

UNIVERSITY OF ALABAMA IN HUNTSVILLE

Interim Policy on Promoting Objectivity in Research

Policy Statement

This University policy requires that researchers disclose certain financial interests. Disclosure by researchers enables the University to determine if a financial interest creates a conflict of interest or the appearance of a conflict of interest, and to properly manage or eliminate the potential conflict of interest.

This policy and related procedures are not intended to substitute for compliance with the Alabama Code of Ethics. This policy is intended to meet the requirements necessary to comply with the conflicts of interest regulations issued by the U.S. Department of Health and Human Services Public Health Service (“PHS”)¹, the National Science Foundation (“NSF”)² and others.³

Applicability

This policy applies to all persons at the University who are “Investigators,” as defined below, on University research projects or sponsored programs, as defined below, funded by the National Science Foundation or the U.S. Department of Health and Human Services Public Health Service. If the University carries out research projects or sponsored programs through sub-grantees, sub-recipients, sub-contractors or collaborators, the University should require that Investigators working for such entities comply with Federal rules on promoting objectivity in research or the University’s Policy on Promoting Objectivity in Research by requiring a signed assurance of compliance from the sub-grantees, sub-recipients, sub-contractors, or collaborators.

This policy does not attempt to address conflicts of commitment, i.e., outside activities that interfere with an employee’s performance of their University responsibilities. Disclosure made in accordance with this policy is not a substitute for a request for permission to consult or other requirements contained within the University’s policies on conflicts of interest or commitment.

This policy and its procedures are intended to be consistent with federal and state law. Where there is a discrepancy, the applicable federal or state law or rule of the funding agency will take precedence, unless the law or rule is less restrictive than the University’s more stringent requirements.

Definitions

a. “Conduct” of research is supervision or management of a research's execution. This is typically done by the principal investigator (PI) and co-principal investigators, but also may be performed by postdoctoral fellows and graduate students who have significant supervisory roles for junior researchers or technicians who are part of the research project. For research involving human subjects, this includes anyone who is responsible for explaining the research, risk-benefit, and/or alternatives to potential participants and/or must complete a sponsor's conflict of interest form.

¹ All United States Public Health Service (“PHS”) agencies (includes National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ)) require awardee institutions to ensure objectivity in research through compliance with its comprehensive regulations, “Promoting Objectivity in Research.” 42 CFR §50.601 et seq.

² NSF, Proposal and Award Policies and Procedures Guide, January 2011, Part II Award and Administration Guide, Chapter IV-Grantee Standards, (A) Conflict of Interest Policies.

³ *Office of Management and Budget*. Executive Office of the President: OMB Circular A-110, C.42 Codes of Conduct.

- b. “Conflict of Interest” means a significant financial interest related to research or sponsored programs activities that could directly and significantly affect the design, conduct, or reporting of research or a sponsored program.
- c. “Conflict of Interest in Research Committee” refers to the University committee that advises the VPR and designated official(s) on financial conflicts of interest in research and sponsored programs.
- d. “Dependent” is any person, regardless of his or her legal residence or domicile, who receives 50 percent or more of his or her support from the Investigator, or the Investigator’s spouse, or anyone who resided with the Investigator for more than 180 days during the reporting period.
- e. “Design” of research is the planning of the scientific strategy to test a research proposal.
- f. “Designated Official” means the Chief Compliance Officer; Investigator’s Department Chair, College Dean, or Research Center Director; or any other member of the senior administration designated by the VPR to review disclosures to determine if there is a relationship between an Investigator’s significant financial interest and his or her research and if a conflict of interest exists.
- g. “Disclosure” means an Investigator’s disclosure of a financial interest to the University.
- h. “Entity” means any domestic or foreign, public or private organization (excluding a federal agency) from which an Investigator or family members receive monetary value or in which any of such persons has an executive position or ownership or equity interest.
- i. “Executive Position” means having administrative or managerial authority in an entity, whether paid or unpaid, including director, officer, partner, owner, trustee, consultant, or board member.
- j. “Family Members” is defined to include spouse or any dependent.
- k. “Financial Interest” is defined as anything of monetary value, whether or not the value is readily ascertainable, or serving in an executive position with an entity, i) that reasonably appears to be related to the Investigator’s institutional responsibilities or, (ii) in entities whose financial interests would reasonably appear to be affected by, or could affect, such institutional responsibilities; other than:
- compensation from the University or income from the University related to intellectual property rights and interests;
 - income from seminars, lectures, or other educational activities or reimbursed travel 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, a medical center, or a research institute that is affiliated with an Institution of higher education;
 - income from service on advisory committees, or review panels for 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, a medical center, or a research institute that is affiliated with an Institution of higher education; or
 - an interest arising solely by means of investment in a mutual, pension, or other institutional investment fund where the Investigator does not exercise control over the management and investments of such fund.

For Investigators who are engaged in PHS sponsored research, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

l. “Institutional Responsibilities” are defined as the professional responsibilities (e.g., academic or research area of interest or expertise) of an Investigator on behalf of the University to perform duties and/or activities that are undertaken to fulfill one’s research, teaching, or service responsibilities within the University.

m. “Investigator” means the principal investigator, any co-principal investigators and any senior/key personnel. For PHS-funded research only, the term also includes University faculty and staff who have independent responsibility for designing, conducting, or reporting research, regardless of title or position and may include, for example, post-doctorals paid on research grants, collaborators or consultants. **For financial interest disclosure purposes, the term also includes the Investigator’s family members.**

n. “Management Plan” is a written document outlining the specific steps to be taken to manage, reduce or eliminate a conflict of interest.

o. “Mitigation Plan” is a written document outlining the key elements of a retrospective review of an Investigator’s activities and a research project, a description of the impact of bias (if any) and the University’s action plan for mitigating the impact of such bias.

p. “Monetary Value” is anything of value, whether or not the value is readily ascertainable, including, but not limited to: remuneration or salary (including payment for services not otherwise identified as salary, e.g., consulting fees, honoraria, paid authorship, board membership fees), commissions, equity interests (includes any stock, stock option, or other ownership interest), interests in real or personal property, dividends, royalties, rent, capital gains, intellectual property rights and interests (e.g., patents, copyrights, trademarks and related income), any reimbursed or sponsored travel and forgiveness of debt.

q. “Related Company” means a commercial entity in which the Investigator, alone or in combination with his or her family, holds a significant financial interest.

r. “Reporting” of research is participating in the publishing, presentation, or discussion of the research results, including anyone who likely will present data at regional/national/ international meetings.

s. “Research” means for the purposes of reporting financial interests, any grant/contract/agreement or application processed by the Office of Sponsored Programs (OSP) and all work involving human subjects regardless of funding source.

t. “Senior/Key Personnel” means the principal investigator or co-principal investigator and any other person identified as senior/key personnel by the University in the research or sponsored program proposal, progress report, or any other report submitted to the funding source of such research or sponsored program.

u. “Significant Financial Interest” means one or more of the following financial interests of the Investigator (alone or in combination with the Investigator’s family members):

- With regard to any publicly traded entity, it is the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, the value of which exceeds \$5,000 from one enterprise or entity, or serving in an executive position with such entity; or
- With regard to any non-publicly traded entity, it is the value of remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator holds any equity interest or serves in an executive position with such entity;
- Intellectual property rights and interests, upon receipt of income related to such rights and interests that exceeds \$5,000 in the twelve months preceding the disclosure paid by an entity other than the University or a University affiliated entity; or

- If an Investigator’s research is funded by any component of the Public Health Service, any reimbursed or sponsored travel, related to an Investigator’s institutional responsibilities; except 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, a medical center, or a research institution that is affiliated with an Institution of higher education.

v. “Sponsored Program” means any externally funded research, instruction, public service, or scholarly activity that has a defined scope of work and set of objectives which provide a basis for accountability and sponsor expectations.

w. “University” or “Institution” refers to the University of Alabama in Huntsville.

x. “Vice President of Research (“VPR”) is the institutional official who provides oversight in the solicitation and review of disclosures of financial interests from Investigators who are planning to participate, or are participating in research or sponsored programs and is the institutional official for purposes of administering the duties outlined in this policy and applicable federal regulations conforming to the references to ‘institutional official’ in 42 CFR Part 50 Subpart F.

Procedures and Implementation

I. Responsibility of Investigators and Disclosure

Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. This policy provides mechanisms for Investigators and the University to manage those conflicts of interest that arise. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the VPR or his designee(s).

Pursuant to that obligation, all Investigators conducting research funded by the PHS or NSF are required to disclose their financial interests and those of family members to the University on an annual and on an event basis, as described below. The VPR, or his designee, is responsible for the distribution, receipt, processing, review and retention of disclosure forms. Regardless of the disclosure requirements, the Investigator is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest.

a. Annual Disclosures. Investigators must disclose their financial interests to the University, through the VPR or his designee(s), on an annual basis. All disclosures should be submitted to the VPR or designee(s) by March 1 for the previous calendar year.

b. Event-based Disclosures. In addition to annual disclosure, certain situations require event-based disclosure.

(i) Material Change in Circumstances: All Investigators must amend their annual reports within 30 days of any material changes to their responses. Material changes include but are not limited to the acquisition of a new financial interest or elimination of a reportable financial interest for the Investigator and family, or a change in, or the initiation of, an executive position or a sponsor, or any change that might affect a current conflict of interest management plan.

(ii) Proposal-Specific Disclosure: Prior to commencing a research or sponsored programs project, all Investigators must certify to the VPR knowledge of and compliance with the University’s Policy on Promoting Objectivity in Research. Accordingly, prior to entering into University research projects or sponsored programs or at the time of submitting applications for sponsored programs, the Investigator must submit through the VPR or his designees (a) a certification of no change in his/her annual disclosure, (b) a proposal-specific updated disclosure of his or her financial interests, including any sponsor-required information, and (c) a statement whether the Investigator’s financial interests may be related to the proposed research, and if so, the relationship of the financial interests to the proposed research. Principal investigators ensure that all Investigators submit

certifications and disclosures prior to proposal submission. The Office of Sponsored Programs will not submit a research proposal unless the Investigator(s) appearing on the principal investigator's personnel list have submitted such disclosures or certifications. An amended disclosure shall be made during the conduct of such research or sponsored programs project as soon as possible, but no later than 30 days, after a material change arises. Similarly, before an Investigator who is new to participating in the research or sponsored project undertakes any activities thereon, a certification and proposal-specific disclosure is required from such Investigator.

(iii) Protocol-Specific Disclosure: Investigators for Institutional Review Board ("IRB") protocols are required to report their project-related financial interests to the IRB at the time they submit a protocol to the IRB. Principal investigators ensure that Investigators submit disclosures and certifications prior to protocol submission. The protocol-specific disclosures must be reviewed by the IRB pursuant to this Policy, subsequently by the designated officials as outlined in Section II and any conflict of interest reported to the VPR, or his designee. Any required management plans shall be implemented by the IRB after approval as provided in Section III and prior to protocol approval.

(iv) Initiating Licensing Activity: Investigators are required to update their annual disclosure at the time the Office of Technology Commercialization begins to negotiate a license for technologies for which the Investigator is named as inventor.

c. Travel (For PHS-Funded Research Only). Investigators who are engaged in Public Health Service sponsored research must also disclose reimbursed or sponsored travel related to their institutional responsibilities unless the trip was paid for or reimbursed by a governmental agency, an academic teaching hospital, medical center or a research institute that is affiliated with an institution of higher education. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The VPR or his designee will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a conflict of interest with the Investigator's research or sponsored program activities.

d. Personnel Lists. Investigators who serve as principal investigator will submit to OSP the names of all Investigators under their supervision who are involved with the research or a sponsored project. Such list shall be updated as new Investigators are added or Investigators terminate their involvement with the research or sponsored project.

II. Review and Decision of the VPR

a. Review. Prior to the University's expenditure of research or sponsored program activity funds or an Investigator's participation in research, the VPR, through the Chief Compliance Officer, will review all disclosures of Investigators listed on the project personnel lists or newly added. In the event an Investigator fails to disclose financial interests as required herein or a disclosure is non-responsive, in addition to sanctions as hereinafter provided, the designated official(s) may treat such non-disclosure or non-responsiveness as a determination that a significant financial interest exists and proceed accordingly. If a disclosure reveals a significant financial interest, the following review process will occur:

(i) If the Investigator holds a faculty appointment, or is a post-doctoral or graduate student, the disclosure will be promptly reviewed by the Investigator's Department Chair and the Chief Compliance Officer to determine whether an Investigator's significant financial interest is related to his or her research or sponsored program activities and, if so, whether the significant financial interest constitutes a conflict of interest. In the event the designated officials cannot agree (a) that a conflict of interest exists or, (b) upon an appropriate conflict of interest management plan, the matter shall be referred for further consideration to the Investigator's College Dean. In any event, the determination and/or management plan must be approved by the College Dean.

(ii) If the Investigator holds solely a staff appointment, the disclosure will be promptly reviewed by the Investigator's assigned Research Center Director and the Chief Compliance Officer to determine whether an Investigator's significant

financial interest is related to his or her research or sponsored program activities and, if so, whether the significant financial interest constitutes a conflict of interest. In the event the designated officials cannot agree (a) that a conflict of interest exists or, (b) upon an appropriate conflict of interest management plan, the matter shall be referred for final consideration to the VPR.

(iii) If an Investigator is assigned to both a research center and an academic department, he or she may elect the supervisory chain that will review the disclosure and make the determination as hereinabove provided. When a designated official is an Investigator whose significant financial interest is being reviewed, the review and determination will be conducted by the next higher individual in the Investigator's supervisory chain and the Chief Compliance Officer. Notwithstanding, when a Dean is an Investigator whose significant financial interest is being reviewed, that review and determination will be conducted by the VPR and Chief Compliance Officer. The President shall review a significant financial interest of the VPR or Provost when either serves as an Investigator and such determination shall be final. IRBs are also responsible for ensuring that IRB members who review research have no conflicting interest.

The Investigator may be consulted as needed for these reviews. The Investigator has the right for a timely decision by all parties in the process. The designated officials may consult the Conflict of Interest in Research Committee for guidance in specific cases, or in the application of the policy to particular circumstances. In all instances hereinabove, the VPR has final approval and authority to determine whether a conflict of interest exists, whether it can be managed and the plan for its management. The IRB Chair will communicate and consult with the VPR if the IRB has concerns regarding any plan for the management of a conflict of interest relating to a research project involving human subjects. The VPR, or his designee, shall certify that no conflict of interest exists or that a conflict of interest management plan will be imposed before a research award is accepted by the University.

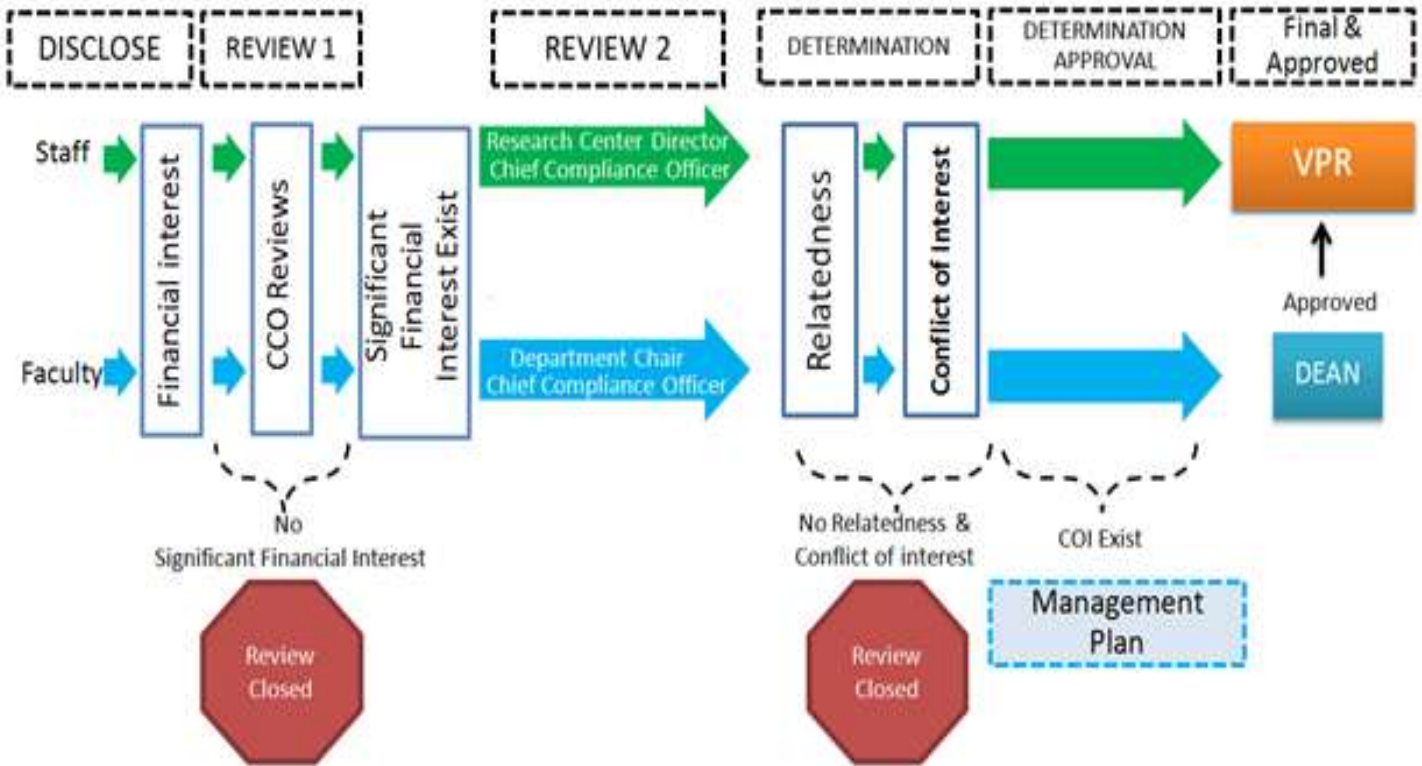
b. Related Significant Financial Interest. A significant financial interest is *related* to research or sponsored program activities when it is reasonably determined that the significant financial interest:

- i. Could be affected by the research or sponsored program activity; or
- ii. Is in an entity whose financial interest could be affected by the research or sponsored program activity.

c. Conflict of Interest. A conflict of interest exists when the VPR or his designated officials determine that a significant financial interest is related to research or sponsored programs activities and could directly and significantly affect the design, conduct, or reporting of research or a sponsored program activity.

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DISCLOSURE AND REVIEW PROCESS



*Conflict of Interest in Research Committee available for advice at any step.

d. Review of Financial Interest Disclosed in the Course of a Research Project. Whenever an existing Investigator discloses a new financial interest, or (ii) whenever the University identifies a financial interest that was not disclosed timely by an Investigator or (iii) for whatever reason a financial interest was not previously reviewed by the University during an on-going research project, the designated officials (as provided in Section II a.) shall, within 60 days, review the financial interest. If a conflict of interest is determined to exist, a management plan shall be implemented, at least on an interim basis. Depending on the nature of the conflict of interest, it may be determined that additional interim measures are necessary with regard to the Investigator’s participation in the research project between the date of the disclosure and the completion of the review.

III. Conflict of Interest Resolution and Management

a. Management Plan. Conflicts of interests shall be satisfactorily managed, reduced, or eliminated in accordance with these requirements prior to expenditures of awarded funds, prior to new Investigators participating in the research project, or they must be disclosed to the sponsoring entity for action. If a conflict of interest is determined to exist, the VPR, through the Department Chair, College Dean and/or Research Center Director and Chief Compliance Officer, is required to reduce, eliminate or manage the conflict through the development and implementation of a written management plan. The Investigator must develop and initially propose a written management plan for approval. Conditions that might be imposed on an Investigator or a research or sponsored project in such management plan include public disclosure of the conflict, modification of the research design, monitoring of the research by independent reviewers, disqualifying participation in all or a portion of the research, divesting significant financial interests, or severing relationships that create actual or potential conflicts of interest. The VPR may consult with the Conflict of Interest in Research Committee. The management plan shall be finally approved by the VPR and incorporated into a Memorandum of Understanding (“MOU”)

between the VPR and the Investigator 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 MOU shall be signed by the Investigator, the Department Chair, the College Dean and/or Research Center Director, the Chief Compliance Officer and the VPR. The MOU will state who is responsible for overseeing the implementation of the management plan and for reporting on compliance at stated intervals to the VPR or his designee.

b. Mitigation Plan (For PHS-Funded Research Only). If bias is found after a retrospective review (as hereinafter provided), the VPR, through the Department Chair, College Dean and/or Research Center Director and Chief Compliance Officer, is required to eliminate or mitigate the effect of the bias through the development and implementation of a written mitigation plan. The effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable) shall determine the conditions that might be imposed by the mitigation plan. The approved mitigation plan shall be incorporated into a MOU between the VPR and the Investigator and shall be signed by the Investigator, the Department Chair, the College Dean and/or Research Center Director, the Chief Compliance Officer and the VPR. The MOU will state who is responsible for overseeing the implementation of the mitigation plan and for reporting on compliance at stated intervals to the VPR or his designee.

c. Additional Input. In making conflict of interest resolution and management decisions, the VPR and his designees may consult with others on an as-needed basis, including the Conflict of Interest in Research Committee, Office of Counsel, or Chief Compliance Officer, as well as the Investigator.

d. Monitoring. Management and mitigation plans shall prescribe monitoring of Investigator compliance with the plan and such shall continue on an ongoing basis until conclusion of the research project. It will describe specifically how the monitoring shall be performed, who shall perform it, what records are to be kept, and what reports are made to the VPR.

IV. Reporting to Sponsoring Agency or Entity

Should any conflict of interest or non-compliance require reporting to the sponsoring agency or entity, the VPR will report in accordance with applicable regulations or sponsor agreement. If the funding for the research is made available from a prime awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to their sponsor. In the case where a project to evaluate a drug, medical device or treatment was conducted by an Investigator with a conflict of interest that was not disclosed or managed, the University will require Investigators to disclose the conflict in each public presentation of the results or request an addendum to previously published presentations.

V. The Conflict of Interest in Research Committee

The Conflict of Interest in Research Committee consists of at least five members selected from full time, tenured faculty and senior research staff members who are experienced with the administration of Federal contracts/grants and sponsored programs appointed by the Vice President for Research, and others as deemed appropriate by the Vice President for Research. The Associate Vice President for Research is an *ex-officio* member and serves as Chair of the Committee. The Chief Compliance Officer and a representative of the Office of Counsel are *ex officio* members of the Committee. The Vice President for Research may appoint other appropriate *ex-officio* members to the Committee. College Deans, Department Chairs, Research Center Directors, and others previously involved in a review of the matter before the Committee will not be eligible to serve as a member of the Committee.

VI. Investigator Non-Compliance

a. Sanctions. Principal responsibility for implementation and enforcement of this policy shall reside with the VPR. As with any University policy, sanctions may apply for an Investigator's non-compliance with this Policy on Promoting Objectivity in Research. The responsibility for initiating disciplinary action resides with the Investigator's supervisor.

The VPR may report instances of non-compliance with this policy to the Investigator's applicable supervisor who may initiate disciplinary action in accordance with University policies and procedures.

b. Retrospective Review (For PHS-Funded Research Only). In addition, if the VPR determines that a conflict of interest was not identified or managed in a timely manner, including, but not limited to, an Investigator's failure to disclose a financial interest that is determined to be a conflict of interest, or failure by an Investigator to materially comply with a management plan for a conflict of interest, the designated review officials appointed by the VPR shall, within 120 days of the VPR's determination of noncompliance, complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the conflict of interest, name of the entity with which the Investigator has the conflict of interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The VPR will update any previously submitted report to the sponsor or the prime -awardee relating to the research, specifying the actions that will be taken to manage the conflict of interest going forward. If bias is found, the report will include a Mitigation Report in accordance with applicable regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

VII. Maintenance of Records

a. The VPR or his designee will maintain disclosures with due care for their confidential nature. The VPR or his designee shall be responsible for maintenance of records relative to all decisions regarding whether or not a conflict of interest exists. Additionally, such official shall maintain all documentation of the VPR's actions to manage, reduce or eliminate conflicts of interest and reports of conflicts of interests to sponsoring agencies or entities.

b. These records shall be maintained until at least three (3) years after the later of the termination or completion of the research or sponsored program to which they relate, or the resolution of any action involving those records, whichever is longer.

c. Disclosure documents, conflict of interest management or mitigation plans, and related information are considered to be personnel records and shall be confidential to the extent permitted by law, except as required for administration of this policy.

VIII. Training

Each Investigator must complete, at a minimum, web-based training regarding promoting objectivity in research prior to engaging in research and at least every four years thereafter. An Investigator must also complete training within a reasonable period of time as determined by the VPR in the event that this policy is substantively amended in a manner that affects requirements of Investigators, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

IX. Sub-recipient Requirements

When Investigators outside the University participate in research as a sub-grantee, contractor, or collaborator, the University, at least to the extent required by the research sponsor, will take reasonable steps to ensure that sub-grantees, sub-contractors, or collaborators are adequately informed of their obligation to comply with all applicable conflict of interest reporting, review, and disclosure requirements as required by federal and state law, as well as all conflict of interest policies of research sponsors. This requirement is satisfied if the University's contract or other agreement with the sub-grantee, contractor, or collaborator includes a provision setting forth these obligations.

For PHS-sponsored research, the University will specify in the written agreement whether the University's or the sub-recipient's conflict of interest in research policy applies, and will specify time frames for the sub-recipient to act to enable the University to meet its reporting obligations to the PHS.

When the University makes a proposal for or receives a sub-award from another organization to carry out a portion of a PHS-funded project, the University must comply with the regulations regarding conflicts of interest. This policy applies to these proposals and awards rather than the policies of the sub-awarding organization. The University provides reports of conflicts of interest to the sub-awarding organization for reporting to PHS as specified in the PHS regulations. Reports are provided in the same form and format as the University uses in connection with its direct awards from PHS. The sub-awarding organization is also responsible for the public accessibility reporting (see above). The sub-awarding organization may choose to do so either by posting the University's report to a publicly available website or responding to written requests within 5 business days.

X. Public Accessibility

Upon implementation, the University will make this policy publicly accessible on its website. Regarding PHS-funded research only, the University will provide in a written response to any requestor within five business days of the request, information concerning any conflict of interest disclosed to the University that meets the following criteria:

- a) The significant financial interest was disclosed and is still held by the Investigator;
- b) A determination has been made that the significant financial interest is related to the PHS-funded research; and
- c) A determination has been made that the significant financial interest is a conflict of interest.

The information to be made available to the requestor shall be consistent with the requirements of 42 CFR 50 and 45 CFR 94.

XI. Federally Funded Research

This policy fulfills federal regulations requiring institutions receiving federal funding to have in place a written, enforced policy and process to identify and manage, reduce, or eliminate conflicts of interest of persons engaged in the design, conduct, or reporting of federally funded research. In addition, this policy implements the requirements of 42 CFR 50 and 45 CFR 94; and where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

Policy Information

- New Policy
- Approved: President
- Approval/Effective Date: August 24, 2012
- Responsible Executive: Vice President for Research
- Responsible Administrator: Chief Compliance Officer
(256) 824-6845