
Title:	Conflict of Interest for Research
Owner:	Barry Brady
Department:	ACRI
Effective Date:	6/22/2012
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Approved By:	ACRI Board of Directors Executive Committee

POLICY

The purpose of this policy is to promote the Arkansas Children's Research Institute's (ACRI) mission and academic integrity in science by ensuring the compliance with Arkansas Children's, Inc.'s policies, federal, and state regulations regarding conflict of interest for research.

PROCEDURES

I. Conflict of Interest Definitions

- A. Academic Staff Member (ASM) and/or Investigators shall mean faculty members, principal investigators, co/sub-investigators, and/or any other individuals who are responsible for the design, conduct, or reporting of research performed at ACRI.
- B. Conflict of Commitment shall mean an external activity that interferes in a substantial way with an ASM/investigator's responsibilities to 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 ASM/investigator's professional role or decision-making responsibilities at ACRI.
- D. Fiduciary Relationship shall mean a legal or ethical obligation (such as service as a board member, officer, executive, or consultant) to act in the best interest of an outside organization, and such obligation could reasonably appear to inappropriately influence the integrity or objectivity of an investigator's professional role or decision-making responsibilities at ACRI.
- E. Healthcare Industry shall mean individuals and organizations involved in the development, manufacture, supply, or delivery of health products or services. Healthcare Industry includes, but is not limited to, pharmaceutical and medical device manufacturers, medical supply companies, patient transportation and ambulance services, hospitals, laboratories, medical imaging providers, physicians, or nursing service providers. Healthcare Industry does not include government agencies, academic medical centers, accredited, public or non-profit institutions of higher education or their affiliated research institutes.
- F. 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.

- G. Immediate Family Members shall mean spouses, domestic partners, children, parents, grandparents, and siblings.
- H. Outside Board shall mean boards of directors, boards of trustees, advisory and other boards for both for profit and non-profit entities that are not affiliated with ACRI.
- I. 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.
- J. Senior/Key Personnel means the PI 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*.
- K. Significant Interest (SI)¹ includes any of the following interests that reasonably appear to be related to an ASM/investigator's ACRI responsibilities and meets the \$5,000 or above threshold:
1. Equity interests (such as stock, stock options, or other ownership interests).
 2. Income (such as licensing fees or royalties) from intellectual property rights (such as patents or copyrights).
 3. Payments or other remuneration (such as salary, consulting fees, honoraria, paid authorship or travel reimbursement) from commercial research sponsors or private organizations.
 4. Fiduciary Relationships with commercial research sponsors or private organizations.
 5. Gifts, endowments, sponsored travel, or other in-kind contributions from commercial research sponsors or private organizations.

Significant Interest shall not include:

1. Salary, royalties, or other remuneration paid by UAMS or Arkansas Children's Inc. 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.
- L. Technology Transfer shall mean the commercialization of ideas, concepts, and inventions through publication, patenting, and licensing, and the formation of business entities.
- M. 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 ASMs on the ACHRI campus are UAMS employees.

II. Conflicts of Interest

At ACRI, considerations of personal financial gain must not influence the decisions or actions of ASM/investigators in carrying out their ACRI responsibilities. Potential 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/investigator's professional obligations to 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

ACRI seeks continuing development of the knowledge, skills, and expertise of its investigators and encourages pursuit of external activities which contribute to personal and professional growth and development. Such external activities, include, but are not limited to, consulting, authoring or editing textbooks and articles, involvement with professional societies, service on Outside Boards, or participation on educational or scientific committees and review panels. However, a conflict of commitment occurs when external activities significantly interfere with an ASM/investigator's responsibilities to ACRI. Therefore, possible conflicts of commitment must be disclosed and possibly managed to assure that ASM/investigators do not engage in external activities that prevent them from fulfilling their responsibilities to ACRI. Conflicts of commitment shall be reviewed and possibly managed by the Arkansas Children's Inc. COI Committee.

IV. Disclosure

ASM/Investigators, as defined in this policy, are required by federal regulations to disclose actual and potential COIs for themselves and their immediate family members prior to engaging in any research projects funded by the Public Health Service (PHS)².

PIs of any research projects conducted under investigational new drug applications

(INDs), or investigational drug exemption applications (IDEs)³ are required by federal regulations to disclose actual and potential COIs for themselves and their immediate family members prior to engaging in the research.

V. Conflict of Interest Committee

The Arkansas Children's Inc. Conflict of Interest Committee shall be a standing committee, chaired by the Arkansas Children's Inc. 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 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.⁴ 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 Disclosure

COIs related to PHS-funded research projects of ASM/investigators who are also Key Personnel shall be made publicly accessible.⁴

VIII. Human Subjects Research

The Institutional Review Board (IRB) shall be notified of any management plans related to 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 C.F.R. 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. Certify that the sub-recipient has a policy that complies with *42 C.F.R. Part 50, Subpart F*; and
 2. Agree that all sub-recipient investigators shall comply with the sub-recipient's policy and shall disclose all identified COIs that are directly related to the sub-recipient's work for ACRI to the ACRI administrative office in a timely manner to allow ACRI to provide timely reports to the PHS as required.⁴

In the event, the sub-recipient cannot provide such certification, the sub-recipient shall be required to comply with this policy and disclose all SIs of sub-recipient investigators to the ACRI administrative office, in a timely manner to allow ACRI to comply with its review, management, and reporting obligations.⁴

X. ASM/Investigator Responsibilities

- A. Investigators shall recuse themselves from participation in any administrative or business decisions at ACRI that are related or may appear to be related to a SI of the investigator or his/her immediate family members.⁵
- 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. ASM/Investigators 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.² Additional training will be required any time revisions are made to this policy that affect an ASM/investigator's responsibilities or an investigator is found to be non-compliant with this policy or a management plan.

XI. Noncompliance

- A. 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:
 - 1. Any COI that has not been timely reported or managed, or
 - 2. Any 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 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.⁹

- B. If an Investigator fails to comply with Arkansas Children's Inc. and/or ACRI's Conflict of Interest Policy or a management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, PHS Awarding Component shall be promptly notified of the corrective action taken or to be taken.⁶
- C. In the event the Department of Health and Human Services determines that a PHS-funded research project 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 COI and request an addendum to previously published presentations.⁶
- D. All other noncompliance will be remediated according to the Arkansas Children's Inc. COI Committee Charter.

XII. Miscellaneous

- A. 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.⁶
- B. This policy will be made publicly available on the ACRI webpage.²

REFERENCES

1. 42 C.F.R. Section 50.603
2. 42 C.F.R. Section 50.604
3. 21 C.F.R. Sections 312.53 and 812.43
4. 42 C.F.R. Section 50.605
5. Arkansas Code Annotated § 19-11-705 1
6. 42 C.F.R. Section 50.606

ENDNOTES

1. Supersedes: September 10, 2015
2. Writers: Barry Brady,