

UAMS ADMINISTRATIVE GUIDE

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SECTION: HUMAN RESOURCES AREA: EMPLOYEE RELATIONS

SUBJECT: INSTITUTIONAL CONFLICT OF INTEREST

PURPOSE

To provide the standards and procedures for reporting and reviewing potential Institutional Conflicts of Interest and to provide a process by which the University of Arkansas for Medical Sciences ("UAMS") will manage, reduce or eliminate those conflicts.

SCOPE

This policy applies to UAMS Officials and UAMS as an Institution. Individual conflicts of interest of UAMS staff members who do not meet the definition of a UAMS Official shall be governed by the UAMS conflict of interest policies for academic and non-academic staff members (UAMS Administrative Guide 4.4.10 and 4.4.11).

POLICY

As a steward of public trust, UAMS has an obligation to conduct its activities with utmost integrity. UAMS strives to ensure that its research, education, clinical care, business transactions, and other activities are not inappropriately affected by, nor appear inappropriately affected by, the financial or business interests of UAMS or of UAMS Officials. Academic-industry relationships are important to advancing science; they are essential to the commercial development of academic and research discoveries for the benefit of the public. Such relationships may lead to financial benefit to UAMS or its Officials.

It is the policy of UAMS to assure that institutional decision-making is free from improper influence resulting from conflicting financial or economic interests. Financial or business interests of UAMS or of UAMS Officials must be identified, disclosed, and reviewed for potential institutional conflicts of interest according to the process set forth below. Gifts, payments, royalty income, equity, and other financial benefits from or interests in for-profit entities can create institutional financial interests. Institutional financial interests can also be created by financial and fiduciary interests of UAMS Officials. UAMS Officials are responsible for disclosing potential Institutional Conflicts of Interest so such conflicts may be appropriately managed. Individual conflicts of interest of UAMS staff members who do not meet the definition of a UAMS Official shall be governed by the UAMS conflict of interest policies for academic and non-academic staff members (UAMS Administrative Guide 4.4.10 and 4.4.11).

DEFINITIONS

BioVentures shall mean BioVentures, LLC, a limited liability company formed by UAMS for the primary purpose of providing support to UAMS in the operation, management and commercialization of medical, pharmaceutical and healthcare related innovation, education,

discoveries, inventions, processes and information resulting therefrom in addition to providing and performing other duties, services and functions in furtherance of the advancement of transfer and development of inventions, intellectual property and other innovative works and services produced by UAMS faculty, staff and students in pursuit of research and education.

Conflict of Commitment shall mean an external activity that interferes, or appears to interfere, with a UAMS Official's clinical, scholarly, or administrative responsibilities to UAMS, even if the external activity is valuable to UAMS or contributes to the UAMS Official's professional development and competence.

Fiduciary Relationship shall mean a relationship that results in a legal or ethical obligation to act in the best interest of an outside organization (such as service as a board member, officer, executive, advisor, or manager), regardless of whether compensation is received for services.

Immediate Family Member shall mean spouse, children, stepchildren, parents, siblings, and domestic partners (individuals not related by blood, not legally married, but currently in a committed relationship and residing in a common household sharing joint responsibility for the household).

Institution shall mean the University of Arkansas for Medical Sciences ("UAMS") in its entirety, including, but not limited to, colleges, departments, and administrative offices.

Institutional Conflict of Interest (or Institutional COI) shall mean a situation where a Significant Interest of UAMS or of a UAMS Official acting within their authority on behalf of UAMS, can inappropriately affect or reasonably appear to inappropriately affect research, education, clinical care, business transactions, or other activities of the Institution

Institutional Responsibilities shall mean an individual's professional responsibilities to UAMS, including, but not limited to, research, research consultation, teaching, clinical and professional practice, administrative responsibilities, committee memberships, and service on professional review panels or advisory boards.

Research shall mean a systematic investigation, study, or experiment designed to develop or contribute to generalized knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). For purposes of this policy, the term includes any such activity authorized under a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Significant Interest (SI) shall mean as follows:

For UAMS Officials: a Significant Interest includes any of the following interests of a UAMS Official or their Immediate Family that reasonably appear to be related to the UAMS Official's Institutional Responsibilities:

- a) Equity interests (such as stock, stock options, or other ownership interests).
- b) Licensed intellectual property (patents, copyrights, etc.) or income from intellectual property rights (licensing fees, royalties, etc.), including intellectual property rights assigned to or licensed through the Board of Trustees of the University of Arkansas or BioVentures.
- c) Payments or other remuneration (such as salary, consulting fees, honoraria, paid authorship or travel reimbursement) from outside organizations.
- d) Fiduciary Relationships with outside organizations.
- e) Receipt of gifts, endowments, sponsored travel, or other in-kind contributions from outside organizations.

For the Institution: a Significant Interest includes the following:

- a) Equity in a publicly-owned company that proposed to sponsor research at the University when that ownership represents more than or equal to 5% of the value of the company or where the equity has a value of more than or equal to \$1 million dollars;
- b) Any equity in a privately owned company that proposes to sponsor research at the University;
- c) Any ownership of Intellectual Property in a technology that is proposed to be studied at the University;
- d) Any current or potential royalty income to the University paid by an entity that proposes to sponsor research at the University;
- e) Any gift (any amount) within the previous three years from an entity that proposes to sponsor research at the University. OR Gifts greater than \$1 million dollars from any for-profit entity or philanthropic entity unit associated with a for-profit entity;
- f) Certain other payments or financial benefits. From time to time, UAMS enters into contractual relationships with outside parties which include a payment or other financial benefit to UAMS from the contracting party that are based on factors outside the course of business between UAMS and the contracting party. UAMS recognizes that certain types of these contracts, if not properly managed or disclosed by UAMS, and which because of UAMS' unique position and relationships, may create the perception that UAMS was improperly influenced to enter into the contract or endorses the contracting party as a "preferred provider" or may improperly influence consumer choices by third parties, in particular University students.

Significant Interest shall **not** include:

- a) Compensation or other remuneration paid by UAMS (except for licensing fees or royalty income from intellectual property rights assigned to the Board of Trustees of the University of Arkansas or BioVentures).
- b) Income from seminars, lectures, or teaching engagements sponsored by government agencies, academic medical centers, or accredited public or non-profit institutions of higher education or their affiliated research institutes.
- c) Income from service on advisory committees or review panels for government agencies, academic medical centers, or accredited public or non-profit institutions of higher education or their affiliated research institutes.
- d) Income from investment vehicles, such as mutual funds and retirement accounts, as long

- as the UAMS Official does not directly control the investment decisions in these vehicles.
- e) Travel sponsored by government agencies, academic medical centers, accredited, public or non-profit institutions of higher education or their affiliated research institutes.

Technology Transfer shall mean the commercialization of ideas, concepts, and inventions through publication, patenting, licensing, and the formation of business entities.

UAMS Official shall mean the Chancellor, Provost, Vice Chancellors, Deans, Institute Directors, Service Line Directors, members of the Patent and Copyright Committee, employees who have been granted or delegated contracting authority on behalf of UAMS, and any other individual in a position to make or significantly influence decisions on behalf of UAMS involving oversight of research, execution of grants or contracts, or licensing of UAMS intellectual property to external parties. UAMS Official also includes the individual's Immediate Family Member.

INSTITUTIONAL CONFLICT OF INTEREST COMMITTEE

The Institutional Conflict of Interest Committee ("ICOIC") shall identify and manage Institutional COIs and COIs for Institutional Officials.

The ICOIC shall be a standing committee of UAMS appointed by the Vice Chancellor for Compliance and Managing General Counsel ("VCIC"). The ICOIC shall consist of a total of seven (7) voting members and a number of non-voting ex-officio members as determined by the VCIC. Members shall serve renewable three (3) year terms. One (1) voting member shall also be a member of the UAMS Academic Conflict of Interest Committee. Members may also be appointed from outside UAMS. The ICOIC will be advisory to the Chancellor, who holds final authority regarding questions of Institutional COIs.

The ICOIC shall meet regularly to fulfill its duties. A quorum shall consist of three (3) voting members. Decisions shall be made by majority vote of the members present.

Conflicts of Commitment

UAMS Officials may engage in external activities which contribute to professional development by enhancing knowledge, skills, and expertise. Such activities may include consulting, acting as an expert witness, authorship, lecturing, public service, editorial services, involvement with professional societies, or participation on educational, advisory or scientific committees and review panels, or pro bono work. Such activities, however, should not interfere with a UAMS Official's Institutional Responsibilities. Therefore, external activities must be reviewed and approved by the appropriate Department Chair and Dean or other UAMS Official(s) prior to engaging in such activities to ensure they do not result in a conflict of commitment. Once prior-approval of an external activity has been obtained, all activities that meet the definition of a Significant Interest must be disclosed to the COI Office by the UAMS Official. Any subsequent review by the COI Office or Institutional COI Committee shall focus on identifying and managing Conflicts of Interest

IDENTIFYING POTENTIAL CONFLICTS OF INTEREST

Administration of Institutional COI matters will be handled by the Conflict of Interest Office (COI Office).

- a) <u>Disclosure of Significant Interests</u>. UAMS Officials are required to complete a Conflict of Interest Disclosure Statement (Disclosure) annually and within thirty (30) days of acquiring a new Significant Interest (SI). New UAMS Officials are required to complete a Disclosure within the first two (2) weeks of employment.
 - Disclosures must include any SI of the UAMS Official or their Immediate Family Members that could reasonably appear to be related to the UAMS Official's Institutional Responsibilities.
- b) <u>Disclosure of Technology Transfers</u>. In accordance with the Bayh-Dole Act, UAMS strives to transfer new technologies developed at UAMS to the private sector in order to benefit public health and welfare. However, the potential for financial gain from Technology Transfers shall be secondary to UAMS' mission.
 - To help identify potential Institutional COIs related to Technology Transfers, the Director of BioVentures, LLC shall communicate with the COI Office regarding proposed Technology Transfers in accordance with Administrative Guide 3.1.13.
- c) <u>Disclosure of Gifts</u>. It is the policy of UAMS to not solicit or accept gifts or philanthropic grants that in any way limit or have the potential to affect the independence or professional and objective judgment of an investigator in the conduct, design, or reporting of research. Further, UAMS shall not solicit or accept gifts or philanthropic grants (including those for the support of research) that are contingent upon any particular business or purchasing decision(s).

All charitable gifts to UAMS are processed by the UAMS Office of Treasurer, and all charitable gifts to the University of Arkansas Foundation for the benefit of UAMS are processed through the University of Arkansas for Medical Sciences Office of Development and Alumni Affairs. Charitable gifts contingent upon the outcome of any research or business transaction conducted at or by UAMS shall not be accepted or allowed, and are not considered charitable gifts.

This policy is not designed to preclude the solicitation or acceptance of philanthropic gifts from entities that sponsor research, or own or control products being tested, or who otherwise are doing business with UAMS. Rather, the goal of this policy is to identify potential Institutional COIs so they may be managed through disclosure, separation of responsibilities, and other appropriate mitigation strategies.

The Office of Development and Alumni Affairs shall notify the Conflict of Interest Office when substantial gifts or in-kind contributions are received from commercial

research sponsors or private entities that own or control products being studied or tested, so the following may be evaluated:

- i. Whether the gift might affect or reasonably appear to affect oversight of research at UAMS;
- ii. Whether the gift is held for the express benefit of a specific college, department, or institute where research that has the potential to benefit the donor is being conducted; and
- iii. Whether any UAMS Official involved in the design, conduct, or review of research that has the potential to benefit the donor was involved in solicitation of the gift.
- d) <u>ICOIC Review</u>. Disclosures of potential COIs will be forwarded to the ICOIC for review.

MANAGEMENT OF POTENTIAL INSTITUTIONAL CONFLICTS OF INTEREST

The UAMS Institutional Conflict of Interest Committee shall review and evaluate the financial or business interests of UAMS or of UAMS Officials to identify potential Institutional Conflicts of Interest; shall create, in collaboration with the appropriate UAMS officials or offices, management plans to manage, reduce, or eliminate Institutional Conflicts of Interest that are identified; and shall provide oversight to the implementation and monitoring of management plans created. UAMS will strive to manage or eliminate each institutional conflict of interest identified before any contract, sponsored project, dedicated gift, or transaction is executed; any contractual relationship is initiated; or any action is take that might be inappropriately affected or appear to be inappropriately affected by the Institutional Conflict of Interest. UAMS prefers to avoid contractual relationships that may result in potential Institutional COIs. When such relationships exist, they shall be for the purpose of supporting the UAMS mission rather than to benefit the economic interests of UAMS or a UAMS Official.

ICOIC review of specific cases will result in one of the following findings:

- a) No Institutional COI. In cases where the ICOIC finds that there is no Institutional COI, written notice of this decision shall be provided to the UAMS Official whose interest was at issue and other appropriate administrative officials.
- b) Manageable Institutional COI. In cases where the ICOIC finds that a manageable Institutional COI exists, the ICOIC will communicate its finding to the disclosing UAMS Official and other appropriate administrative officials and prepare, with the assistance of the Conflict of Interest Director, a management plan in accordance with the guidelines set forth in this policy. The UAMS Official may accept the plan or file an appeal. If the management plan is accepted, the UAMS Official shall be responsible for complying with the plan and assuring compliance of other affected departments and individuals. The UAMS Official shall also be responsible for providing annual reports to the Director of Conflict of Interest on the management of the Institutional COI until such time as the conflict is eliminated.

c) <u>Unmanageable Institutional COI</u>. In cases where the ICOIC finds that an unmanageable Institutional COI exists, the ICOIC shall provide the conflicted UAMS Official with written notice of the rationale for its finding and its recommendation for eliminating the conflict. The UAMS Official may accept this recommendation or file an appeal. If the recommendation is accepted, the UAMS Official shall be responsible for complying with the recommendation and providing the ICOIC with documentation of conflict elimination within the time period specified by the ICOIC.

Goals of management of Institutional COIs include assuring that Significant Interests do not inappropriately affect or reasonably appear to inappropriately affect research, education, clinical care, business transactions, or other activities of the Institution.

When UAMS has an equity or proprietary interest in a Technology Transfer, this interest will be disclosed in any related academic publications and presentations related to the Technology that are authored or presented by UAMS employees.

Additional methods for managing Institutional COIs may vary based on the specific facts of each situation. Management strategies include, but are not limited to:

- a) Requiring recusal of conflicted UAMS Officials from administrative decision-making with respect to the Institutional COI;
- b) Requiring removal of conflicted UAMS Officials from supervision of junior faculty or students in connection with the Institutional COI;
- c) Requiring recusal of conflicted UAMS Officials from negotiation of contracts related to the Institutional COI;
- d) Designating non-conflicted UAMS Officials to address conflict-related concerns and oversee management of the Institutional COI and the conflicted UAMS Official;
- e) Requiring divestment of financial or economic interests when management would be ineffective.
- f) Disclosing the Institutional COI to research subjects, in publications and presentations, and to other researchers and institutions in multicenter trials.
- g) Disclosing Institutional COIs with the potential to affect Human Subjects Research to the Institutional Review Board (IRB) and assuring compliance with approved protocols;
- h) Designating a non-conflicted UAMS Official to monitor compliance with management plans implemented by the Academic Conflict of Interest Committee to manage individual conflicts of interest that also relate to an Institutional COI.

A final decision of the ICOIC may be appealed by a UAMS Official in accordance with the "Appeals" section of this policy.

NONCOMPLIANCE

For purposes of this policy, non-compliance shall include:

a) Failure to report SIs accurately, fully, and in a timely manner;

- b) Failure to provide additional information as requested by the ICOIC;
- c) Failure to comply fully and promptly with management plans or decisions of the ICOIC, subject to the appeals process set forth herein; and
- d) Failure to update disclosures as required herein.

<u>ICOIC Actions</u>. If the ICOIC has reasonable cause to believe that a UAMS Official has failed to comply with this policy or a management plan, it shall inform the UAMS Official of the basis for such belief and afford the UAMS Official an opportunity to explain the alleged noncompliance. If, after hearing the UAMS Official's response and making further investigation as warranted by the circumstances, the ICOIC determines that the UAMS Official is noncompliant, the UAMS Official shall have ten (10) days to cure the noncompliance.

For non-research related matters, if the UAMS Official fails to provide the ICOIC with documentation of compliance within this time period, the ICOC may recommend that the Chancellor take disciplinary action against the Official.

For research-related matters, if the UAMS Official fails to provide the ICOIC with documentation of compliance within this time period, the ICOIC, in consultation with the Vice Chancellor for Research, has the authority to impose sanctions, including, but not limited to:

- a) Termination of conflicted research studies if necessary to address concerns relating to research objectivity or subject safety;
- b) Termination of authority for any actions related to conflicted research;
- c) Amendment of conflicted research protocols;
- d) Removal from conflicted research projects;
- e) Suspension of research funding:
- f) Suspension from submission of grant applications or research protocols; or
- g) Other appropriate sanctions depending on the nature and severity of non-compliance.

The ICOIC may also recommend that the Chancellor take disciplinary action against the Official.

Applicable state and federal law and UAMS policies and procedures shall govern the procedures for imposing any disciplinary action pursuant to this policy.

APPEALS

A final decision of the ICOIC may be appealed by a UAMS Official by filing a written request for appeal with the Director of Conflict of Interest within thirty (30) days of receipt of the decision of the ICOIC. The request shall include the rationale for appeal.

Upon receipt of a written request for appeal, the Director of Conflict of Interest shall notify the Chair of the ICOIC and a hearing shall be scheduled within thirty (30) days to allow the conflicted UAMS Official to appear before the ICOIC and provide additional information as to why they believe no Institutional COI exists.

Following the hearing, the ICOIC may decide to uphold its initial determination, revise its

recommended plan for management or elimination, or reverse its initial determination based on additional evidence presented at the hearing.

If the decision of the ICOIC following the hearing is unsatisfactory to the UAMS Official, a written request for appeal may be filed with the Chancellor within thirty (30) days of receipt of the decision of the ICOIC's hearing decision. The decision of the Chancellor shall be final. In the event the Chancellor is the conflicted UAMS Individual, an appeal may be filed with the President of the University of Arkansas System.

Failure to timely file an appeal as specified herein shall be considered a waiver of appeal rights.

MISCELLANEOUS

- a) Additional Reporting Options. Individuals concerned about possible Institutional COIs may report their concerns to the Director of Conflict of Interest. No adverse action shall be taken against any individual who files a report in good faith, and such reports shall remain confidential to the extent possible. The Director of Conflict of Interest will investigate the report and notify the Chair of the ICOIC of any findings. If the Chair determines that a potential Institutional COI exists, the ICOIC shall be convened to review the issue.
- b) <u>Clinical Disclosures</u>. A statement will be included in patient information materials provided to all patients acknowledging that UAMS has institutional relationships with medically related commercial entities. These relationships may result from licensing agreements, institutional partnerships, or leadership activities. Patients will be informed that they may contact the Conflict of Interest Office for general information about UAMS's institutional relationships with commercial entities.
- c) **Record Retention.** Records of disclosures shall be retained for a minimum of five (5) years. In the event of litigation or audit prior to record destruction, applicable records shall be retained until litigation or audit findings involving the records have been resolved and final action taken.
- d) Outside Employment. In accordance with University of Arkansas Board of Trustees Policy 450.1, Institutional Officials shall not engage in outside employment that interferes in any substantial way with their UAMS duties or conflicts with their UAMS assignments. Institutional Officials must receive pre-approval for outside employment from their Department Chair/Dean or equivalent official. Outside employment may only be performed while on leave or during UAMS nonworking hours.
- e) **Questions.** Any questions about this policy may be directed to the Conflict of Interest Office at 501-686-6447.

Signature:

Date: October 14, 2020