

Policy RP06 DISCLOSURE AND MANAGEMENT OF SIGNIFICANT FINANCIAL INTERESTS (Formerly RA20)

Policy Steward: Associate Vice President for Research, Director of the Office for Research Protections

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PURPOSE:

The purpose of this Policy is to maintain the objectivity and integrity of Research at The Pennsylvania State University (the "University") and to ensure transparency in relationships with outside Entities and individuals as they relate to the academic and scholarly mission of the University. Among its many missions, the University seeks to foster interactions between the private sector and academia, as interdisciplinary and translational research is of ever-increasing importance in transforming newfound knowledge into useable technologies and scholarship that benefit the public. There is, however, the potential for financial conflicts of interest in such collaborations. In most cases those conflicts can be managed appropriately, rather than eliminated, thereby enabling those involved in University Research to engage in that Research objectively and with integrity and at the same time maintain acceptable financial relationships with outside Entities and individuals. Disclosure of financial interests to the University will protect both investigators and the University from potential criticism or even government sanctions in the event such relationships are subsequently called into question.

POLICY:

All Significant Financial Interests ("SFI") (defined below) shall be disclosed annually, and within thirty (30) days of the discovery or acquisition (e.g. through purchase, marriage, or inheritance) of a new SFI, to the Conflict of Interest Official ("COIO"), who reports to the Executive Vice President and Provost. All SFI shall be disclosed prior to an application for funding as required by this Policy and/or by the sponsoring agency (see, e.g., Department of Health and Human Services, 42 C.F.R. § 50.604(e)(1)).

If the SFI is evaluated by the COIO or the Conflict of Interest Committee ("Committee") and found to present a Financial Conflict of Interest ("FCOI"), the FCOI shall be properly managed or eliminated, and the Investigator shall agree in writing to the FCOI Management Plan, if one is implemented, before any related contract, grant, sponsored project (e.g., research, instruction or outreach), dedicated gift, or other transaction is executed, any relationship is initiated, or any action is taken that could be influenced by the SFI. All Investigators shall be required to complete FCOI training

identified by the University at least every four (4) years or immediately upon the occurrence of one of the three circumstances referenced in Section IV.E below.

This policy is in compliance with:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- Title 45 Code of Federal Regulations (CFR), Part 94, Responsible Prospective Contractors
- Title 21 Code of Federal Regulations (CFR), Part 54, Financial Disclosure by Clinical Investigators

DEFINITIONS:

Conflict of Interest Committee ("Committee") means the committee(s) established by the University to assist the Conflict of Interest Official ("COIO") in implementing and enforcing this Policy. The University shall establish at least one Conflict of Interest Committee but may establish more than one. Members shall be appointed by the Executive Vice President and Provost. The membership of each Committee shall represent the diversity of academic disciplines at the University, but shall include at least one individual who conducts Research at the University involving human participants. The COIO (or the individual to whom this responsibility has been delegated at the College of Medicine) shall serve as Chair or appoint a Chair for each Committee, and shall also serve as the liaison to the University's Institutional Review Board(s) ("IRB"). Responsibilities of the Committee shall include:

- Review of all SFI disclosures referred to it by the COIO;
- FCOI determinations (as outlined below);
- Development and implementation of FCOI Management Plans (as outlined below);
- Review of noncompliance issues brought to it by the COIO and recommendations for sanctions to ensure compliance with this Policy and federal regulations.

Conflict of Interest Official ("COIO") means the Associate Vice President for Research and the Director of the Office for Research Protections ("ORP"), who shall be responsible for overseeing the implementation and enforcement of this Policy and shall report directly to the Vice President for Research, and for matters related directly to this Policy, to the Executive Vice President and Provost. The COIO is responsible for developing, promulgating, and updating procedures and guidelines for the implementation of this Policy and for providing administrative support to the Committee. The COIO also shall be responsible for ensuring compliance with all federal regulations and requirements concerning conflicts of interest (see, e.g., 42 C.F.R. §§ 50.604(d) and 50.605(A)(1) – (3)), including but not limited to: conflict of interest training, FCOI management (as more fully described below), FCOI reporting to sponsoring agencies, monitoring for compliance with FCOI Management Plans, enforcement of sanctions for noncompliance with this Policy and/or federal regulations, and maintenance of all records relating to disclosures and FCOI management. The COIO shall make an annual report to the Provost of matters managed pursuant to this policy. The COIO may delegate responsibilities under this Policy to staff within the ORP and to the Associate Dean for Administration at the College of Medicine.

"Dependent Child(ren)" means a natural or adopted child of the Investigator who is under the age of 18.

"Entity" means any domestic or foreign, public or private, for-profit or not for-profit, business, organization, or association; including but not limited to, a sole proprietorship, partnership, corporation, limited liability company (excluding U.S. federal, state, and local government agencies).

"Equity Interest" means any ownership interest in an Entity, including but not limited to, stock or stock option, or partnership interest, as determined through reference to public prices or other reasonable measures of fair market value.

"Financial Interest" ("FI") means anything of monetary value, whether or not that value is readily ascertainable.

"Financial Conflict of Interest" ("FCOI") means any situation in which an SFI could directly and significantly affect the design, conduct, or reporting of Research.

"FCOI Management Plan" means the action(s) taken to address an FCOI, which may include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct and reporting of Research will be objective and free from bias.

"Institutional Responsibility(ies)" ("IR") means an Investigator's professional responsibilities on behalf of the University. Examples of an IR include, but are not limited to:

- (1) research (regardless of whether or not it is funded);
- (2) research consultation;
- (3) teaching;
- (4) outreach;
- (5) professional practice (e.g., clinical medical practice, veterinarian practice, practice of law);
- (6) University committee memberships (e.g., Faculty Senate, Purchasing Committees); and
- (7) service on University panels, such as an Institutional Review Board ("IRB") or Data or

Safety Monitoring Boards.

"Investigator" means any individual, regardless of his or her title or position, whether faculty, staff, or student, who has the ability to make independent decisions related to the design, conduct or reporting of University Research, but not including individuals who perform only incidental or isolated tasks related to a University Research project.

"Remuneration" means salary and any payment for services not otherwise identified as salary, including, but not limited to, consulting fees, honoraria, and paid authorship.

"Research" means systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research that may or may not be published in an article, book or book chapter and product development (e.g., a diagnostic test or drug). As used in this Policy, the term includes, but is not limited to, any such activity for which research funding is available from a federal, state or local government agency, or a public or private Entity, through a grant, contract or cooperative agreement (e.g., a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award). As used in this Policy, Research also includes research activities that are not funded or sponsored.

"Senior or Key Personnel" means the project director or principal Investigator and any other person identified as senior or key personnel in the grant application, progress report, or any other report required to be submitted by law or regulation.

"Significant Financial Interest" ("SFI") means an FI consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or partner and dependent child(ren)) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

(1) **For publicly traded Entities**, if the value of any Remuneration received from the Entity in the twelve months preceding the disclosure combined with the value of any Equity Interest of the Investigator in the Entity as of the date of disclosure, when aggregated, exceeds \$5,000.

(2) **For non-publicly traded Entities** (including but not limited to private "start-up" companies, closely held corporations, partnerships or sole proprietorships), if either:

- (a) the value of any Remuneration received from the Entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or
- (b) the Investigator holds any Equity Interest (i.e., there is no *de minimis* amount for Equity Interests in a non-publicly traded Entity) in the Entity;

(3) Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of

income related to such rights and interests (including but not limited to royalties, or licensing revenues) that exceeds \$5,000 in the previous twelve months; or

(4) All reimbursed or Sponsored Travel exceeding \$5,000 from an Entity in the twelve months preceding disclosure; however, travel that is reimbursed or sponsored by a federal, state, or local government agency in the United States, an American institution of higher education as defined at 20 U.S.C. 1001(a), an American academic teaching hospital, an American medical center, or a research institute that is affiliated with an American Institution of higher education does **not** need to be disclosed as an SFI.

The term SFI does **NOT** include the following types of FI:

(1) salary, royalties, or other remuneration paid by the University (this includes any intellectual property rights assigned to the University and any agreements to share in royalties or licensing revenue related to the intellectual property rights) provided that the remuneration was not routed to the University by an Entity and intended for the Investigator at the direction of the Investigator in order to avoid disclosure as required by this Policy;

(2) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;

(3) income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, an American institution of higher education as defined at 20 U.S.C. §1001(a), an American academic teaching hospital, an American medical center, or a research institute that is affiliated with an American institution of higher education; or

(4) income from service on advisory committees or review panels for a federal, state, or local government agency in the United States, an American institution of higher education as defined at 20 U.S.C. §1001(a), an American academic teaching hospital, an American medical center, or a research institute that is affiliated with an American institution of higher education.

"Sponsored Travel" means travel that is paid for on behalf of an Investigator and not reimbursed to the Investigator directly.

IMPLEMENTATION:

A. Disclosure:

Investigators shall disclose all SFI (i) prior to the submission of an application for Research funding, (ii) at least annually and (iii) within thirty (30) days of the discovery or acquisition (e.g., through purchase, marriage, or inheritance) of a new SFI. Disclosures of reimbursed or Sponsored Travel shall include the following details:

- Purpose of the travel;
- Identity of the sponsor or source of reimbursement;
- Destination;
- Duration of the travel; and
- Amount of Sponsored Travel or reimbursed travel, if known by the Investigator.

All disclosures shall be made by completing the financial disclosure form on the University's electronic Conflict of Interest System ("COINS"). All SFI must be disclosed **prior** to an application for Research funding when the proposed Research is related to the SFI (see below for more information on relatedness to Research) and when required by the funding agency (see generally 42 C.F.R. § 50.605(a) – (b))). This requirement for prior disclosure applies to all Investigators, including

principal investigators, project directors and any other person who is responsible for the design, conduct or reporting of the Research. Thus, all Investigators should disclose in a timely manner according to this Policy so they do not delay the submission of funding applications.

All disclosures submitted are first routed electronically by COINS to the Investigator's department/unit head for review. If the Investigator has no SFI to disclose, then his/her disclosure will bypass department/unit head review and be electronically routed directly to the COIO.

Department/unit heads may view such disclosures within COINS but need not review them. Once department/unit head review, if required, is completed all disclosures will be electronically routed by COINS to the COIO.

Disclosures made under this Policy shall be reported by the University to governmental agencies or to the general public as required by law or regulation.

B. FCOI Review and Determination:

The COIO shall be responsible for (i) the review of all SFI disclosed in order to determine whether the SFI is related to Research and (ii) if so related, referral to the Committee in order to determine whether the SFI is a FCOI, unless the Committee has delegated its authority to the COIO to make this determination.

(1)Related to Research: An SFI will be deemed to be related to Research if the SFI could be affected by the Research or is in an Entity or individual whose financial interest could be affected by the Research. The COIO may seek the input of the Investigator and/or his/her department/unit head in the determination of whether the SFI is related to Research.

The COIO shall refer SFI disclosures related to Research to the Committee for review and determination of whether an FCOI is present; provided, however, that the Committee is authorized to delegate to the COIO its authority to determine whether an SFI constitutes an FCOI, and in the event the Committee has delegated that authority to the COIO through specific guidelines set forth in a Standard Operating Procedure, the COIO may determine whether the SFI constitutes an FCOI without referral to the Committee.

(2)FCOI Determination: The Committee or the COIO, under authority granted by the Committee, shall determine whether the SFI **could** directly and significantly affect the design, conduct or reporting of related Research. If the Committee or COIO shall find that an FCOI exists, then it shall also determine whether the FCOI shall be managed or eliminated prior to the expenditure of funds for the related Research.

If, in the course of on-going Research, an Investigator who is new to the Research discloses an SFI or an existing Investigator discloses a new SFI, then the COIO or Committee shall review the SFI, make an FCOI determination, as provided in the previous paragraph and, if the SFI is determined to constitute an FCOI, implement an FCOI Management Plan (see Section IV. C below) within sixty (60) days of the date of the disclosure. If, in the course of on-going Research, an Investigator discloses an SFI that was not disclosed in a timely manner as required by this Policy (see Section IV.A above), the COIO or Committee shall review the SFI, make an FCOI determination, as provided in the previous paragraph and, if the SFI is determined to constitute an FCOI, implement an FCOI Management Plan (see Section IV. C below) within sixty (60) days of the date of the disclosure. See Section VI below for more details on failure to properly disclose according to this Policy.

If human participants are involved in the related research, the Committee also shall determine whether the SFI will adversely affect the protection of participants. If the Committee has determined that the SFI will adversely affect the protection of human participants, then disclosure to potential participants or the public cannot be used as the sole method of FCOI management (see Section IV.C below).

C. FCOI Management Plans:

The Committee or COIO shall document its FCOI Management Plan, which shall specify the actions that have been, and/or shall be, taken to manage the FCOI. The Investigator's input regarding what actions should be included in the FCOI Management Plan shall be considered by the Committee or COIO. Examples of conditions and restrictions that may be imposed to manage an FCOI, either as a single condition or restriction, or as a combination of conditions and restrictions, and on either an interim or permanent basis include, but are not limited to:

- Public disclosure of the FCOI (e.g., in public presentations or publications of the related Research);
- Disclosure of the FCOI to human participants, if applicable;
- Appointment of an independent monitor capable and willing to take appropriate measures to protect the design, conduct and reporting of the Research against potential bias resulting from the FCOI;
- In instances in which students are involved in the Research, given the educational mission of the University, taking steps, to the extent possible, to protect the students' academic progress, intellectual property interests, and welfare (e.g., appointment of an independent monitor);
- Modification of the Research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research, including interim disqualification of personnel from the Research between the date of disclosure and the completion of the University's review of the matter;
- Reduction or elimination of the SFI (e.g., sale of an equity interest); or
- Severance of the relationship giving rise to the FCOI.

The COIO shall communicate to the IRB summary information about the nature and amount of any SFI related to human participants in research, along with the Committee's findings, FCOI determination and any FCOI Management Plan approved by the Committee. Investigators conducting Research involving human participants should note that review of SFI and implementation of an FCOI Management Plan, if such a Plan is necessary, by the Committee or the COIO does not constitute approval of the Research proposed. The IRB has final authority on whether the proposed Research should be approved and shall not render its decision until after the Committee has reviewed the SFI and implemented any necessary FCOI Management Plan. The IRB shall consider the FCOI Management Plan, if any, in its final determination and also may include additional protections to the FCOI Management Plan if it deems they are necessary for the protection of human participants.

The Investigator shall document his/her agreement to abide by the FCOI Management Plan before the FCOI Management Plan may be finalized. This documentation of agreement may be recorded within COINS. The Investigator may request changes to the provisions set forth in the FCOI Management Plan, **if** such changes are requested **within five (5) days** of the FCOI Management Plan being sent electronically to the Investigator by COINS. The COIO or Committee shall consider the changes requested and make a determination whether to accept any of them.

Funding for the related Research shall not be released unless and until the FCOI Management Plan has been implemented and agreed to by the Investigator. If funding has already begun, the COIO or Committee may request the funding to be held pending the FCOI determination and the Investigator's agreement to the FCOI Management Plan, if any.

D. Required Updates:

All SFI disclosures shall be updated at least annually and within thirty (30) days after any new SFI is discovered or acquired.

E. Required FCOI Training:

The University shall identify appropriate training regarding this Policy that shall be completed by all Investigators at least once every four (4) years or immediately upon the occurrence of one of the

circumstances listed below. The training shall inform each Investigator of this Policy, the Investigator's responsibilities regarding disclosure of his/her SFI, and of the federal regulations pertaining to FCOI (e.g., 42 C.F.R. § 50.601 *et seq.*). Immediate training for Investigators shall be required under the following circumstances:

1. When the University makes revisions to this Policy that impact an Investigator's responsibilities under this Policy;
2. When an Investigator is new to the University; and
3. When the University finds that an Investigator is not in compliance with this Policy or with his/her FCOI Management Plan

RESPONSIBILITIES:

A. Investigators:

1. Investigators are responsible for complying with the requirements of this Policy.
2. Investigators are responsible for making disclosures, both annually and as they arise (within 30 days), as outlined in this Policy (see Sections I and IV above).
3. Investigators are responsible for completing FCOI training at least once every four (4) years or as outlined above (see Section IV.E above).
4. Investigators are responsible for providing to the COIO and/or Committee information requested in order for the COIO or Committee to review and make an FCOI determination regarding the Investigator's disclosure.
5. Investigators are responsible for accepting the FCOI Management Plan, or making a timely request for any changes to the FCOI Management Plan as outlined above (see Section IV.C above), and for providing documentation of his/her agreement to abide by the FCOI Management Plan. Investigators are responsible for abiding by all the terms, conditions and actions set forth in the FCOI Management Plan. This responsibility carries with it the responsibility to respond to requests from the COIO or Committee for information and/or meetings related to the University's responsibility to monitor compliance with this Policy, the applicable FCOI Management Plan, if any, and applicable federal regulations (see, e.g., 42 C.F.R. § 50.601 *et seq.*).
6. If the University finds the Investigator is not in compliance with this Policy, his/her FCOI Management Plan, if any, and/or federal FCOI regulations (42 C.F.R. 50.601 *et seq.*), the Investigator is responsible for complying with all corrective actions, enforcement mechanisms and/or sanctions imposed by the University.

B. The University:

1. The University is responsible for maintaining this Policy, making it available publicly as required by law or regulation, and ensuring it complies with all applicable federal FCOI regulations (42 C.F.R. § 50.601 *et seq.*) and rules (National Science Foundation, Grant Policy Manual, Ch. 510, Conflict of Interests Policy ("NSF 510)). See the University's Standard Operating Procedure/Guidelines for Federally Sponsored Research ("SOP").
2. The University shall make available FCOI training to Investigators that complies with this Policy and all applicable federal FCOI regulations and rules.
3. The University shall provide all FCOI reports to Research sponsors as required by federal FCOI regulations (42 C.F.R. §§ 50.604(h) and 50.605(b)) and rules (NSF 510), sponsor terms and

conditions, and/or as may be required by an FCOI Management Plan.

4. The University shall be responsible for establishing enforcement mechanisms (See Section VI below) to ensure Investigator compliance with this Policy and federal FCOI regulations (42 C.F.R. § 50.604(g) and (h)) and rules (NSF 510). See SOP.

5. The University shall maintain records relating to Investigator SFI disclosures and the University's review and determination related to each disclosure (whether or not an FCOI was found and any FCOI Management Plan required) as is required by federal FCOI regulations (42 C.F.R. § 50.604(i)).

6. The University shall be responsible for making information relating to Investigator SFI disclosures and the University's review and determination related to each disclosure (whether or not an FCOI was found and any FCOI Management Plan required) available upon request to the sponsoring agency as outlined in federal FCOI regulations (42 C.F.R. § 50.605(a)(5)(i)-(iii) and rules (NSF 510).

APPEAL:

An Investigator may appeal a determination made by the Committee if new information regarding the conflict becomes available, or if the Investigator believes there was a procedural error in the COI review process. A written appeal based upon the availability of new information shall be directed at the Committee making the COI determination. A written appeal based upon a procedural error shall be directed to the Provost for Investigators at all Penn State locations except the College of Medicine and to the Dean of the College of Medicine for Investigators at the College of Medicine.

NONCOMPLIANCE/INVESTIGATOR FAILURE TO DISCLOSE OR TO ABIDE BY FCOI MANAGEMENT PLAN:

Any suspected non-compliance with this Policy, including but not limited to an Investigator's failure to disclose according to this Policy and an Investigator's failure to abide by an applicable FCOI Management Plan, shall be handled by the COIO as described in the applicable procedures on the handling of non-compliance as approved by the Committee and incorporated herein by reference, and in accordance with any applicable regulatory requirements (see, e.g., 42 C.F.R. § 50.605(a)(1)-(6)). See SOP. The COIO or Committee is authorized to stop Research or hold Research funding in order ensure compliance with this Policy, an FCOI Management Plan and/or applicable federal FCOI regulations (see 42 C.F.R. § 50.605(a)(1)(i)-(vii) and (a)(2) or rules (NSF 510). See SOP. If the Investigator has no active, funded Research, the COIO or Committee shall recommend other appropriate sanctions, including but not limited to actions related to the Investigator's employment at the University, to the appropriate administrator for action.

FURTHER INFORMATION:

For questions, additional detail, or to request changes to this policy, please contact the Office of the Associate Vice President for Research, Director of the Office for Research Protections.

CROSS REFERENCES:

Other Policies may have specific application and should be referred to, especially:

[AD47](#) - General Standards of Professional Ethics;

[AD77](#) - Engaging in Outside Professional Activities (Conflict of Commitment);

[AD83](#) - Institutional Financial Conflict of Interest;

[FN14](#) - Use of Tangible Assets, Equipment, Supplies and Services;

[HR35](#) - Public Service by Members of the Faculty and Staff;

HR42 - Personal Compensation by a State Agency or Department;

HR80 - Private Consulting Practice;

HR91 - Conflict of Interest;

IP01 - Ownership and Management of Intellectual Property (Formerly RA11 - Patents and Copyrights [Intellectual Property]);

IP03 - Courseware (Formerly RA17);

IP04 - Royalty Payments for Course Materials (Formerly AD17);

BS07 - Authority and Procurement;

BS17 - Use and Procurement of External Consultants;

RA07 - Use of Equipment Purchased on Federally Sponsored Programs;

RA12 - Technology Transfer and Entrepreneurial Activity (Faculty Research):

RP02 - Addressing Allegations of Research Misconduct (Formerly RA10, Handling Inquiries/Investigations Into Questions of Ethics in Research and in Other Scholarly Activities)and

RPG01 - The Responsible Conduct of Research

Effective Date: June 8, 2015

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Most recent changes:

- June 8, 2015 - This policy was previously a Research Administration policy, Policy RA20. It has been moved from the Research Administration section to the Research Protections section to reflect the reorganization, and links/cross references have been edited as appropriate.

Revision History (and effective dates):

- September 10, 2013 - Editorial change in CROSS REFERENCES section; replaced reference to Policy RA21 - *Institutional Financial Conflict of Interest Involving Sponsored Projects, Dedicated Gifts, Research, Scholarship, and Technology Transfer* (obsoleted) with Policy AD83- *Institutional Financial Conflict of Interest*.
- August 14, 2013 - Editorial changes in the DEFINITIONS section, clarifying details in the definition of "*Significant Financial Interest*" ("*SFI*"). Correction/clarification of RA11, RA17 and AD17 in the CROSS REFERENCES section; these policies are now IP01, IP03 and IP04, respectively.
- August 16, 2012 - This policy, formerly entitled *Individual Conflict of Interest*, has been renamed *Disclosure and Management of Significant Financial Interests* and revised to reflect current operations.
- January 1, 2010 - Editorial changes. Title changed FROM "Senior Vice President for Research and Dean of the Graduate School" TO "Vice President for Research and Dean of the Graduate School," to reflect position changes, effective January 1, 2010.
- June 17, 2009 - Revisions made to the POLICY, DEFINITIONS and IMPLEMENTATION sections, per AAHRPP (accreditation for the human research program) requirements/expectations.
- May 24, 2007 - Revisions made to the POLICY, DEFINITIONS and IMPLEMENTATION sections to clarify the handling of conflicts of interest.
- November 8, 2006 - Editorial change - changed Vice President for Research to Senior Vice

President for Research.

- April 17, 2006 - Revisions made to the POLICY section, clarifying that any real or perceived conflict of interest must be "disclosed" as well as properly managed, and that this applies to all research, whether sponsored or unsponsored. Multiple revisions made throughout the DEFINITION section. In the BACKGROUND section, clarification on when "no De minimis" applies. The Executive Vice President and Provost added for reporting on such matters in the IMPLEMENTATION section.
 - December 15, 2005 - verbiage added to the "Disclosure Process" section to clarify the handling of consulting activities involving the licensing or other transfer of University technology to third parties and potential conflicts of interest.
 - December 3, 2003 - New Policy.
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