

AACR 3

Office of the President
December 11, 2007

Members, Board of Trustees:

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

Recommendation: that the Board of Trustees approve the attached revision of Administrative Regulation (AR) II-4.0-4, Conflict of Interest/Financial Disclosure Policy – Research. The proposed revision consists primarily of clarifying the requirements and procedure for employees to disclose potential financial conflicts of interest related to research, and adding human subject research to the regulation in accordance with the requirements of 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, 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. The revision is intended to:

- Add human subject research to the regulation to conform to the standards of the Association for the Accreditation of Human Research Protection Programs (AAHRPP);
- Clarify the requirements and procedures for disclosing potential conflicts and the procedure by which the university reviews such disclosures;
- Update the language to conform to the current university administrative organization (i.e., provost model) and update the general formatting to make the regulation consistent with other revised university regulations;
- Change the name of the regulation to “Research Conflict of Interest and Financial Disclosure Policy” to clarify that it relates only to research; and
- Allow the Senate Council to make nominations to the president for appointment to the Research Conflict of Interest Committee.

A revised copy of AR II-4.0-4 is attached. Proposed additions are underlined; proposed deletions are lined through.

Action taken: Approved Disapproved Other _____

UNIVERSITY OF KENTUCKY ADMINISTRATIVE REGULATIONS	IDENTIFICATION AR II-4.0-4	PAGE 1
	DATE EFFECTIVE <u>9/19/95/07</u>	SUPERSEDES REGULATION DATED <u>9/19/95</u>

**RESEARCH CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE POLICY--
RESEARCH**

(Approved by the Board of Trustees)

I. Statement of General Policy

A.—Integrity, objectivity, and absence of self-dealing are essential at all levels and in all aspects of University governmental and private activities, including research. The University of Kentucky and its employees are committed to conducting themselves and their activities in accordance with the highest standards of integrity and ethics. B.—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' the significant potential for conflicts financial interests related to research be disclosed and for review reviewed by the University. After disclosure the University can make an informed judgment about a particular activity and require appropriate oversight, limitations, or prohibitions in ~~accord~~ accordance with this policy.

~~C.—It is the purpose of this regulation: (i) to set forth policies, principles, and procedures to ensure that the financial interests of University of Kentucky employees do not compromise the objectivity with which research is designed, conducted, and reported, as well as the objectivity with which intellectual property is developed; and (ii) to comply with state and federal regulations that are designed to promote objectivity in research activities.~~

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. ~~;~~ and

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

III. Scope~~Applicability~~

This regulation ~~policy~~ 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~~H~~. Definitions

The following definitions apply to this regulation ~~policy~~, 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 ~~and~~/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, ~~and~~/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. The term does not include any of the following:

1. Salary; ~~royalties~~; 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.~~00~~ 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.

~~G. "Conflict of Interest Committee" means a committee of at least five members recommended by the Vice President for Research and Graduate Studies and appointed by the President. Membership on the committee shall be limited to deans of colleges, directors of centers or institutes, faculty members, and other persons employed by the University of Kentucky. Appointments to the Committee shall normally be for three (3) year terms.~~

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.III. 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 ~~Vice President for Research and Graduate Studies~~ VPR and conducted in full accord with conditions and restrictions imposed by the ~~Vice President~~ VPR.

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

1.(i) at the time ~~an of the~~ application is submitted for external research support ~~(from internal or external sources); and~~

2.(ii) prior to submission of intellectual property (~~specifically, e.g.,~~ copyrights, patents, and trademarks) for registration ~~and/or~~ filing, ~~and~~.

3.(iii) 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 ~~VPRice President~~ may also require an investigator to update a disclosure at any time.

~~D.B.~~ 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 non-academic 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.C.~~ Disclosures shall be made on standard disclosure forms available from OSPA ~~the Office of Sponsored Projects Administration~~;
<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, ~~or~~ 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 ~~the Office of Sponsored Projects Administration (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 interest could affect~~ 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, ~~or~~ director, or senior administrator shall consult with the investigator and the parties ~~shall~~ will 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, ~~etc.~~), no further action is required except that the dean ~~or~~ director, or senior administrator shall provide a written confirmation of the agreement of the parties to the ~~VPR~~ ice ~~President for Research and Graduate Studies~~ and forward the disclosure statement to OSPA ~~the Office of Sponsored Projects Administration~~.
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 parties will attempt to make a joint recommendation for the management or reduction of the conflict to the Vice President. If the parties are unable to propose a joint management plan, each individual may submit a proposed management plan. If the parties have submitted a joint plan, the Vice President may either accept the proposed course of action or refer the matter to the Conflicts of Interest Committee. If the parties have been unable to agree to a joint plan, the matter shall automatically be submitted to the Committee. The dean, or director, or senior administrator may offer assistance with the plan and OSPA may also be consulted for guidance. In any case, the dean, or 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~~ must 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. ~~In such instances, the Committee shall formulate a course of action to be taken in the management, reduction, or elimination of the conflict.~~

4. The RCOIC shall review all the material. The RCOIC may accept ~~at the recommended~~ ~~ation~~ ~~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~~ ~~Committee~~ shall provide the investigator an opportunity to meet with the ~~RCOIC~~ ~~Committee~~ to discuss the situation and possible courses of action. The ~~RCOIC~~ ~~Committee~~ may request the investigator, ~~and/or the dean, or~~ director, ~~or senior administrator~~ to meet with the ~~RCOIC~~ ~~Committee~~ or to provide information pertinent to the issue. The ~~RCOIC~~ ~~Committee~~ may, in its discretion, consult with experts ~~if necessary or advisable~~.

~~(b)-~~ The ~~RCOIC~~ ~~Committee~~ shall propose appropriate conditions or restrictions to the ~~VPR~~ ~~Vice President for Research and Graduate Studies~~. The ~~RCOIC~~ ~~Committee~~ 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~~ ~~will~~ be provided to the investigator. The investigator may also submit written objections or exceptions to the proposal to the ~~VPR~~ ~~Vice President~~. 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~~ ~~Committee~~ has wide discretion to recommend, ~~—~~and the ~~VPR~~ ~~Vice President~~ 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.1)-~~ ~~—~~public disclosure of significant financial interests;

~~(ii.2)-~~ ~~—~~monitoring of the research by independent reviewers;

~~(iii.3)-~~ ~~—~~modification of the research plan;

~~(iv.4)-~~ ~~—~~disqualification from participation in all or a portion of the research;

~~(v.5)-~~ ~~—~~divestiture of the significant financial interest; or

~~(vi.6.)~~ severance of relationships that create the actual or potential conflict of interest.

5. The VPR ~~ice President~~ may accept the report and recommendations of the RCOIC ~~Committee~~, or return the matter to the RCOIC ~~Committee~~ with stated concerns or suggestions. The VPR ~~ice President~~ ~~shall~~ will render the final decision, and shall notify the researcher, the dean, or director and the RCOIC ~~Committee~~ of any terms and conditions that ~~shall~~ will 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.

~~5. — Decisions of the Vice President are final, although affected parties may request the Vice President to reconsider the decision.~~ 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.

~~VII~~X. Enforcement

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

~~(1.)~~ intentionally or recklessly providing incomplete, erroneous, or misleading information on a disclosure form;

~~(2.)~~ failing for any reason to make any required disclosure; and

~~(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~~ ~~policy~~ 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, ~~etc.~~);
- (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 policy shall will be conducted in accordance with the Governing and Administrative Regulations ~~and, where appropriate, the Staff Personnel Policy and Procedure Administrative Regulations Human Resources Policy and Procedures, and or the Manual~~ Student Code of Conduct.

X.VII. 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, ~~and/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 ~~VPRice President for Research and Graduate Studies,~~ whichever is longer. To the extent permitted by law, such records shall be maintained confidentially.

B. The University shallwill 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 ~~will~~ 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~~^{will} promptly inform the relevant external funding agencies of that fact as required by the agency policy.

D. ~~The University shall will publish this policy so that it is known to University investigators.~~—In making applications for external funding of research activities, investigators will be required to certify that they have read and understand this regulation policy.

References:

National Institutes of Health 42 CFR Part 50 Subpart F

National Science Foundation "Award and Administrative Guide" Chapter IV.A.

Association for the Accreditation of Human Research Protection Programs (AAHRPP)