Title:	Conflict of Interest for Research
Owner:	Andrea Dixon (Corporate Counsel)
Department:	Arkansas Children's Research Institute
Approval By:	ACRI Board of Directors Executive Committee
Effective Date:	5/26/2022

POLICY

The purpose of this policy is to promote the Arkansas Children's Research Institute's (ACRI) mission and academic integrity in science through disclosure and appropriate management of potential conflicts of interest related to research.

PROCEDURES

I. Conflict of Interest Definitions

A. Investigators shall mean Academic Staff Members, principal investigators (PI), co/sub-investigators, and/or any other individuals who are responsible for the design, conduct, or reporting of research performed at Arkansas Children's/Arkansas Children's Research Institute (AC/ACRI).

B. Conflict of Commitment shall mean an external activity that interferes in a substantial way with an Investigator's responsibilities to AC/ACRI.

C. 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 Investigator's professional role or decision-making responsibilities at AC/ACRI.

D. 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, or consultant) regardless of whether compensation is received for services.

E. 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.

F. Immediate Family Members shall mean spouses and dependent children.

G. Institutional Responsibilities shall mean an individual's professional responsibilities to AC/ACRI, 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.

H. 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.

I. Senior/Key Personnel means the PI and any other person identified as key personnel in a grant application, progress report, or other report submitted to the PHS by the Institution.

J. Significant Interest (SI) includes any of the following interests of an Investigator or his/her Immediate Family that reasonably appear to be related to an Investigator's Institutional Responsibilities and meets the $5,000 or above threshold for federally funded projects:

1. Equity interests (such as stock, stock options, or other ownership interests).
2. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. This interest is not related to the $5,000 threshold.
3. Payments or other remuneration (such as salary, consulting fees, honoraria, paid authorship or travel reimbursement) from outside organizations.
4. Fiduciary Relationships with outside organizations.
5. 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 with the research sponsor or in the product or service being tested.

Significant Interest shall **not** include:

1. Compensation or other remuneration paid by UAMS or Arkansas Children's on behalf of ACRI.
2. 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.
3. 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.

4. 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.
5. Travel sponsored by government agencies, academic teaching hospitals, medical centers, and/or accredited public or non-profit institutions of higher education or their affiliated research institutes.

K. UAMS shall mean the University of Arkansas for Medical Sciences in its entirety, including, but not limited to, colleges, departments, and administrative offices. The majority of Investigators on the AC/ACRI campus are UAMS employees.

II. 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 Investigator's professional obligations to AC/ACRI. These situations do not necessarily imply wrongdoing. However, the perception that such incentives might adversely affect research objectivity, the protection of human subjects, or the ACRI mission is sufficient to require that both potential and actual COIs be disclosed and appropriately managed.

III. Conflicts of Commitment

Investigators 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/boards and review panels. Such activities, however, should not interfere with an Investigator's Institutional Responsibilities. Therefore, external activities must be disclosed and reviewed and possibly managed by the Arkansas Children's COI Committee to assure they do not result in a conflict of commitment.

IV. Disclosure

Investigators, as defined in this policy, are required by federal regulations to disclose actual and potential COIs for themselves and their immediate family members no later than the time of application for research projects funded by the Public Health Service (PHS), and prior to engaging in the research conducted under investigational new drug applications (INDs), or investigational drug exemption applications (IDEs).

Per federal regulations and Institutional Policy, all Investigators are required to complete a disclosure statement annually and within thirty (30) days of acquiring a new SI or conflict of commitment.

V. Conflict of Interest Committee

The Arkansas Children's Conflict of Interest Committee shall be a standing committee, chaired by the Arkansas Children's Vice President/System Compliance Officer and other members as outlined in the Arkansas

Children's Conflict of Interest Committee Charter. This committee will review potential conflicts, determine whether a conflict of interest exists, and institute and monitor compliance with management plans.

VI. PHS-Funded Research

When a significant 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. 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.

VII. Public Accessibility

COIs related to PHS-funded research projects of Senior/ Key Personnel shall be made publicly accessible in accordance with 42 CFR 50.605(a)(5). Accessible information shall include the Investigator's name, title and position on the research project, name of the entity with which the COI is held, the nature of the COI, and the approximate dollar value of the COI.

VIII. Human Subjects Research

The Institutional Review Board (IRB) shall be notified of any management plans related to the human subjects research.

IX. PHS-Funded Research Sub-recipient Agreements

A. In the event a PHS-funded research project is carried out through a sub-recipient, the sub-recipient shall be required to comply with *42 CFR. Part 50*, Subpart F through a legally enforceable provision in the written agreement between ACRI and the sub-recipient that requires the sub-recipient to do one of the following:

   1. Comply with the applicable requirements of this policy or;
   2. Certify that the sub-recipient has a COI policy that complies with *42 CFR. Part 50, Subpart F*; and timely report any related COIs to ACRI.

X. Investigator Responsibilities

A. Investigators shall recuse themselves from participation in any administrative or business decisions at AC/ACRI that are related or may appear to be related to a SI of the investigator or his/her immediate family members.

B. To protect the interests of junior faculty, students, fellows, and other trainees that may be affected by an investigator's COI, such individuals may have required supervision by a non-conflicted investigator.

C. Investigators who participate in federally-funded research 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. Additional training will be required any time revisions are made to this policy that affect an Investigator's responsibilities or an investigator is found to be non-compliant with this policy or a management plan.

XI. Noncompliance

A. Committee Actions: If the COI Committee has reasonable cause to believe than an Investigator has failed to comply with this policy or a management plan, the committee will follow the procedures and disciplinary measures outlined in the COI Charter.

B. Retrospective Reviews: In the event an SI is identified that was not timely disclosed or reviewed, the COI 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:

1. Failure of Investigator to timely disclose an SI that the Committee determines to be a COI;
2. Failure of the Committee to timely identify and manage a COI; or
3. Failure of an Investigator to comply with a management plan.

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 completed within one hundred-twenty (120) days, 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, including all reporting elements as required by 42 CFR Section 50.605(a)(3)(iii)

C. Noncompliance Reporting. Noncompliance with a management plan related to federally-funded research that appears to have biased the design, conduct, or reporting of such research, shall be promptly reported to the appropriate PHS Awarding Component and notified of the corrective action taken or to be taken.

D. DHHS Requirements. In the event the Department of Health and Human Services determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with a financial conflict of interest that was not appropriately managed or reported, the Investigator shall be required to publicly disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

XII. Miscellaneous

A. All applicable records related to disclosures of PHS-funded research projects shall be retained for a minimum of three (3) years from the date of submission of the final expenditures report. Or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b). Records of other disclosures shall be retained according to institutional policy.

B. This policy will be made publicly available on the ACRI webpage.

C. Researchers are also expected to comply with the Arkansas Children's System Conflict of Interest Policy.

REFERENCES

1. 42 CFR 50, Subpart F [Promoting Objectivity in Research 2011]
2. Conflict of Interest (AC System)

ENDNOTES

1. Supersedes: 5/23/2019
2. Writers: ACRI Chief Operating Officer