

AACR 3

Office of the President
March 9, 2009

Members, Board of Trustees:

PROPOSED REVISION TO ADMINISTRATIVE REGULATION:
RESEARCH CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE POLICY

Recommendation: that the Board of Trustees approve the attached revision of Administrative Regulation (AR) 7:2, Research Conflict of Interest and Financial Disclosure Policy. The proposed revision consists of clarifying the definition of “Significant Financial Interest” pursuant to a recommendation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

Background: The university’s mission involves three primary functions: instruction, research, and service. In compliance with state and Federal law, AR 7:2 sets forth policies, principles, and procedures to ensure that the personal financial interests of University employees do not compromise: a) the objectivity with which research is designed, conducted, and reported; b) the welfare of research participants; or, c) the objectivity with which intellectual property is developed.

The revision clarifies the definition of “Significant Financial Interest” according to the standards of the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The AR is also renumbered according to the new University Administrative Regulation numbering system.

A revised copy of AR 7:2, is attached. Proposed additions are underlined; proposed deletions are lined through.

Action taken: Approved Disapproved Other _____

UNIVERSITY OF KENTUCKY ADMINISTRATIVE REGULATIONS	IDENTIFICATION AR <u>7:2</u>	PAGE 1
	DATE EFFECTIVE <u>3/9/10</u>	SUPERSEDES REGULATION DATED AR II-4.0-4: 9/19/95; <u>12/11/07</u>

Deleted: II-4.0-4

Deleted: 12/11/07

RESEARCH CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE POLICY
(Approved by the Board of Trustees)

I. Policy

Integrity, objectivity, and absence of self-dealing are essential at all levels and in all aspects of University activities, including research. The University and its employees are committed to conducting themselves and their activities in accordance with the highest standards of integrity and ethics. The University recognizes that actual or potential conflicts of interest may occur in the normal conduct of research and other activities. Thus, it is essential that investigators disclose their and their family members' financial interests related to research for review by the University. After disclosure the University can make an informed judgment about a particular activity and require appropriate oversight, limitations, or prohibitions in accordance with this policy.

II. Purpose

In compliance with state and Federal law, this regulation sets forth policies, principles, and procedures to ensure that the personal financial interests of University employees do not compromise:

- A. the objectivity with which research is designed, conducted, and reported;
- B. the welfare of research participants; or
- C. the objectivity with which intellectual property is developed.

(NOTE: For regulations on consulting activities and conflict of interest, see AR II-1.1-1)

III. Scope

This regulation applies to all faculty and staff employees, and students involved in research and related activities and to the disclosure and subsequent development of intellectual property.

IV. Definitions

The following definitions apply to this regulation, unless a different definition is used by an applicable federal agency. In that case, the definition used in the federal agency's regulations will apply.

A. "Investigator" means the principal investigator, a co-principal investigator, and any other person at the University who is responsible for the design, conduct, or reporting of research.

B. "Family Member" means spouse or dependent child.

C. "Associated Entity" means any trust, organization, or enterprise over which an investigator or a family member of the investigator, individually or collectively, exercises a controlling interest.

D. "Relevant Significant Financial Interest" means an interest that would reasonably appear to be affected by the research for which funding is sought.

E. "Research" or "Research Activity" means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research such as bench work, clinical trials or other work and product development, and other forms of creative activity. The term includes any such research or creative activity conducted at the University, by University personnel under the auspices of the University, or conducted in situations in which University positions or titles are utilized in resultant publications, presentations, or other forms of intellectual property, irrespective of whether such research is funded by contract, gift, cooperative agreement, or general funds of the Commonwealth. The term also includes collaborative work with a manufacturer, a distributor, or a sponsor of the research and includes any tangible or intangible inventions, discoveries, patents, or ideas necessary for development, utilization or processes associated with the activity.

F. "Significant Financial Interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). For research involving human subjects, "significant financial interest" also includes employee or executive relationships with entities that have a financial interest in the research even when no remuneration is involved or financial interest in the sponsor, product, or service being tested. The term does not include any of the following:

1. Salary or other remuneration from the University;

2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
3. Income from service on advisory committees or review panels for public or nonprofit entities;
4. Income (e.g., salary, fees, or other continuing payments) in an amount of \$10,000 or less per annum from any one business enterprise or entity when aggregated for the investigator and members of the investigator's family; and
5. Financial interests in any one business enterprise or entity if the value of those interests does not exceed \$10,000 in value as determined through public prices or other reasonable measures of fair market value, and does not represent more than a five percent (5%) ownership interest when aggregated for the investigator and members of the investigator's family.

V. Research Conflict of Interest Committee (RCOIC)

A. Membership

1. The RCOIC is appointed by the President and reports to the Vice President for Research (VPR). The President shall designate the chair and appoint ex officio members.
2. The RCOIC shall be composed of a minimum of five (5) members appointed by the President and selected from recommendations submitted separately by the VPR and the University Senate Council.
3. A majority of the membership shall consist of faculty employees without administrative appointments. The remaining appointments shall be comprised of faculty employees with administrative appointments (e.g., associate deans, deans, directors of centers or institutes) or staff.
4. The RCOIC members, other than those with ex officio status, shall have staggered three (3)-year appointments.

B. Responsibilities

1. The RCOIC provides assistance on matters involving conflicts of interest and disclosures of significant financial interests in research as defined by this regulation. The RCOIC makes recommendations on courses of action designed to manage, reduce, or eliminate the conflict. More specific responsibilities are outlined in section VIII of this regulation.

2. The RCOIC shall maintain written minutes of meetings and, on request, shall prepare reports for the VPR.

VI. Conflicts of Interest

A. A potential or actual conflict of interest exists when a significant financial interest (as defined herein) of an investigator, a family member of the investigator or an associated entity, would reasonably appear to be affected by the research activities of the investigator or the development of intellectual property.

B. An investigator may not engage in research activities in which a potential or actual conflict of interest exists in fact or develop intellectual property for which actual or potential conflict exists, unless authorized in writing by the VPR and conducted in full accord with conditions and restrictions imposed by the VPR.

VII. Disclosure Requirements

A. No application for funding from an external agency may be submitted to the agency until all investigators have completed required disclosure forms. Disclosure forms must be completed even if no relevant significant financial interest exists.

B. An investigator shall disclose relevant significant financial interests of the investigator and the investigator's family members:

1. at the time an application is submitted for external research support;
2. prior to submission of intellectual property (e.g., copyrights, patents, and trademarks) for registration or filing, or
3. at the time an application is submitted for review by the Institutional Review Board (IRB).

C. For so long as the research is ongoing, disclosures under this provision relating to ongoing research must be updated any time a relevant significant financial interest, not originally disclosed, develops or is acquired. Disclosures under this provision related to intellectual property shall be updated prior to the execution of any contract, license, or other transaction involving the intellectual property. The VPR may also require an investigator to update a disclosure at any time.

D. Disclosures required by this provision shall be submitted to the dean of the investigator's college or the director of the institute or center, or other appropriate senior administrator of the educational or administrative unit where the investigator has a primary appointment. In any instance in which the required disclosure statement(s) are not submitted at the time the application is submitted to the Office of Sponsored Projects

Administration (OSPA) or an application is submitted to the IRB, the dean or director shall solicit such statements from the investigator.

E. Disclosures shall be made on standard disclosure forms available from OSPA:
<http://www.uky.edu/eForms/forms/discfin.pdf>

VIII. Review of Financial Interest Disclosure Statements and Management of Conflicts

A. Review of Financial Interest Disclosure Statements

Disclosure statements shall be promptly reviewed by the dean, director, or senior administrator for the purpose of determining if a relevant significant financial interest is disclosed. If the disclosure statement reveals any relevant significant financial interest, a potential or actual conflict exists.

B. No Relevant Significant Financial Interest Disclosed

If the review reveals no relevant significant financial interest, disclosure statements shall immediately be forwarded to OSPA, and no further action is required.

C. Significant Financial Interest Disclosed and Management

A conflict of interest exists and management of a relevant significant financial interest is required if a person could reasonably conclude that the interest could directly and significantly affect the design, conduct, or reporting of the research activity under consideration, the protection of research participants, or the development of intellectual property. When a relevant significant financial interest is disclosed, the following actions must be completed prior to expenditure of any funds under the award, prior to approval by the IRB or prior to the submission of intellectual property for registration:

1. The dean, director, or senior administrator shall consult with the investigator and the parties shall jointly review the disclosure statement. If a potential or actual conflict of interest is eliminated by agreement of the parties (e.g., through divestiture of interest, severance of relationships), no further action is required except that the dean, director, or senior administrator shall provide a written confirmation of the agreement of the parties to the VPR and forward the disclosure statement to OSPA.

2. If elimination of the conflict or potential conflict is not possible, the investigator shall propose a course of action to manage or reduce the conflict. The dean, director, or senior administrator may offer assistance with the plan and OSPA may also be consulted for guidance. In any case, the dean, director, or senior administrator shall review the plan proposed by the investigator and may attach additional comments or information. For research involving human

subjects the plan shall be designed so that the financial interest does not affect the risk to or welfare of research participants.

3. The plan shall be forwarded to OSPA, either directly or through the IRB in the case of non-externally funded human subjects research. OSPA shall review the disclosure for completeness and may request additional information. The disclosure and recommended management plan shall be forwarded to the RCOIC for review.

4. The RCOIC shall review all the material. The RCOIC may accept the recommended plan, add to the plan or formulate a different course of action to be taken in the management, reduction, or elimination of the conflict.

(a) The RCOIC shall provide the investigator an opportunity to meet with the RCOIC to discuss the situation and possible courses of action. The RCOIC may request the investigator, dean, director, or senior administrator to meet with the RCOIC or to provide information pertinent to the issue. The RCOIC may, in its discretion, consult with experts.

(b) The RCOIC shall propose appropriate conditions or restrictions to the VPR. The RCOIC may also conclude that the potential or actual conflict is sufficiently remote or unrelated to the research or intellectual property so that no action, other than the disclosure and annual reporting requirements, is required. In either event, the proposal shall be in writing, and a copy of the proposal shall be provided to the investigator. The investigator may also submit written objections or exceptions to the proposal to the VPR. The investigator's response must be submitted within five (5) business days following delivery of the proposal, unless time requirements of any agency or sponsor require shorter time frames.

(c) The RCOIC has wide discretion to recommend, and the VPR to impose, conditions or restrictions on investigators in formulating courses of action designed to deal with potential or actual conflicts of interest. Examples of conditions or restrictions that may be employed to manage, reduce, or eliminate such conflicts include:

- i. public disclosure of significant financial interests;
- ii. monitoring of the research by independent reviewers;
- iii. modification of the research plan;
- iv. disqualification from participation in all or a portion of the research;

- v. divestiture of the significant financial interest; or
- vi. severance of relationships that create the actual or potential conflict of interest.

5. The VPR may accept the report and recommendations of the RCOIC, or return the matter to the RCOIC with stated concerns or suggestions. The VPR shall render the final decision, and shall notify the researcher, the dean, or director and the RCOIC of any terms and conditions that shall be employed to manage, reduce or eliminate the conflict.

6. If the research involves human subjects, a copy of the final accepted report and recommendations of the RCOIC shall be forwarded to the IRB. Disclosure of the financial interest to the research participant alone is not a sufficient plan.

D. Conflict of Interest Management Reports

The plan recommended by the RCOIC and accepted by the VPR may require a report. In most cases a report shall be filed annually and at the end of the project. Reports shall be submitted to the RCOIC and shall document the actions taken to implement the conditions outlined in the plan.

IX. Enforcement

A. The following acts and failures violate the provisions of this regulation:

- 1. intentionally or recklessly providing incomplete, erroneous, or misleading information on a disclosure form;
- 2. failing for any reason to make any required disclosure;
- 3. failing to provide requested information needed for an appropriate review of potential or actual conflict of interest situations.

B. A violation of this regulation is grounds for the discipline of an investigator or other employee. Sanctions that may be imposed for such a violation include but are not limited to any one or more of the following:

- 1. involuntary termination of employment;
- 2. non-renewal of appointment;
- 3. suspension;

4. letter of admonition;
5. public disaffirmation of the research;
6. notification to regulatory bodies (e.g., U.S. Patent Office, Copyright Office);
7. notification to actual or potential research funding agencies; and
8. protest to editorial boards. Additionally, the University may decline the sponsored research agreement, or decline to submit or further process any intellectual property.

C. Disciplinary proceedings initiated under this regulation shall be conducted in accordance with the Governing and Administrative Regulations the Human Resources Policy and Procedures, or the Student Code of Conduct.

X. Miscellaneous

A. Disclosure statements, other documentation used in the review of such statements, and records of institutional action taken pursuant to this policy shall be maintained in OSPA for a period of three (3) years following completion of the research project that generated the disclosure statements, documentation, or institutional actions, for a period of time needed for resolution of government action involving such records, or for a period of time fixed by the VPR, whichever is longer. To the extent permitted by law, such records shall be maintained confidentially.

B. The University shall make the information described in the preceding paragraph available as prescribed by the sponsoring agency's policy or, upon request, to external funding agencies, along with requested information as to how a relevant potential or actual conflict of interest was managed, reduced, or eliminated to protect the objectivity of the research. If a potential or actual conflict of interest is identified after a grant or contract has been awarded, the University shall inform the awarding agency of that conflict within sixty (60) days of its discovery (or as otherwise required by law) along with actions taken to manage, reduce, or eliminate the actual or potential conflict of interest.

C. If the University ever determines that it is unable to manage satisfactorily a potential or actual conflict of interest that threatens the objectivity of particular research activity, the University shall promptly inform the relevant external funding agencies of that fact as required by the agency policy.

D. In making applications for external funding of research activities, investigators will be required to certify that they have read and understand this regulation.

References:

National Institutes of Health 42 CFR Part 50 Subpart F Formatted: Font color: Auto
National Science Foundation "Award and Administrative Guide" Chapter IV.A. Formatted: Font color: Auto
Association for the Accreditation of Human Research Protection Programs (AAHRPP)