

NUMBER: 4.4.13

DATE: 04/29/2011

REVISION: 11/16/11; 6/27/12; 6/15/15; 7/13/15; 12/09/15; 11/08/16

PAGE: 1 of 8

SECTION: HUMAN RESOURCES

AREA: EMPLOYEE RELATIONS

SUBJECT: INSTITUTIONAL CONFLICT OF INTEREST IN RESEARCH

PURPOSE

Research at UAMS is devoted to the advancement and dissemination of knowledge, education of students, and improvement of the public health and welfare. Research devoted to these ends may also generate financial benefits to UAMS and individual investigators, such as through patents and licensing. The purpose of this policy is to provide appropriate institutional safeguards to assure that the potential for financial gain is not allowed to inappropriately influence the design, conduct, review, or oversight of research performed at UAMS.

SCOPE

This policy applies to UAMS Officials. UAMS Officials who are also Academic Staff Members are also governed by the UAMS Academic Conflict of Interest Policy (UAMS Administrative Guide 4.4.10).

POLICY

It is the policy of UAMS to assure that institutional decision-making is free from improper influence resulting from conflicting financial or economic interests. This policy addresses situations where the decision-making of a UAMS Official with respect to research activities may be or appear to be affected by a conflicting financial or economic interest of the Official or UAMS. Because the existence or appearance of such Institutional Conflicts of Interest can lead to perceived or actual bias, an environment of transparency is essential to allow UAMS leaders to deal appropriately with actual and potential conflicts of interest to assure integrity in research and education while allowing for newly discovered technologies to be used for public benefit.

DEFINITIONS

Academic Staff Member shall mean all UAMS faculty members, all UAMS principal investigators and co-principal investigators, and any other individuals at UAMS who are responsible for the design, conduct, or reporting of research performed at UAMS.

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.

Human Subjects Research shall mean all research meeting the definition of "research" performed with "human subjects" as defined in the Federal Common Rule (45 C.F.R. Part 46 and 21 C.F.R. Part 56), as may be amended from time to time.

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 a UAMS Official has the ability to inappropriately influence the design, conduct, review, or oversight of research being performed at UAMS and an unbiased observer could reasonably conclude that as a result of such interest, research activities were being undertaken for financial gain rather than to support the mission of UAMS.

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.

Key Investigator means the principal investigator and any other person identified as key personnel in a grant application, progress report, or other report made pursuant to 42 C.F.R. Part 50.

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)¹ includes any of the following interests of a UAMS Official or his/her 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 UAMS.
- 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.

¹ See 42 C.F.R. Section 50.603.

Significant Interests related to research may include any of the interests as defined above in the research sponsor or in the product or service being tested.

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 UAMS).
- 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, and employees who have been granted or delegated contracting authority on behalf of UAMS. 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 related to research. The ICOIC shall also manage non-research related COIs of UAMS Officials in accordance with the UAMS Academic Conflict of Interest Policy (UAMS Administrative Guide 4.4.10).

The ICOIC shall be a standing committee of UAMS appointed by the Vice Chancellor for Institutional Compliance (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. Two (2) voting members shall also be members 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 four (4) voting members. Decisions shall be made by majority vote of the members present.

IDENTIFYING POTENTIAL CONFLICTS OF INTEREST

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

- a) Disclosure of Significant Interests. 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 be current any time a grant application or research protocol is submitted and must remain current throughout the duration of the research project.² A UAMS Official whose disclosure has expired will not be allowed to conduct research until the deficiency is cured.

Disclosures must include any SI of the UAMS Official or his/her Immediate Family Members that could reasonably appear to be related to the UAMS Official's Institutional Responsibilities.³

- b) Disclosure of Technology Transfers. 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 UAMS BioVentures Office shall communicate with the COI Office regarding proposed Technology Transfers in accordance with Administrative Guide 3.1.13.

- c) Disclosure of Research Projects. The Office of Research and Sponsored Programs, Institutional Review Board, and Office of Research Regulatory Affairs shall provide information to the COI Office regarding current and pending research projects and proposals of UAMS Officials whose Disclosures are scheduled for routine or expedited review and any current and pending research projects and proposals that may be related to or affected by UAMS Technology Transfers.
- d) Disclosure of Gifts. 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).

² Federal regulations require disclosure of actual and potential COIs prior to engaging in any research projects funded by the Public Health Service and or conducted under investigational new drug applications (INDs) or investigational drug exemption applications (IDEs). See 42 C.F.R. Section 50.604(e) and 21 C.F.R. Sections 312.53(c), 812.20(b)(5) and 812.43(c).

³ See 42 C.F.R. Sections 50.603 and 50.604(e).

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.

e) ICOIC Review. Disclosures of potential COIs will be forwarded to the ICOIC for review.

MANAGEMENT OF POTENTIAL INSTITUTIONAL CONFLICTS 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.

An Institutional COI related to research will be determined to exist when a research project could reasonably appear to be directly and significantly impacted by the SI of UAMS or a UAMS Official. A direct impact is one where research results could be directly relevant to development, manufacturing, or improving products or services of an entity or technology in which the UAMS Official has an SI. A significant impact is one where research results could materially affect the value of the technology or the entity, its earnings, or sales.⁴ Common SIs resulting in Institutional COIs that require management include, but are not limited to:

- a) Equity or proprietary interests that could increase in value based on the outcome of research.

⁴ See 42 C.F.R. Section 50.604(f).

- b) Financial or fiduciary relationships with private entities that could benefit based on the outcome of research.
- c) Gifts, endowments, or contributions from private entities that could benefit based on the outcome of research.

When the ICOIC determines that an Institutional COI exists, the UAMS Official and appropriate administrative officials will be notified. The Official may accept the ICOIC's determination or file an appeal as set forth herein. If the determination is accepted, a management plan shall be implemented to mitigate the Institutional COI until it is eliminated. The management plan must be approved by the ICOIC and will be reviewed and monitored for compliance at least annually. The ICOIC may prescribe more frequent monitoring at its discretion.

Goals of management of Institutional COIs include assuring:

- a) Safety of patients and human research subjects;
- b) Integrity and objectivity of research results;
- c) Appropriate allocation of research resources;
- d) Objectivity and independence of research and educational activities;
- e) Protection of students and junior faculty.

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) Disclosure to patients and research subjects during the informed consent process;
- b) Monitoring, data management, or peer review of research by a non-conflicted UAMS Official or committee to assure protocol compliance and data integrity;
- c) Disclosure to appropriate administrative officials and/or committees and recusal from participation in negotiations, transactions, and decision-making related to the Institutional COI;
- d) Disclosure to other researchers and institutions in multicenter trials.
- e) Designation of a non-conflicted UAMS Official to address conflict-related concerns, supervise affected faculty or students, and oversee management of the Institutional COI;
- f) Designation of a non-conflicted individual to serve as principal investigator or co-principal investigator on conflicted research.
- g) Assurance that technology and intellectual property affected by the Institutional COI are not inappropriately shared.
- h) Divestment when management would be ineffective.

PHS-Funded Research. To assure compliance with 42 C.F.R. Part 50, Subpart F, UAMS Officials who engage in PHS-funded research shall also be governed by provisions of the UAMS Academic Conflict of Interest Policy (Admin. Guide 4.4.10) addressing PHS-funded research.

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

ICOIC Actions. 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. 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 he or she believes 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.

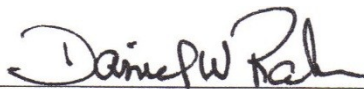
If the decision of the ICOIC following the hearing is unsatisfactory to the UAMS Official, a written request for appeal may be filed with the Chancellor within thirty (30) days of receipt of the decision of the ICOIC's hearing decision. The decision of the Chancellor shall be final. In the event the 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) **Record Retention.** Records of disclosures for PHS-funded projects shall be retained for a minimum of three (3) years from the date of submission of the final expenditures report. Records related to non-federally funded projects 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.
- c) **Questions.** Any questions about this policy may be directed to the Conflict of Interest Office at 501-686-6447.

Signature: _____



Date: November 8, 2016