

# *Policies and Procedures Manual*

Kansas State University

## **Conflict of Interest Policy Applicable Only to Public Health Service (PHS)-Supported Investigators and their Staff**

Chapter 4090

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### **.010 Introduction**

Conflicts of interest and time commitment are endemic to the modern university. These conflicts are a consequence of the many and varied roles that university members play in such areas as technology transfer and applied research, the creation of new multimedia teaching tools, and activities as expert consultants to local, state, and national governments as well as to the business community. The goal of this policy is to manage perceived, potential, and actual conflicts of interest and time commitment. A system of self-disclosure is most effective for Kansas State University, since conflicts of interest and time commitment must be dealt with on a case-by-case basis. Discussion, disclosure, and negotiation generally can resolve disputes related to conflicts of interest and time commitment.

This statement of policy concerning conflicts of interest and time commitment has been developed by a university task force in order to ensure compliance with the laws of the State of Kansas and mandates from the Board of Regents (BOR) and federal funding agencies, the latter as a prerequisite for their future support. This policy applies **only to personnel involved in research funded through the Public Health Service (“PHS”) of the United States Department of Health and Human Services**, and is intended to, in large part, mirror the Conflict of Interest Policy currently located at Appendix S of the University Handbook that applies more broadly to University personnel. The difference is that this policy additionally includes the requirements mandated by federal regulations, and its provisions shall be interpreted to promote such purposes. PHS-Supported means any person who works in a laboratory or program supported by PHS funds through contract, grant, or other cooperative agreement.

### **.020 General Principles**

This policy is based, in part, on the Board of Regents' policy entitled [Commitment of Time, Conflict of Interest, Consulting and Other Employment](#) (11-16-11)

## **1. Conflict of Time Commitment.**

(a) Attempts to balance university responsibilities outlined in the preamble with external activities, such as, but not limited to, consulting, public service or pro bono work, can result in real or apparent conflicts regarding commitment of time and effort. Whenever a faculty or staff member's external activities exceed reasonable time limits, or whenever an unclassified staff or faculty member's primary professional responsibility is not to the University, a conflict of time commitment exists.

(b) Conflicts of commitment usually involve issues of time allocation. Faculty members and unclassified staff of state universities owe their primary professional responsibility to their employing University, and their primary commitment of time and intellectual effort must be to the education, service, research and scholarship missions of that University. Faculty and unclassified staff should maintain a presence on campus commensurate with their appointments. The specific responsibilities, position requirements, employment obligations and professional activities that constitute an appropriate and primary commitment of time will differ across schools and departments, but said responsibilities, requirements, obligations and activities should be initially premised on a general understanding of full-time commitment for full-time faculty or unclassified staff of the University. Exceptions must be justified and shown to enhance the institutional mission.

## **2. Conflicts of Interest.**

(a) A conflict of interest occurs when there is a divergence between an individual's private, personal relationships or interests and his/her professional obligations to the university or to the objectivity of research, such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined or substantially influenced by considerations of personal benefit, gain or advantage.

(b) In addition, and without limiting the foregoing definition of conflicts of interest, conflicts of interest related to research that are in whole or part funded by a PHS-funded grant, cooperative agreement or contract, are referred to in this policy as Financial Conflicts of Interest ("FCOI" or "FCOIs"). FCOIs are types of "conflicts of interest" referenced in this policy, and are distinguished from the more general conflicts of interest only where necessary based on applicable regulations. FCOIs exist where an Investigator's significant financial interest ("SFI") could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

(i) "Investigators" are project directors, principal investigators, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research, which includes without limitation, collaborators and consultants.

(ii) An SFI, as related to FCOIs, is a financial interest that reasonably appears to be related to an Investigator's "institutional responsibilities" in the following manners:

1. The value of remuneration (salary and any other payment for services) received by the Investigator, Investigator's spouse, and/or dependent children in the 12 months preceding a disclosure (see .040) from a publicly traded entity, plus the value of any equity interest held by such persons in the entity (stock, stock option or other ownership interest as determined by public prices or other reasonable measures of fair market value) as of the date of the disclosure, exceeds \$5,000;

2. The value of remuneration received by an Investigator, Investigator's spouse, and/or dependent children from any non-publicly traded entity in the 12 months preceding the disclosure exceeds \$5,000, OR when the Investigator, Investigator's spouse, and/or dependent children hold(s) any equity interest; or

3. Upon receipt of income related to intellectual property rights and interests (such as patents and copyrights); provided however, this shall not include intellectual property rights assigned to Kansas State University and agreements to share in royalties related to such assigned rights.

4. Reimbursed or sponsored travel related to institutional responsibilities, as further detailed in .040(3), about which the university shall make a determination of whether such travel constitutes an SFI.

(c) Significant financial interests, or SFIs, as used in this policy, may also exist, even though not pertaining to PHS-funded research, when a faculty or unclassified staff member holds greater than \$10,000 or more than 5% ownership in a company, in accordance with the BOR's policy.

(d) An Investigator's "institutional responsibilities" include his or her professional responsibilities on behalf of Kansas State University, including without limitation, research, research consultation, teaching, directed and non-directed service, professional practice, institutional committee memberships, service on panels such as institutional review boards or data and safety monitoring boards, and other administrative/programmatic service committees or panels.

(e) Whether a conflict of interest or the appearance of one exists depends on the situation and foregoing guidelines and definitions, not on the character or actions of the individual, and must be determined on a case-by-case basis. The appearance of a conflict of interest can be as damaging or detrimental as an actual conflict and thus, for purposes of this policy, perceived and potential conflicts are treated the same as actual conflicts. Whether or not a conflict of interest exists is determined according to the process set forth at .040 and .050.

(f) Situations involving potential conflicts of interest are not uncommon in a modern university and must be addressed. State universities have as part of their mission the promotion of the public good by fostering the transfer of knowledge gained through university research and scholarship to the private sector. Two important means of accomplishing this institutional mission include consulting and the commercialization of technologies derived from research. It is generally appropriate that university personnel be rewarded for participating in these activities through consulting fees and sharing in royalties resulting from the commercialization of their work, but such is subject to the mandates of the aforementioned federal regulations. It is not appropriate, however, for an individual's actions or decisions made in the course of his or her university activities and/or in PHS-funded research to be determined or substantially influenced by considerations of personal financial gain and/or SFIs. Such behavior calls into question the professional objectivity of the decisions and research, as well as the ethics of the individual. It also reflects negatively on the employing university. State universities are institutions of public trust; faculty and unclassified staff, as well as any other Investigator, must respect that status and conduct their affairs in ways that will not compromise the integrity of the university or the objectivity of PHS-funded research.

(g) Except in purely incidental ways, University resources, including but not limited to facilities, materials, personnel, or equipment, may not be used in external activities unless prior written approval has been received from the University's chief executive officer or his/her designee. Such permission shall be granted only when the use of University resources is determined to further the mission of the University. When such permission is granted, the faculty member or unclassified staff member will make arrangements for reimbursement of the University for institutional materials, facilities or services used in the external activity. Such use may never be authorized if it violates the Board of Regents policy on Sales of Products and Services.

(h) Proprietary or other information confidential to the University may never be used in external activities unless prior written approval has been received from the University's chief executive officer or designee.

(i) Faculty or unclassified staff may not involve University students, classified staff, unclassified staff or faculty in their external activities if such involvement is in any way coerced or in any way conflicts with the involved participants' required commitment of time to their University. For example, a student's grades or progress towards a degree may not be conditioned on participation in a University employee's external activities.

(j) At Kansas State University a college or unit may, in consultation with the provost, add clarification to the above definitions of actual, perceived, and potential conflicts relating to other actions leading to conflicts of interest or time commitment that are unique to the unit's professional mission; provided however, any such clarification shall be in accordance with the regulations pertaining to FCOIs, if applicable. The final determination of such clarification shall be by the provost or an official designated by the provost.

(k) The University's nepotism policy is stated in PPM chapter 4095.

### **.030 Consulting and Other Employment (see University Handbook [Section D40](#))**

The Consulting Request form available at <http://www.k-state.edu/academicpersonnel/forms/consult.pdf> must

be filed with and approved by the same process set forth in .050 in advance of undertaking any consulting activity.

**1. Consulting for Other State of Kansas Agencies.** Consulting by faculty members and employees of institutions under the jurisdiction of the Board for another institution under the jurisdiction of the Board, as well as consultation for other state agencies, shall be approved in advance by both (a) the institution or agency seeking these services, and (b) approved by the employee's home institution. The home institution shall effect payment through the regular process and shall receive reimbursement through the interfund transfer process. (12-16-77; 11-19-82; 5-1 7-85)

**2. Consulting Outside the University.** For members of the faculty and unclassified professionals, the state university permits, and indeed encourages, a limited amount of personal, professional activity outside the faculty member's or unclassified professional's reasonable construed total professional responsibilities of employment by and for the University, provided such activity: (a) further develops the faculty member or unclassified professional in a professional sense or serves the community, state, or nation in a professional capacity; (b) does not interfere with the faculty member's or unclassified professional's teaching, research and service to the university; (c) is consistent with the objectives of the University; and (d) any such consulting or remuneration therefor is not a conflict of interest that cannot be satisfactorily managed. Regular instructional service to other educational institutions is normally regarded as an inappropriate personal, professional activity and is thus generally prohibited. Without prior written approval, faculty members or unclassified professionals on full-time appointments must not have significant outside managerial responsibilities nor act as principal investigators on sponsored projects that could be conducted at their employing university but instead are submitted and managed through another organization.

**3. Other Employment.** The Board of Regents expects faculty and unclassified staff employed by the state universities to give full professional effort to their assignments. It is, therefore, considered inappropriate to engage in gainful employment outside the state university that is incompatible with institutional commitments. It is inappropriate to transact business for personal gain unrelated to the University from one's University office, or at times when it might interfere with commitments to the University. Uncompensated participation in academic conferences, workshops and seminars on matters relating to education or the other functions of the University does not usually constitute consulting or outside employment. However, organizing and operating such meeting for profit may be construed as consulting or outside employment as defined in this policy.

#### **.040 Reporting and Disclosure Requirements; Training; Duties of Investigators; Records**

**1. Annual Reporting.** All faculty and unclassified staff with 100% appointments as part of the initial appointment process, all faculty and unclassified staff, who hold fractional appointments on an annual basis, and any other personnel who may qualify as an Investigator pursuant to the definition at .020(2)(b)(i) on an annual basis, must disclose to the University, at the applicable specified times, whether they or members of their immediate family (spouse and dependent children), personal household, or associate entities (e.g., corporations, partnerships or trusts) have any SFI and/or conflict of interest, as defined at .020(2). Such disclosures are to be made on the annual Declaration for Conflict of Interest and Time Commitment Form and the Supplemental Declaration of Financial Conflict of Interest (FCOI) Applicable Only to Public Health Service-Supported Investigators and Their Staff, both of which may be found at <http://www.k-state.edu/conflict/forms/sdfcoi.pdf>.

The annual Declaration for Conflict of Interest and Time Commitment form ("Declaration"), which can be accessed through HRIS Employee Self-Service at: <https://www.as.ksu.edu/HRIS> (Path: Employee Self Service > Personal Information > Conflict of Interest) must be filed annually. These will continue to be filled out and signed electronically. Two additional forms have also been developed to implement this policy as it pertains to federal regulations, which are currently available to be filled out in hard copy: the annual Supplemental Declaration of Financial Conflict of Interest (FCOI) Applicable Only to Public Health Service (PHS)-Supported Investigators and Their Staff (including any necessary Supplemental Disclosure and Management Plan) ("Supplemental Declaration"), and the Sponsored Travel Form (defined below). **The 2012-13 Supplemental Declaration and related documents must be filed by each investigator within 30 days of the posting of this policy and must be reviewed as set forth in .050, below, prior to any expenditure of funds under a PHS-funded research project; thereafter, the declaration shall be filed annually, or sooner if updates are necessary as required by this policy.**

If the faculty or unclassified staff member, or other Investigator, answers yes on any question on the Declaration or Supplemental Declaration, he or she shall submit along with the Declaration or Supplemental Declaration a completed “Disclosure Statement of Significant Financial and/or Time Commitment Interests” (“Disclosure”), or “Supplemental Disclosure Statement of Significant Financial Interests Pursuant to Federal Public Health Service Regulations” (“Supplemental Disclosure”) with the applicable Declaration form. If the faculty or unclassified staff member, or other Investigator, believes there to be a perceived, potential or actual conflict of interest, he or she shall also submit along with the above documents the applicable [Management Plan](#). Additionally, when the University, through the review process in .050, determines that the information submitted indicates that a perceived, potential or actual conflict of time commitment or conflict of interest does or may exist, the University may require that the faculty or unclassified staff member, or other Investigator, submit additional information and explanation regarding such conflict, including without limitation, an additional Declaration, Supplemental Declaration, Disclosure, Supplemental Disclosure, and/or a Management Plan.

**2. Ongoing Duty to Report SFIs and Conflicts As They Occur.** In addition to the initial and annual report that must be filed, such individuals must also disclose to the direct supervisor, department head/chair or dean on an *ad hoc* basis any current or prospective situations that may raise questions or conflict of time commitment, conflict of interest, or SFI, including without limitation new conflicts of interest or SFIs and updated information from a previously disclosed conflict of interest or SFI, as soon as such situations become known, and in any instance, not later than thirty (30) days after discovery or acquisition of the SFI. To make such a disclosure, a new Declaration and/or Supplemental Declaration, as applicable, shall be filled out and submitted to the direct supervisor and through the review process at .050.

**3. Sponsored and Reimbursed Travel.** Investigators must report travel reimbursements and sponsored travel relating to their institutional responsibilities that are directly reimbursed to them or where travel costs are paid on behalf of the employee by another party other than those exempted entities expressly excluded in this paragraph. Reports must include purpose of the trip, sponsor/organizer, destination, and trip duration, and shall be submitted within 30 days of travel. Provided however, travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute does not have to be reported. Such disclosures shall be made on the Sponsored Project Personnel Report of Direct Reimbursed/Sponsored Travel Received Form (“Sponsored Travel Form”). <http://www.k-state.edu/conflict/forms/nihtravel.pdf>.

After disclosure of information, the form shall be submitted to the immediate supervisor and the review process at .050 shall be followed to determine if there is an SFI and if so, a conflict of interest based on such reimbursed or sponsored travel.

**4. Federal Reporting Requirements.** State universities are required to adhere to and implement any additional policies and procedures and disclosure requirements that are imposed by applicable federal conflict of interest laws. As set forth above, policies pertaining to federal PHS-funded research conflicts of interest are included within this policy. The University has composed additional form(s) regarding conflicts of interest to comply with federal regulations without approval of the Council of Presidents, as permitted by BOR policy. These are in addition to the information required on the form(s) developed by the Council of Presidents.

**5. Reporting of Consulting.** Aside from the exception specified below, the faculty member or unclassified professional must report the proposed arrangements for personal professional activities on the Consulting Request Form and secure written or electronic approval prior to engaging in the activities. For all activities concerned, the report should indicate the extent and nature of the activities, the amount of time to be spent in the activities, and the total amount of time spent or expected to be spent on all such outside activities during the current academic year. To the extent applicable, if the consulting presents an SFI or conflict of interest, such SFI and conflict shall also be disclosed on the applicable Declaration and Disclosure form(s).

The faculty member or unclassified professional staff must inform the provost, through the direct supervisor, department chair or head and the dean, of all external personal, professional activities. For faculty members only, personal, professional activities that occur within a single 24-hour period need not have prior approval but must be reported annually in writing on the electronic annual Declaration for Conflict of Interest and Time Commitment (<https://www.as.ksu.edu/HRIS>; path: Employee Self Service > Personal Information > Conflict of Interest).

Unclassified professionals must inform the appropriate vice president or the provost, through the unit head and appropriate supervising administrator, of all external personal professional activities. Unclassified professionals must obtain written approval prior to engagement in all external personal professional activity regardless of the length of engagement.

**6. Disposition of Reports; Maintenance of Records.** All required documentation and reports shall be submitted in accordance with institutional requirements and shall be included in individual personnel files to be used for the determination of whether an individual is in compliance with this policy. Such documents and reports will also be available to institutional research officers to permit certification and/or verification of compliance with federal regulations. The University must maintain these records and reports for a minimum of three years. Regarding PHS-funding through grants or cooperative agreements, the University shall maintain records, through the "Office", as defined below, relating to all Investigator disclosures of financial interests and the University's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in federal regulations for different situations. Regarding PHS-funding through contracts, the "Office" shall maintain records relating to all Investigator disclosures of financial interests and the University's review of, and response to, such disclosures (whether or not a disclosure resulted in the University's determination of a FCOI), and all actions under the University's policy or retrospective review, if applicable, for at least three years from the date of final payment or, as specified in the applicable federal regulations.

**7. Training.** Each Investigator shall complete training regarding SFIs and FCOIs prior to engaging in research related to PHS-funded research and at least every four years, and immediately when any of the following circumstances apply:

- (a) The University revises any policy pertaining to FCOIs or procedures that affect the requirements of Investigators;
- (b) An Investigator is new to the University; or
- (c) When a University finds that an Investigator is not in compliance with the FCOI policies or a management plan pertaining to a FCOI.

The Associate Vice President for Research Compliance is responsible for the training and any questions about the training, the requirements, or the frequency shall be directed to him or her. The training can be accessed at <http://www.k-state.edu/research/comply/coi/training/index.htm>.

As part of such training and as part of the Supplemental Declaration, each person shall certify receipt of the federal regulations found at [42 CFR Part 50](#), and [45 CFR Part 94](#).

### **.050 Kansas State University Review Process**

Upon submission of any Declaration or Supplemental Declaration, or other related information or disclosures, or any updates related to any of the foregoing (see .040(1)-(2), above), a review process shall take place as follows:

#### **1. Responsibilities of Direct Supervisors and Unit Heads.**

(a) First, the direct supervisor and then unit head will review the Declaration, Supplemental Declaration, the Consulting Request, and/or the Sponsored-Travel Form and any information submitted pursuant to the ongoing duty to report. Any information submitted pursuant to the ongoing duty to report, shall be reviewed as set forth herein, and forwarded in a timely manner such that the provost can make a final determination within 60 days of the disclosure.

(b) The direct supervisor and unit head will review any SFI and other information, and indicate by an approval signature (either electronically or by hard copy, as applicable) when a report or request does not appear to indicate a possible conflict of interest or where a satisfactory management plan has been developed at the unit level. The reports or requests and any management plans that have been developed shall be forwarded to the dean or appropriate administrator.

(c) Guidelines to determine whether an SFI is related to PHS-funded research include a reasonable determination by the supervisor or unit head, as applicable, that the SFI: (i) could be affected by the PHS-funded research; or (ii) is an entity whose financial interest could be affected by the research. A determination as to whether there is a FCOI shall be made based on a reasonable determination that the SFI

could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. The direct supervisor and unit head may involve the Investigator in his or her determinations.

(d) In cases where the direct supervisor or unit head determines that there may be a possible conflict of interest or time commitment, the direct supervisor or unit head may require that the individual submit additional information and explanation regarding that conflict and participate in the development of a management plan, or in the absence of the ability for the conflict to be managed, the elimination of such conflict.

(e) If the management of a conflict of interest is unresolved at the unit head level, the following procedures will be followed: (i) the unit head will prepare a written summary of the case, with the faculty or unclassified staff member affected having the opportunity to review and discuss the summary with the unit head and having the opportunity to submit to the unit head a written response recording his or her perception of the case; (ii) before the unit head submits the summary to the next administrative level, the faculty or unclassified staff member must sign a statement acknowledging the opportunity to review and to discuss the summary and indicating whether he or she submitted a written response; (iii) the unit head who prepared the summary must submit to the dean or appropriate administrator all forms, the summary of the case, including the facts indicating a possible conflict of interest or time commitment, and any written responses prepared by the faculty or unclassified staff member.

(f) In the event that there is a conflict of interest for which a management plan is approved, the immediate supervisor shall regularly monitor compliance with such plan, until the completion of the PHS-funded research project if applicable, and report to the unit head any failures to comply, who shall report any such issues through the same review procedure and order of administrators as in this section. Failures to comply with the conflict management plan will be addressed on a case-by-case basis in accordance with .070 below.

## **2. Responsibilities of Deans/Comparable Administrators**

(a) The dean will review all of the materials submitted to ensure that the correct procedures have been followed. The dean will then determine whether the case involves an SFI, conflict of interest or the appearance of one, and whether any conflict management plan which has been developed is acceptable. The dean will take into consideration, as applicable, the guidelines set forth at .050(1)(c) if applicable, or such other information that the dean deems appropriate in determining whether there is a conflict of interest. In cases where there is no such conflict or where the conflict management plan is acceptable, the dean will show approval by signing the Supplemental Declaration in question.

(b) The dean will make recommendations for managing any perceived, potential or actual conflict that has not been resolved at the unit level, all in a manner acceptable to the dean. The dean may require that the individual submit additional information and explanation regarding that conflict and participate in the development of a management plan, or in the absence of the ability for the conflict to be managed, the elimination of such conflict. The recommendations will be presented to the unit head and the faculty, unclassified staff member or other Investigator. Those individuals must indicate in writing their acceptance of the dean's recommendation or their rejection of the recommendation. A written rejection must include the reasons why the individuals find the recommendation unacceptable.

(c) The dean must forward to the provost the form(s) and associated documentation (plans of management, recommended plans of management, and written statements of agreement or unresolved differences).

## **3. Responsibilities of the Provost.**

(a) The provost's Office of Academic Personnel ("Office") will review all the reports or requests and supporting materials and recommendations. The Office will assess whether any SFIs, conflicts or apparent conflicts of interest or time commitment exist. The Office will take into consideration the guidelines set forth at .050(1)(c), if applicable, and/or such other information that the Office deems appropriate in determining whether there is a conflict of interest. The Office and/or the Committee, as applicable, will evaluate the information, take into consideration, as applicable, the guidelines set forth at .050(1)(c), whether an SFI exists, whether the SFI constitutes a FCOI or other conflict of interest or time commitment, whether management plans which have been developed adequately manage any conflicts of interest and time commitment, and whether there are any inequities in the recommendations for management of conflicts. The

Office and/or Committee, as applicable, will make a recommendation to the provost regarding any SFI or conflict.

(b) If the provost agrees with the recommendation, then after considering, as applicable, the guidelines set forth at .050(1)(c), such other information that the provost deems appropriate in determining whether there is a conflict of interest or of time commitment, the provost may approve the recommendation by signing the applicable form(s). If the provost does not agree with recommendations for conflict management or elimination made by subordinate administrators, including without limitation the Committee, an attempt must be made to reach consensus through consultation. If this fails, the provost's recommendation will be used. The provost may require that the individual submit additional information and explanation regarding that conflict and participate in the development of a management plan, or in the absence of the ability for the conflict to be managed, the elimination of such conflict. The individual(s) affected by the disagreement must be notified by the provost, in writing, of the provost's decision and its rationale.

(c) If the provost determines that there is a conflict of interest that can be satisfactorily managed, a management plan must be developed and implemented and if not already submitted, then submitted through the review process in this section .050. Additionally, an FCOI that is not eliminated but is managed pursuant to a management plan must be reported to the PHS Awarding Component through an FCOI report including the applicable federal regulation requirements.

(d) If, as set forth in this .050, there is determined to be an SFI or FCOI, a record shall be retained by the Office, for three years from the date the information was last updated, and be available and provided within five (5) business days of a request, as mandated under federal regulations. The Office shall provide the most updated information concerning such FCOI disclosed to the University that meets the following criteria: (i) the SFI was disclosed and is still held by the senior/key personnel; (ii) the University determines that the SFI is related to PHS-funded research; and (iii) the University determines that the SFI is an FCOI.

(e) In accordance with federal regulations, the University, through the Assistant Vice President for Research, must certify in each application for funding the requirements set forth in those applicable federal regulation(s). Prior to the expenditure of any PHS funds, the University shall submit an FCOI report regarding any Investigator's SFI found by the University to be conflicting and ensure that an adequate management plan has been implemented; if the conflict of interest is eliminated, rather than managed, no such report is required to be made. Within sixty (60) days of identification of a FCOI after the initial FCOI report, either due to a new Investigator, or a new or newly identified FCOI for existing Investigators, the University, through the provost's designee shall provide the PHS Awarding Component an FCOI report regarding the FCOI and ensure that a management plan has been implemented; when applicable, this shall be in addition to any reviews and mitigation reports related to noncompliance, as set forth below. The University shall also provide to the PHS Awarding Component an annual FCOI report that addresses the status of a previously reported FCOI and any changes to the management plan for the duration of the research project, as required by federal regulation. All FCOI reports shall be compliant with and include federal regulation requirements. The provost's designee is responsible for sending initial, annual, and revised FCOI reports to the PHS Awarding Component.

#### **4. Nondisclosure; Noncompliance.**

(a) Within 60 days of a determination by any of the above-listed University officials of nondisclosure by an Investigator, failure by the University to review or manage a FCOI, or failure of an Investigator to comply with a management plan, all as pertaining to an FCOI, the direct supervisor and the unit head shall be notified and the review process in .050(1)-(3) initiated. This review process should be expedited by all University officials and immediately forwarded through the review process.

(b) If after the above-referenced review, the provost determines there is a FCOI, the University shall complete a retrospective review, within 120 days of the determination of nondisclosure, pursuant to the same order of review set forth in this .050, to (i) determine whether any PHS-funded research conducted during the period of noncompliance, was biased in the design, conduct or reporting of such research, (ii) implement any management plan as necessary, and (iii) document such review. The documentation shall include, as applicable, the following details: (i) project/contract number; (2) project title; (3) the principal Investigator or the contact Investigator if more than one; (4) name of the Investigator associated with the FCOI; (5) name of the entity with which the Investigator has a FCOI; (6) reason for the retrospective review; (7) detailed methodology used for retrospective review (e.g., methodology of review process, composition of the review panel, documents reviewed); (8) findings of the review; and (9) conclusions of the review.



(c) Based on the results of the retrospective review, the University, through the provost's designee, shall update a previously submitted FCOI report and specify actions being taken to manage the FCOI.

(d) If bias is found, the University, through the provost's designee, shall notify the PHS Awarding Component promptly and submit a mitigation report to it. The mitigation report must include: (i) the key elements documented in the retrospective review, (ii) a description of the bias on the research project, (iii) the University's plan of action taken to eliminate or mitigate the effect of bias, (iv) extent of harm done including any qualitative and quantitative data to support any actual or future harm, and (v) analysis of whether the research project is salvageable.

(e) Depending on the nature of the FCOI, the University, through the provost's designee, may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the determination of noncompliance and the completion of the retrospective review. The provost's designee shall notify the Investigator of any such interim measures.

(f) In addition to the foregoing, if the failure of an Investigator to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the University, through the provost's designee, shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken, which action should also be included in the mitigation report referenced above. The University shall comply with directions from the PHS Awarding Component provided after such notification.

(g) In any case in which the U.S. Department of Health and Human Services determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or a treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by the University, the University, through the provost's designee, shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

**5. Appeals.** In the event that agreement is not reached by all parties concerned with the management of a case of conflict of interest or potential or perceived conflict of interest, the aggrieved parties may pursue a grievance following the procedures in Appendix G of the University Handbook, but in no circumstances shall such appeal delay any time limitations with which the University must comply pursuant to federal regulations.

#### **.060 Use of University Name**

The name of the Board of Regents, a Regents institution, or the Regents System may never be used as an endorsement of a faculty member or unclassified staff member's external activities without expressed and advance written approval of the University chief executive officer and/or the Board's President and Executive Officer, as appropriate. Faculty members or unclassified staff members may list their institutional affiliation in professional books, articles and monographs they author or edit and in connection with professional workshops they conduct or presentations they make without securing approval.

#### **.070 Sanctions**

Failure to make any annual report or other disclosure required herein, and any updates thereto, may result in a temporary moratorium on expenditure of federally sponsored project funding until compliance is achieved and may result in discipline in accordance with University procedures, ranging, for example, from the loss of the privilege of submitting grant proposals and receiving extramural support to, in extreme cases, dismissal for cause (University Handbook C161.1).

#### **.080 Distribution and Dissemination**

The policy statement will be distributed upon initial appointment to all applicable faculty and unclassified staff members by the University, and to all Investigators as defined herein, and when any revisions to this policy are made.

#### **.090 Questions**

Questions concerning this policy should be addressed to the Director of Academic Personnel (785) 532-4392.