committee, and/or (5) other measures as deemed appropriate.

C. Institutional Conflict in Human Subject Research and Clinical Care
   For arrangements involving institutional conflicts with Human Subject research and clinical care, there must be particularly close scrutiny. Primary consideration will be given to potential impact on the safety and welfare of human Research subjects and patients. In addition, the potential impact of real or perceived institutional conflict on the integrity or credibility of Research data that could affect future clinical use will be considered carefully. As appropriate, the ERC review will be coordinated with and provided to the University’s Institutional Review Board for its consideration in exercising its responsibility for the protection of human research subjects.

D. Unmanageable Institutional Conflict
   In cases the ERC considers not manageable, it will report its recommendation to the appropriate recipient of the recommendation with written justification. In cases judged to involve an unmanageable institutional conflict, it is expected that the ERC will make recommendations to eliminate conflicting financial interests where practical in ways that do not compromise the proposed Research, clinical, professional, or educational activity. The ERC and the Institution should generally give precedence to activities that carry out Institutional missions over conflicting financial interests.

In all cases reviewed, the ERC will retain documentation of its review and recommendations.
VII. ERC Recommendation Implementation

On receiving a recommendation regarding an institutional conflict case, the individual designated to receive the recommendation will make a decision to accept, reject, or revise the recommendation. An aggrieved party may appeal the decision to the UA President. Decisions by the President will be final.

VIII. Sanctions and Disciplinary Actions

Non-compliance with this policy may result in sanctions or disciplinary action, including but not limited to one or more of the following:

- Written reprimand;
- Suspension of project funding;
- Restriction of privileges;
- Suspension without pay;
- Dismissal; and/or
- Other appropriate sanctions or discipline, depending on the severity and nature of the non-compliance.
- Potential notification of non-compliance to the research sponsor.

Existing Arizona Board of Regents (ABOR) and University policies and procedures, and applicable state and federal laws shall govern the procedures for imposing sanctions or discipline, and the nature of the sanctions.