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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 all UAMS Officials.

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.

UAMS Officials are responsible for disclosing potential Institutional Conflicts of Interest so such conflicts may be appropriately managed in accordance with the mission of UAMS. 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

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 legal or ethical obligation (such as service as a board member, officer, executive, or consultant) of a UAMS Official to act in the best interest of a

private entity, and such obligation could reasonably appear to affect the integrity or objectivity of the UAMS Official's professional role or decision-making responsibilities with respect to research being performed at UAMS.

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 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.

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 may include any of the following interests of a UAMS Official or his or her Immediate Family Members that could reasonably appear to be related to the Official's UAMS responsibilities:

- a) Equity interests (such as stock, stock options, or other ownership interests).
- b) Income (such as licensing fees or royalties) from intellectual property rights (such as patents or copyrights).
- c) Payments or other remuneration (such as salary, consulting fees, honoraria, paid authorship or travel reimbursement) from commercial research sponsors or private organizations.
- d) Fiduciary Relationships with commercial research sponsors or private organizations.
- e) Gifts, endowments, sponsored travel, or other in-kind contributions from commercial research sponsors or private organizations.

Significant Interest shall **not** include:

- a) Salary, royalties, or other remuneration paid by UAMS.
- b) Income from seminars, lectures, or teaching engagements sponsored by government agencies, academic teaching hospitals, 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 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 Investigator does not directly control the investment decisions in these vehicles.
- e) Travel sponsored by government agencies, academic teaching hospitals, 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, Vice Chancellors, Deans, Executive Associate Deans, Department Chairs, Directors of Centers of Excellence, members of the Patent and Copyright Committee, 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 Members.

INSTITUTIONAL CONFLICT OF INTEREST COMMITTEE

The Institutional Conflict of Interest Committee (ICOIC) shall review and manage Institutional COIs related to research. 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. A quorum shall consist of four (4) voting members. Decisions of the ICOIC shall be by majority vote of the members present. The ICOIC will be advisory to the Chancellor, who holds final authority regarding questions of Institutional COIs.

The ICOIC shall meet regularly to initially implement this policy and to manage any existing Institutional COIs until such time as it determines that such conflicts are adequately managed. At that time, the ICOIC shall meet annually and on an ad hoc basis at the direction of the Chair to review existing and newly identified Institutional COIs.

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 by federal regulations to disclose actual and potential COIs prior to engaging in any research projects funded by the Public Health Service (PHS)¹ or conducted under investigational new drug applications (INDs) or investigational device exemption applications (IDEs)². With respect to federally funded research, such disclosures must be made no later than the time of application for funding.³ To meet this requirement, All UAMS Officials shall complete a UAMS Official Institutional COI Disclosure Statement (Disclosure) on an annual basis and within thirty (30) days of acquiring a new Significant Interest (SI). Newly appointed UAMS Officials shall complete a Disclosure within two (2) weeks of appointment. UAMS Officials are responsible for ensuring that their Disclosures are current any time an application for PHS-funded research is submitted.

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 job responsibilities.⁴

- 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](#). BioVentures shall provide information to the COI Office regarding current Technology Transfers upon request.

- c) Disclosure of Industry Support. To help identify potential Institutional COIs related to industry-sponsored research, the Office of Research and Sponsored Programs and the Research Support Center shall communicate with the COI Office regarding industry-sponsored research, including names of commercial research sponsors and private entities that own or control products being studied or tested.
- 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).

¹ See 42 C.F.R. Section 50.604(e).

² See 21 C.F.R. Sections 312.53(c), 812.20(b)(5) and 812.43(c).

³ See 42 C.F.R. Section 50.604(e).

⁴ 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.

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, the Office of Development and Alumni Affairs will evaluate the following and notify the COI Office as appropriate:

- 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 Reports. The COI Director shall review all Disclosures and report any potential Institutional COIs 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 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 a SI. A significant impact is one where research results could materially affect the value of the technology or the entity, its earnings, or sales.⁵ Common SIs resulting in Institutional COIs that require management include, but are not limited to:

⁵ See 42 C.F.R. Section 50.604(f).

- a) Equity or proprietary interests where the value of the interest could reasonably appear to be impacted by the outcome of research being performed at UAMS.
- b) Financial relationships with private entities that could reasonably appear to have an interest in the outcome of research being performed at UAMS.
- c) Fiduciary Relationships with private entities that could reasonably appear to have an interest in the outcome of research being performed at UAMS.
- d) Gifts, endowments, or contributions from private entities that could reasonably appear to have an interest in the outcome of research being performed at UAMS.

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) Unmanageable Institutional COI. 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:

- 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) Objectivity of decision making; and
- f) Protection of students and junior faculty.

Methods for managing Institutional COIs will vary based on the specific facts of each situation. Possible management plans may include, without limitation:

- 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.

PHS-Funded Research. When an Institutional COI related to PHS-funded research is determined to exist, it shall be reported to the PHS-Awarding Component prior to the expenditure of any funds under the PHS-funded research project.⁶ Any COI identified subsequent to this initial report shall be managed and reported within sixty (60) days. PHS reports shall be updated on an annual basis for the duration of the PHS-funded research project.

Public Disclosure. Institutional COIs related to PHS-funded research projects of UAMS Officials who are also Key Investigators shall be made publicly accessible in accordance with 42 C.F.R. Section 50.605(a)(5). Accessible information shall include the UAMS Official's name, position on the research project, name of the entity with which the SI is held, the nature of the SI, and the dollar value, within a numeric range.

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

⁶ See 42 C.F.R. Section 50.605.

as warranted by the circumstances, the ICOIC determines that the UAMS Official is noncompliant, the UAMS Official shall have thirty (30) 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.

Retrospective Reviews. In the event of noncompliance with this policy or a management plan where such noncompliance could potentially impact PHS-funded research, a retrospective review will be undertaken within one hundred twenty (120) days of discovery of:

- a) Any COI that has not been timely reported or managed, or
- b) Any failure of a UAMS Official to comply with a management plan.⁷

The purpose of the retrospective review is to determine whether any research conducted during the time period of noncompliance was biased. The retrospective review shall be documented, and a report made to PHS, if appropriate. If the retrospective review results in a finding that research has been biased, the PHS Awarding Component shall be promptly notified and a mitigation report submitted, as required by 42 C.F.R. Section 50.605(a)(3)(iii).

Noncompliance Reporting. Noncompliance with a plan to manage or eliminate a COI related to PHS-funded research that appears to have biased the design, conduct, or reporting of such research, shall promptly be reported to the appropriate PHS Awarding Component.⁸

DHHS Requirements. In the event the Department of Health and Human Services determines that a PHS-funded research project was designed, conducted, or reported by a UAMS Official with a financial conflict of interest that was not appropriately managed or reported, the Official shall be required to publicly disclose the COI.⁹

⁷ See 42 C.F.R. Section 50.605(a)(3)(ii)(A),

⁸ See 42 C.F.R. Section 50.606(a).

⁹ See 42 C.F.R. Section 60.606(c).

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.

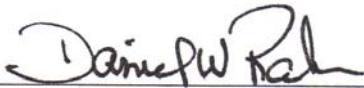
MISCELLANEOUS

- a) **Additional Reporting Options.** Employees or other UAMS affiliates 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) **Mandatory Training.** UAMS Officials will receive training on the federal financial conflict of interest regulations, this policy, and their responsibilities regarding disclosure of SIs prior to engaging in research and at least every four (4) years thereafter.¹⁰ Additional training will be required any time revisions are made to this policy that affect responsibilities of UAMS Officials or a UAMS Official is found to be non-compliant with this policy or a management plan.
- c) **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

¹⁰ See 42 C.F.R. Section 50.604(b).

shall be retained until litigation or audit findings involving the records have been resolved and final action taken.

- d) **Policy Disclosure.** This policy will be made publicly available on the UAMS Website in accordance with 42 C.F.R. Section 50.604(a).
- e) **Questions.** Any questions about this policy may be directed to the Conflict of Interest Office at 501-686-6447.

Signature: 

Date: November 16, 2011