Kutztown University Policy ACA-068

Conflict of Interest Policy

A) Purpose

Conducting high quality research and instructional activities is integral to the primary mission of Kutztown University of Pennsylvania. Active participation by faculty and other employees in external activities that enhance their professional skills or constitute public service can be beneficial to the University as well as the individual.

Thus, policy should encourage both public and private support for research and innovative educational programs through grants and contracts. Similarly, Kutztown University recognizes the value of outside consulting by faculty and other employees, both to the community and to the faculty/employees, but cautions that such consulting can come into conflict or appear to come into conflict with other legitimate University interests.

The purpose of this policy is to provide the members of this academic community with a framework to *promote quality and objectivity in* ---

A) *research by establishing standards to ensure that the design, conduct or reporting of research will NOT be biased by any conflicting financial interests of an investigator.*
B) *education by establishing standards to ensure that instruction and curriculum are NOT biased or deficient due to conflicting personal or financial interests.*
C) *management of the University's affairs to ensure that the institution's resources are expended in a manner that does NOT promote personal financial interest of faculty or staff above that of the University.*

The policy provides a framework to manage, reduce or eliminate conflicts of interest in research, education, and service activities. This policy protects the credibility and integrity of faculty and staff, so that public trust and confidence in the sponsored activities are ensured. It is also intended that any such action be in accordance with applicable federal and state law as well as Collective Bargaining Agreements.

B) Scope

This policy is intended to carry out the University's responsibilities for all research including, but not limited to, federal, state, local and private grant opportunities. This policy is also intended to provide guidance for complying with the provisions of 2 CFR Part 215 (Federal Circular A-110). This policy applies to all faculty and staff employed by the University.

A potential Conflict of Interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to the University such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise.

Potential conflicts of interest or the appearance of conflicts of interest may be complex and may involve many different considerations. These include both ethical and financial considerations; guidance of students' research; guidance of contractual research; consulting; contractual obligations to research sponsors, both governmental and private; and access to privileged information. Federal and state regulations also address the role of the spouse and of dependent children as potential sources of Conflict of Interest. These diverse considerations and the many interactions among them must be addressed in light of the University's designated missions. Even when behavior itself is exemplary, the appearance of Conflict of Interest should be avoided.

Both outside consulting and outside research support lead inevitably to awareness of privileged information on research, business, and timing objectives and on progress toward these objectives. University employees should not use their knowledge of privileged information for personal gain and should not disclose such information to third parties. Further, to avoid potential adverse publicity and negative consequences to the University, to research sponsors, or to users of consulting services, privileged information should not be disclosed even when personal gain is not involved.

Multiple projects in a researcher's field of interest are another potential source of Conflict of Interest. Such efforts can be mutually beneficial, but one project should not be conducted at the expense of another in terms of either human or material resources. To avoid problems in this area, when new research programs are initiated, their objectives should be considered in light of ongoing work.

With consultation clients, care should be taken to give advice that is objective and not slanted toward research program goals; conversely, research program goals should not be altered to fill consultation client needs. In short, if consultation clients and research sponsors are each informed of commitments involving the other, these conflicts of interest can be avoided.

In accordance with Federal regulations, the University has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an Investigator. Thus, the University requires that Investigators disclose any Significant Financial Interest that may present an actual or potential Conflict of Interest with a sponsored project.

C) Definitions

Significant Financial Interest: Anything of monetary value, including but not limited to, salary or other payment 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). The term does not include the following:

- Salary, royalties, or remuneration from the employing institution.
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.

- Income from service on advisory committees or review panels for public or nonprofit entities.
- An equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests:
  - Does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value.
  - Does not represent more than 5% ownership interest in a single entity.
- Salary, royalties, or other payments that, when aggregated for the investigator and the Investigator's spouse and dependent children, are not expected to exceed $10,000 during the next 12- month period.

Investigator: The principal Investigator, co-principal Investigator(s), project director, and any other person at the University who is responsible for the design, conduct, or reporting of research or educational activities funded by or proposed for funding by sponsored projects.

Immediate Family: Spouse and dependent children of the Investigator.

Intellectual Property: Any term used to describe the patents, copyrights, mask work protection, trade secrets, and plant variety protection certificates, which cover, or pertain to, inventions.

Potential Conflict of Interest: Any outside activity, commitment, or interest that may reasonably give the appearance of adversely affecting, compromising, or being incompatible with the University obligations of the Investigator.

Business Enterprise or Entity: Any person or entity or organization, or any combination of one or more of them. A business entity includes, but is not limited to, a sole proprietorship, partnership, association, joint venture, corporation, firm, trust, foundation, or other organization or entity used in carrying on a business, including parent organizations of such entities or any other arrangement in which an entity operates through a subsidiary.

Research: A systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development. The term includes any such activity for which funding is available from a sponsor through a grant or cooperative agreement.

University: Kutztown University

Collective Bargaining Agreement (CBA): The agreements between the Association of Pennsylvania College and University Faculties (APSCUF) and the Pennsylvania State System of Higher Education (PASSHE) or any other applicable CBA covering PASSHE employees.

Resolution Plan: A Plan developed by the Investigator and his/her academic dean or division administrator, approved by the University Reviewer and resulting in a Letter of Agreement between the University and the Investigator. It outlines the steps that must occur by the Investigator and/or the University to manage or eliminate a potential Conflict of Interest situation.

Significant Financial Interests Disclosure Form: A University form used to disclose significant financial interest by an Investigator prior to the submission of a proposal through the University's Office of Grants and Sponsored Projects.

University Reviewer: The University Reviewer may be the Provost or official designees. A committee may perform this function at the discretion of the University Provost. The University Reviewer determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project. The University Reviewer shall determine what conditions or restrictions, if any, should be imposed by the institution to manage actual or potential conflicts of interest arising from disclosed Significant Financial Interests.

D) Policy and Procedure(s)

Conflict of Interest Laws

Many of the activities described in the following list are specifically prohibited by federal or state law. Compliance with all applicable laws, including the State Ethics Act, 65 Pa.C.S.A. §1101 et seq, and the State Adverse Interest Act 71 P.S. §776.1 et seq. will be required of covered employees. Others are situations that are inherently unethical. A Conflict of Interest may exist even if no wrongdoing actually occurs, and even those examples where no wrongdoing is intended should be avoided to preclude the perception of wrongdoing and to protect the reputation of the individual and the University.

The Public Health Service, the National Science Foundation and other federal agencies have promulgated regulations that apply to institutions and individual investigators who seek and receive federal grants and contracts. Institutions are required to enforce such rules through written policies and procedures that govern their employees' conduct. Investigators are required to comply with these rules as a condition when seeking and administering federal grants and contracts. These rules can be found at Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F, within the NSF Grant Policy Manual, and within other federal agencies' regulations. Finally, as a recipient of federal grants and contracts, the University must maintain standards for all employees engaged in the award and administration of contracts in order to prevent conflicts of interest.

Examples of Conflict of Interest

The following list illustrates some of the most common conflicts of interest as related to both sponsored projects and general conduct:

Bias in research or instruction or other duties:

1. Using or releasing privileged information for personal or third party gain.
2. Altering the focus of a research program for the benefit of one's outside interests or for financial gain.
3. Compromising the educational benefit of student research to obtain results supporting outside interests.
4. Accepting outside employment that might impair independence of judgment in the performance of University duties and responsibilities.

5. Accepting gratuities or special favors in return for influencing the conduct of research or award of contracts for goods and services.
6. Consulting for one or more government agencies or other contractors in the same technical field as one's current government supported research project, which may result in giving advice of questionable objectivity.

Personal or financial gains:

7. Having personal investments in any business entity that could create a substantial conflict between those private interests and University duties.
8. Using PASSHE facilities and resources (including staff) for private enterprise without fair compensation to the University and prior administrative approval.
9. Accepting money, goods, services, entertainment, or any form of gratuity either directly or indirectly from any individual or company that has been or may be awarded a contract for goods or services with the University.
10. Obtaining personal gain by influencing purchases of equipment, instruments, etc.
11. Influencing the negotiation of contracts for goods and services for inappropriate personal or third party benefit.
12. Receiving extra compensation for duties that are a normal part of one's job description.
13. Consulting for compensation on any University research project for which one is already being compensated.

Disclosure and Reporting Requirements

a. General Disclosure

As soon as any faculty/staff or other person becomes aware of any actual, potential or appearance of Conflict of Interest that falls within any of the above definitions, he/she is to notify the University's Office of Grants and Sponsored Projects. The Office of Grants and Sponsored Projects shall ensure that follow-up is taken pursuant to the *Managing Conflicts of Interest* section of this policy.

b. Disclosure at proposal submission

With sponsored projects, all Investigators specifically named in a proposal are required to report and disclose any potential Conflict of Interest prior to submission of the proposal to the funding agency. Within the University's Office of Grants and Sponsored Projects, a form will be used that will require Principal Investigators applying for sponsored projects to indicate whether a potential or actual Conflict of Interest exists involving the grant proposal that is being submitted. The University reserves the right to <u>not process</u> grant proposals and applications if all required disclosures are not submitted.

Each Investigator is required to disclose the following Significant Financial Interests (see definitions):

- Any Significant Financial Interest of the Investigator and the Investigator's spouse and dependent children that would reasonably appear to be directly and significantly affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or
- Any Significant Financial Interest of the Investigator and the Investigator's spouse and dependent children in an entity whose financial interest would

reasonably appear to be directly and significantly affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

Regardless of the above minimum requirements, a faculty or staff member, in his or her own best interest, may choose to disclose any other financial or related interest that could present an actual or perceived Conflict of Interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

Each Investigator named in the proposal will complete a Conflict of Interest Certification. This Certification is part of the Office of Grants and Sponsored Project's Application Approval Form. Each Investigator who has a Significant Financial Interest requiring disclosure shall complete a Significant Financial Interest Disclosure Form and attach all required supporting documentation. The completed Disclosure Form and the proposal must be submitted to the University's Office of Grants and Sponsored Projects. The Director of the Office will review this documentation. Supporting documentation that identifies the business enterprise or entity involved and the nature and amount of the interest should be submitted in a sealed envelope marked confidential and accompany the Disclosure Form. This information is stored in a secure file in the Office of Grants and Sponsored Projects. Disclosure materials are not sent to the sponsor with the proposal.

c. Compliance of Collaborators, Subgrantees and Subcontractors

Collaborators, subgrantees and subcontractors from other institutions are required to either comply with this policy or provide certification that their institutions comply with Federal policies regarding Investigator Significant Financial Interest disclosure and that their portion of the project complies with their institutional policies. Further, the collaborators must state conflict(s) of interests or a lack thereof in adherence to University guidelines.

Subcontractors from commercial firms need not make a certification, except when the award is from HHS. HHS requires a certification from any subcontractor, including commercial firms, stating that it is in compliance with Federal policies regarding Investigator Significant Financial Interest disclosure and that its portion of the project is in compliance with their company policies.

d. Review of Disclosures

If any Investigator makes a disclosure of Significant Financial Interest, the Office of Grants and Sponsored Projects will review the disclosure to determine if a full review by the University Provost or his or her designee (the "University Reviewer") is required. If the initial determination is made that there may be a potential for Conflict of Interest covered by this policy, then the disclosure information will be provided to the University Reviewer. A Conflict of Interest exists when the University Reviewer reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project. In cases where a Conflict of Interest may exist, the procedure below for managing conflicts of interest will be initiated only after the University receives notice from the sponsor that an award will be made. The University Reviewer shall determine what conditions or restrictions, if any, should be imposed by the institution to manage actual or potential conflicts of interest arising from disclosed Significant Financial Interests.

e. Reporting of Changes in Significant Financial Interest and Other disclosures/reports

As required by Federal regulation, all Significant Financial Interests must be disclosed *prior to the time a proposal is submitted*. The responsibility rests with each Investigator to update information when there is a change in Significant Financial Interest. All financial disclosures must be updated by Investigators during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

Managing Conflicts of Interests

a. Resolution Plan

The Office of Grants and Sponsored Projects will notify the Investigator that a Conflict of Interest Resolution Plan is needed upon indication from the sponsor that an award will be made. The Investigator, in cooperation with the academic dean of the college or division administrator, will develop and present to the University Reviewer a Conflict of Interest Resolution Plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential Conflict of Interest presented by a Significant Financial Interest. At a minimum, the Resolution Plan shall address such issues as:

- Public disclosure of significant financial interests;
- Review of research protocol by independent reviewers; and,
- Monitoring of research by independent reviewers, who will be required to sign a confidentiality agreement.

The University Reviewer will review the Resolution Plan and approve it, or add conditions or restrictions, which may include the following:

- Modification of the research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divestiture of significant financial interests; or
- Severance of relationships that create actual or potential conflicts of interest.

If the University Reviewer determines that imposing the above referenced conditions or restrictions would be inequitable, or that the potential negative impacts that may arise from a Significant Financial Interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the University Reviewer may recommend that, to the extent permitted by Federal regulations and the sponsoring agency, the research go forward without imposing such conditions or restrictions.

If the Investigator cannot fulfill the recommendation outlined in the Resolution Plan, it is the responsibility of the Investigator to notify the University Reviewer. The Office of Grants and Sponsored Projects will be responsible for notifying the sponsor if it finds the University is unable to satisfactorily manage, reduce or eliminate a Conflict of Interest.

b. Letter of Agreement

The approved Resolution Plan shall be incorporated into a Letter of Agreement between the University and the faculty/employee that details the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the Business Enterprise or Entity. The Letter of Agreement shall be signed by the Investigator, the Department Chair, Academic Dean or Division Administrator, the University Reviewer, and the President or Provost/Vice President for Academic and Student Affairs. Actual or potential conflicts of interest will be satisfactorily managed, reduced, or eliminated in accordance with the Letter of

Agreement. All required reports regarding the conflict of interest shall be submitted to the sponsor prior to the expenditure of any funds under an award. The Resolution Plan and the Letter of Agreement must be signed and all conditions or restrictions in the Letter must be satisfied prior to the expenditure of any funds under the award.

c. Report to U.S. Department of Health and Human Services (DHHS) (for awards from DHHS only)

Prior to expenditure of any funds under the award, the University will report to DHHS the existence of a Conflict of Interest (but not the nature of the Conflict of Interest or the details) and that it has been managed, reduced or eliminated. The Office of Grants and Sponsored Projects will prepare the report and submit it to the DHHS awarding unit. For Conflicts of Interest identified subsequent to the award, the University shall advise the DHHS awarding unit within 60 days of identification.

University Official Certifications

To ensure that all proposals submitted by the University have been checked for potential Conflict of Interest, the University's Authorized Organizational Representative must certify on each proposal that

A. the University has implemented and is enforcing a written policy of Conflict of Interest consistent with the provisions of the appropriate agency regulations;
B. to the best of his/her knowledge and belief, all financial disclosures required by the Conflict of Interest policy have been made; and,
C. all identified conflicts of interest will have been satisfactorily managed, reduced, or eliminated prior to the expenditure of funds under the award, in accordance with the University's Conflict of Interest policy.

Record Retention

Conflict of Interest financial disclosures and Resolution Plans/Letters of Agreement compiled to manage actual or potential Conflicts of Interest shall be retained by the Office of Grants and Sponsored Projects until three years after the termination or completion of the award to which they relate, or the resolution of any government action involving those records. The University will exert reasonable efforts to keep records secure. Federal sponsors have the right to review records pertaining to their awards. Investigators will be informed of any records requests from a Federal sponsor.

Sanctions for Noncompliance

In the event that an Investigator is found to have violated this policy or the terms of the Letter of Agreement, the University Reviewer will recommend sanctions, which may include disciplinary action in accordance with the applicable CBA or existing University rule or regulation, such as the Board of Governor's Merit Principles Policy and rules regarding discipline of students. If the violation results in a collateral proceeding under University policies regarding misconduct in research, then the University Reviewer shall defer a decision on sanctions until the misconduct in research process is completed. The University Reviewer's recommendation on sanctions shall be presented to the Investigator's Dean or Division Administrator. The University Reviewer shall then present recommendations to the President for enforcement of any disciplinary action, as identified in the applicable CBA.

In addition, the University shall follow Federal regulations regarding the notification of the sponsoring agency in the event that an Investigator has failed to comply with this policy. The sponsor may take its own action, as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved, or in more severe cases, suspension or debarment from all federal grants for a period of time specified by Federal policy.

Sources:

- The Pennsylvania State University, "Investigator Significant Financial Interest Disclosure Policy for Sponsored Projects", 1995.
- "Investigator Financial Disclosure Policy". Federal Register, 59 (123):38-42, 1994 and 60 (132):35820-35823, 1995.
- "Principles to Govern College and University Compensation Policies for Faculty Engaged in Sponsored Research", A Joint Statement of The Association of American Universities, The American Council on Education, and the National Association of State Universities and Land Grant Colleges, 1978.
- "On Preventing Conflicts of Interest in Government - Sponsored Research at Universities", A Joint Statement of the Council of the American Association of University Professors and the American Council on Education, December, 1964.
- National Council of University Research Administrators, “Regulation and Compliance”, 2007.
- West Chester University, “Conflict of Interest Policy for Sponsored Projects and Disclosures of Significant Financial Interest”, 1995.
- Indiana University of Pennsylvania, “Conflict of Interest Policy,” 2003.
- Lehigh University, “Policy on Disclosure of Investigator Significant Financial Interests Related to Sponsored Projects”

E) Effective Date

December 1, 2009

F) Endorsed By

University Senate
Administrative Council
APSCUF Representative Council

G) Approved By

President F. Javier Cevallos

H) Last Review

December 1, 2009
August, 2010
August, 2011
August, 2012
August, 2013