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**SECTION: HUMAN RESOURCES**

**AREA: EMPLOYEE RELATIONS**

**SUBJECT: CONFLICT OF INTEREST FOR ACADEMIC STAFF MEMBERS**

## **PURPOSE**

The purpose of this policy is to promote the UAMS mission (education, patient care, research, and outreach) and assure professional and academic integrity through disclosure and appropriate management of potential conflicts of interest of Academic Staff Members.

## **SCOPE**

This policy applies to Academic Staff Members. Academic Staff Members who are also UAMS Officials are also governed by the UAMS Institutional Conflict of Interest Policy (UAMS Administrative Guide 4.4.13).

## **DEFINITIONS**

**Academic Staff Member (ASM)** 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. ASM also includes the individual's Immediate Family Members.

**Conflict of Commitment** shall mean an external activity that interferes with an ASM's clinical, scholarly, or administrative responsibilities to UAMS.

**Conflict of Interest (COI)** shall mean a Significant Interest that could inappropriately influence or reasonably appear to inappropriately influence the integrity or objectivity of an ASM's professional role or decision-making responsibilities at UAMS.

**Fiduciary Relationship** shall mean a relationship that results in a legal or ethical obligation to act in the best interest of an 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 Members** shall mean spouses, domestic partners, children, parents, grandparents, and siblings.

**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)**<sup>1</sup> includes any of the following interests of an ASM or his/her Immediate Family **that reasonably appear to be related to the ASM'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.

**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.

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<sup>1</sup> See 42 C.F.R. Section 50.603.

- d) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the ASM 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, and licensing, and the formation of business entities.

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

**UAMS Official** shall mean the Chancellor, Provost, Vice Chancellors, Deans, Executive Associate Deans, and Institute Directors, UAMS Official also includes the individual's Immediate Family Members.

## **POLICY**

**Conflicts of Interest.** COIs arise when private interests (such as outside professional or financial relationships) have the potential to inappropriately influence or appear to inappropriately influence an ASM's professional responsibilities to UAMS. These situations do not necessarily imply wrongdoing. However, the perception that such incentives might adversely affect patients, research objectivity, the protection of human subjects, or the UAMS mission is sufficient to require that both potential and actual COIs be disclosed and appropriately managed.

**Conflicts of Commitment.** ASMs may engage in external activities which contribute to professional development by enhancing knowledge, skills, and expertise. Such activities may include consulting, authorship, editorial services, involvement with professional societies, or participation on educational, advisory or scientific committees and review panels. Such activities, however, should not interfere with an ASM's Institutional Responsibilities. Therefore, external activities must be reviewed and approved by the appropriate UAMS Official(s) to assure they do not result in a conflict of commitment.

## **PROCEDURES**

**Conflict of Interest Committee.** The Academic Conflict of Interest Committee (Committee) shall be a standing committee of UAMS, appointed by the Vice Chancellor for Institutional Compliance (VCIC). The Committee shall consist of not fewer than six (6) voting members representing a variety of constituencies at UAMS and a number of non-voting ex-officio members as determined by the VCIC. Members shall serve without term limits. The Committee shall meet monthly and on an ad hoc basis. A quorum shall consist of three (3) voting members. Decisions will be made by majority vote of the members present. Expedited decisions may be made by a single member when necessary, but shall be reviewed by the full Committee at its next meeting.

The Committee shall identify and manage COIs of ASMs. Any conflicts of commitment identified will be referred to the appropriate UAMS Official.

### **Identifying Potential Conflicts.**

- a) **Disclosure.** ASMs are required to complete a Conflict of Interest Disclosure Statement (Disclosure) annually and within thirty (30) days of acquiring a new SI. New ASMs are required to complete a Disclosure within the first two (2) weeks of employment. Disclosures must also be current any time a grant application or research protocol is submitted and must remain current throughout the duration of the research project.<sup>2</sup> An ASM whose Disclosure has expired will not be allowed to conduct research or submit new grant applications until the deficiency is cured.

Disclosures must include any SI of the ASM or his/her Immediate Family Members that could reasonably appear to be related to the ASM's Institutional Responsibilities.<sup>3</sup> Disclosures containing potential COIs shall be forwarded to the Committee for review.

**Committee Determinations.** In determining whether an SI constitutes a COI, the Committee shall consider relevant factors, including, but not limited to, whether the SI has the potential to adversely impact:

- a) Safety of patients or human research subjects;
- b) Independence of clinical practice and professional judgment;
- c) Objectivity and independence of educational activities;
- d) Academic achievements of students or junior faculty; or
- e) Procurement or purchasing decisions.

With respect to research, the Committee shall consider whether the SI could directly and significantly impact the research. 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 ASM has a SI. A significant impact is one that could materially affect the value of the technology or the entity, its earnings, or sales.<sup>4</sup> Common COIs related to research include, but are not limited to:

- a) Equity or proprietary interests that could increase or decrease in value based on the outcome of research.
- b) Financial or fiduciary relationships with private entities that could benefit based on the outcome of research.

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<sup>2</sup> 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).

<sup>3</sup> *See* 42 C.F.R. Sections 50.603 and 50.604(e).

<sup>4</sup> *See* 42 C.F.R. Section 50.604(f).

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

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

**Management of COIs.** Methods for managing 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 individual or committee to assure protocol compliance and data integrity;
- c) Disclosure in public presentations and publications and to other researchers and institutions in multicenter trials;
- d) Designation of a non-conflicted individual to serve as principal investigator or co-principal investigator on conflicted research.
- e) Designation of a non-conflicted individual to address conflict-related concerns, assure that students and junior faculty are not adversely impacted by the conflict, and oversee management of the conflict and the conflicted ASM;
- f) Assurance that technology and intellectual property affected by the conflict are not inappropriately shared;
- g) Disclosure to appropriate administrative officials and/or committees and recusal from participation in negotiations, transactions, and decision-making related to the COI;
- h) Divestment when management would be ineffective.

**PHS-Funded Research.** Any COIs related to PHS-funded research shall be identified, managed, and reported to the PHS-Awarding Component prior to the expenditure of any funds under the research project. Any related COIs that arise after the project begins shall be managed and reported within sixty (60) days of disclosure. PHS reports shall be updated on an annual basis for the duration of the research project.<sup>5</sup>

**Public Accessibility.** COIs related to PHS-funded research projects shall be made publicly accessible in accordance with 42 C.F.R. Section 50.605(a)(5). Accessible information shall include the ASM's name, position on the research project, name of the entity with which the COI is held, the nature of the COI, and the dollar value, within a numeric range.

**PHS-Funded Research and Subrecipient Agreements.** To allow UAMS to fulfill its obligations under 42 C.F.R. Section 50.605, subrecipients who participate in PHS-funded research shall agree in writing to either: (i) comply with the applicable requirements of this

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<sup>5</sup> See 42 C.F.R. Section 50.605.

policy or; (ii) certify that the subrecipient has a COI policy that complies with 42 C.F.R. Part 50, Subpart F and timely report any related COIs to the UAMS COI Office.

### **ASM Responsibilities:**

- a) **Administrative and Business Decisions.** ASMs shall recuse themselves from participation in any administrative or business decisions at UAMS that are related or may appear to be related to a SI of the ASM or his/her Immediate Family Members.<sup>6</sup>
- b) **Committee Memberships:** ASMs who have SIs that are related or may appear to be related to their service on any UAMS committees (e.g. purchasing, formulary, clinical practice guideline committees, etc.) shall disclose their Financial Interest to committee members and recuse themselves from participation in discussions and voting related to their SI.<sup>7</sup>
- c) **Outside Employment.** In accordance with University of Arkansas Board of Trustees Policy 450.1, full-time ASMs shall not engage in outside employment that interferes in any substantial way with the ASM's UAMS duties or conflicts with the ASM's UAMS assignments. Full-time ASMs must receive pre-approval for outside employment from their Department Chair and Dean. College of Medicine faculty members are also subject to Faculty Group Practice policies ([7000-0100-600 FGP Principles and Rules of Operation](#)) governing outside activities.
- d) **Junior Faculty, Students, Fellows, and Trainees.** To protect the interests of junior faculty, students, fellows, and other trainees that may be affected by a COI, conflicted ASMs shall not assign such individuals to projects related to their COI. In circumstances where there is a compelling need for junior faculty, students, fellows, or other trainees to serve on conflicted projects, such individuals shall be supervised by a non-conflicted ASM.
- e) **Activities Related to Immediate Family Members.** ASMs shall not participate in the hiring process or any employment-related decisions pertaining to their Immediate Family Members. Likewise, ASMs shall not directly supervise any Immediate Family Member who is an employee of UAMS or participate in reviewing an Immediate Family Member's job performance.
- f) **Mandatory Training.** ASMs who participate in federally-funded research will receive training on the federal financial conflict of interest regulations, this policy,

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<sup>6</sup> See Arkansas Code Annotated § 19-11-705.

<sup>7</sup> See Arkansas Code Annotated § 19-11-705.

and their obligations regarding disclosure of SIs prior to engaging in research and at least every four (4) years thereafter.<sup>8</sup> Additional training will be required any time revisions are made to this policy that affect an ASM's obligations or an ASM is found to be non-compliant with this policy or a management plan.

- g) **Publications.** When submitting manuscripts for publication, ASM's are responsible for disclosing all financial and personal relationships that might bias their work and whether any potential conflicts of interest do or do not exist.

### **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 Committee;
- d) Failure to comply fully and promptly with management plans or decisions of the Committee, subject to the reconsideration process set forth herein; and
- e) Failure to update disclosures as required herein.

**Committee Actions.** If the Committee has reasonable cause to believe that an ASM has failed to comply with this policy or a management plan, it shall inform the ASM of the basis for such belief and afford the ASM an opportunity to explain the alleged compliance failure. After hearing the ASM's response and making further investigation as warranted by the circumstances, if the Committee determines that the ASM has failed to comply with this policy, the ASM shall have ten (10) days to cure the noncompliance. If the ASM fails to provide the Committee with documentation of compliance within this time period, the Committee, 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 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 Committee may further recommend that the appropriate college Dean take appropriate disciplinary action. Applicable state and federal law and UAMS policies and procedures shall govern the procedures for imposing any disciplinary action pursuant to this policy.

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<sup>8</sup> See 42 C.F.R. Section 50.604(b).

**Retrospective Reviews.** In the event an SI is identified that was not timely disclosed or reviewed, the Committee shall determine if the SI constitutes a COI and whether it is related to PHS-funded research within sixty (60) days of discovery. If a COI exists, a management plan will be implemented to manage the COI going forward and the PHS-awarding component shall be notified. In addition, a retrospective review will be conducted anytime a COI related to PHS-funded research is not identified and managed in a timely manner due to:

- a) Failure of an ASM to timely disclose an SI that the Committee determines to be a COI;
- b) Failure of the Committee to timely identify and manage a COI; or
- c) Failure of an ASM to comply with a management plan.<sup>9</sup>

The VCIC, in consultation with the Vice Chancellor for Research, will impanel a committee to conduct the retrospective review. The committee members will be chosen from a pool of faculty members that will be designated by the Dean of each college. The purpose of the review is to determine whether any research conducted by the ASM during the period of noncompliance was biased. The review shall be completed within one hundred-twenty (120) days. 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).

Any expenses incurred for a retrospective review shall be borne by the department or division of the ASM whose conduct resulted in the need for the review.

**Noncompliance Reporting.** Noncompliance with a plan to manage or eliminate a COI related to federally-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.<sup>10</sup>

**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 an ASM with a financial conflict of interest that was not appropriately managed or reported, the ASM shall be required to publicly disclose the COI.<sup>11</sup>

### **REQUESTS FOR RECONSIDERATION:**

If an ASM is dissatisfied with any disciplinary action imposed by a college Dean pursuant to a Committee recommendation, the appropriate UAMS Grievance Procedure should be followed.

If an ASM is dissatisfied with a final decision of the Committee regarding whether a conflict of interest exists, terms of a management plan, or imposition of a sanction, the ASM may submit a written request for reconsideration with the Director of Conflict of Interest within thirty (30) days of receipt of the Committee's decision. The request for reconsideration should include any

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<sup>9</sup> See 42 C.F.R. Section 50.605

<sup>10</sup> See 42 C.F.R. Section 50.606(a).

<sup>11</sup> See 42 C.F.R. Section 60.606(c).



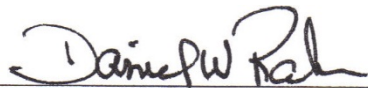
additional information the ASM would like the Committee to consider. The reconsideration decision shall be final.

**MISCELLANEOUS:**

**Record Retention.** Records of disclosures related to PHS-funded research projects shall be retained for a minimum of three (3) years from the date of submission of the final expenditures report. Records of other 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.<sup>12</sup>

**Policy Disclosure.** This policy will be made publicly available on the UAMS Website in accordance with 42 C.F.R. Section 50.604(a).

**Questions.** Any questions about this policy may be directed to the Conflict of Interest Office at 501-686-6447.

Signature: 

**Date: December 9, 2015**

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<sup>12</sup> See 42 C.F.R. Section 50.604(i).