University of Kentucky

Office of the Vice President of Research
Policy on Financial Conflict of Interest in Research

I. Introduction

As a public land-grant institution, the University has an obligation to the citizens of the Commonwealth and the general public to conduct its activities transparently and with integrity. The University is committed to avoiding financial conflicts of interest that may compromise, or appear to compromise, the integrity and objectivity of research and the safety of human research subjects. Because the University encourages its members to engage in outside activities and relationships that enhance its missions, real or perceived conflicts of interest may arise.

The keystone of an effective program for identifying and dealing with financial conflicts of interest is full disclosure of those financial interests that reasonably appear related to one's institutional responsibilities. This regulation provides guidance and procedures for disclosure by Investigators of their relative significant financial interests. After the disclosure, the University can make an informed judgment about a particular activity and require appropriate oversight, limitations, or prohibitions in accordance with this policy.

This policy deals with financial conflicts of interest of individual investigators. Federal regulations governing financial conflicts of interest for Public Health Service-funded activities are promulgated at 42 CFR Part 50 and 45 CFR Part 94.

II. Purpose

Pursuant to state statutes and Federal regulations, this policy sets forth policies and procedures to ensure that the personal financial interests of an Investigator do not compromise the objectivity with which research is designed, conducted, and reported or the welfare of human research subjects.

III. Entities Affected

This policy shall apply to Investigators on any sponsored agreement that is in preparation, has been submitted to a sponsor, or is currently funded, and to Investigators involved in institutionally-sponsored research.

IV. Definitions

The following definitions apply to this 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. Equity Interest

Equity interest means stock, stock options, warrants, partnership or other ownership interests. Excluded from this definition are equity interests held in publicly-traded mutual funds or retirement programs the investment of which is not under the control of the Investigator or family member, including University of Kentucky retirement programs.

B. Family Member

Family member means an Investigator's spouse and dependent children.

C. Financial Conflict of Interest

Financial conflict of interest means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research or other activity that is sponsored by an extramural agency.

D. Financial Interest

Financial interest means anything of monetary value or potential monetary value, whether or not the value is readily ascertainable.

E. Human Subjects Research and Clinical Investigations

Human subjects research and clinical Investigations means any activity that meets either (a) the Department of Health & Human Services definitions of both "research" and "human subjects" or (b) the Food & Drug Administration (FDA) definitions of both "clinical investigation" and "human subjects." These activities require review and approval of the activity by the Institutional Review Board (IRB).

F. Investigator

Investigator means the project director or principal investigator/program director, co-investigator, collaborator, senior/key personnel, faculty associate, and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, or proposing of research or other activity that is sponsored by an extramural agency.

For the purposes of this policy, graduate and undergraduate students generally are not considered investigators. Postdoctoral scholars and fellows may be considered investigators if designated as such by the Principal Investigator on a case-by-case basis.

G. Institutional Official

Institutional Official (IO) means the individual with authority and responsibility for overseeing implementation of this policy and for ensuring consistent administrative review of Disclosure Statements. The Vice President for Research shall serve as the Institutional Official.

H. Institutional Responsibilities

Institutional responsibilities means an individual's professional responsibilities on behalf of the University including, but not limited to, activities such as research, consulting for outside entities, teaching, professional practice, committee memberships, administration, extension or outreach, as well as service on institutional panels such as Institutional Animal Care and Use Committees, Institutional Biosafety Committees, and Institutional Review Boards, or Data and Safety Monitoring Boards.

I. Manage

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

J. Outside Entity

Outside entity means any entity recognized by law through which business for profit is conducted (including sole proprietorship, partnership, firm, corporation, holding company, joint stock company, receivership or trust), or not-for-profit organization (including association, foundation, charitable organization, etc.).

K. Public Health Service (PHS)

Public Health Service (PHS) means an operating unit of the U.S. Department of Health and Human Services (HHS) that includes all PHS Awarding Components.

L. Remuneration

Remuneration means all salary and wages, including professional income from non-University faculty practice plans, consulting fees, speaking fees, any payment for services not otherwise identified as salary or wages (e.g., honoraria, paid authorship, travel reimbursement, gifts), licensing revenue (royalty payments for inventions), royalties for books, publications or reports, or equity interests. Excluded from this definition is University salary and equity interests held in publicly-traded mutual funds or retirement programs the investment of which is not under the control of the Investigator or family member.

M. Research

Research means a systematic investigation, study or experiment 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 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 grant, contract, cooperative agreement, gift, 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 tangible or intangible inventions, discoveries, patents, or ideas necessary for development, utilization, or processes associated with the activity.

N. Research Conflict of Interest Committee (RCOIC)

The RCOIC is a committee that makes recommendations on courses of action designed to manage, reduce, or eliminate conflicts of interest in Research.

O. Significant Financial Interest

Significant financial interest means a financial interest consisting of one or more of the following interests of an Investigator or family member that reasonably appears related to the individual's institutional responsibilities:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000.

2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity during the 12 months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator or family member holds any equity interest in the entity.

4. A significant financial interest includes any intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

5. For an Investigator who applies for or receives funding through a PHS grant, cooperative agreement, or contract, a significant financial interest includes any reimbursed or sponsored travel (i.e., paid on behalf of the investigator rather than being reimbursed) that reasonably appears related to their institutional responsibilities. Excluded is travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, or a medical center or a research institute that is affiliated with an institution of higher education.

6. Exclusions: The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the University to the Investigator or family member if the Investigator is currently employed or otherwise appointed by the University; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency; or income from service on advisory committees or review panels for a Federal, state, or local government agency.

P. Sponsored Agreement

Sponsored agreement means a grant, contract, cooperative agreement, clinical study or clinical trial agreement, and subagreements or subcontracts thereof.

V. Policy

A. An individual covered by this policy shall complete at least annually a Financial Interests Disclosure Statement (Disclosure Statement) whether or not he or she has financial interest to report. The Disclosure Statement shall include the financial interests of the Investigator and those of his or her spouse and dependent children.

B. An individual required to disclose under this policy shall submit an updated Disclosure Statement within 30 days of acquiring a new financial interest that reasonably appears related to his or her institutional responsibilities.

C. New employees who are required to disclose under this policy shall complete a Disclosure Statement within 30 days of their employment start date.

D. An individual covered by this policy shall submit a Disclosure Statement prior to submitting a proposal seeking external funding, or prior to participating in any research activity regardless of the source of funding.

E. Investigators who apply for or receive funding through a PHS grant, cooperative agreement, or contract, shall disclose each instance of reimbursed or sponsored travel (i.e., paid on behalf of the Investigator rather than being reimbursed) that reasonably appears related to their institutional responsibilities within 30 days of the completion of such travel.

F. Disclosure Statements shall be reviewed by the Institutional Official or designee to assess whether or not a significant financial interest constitutes a financial conflict of interest. If a financial conflict of interest appears to exist, the Institutional Official shall involve the appropriate dean or director and shall refer the case to the RCOIC as needed for review and input.

VI. Research Conflict of Interest Committee (RCOIC)

A. Membership

1. The RCOIC is appointed by and reports to the Vice President of Research as the Institutional Official. The Vice President of Research 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 Vice President of Research.

3. A majority of the membership shall be comprised 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 real or perceived financial conflicts of interest of Investigators as defined by this policy. The RCOIC makes recommendations on courses of action designed to manage, reduce, or eliminate the conflict.

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

VII. Disclosure Procedures

A. Disclosures shall be made using a secure, web-based Disclosure Statement maintained by the Institutional Official. Access requires a University username and password. The Disclosure Statement shall be automatically populated with personal data based on the educational unit where the Investigator has a primary appointment.

B. Individuals required to disclose under this policy shall be notified electronically during the month of February each year of the need to file a Disclosure Statement during the month of March.

C. Individuals required to disclose under this policy to report a new financial interest may access the Disclosure Statement website at any time in order to file an updated Disclosure Statement and to review their current Disclosure Statement.

D. Individuals may access their Disclosure Statement history at any time.

E. After completing a Disclosure Statement, the individual shall be required to certify that:

1. He or she has read and understands their responsibilities under the University *Ethical Principles and Code of Conduct*, relevant *Governing Regulations, Administrative Regulations*, and other applicable University policies;

2. The disclosure is accurate and complete to the best of their knowledge; and

3. He or she agrees to update their disclosure with thirty (30) days of acquiring a new financial interest that reasonably appears related to their institutional responsibilities.

VIII. Disclosure Statement Review Procedures

A. The Disclosure Statement review shall be done using a secure, web-based system maintained by the Institutional Official. Access shall be restricted to those individuals authorized in writing by the Institutional Official.

B. The review shall be the responsibility of the Institutional Official, who may delegate in writing to one or more persons day-to-day responsibility for reviewing Disclosure Statements. The Institutional Official will provide guidelines to assist the reviewer(s) in assessing whether or not a significant financial interest appears to constitute a financial conflict of interest. However, the Institutional Official shall be directly responsible for reviewing each Disclosure Statement where a real or perceived financial conflict of interest appears to exist. The administrative review shall be completed within 60 days after the certified Disclosure Statement has been submitted.

The Institutional Official may involve the Investigator in the determination of whether a disclosed significant financial interest is related to the Investigator's research or other sponsored project.

C. If the administrative review reveals that the disclosed significant financial interests do not represent a financial conflict of interest, that determination shall be recorded and no further action will be required.

D. If a real or perceived financial conflict of interest appears to exist, a financial conflict of interest case number will be assigned and the Institutional Official shall notify the Investigator and the appropriate dean or director for their review and input following procedures outlined in Section IX below.

   The case shall be satisfactorily resolved and a final decision rendered by the Institutional Official before any funds may be expended from any related sponsored project award and before approval by the IRB can be granted for any related human subjects research.

E. No individual may participate in the administrative review of his or her own Disclosure Statement.

IX. Management and Reporting of Financial Conflicts of Interest

A. After being notified by the Institutional Official that a financial conflict of interest appears to exist, the dean or director shall consult with the Investigator and the parties shall jointly review the Disclosure Statement.

   1. If the parties determine that no financial conflict of interest exists, the dean or director shall forward the opinion to the Institutional Official. The Institutional Official may (a) agree that there is no conflict of interest; (b) ask the parties to continue the process and propose a management plan; or (c) refer the matter to the RCOIC for review and comment.

   2. If the parties determine that a financial conflict of interest does exist, they may agree to eliminate the conflict through divestiture of the significant financial interest or severance of relationships. In this case, the dean or director shall provide a written copy of the agreement to the Institutional Official.

   3. If elimination of the financial conflict of interest is not possible, the Investigator shall propose a course of action to manage or reduce the conflict of interest. The dean or director may assist with the plan and the Office of Sponsored Projects Administration (OSPA) may be consulted for guidance. In any case, the dean or director shall review the proposed management plan and shall forward it along with any additional comments or information, to the Institutional Official. The Institutional Official shall refer the matter to the RCOIC for review and input.

B. If a case is referred to the RCOIC, the RCOIC may accept the proposed management plan, amend the plan, or formulate a different course of action to be taken in the management, reduction, or elimination of the conflict. The RCOIC shall make its decision in accordance with the following:

   1. The RCOIC shall review all the material related to the case.

   2. 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 and dean or director to meet with the RCOIC or to provide information pertinent to the issue.

The RCOIC may, at its discretion, consult with experts.

3. The RCOIC shall propose appropriate conditions or restrictions to the Institutional Official. The RCOIC may also conclude that the potential or actual conflict is sufficiently remote or unrelated to the research 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 Institutional Official. 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.

4. The RCOIC has wide discretion to recommend, and the Institutional Official 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:

   (a) Public disclosure of significant financial interests;

   (b) Monitoring of the research by independent reviewers;

   (c) Modification of the research plan;

   (d) Disqualification from participation in all or a portion of the research;

   (e) Divestiture of the significant financial interest; or

   (f) Severance of relationships that create the actual or potential conflict of interest.

5. The Institutional Official may accept the report and recommendations of the RCOIC, or return the matter to the RCOIC with stated concerns or suggestions. The Institutional Official shall render a final decision, and shall notify the Investigator and the dean or director, and the RCOIC in writing 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.

C. Once an appropriate management plan has been recommended by the RCOIC and accepted by the Institutional Official, the Investigator shall file a report annually with the RCOIC that documents the actions taken to implement the terms and conditions outlined in the plan. A final report shall also be submitted at the end of the project. The RCOIC shall inform the Institutional Official if an Investigator fails to submit the required report in a timely fashion.

X. Institutional Reporting Requirements and Record Retention

A. The Institutional Official shall be responsible for institutional compliance with sponsoring agency reporting requirements.

B. Disclosure Statements and other documentation used for the review of such statements and the records of any institutional actions taken pursuant to this policy shall be maintained by the Institutional Official for a period of three years. If the record is related to a research project or other sponsored agreement, the records shall be retained for a period of no less than three years following the date of submission of the final narrative and financial reports, unless a longer record retention period is stipulated by the sponsor.

C. To the extent permitted by law, such records shall be maintained confidentially.

XI. Certification of Compliance

An individual required to disclose under this policy shall certify on the Internal Approval Form at the time of application for extramural support that he or she:

A. Understands the requirements of this policy and all other relevant *Governing Regulations* and *Administrative Regulations* governing financial conflicts of interest.

B. Has disclosed as of the date of the application all significant financial interests that reasonably appear related to his/her institutional responsibilities; and

C. At the conclusion of the review process, will comply with any conditions or restrictions imposed by the University to manage, reduce, or eliminate actual or potential financial conflicts of interest.

XII. Training

Pursuant to Federal regulations, the Institutional Official shall inform each Investigator about this policy and of his/her responsibilities to comply. Prior to engaging in sponsored research, each Investigator shall complete training regarding the disclosure of significant financial interests and the management, reduction or elimination of financial conflicts of interest. Training shall be repeated at least every four years or when (a) this policy is substantially revised; (b) an Investigator is new to the University; or (c) if an Investigator is determined to not be in compliance with this policy.

XIII. Enforcement

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

3. Failing to provide requested information needed for an appropriate review of potential or actual conflict of interest situations.

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

1. Any Investigator who has not filed the required annual Disclosure Statement within 30 days of the end of the designated reporting period shall be administratively prohibited from apply for extramural support, including renewal of any active sponsored agreement, until the Disclosure Statement has been submitted and administratively reviewed.

2. Any Investigator who fails to file the required annual Disclosure Statement within 60 days of the end of the designated reporting period, shall have his or her active research or other sponsored agreements suspended. No funds may be expended for any sponsored activity until the Disclosure Statement has been submitted and administratively reviewed.

3. Involuntary termination of employment;

4. Non-renewal of appointment;

5. Suspension;

6. Letter of admonition;

7. Public disaffirmation of the research;

8. Notification to regulatory bodies (e.g., U.S. Patent Office, Copyright Office);

9. Notification to actual or potential research funding agencies; and

10. 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 policy shall be conducted in accordance with the Governing and Administrative Regulations, the Human Resources Policy and Procedures, or the Student Code of Conduct, as appropriate.

XIV. Miscellaneous

A. 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.

B. 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.

References and Related Materials

Public Health Service 42 CFR Part 50 Subpart F and 45 CFR Part 94

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