ACTION: School

3356-10-17 Objectivity in research – avoidance of conflicts of interest and/or commitment in sponsored research.

- (A) Policy statement. Recognizing the need for objectivity in research, the university shall maintain procedures that control conflicts and potential conflicts in funded research. Such procedures are consistent with the Youngstown state university professional conduct policy (see rule 3356-9-06 of the Administrative Code) and relevant state and federal laws.
- (B) Purpose. The intent of this policy and these procedures is to ensure that the design, conduct, and reporting of research projects and other sponsored activities are not compromised by, nor would reasonably appear to be affected, by any significant financial interest of the responsible faculty and staff members.
- (C) Definitions.
 - (1) "Project" is an externally funded scholarly activity such as basic, applied, or developmental research, instructional or curricular activities, student aid, career development, or other activity conducted by faculty or staff members on behalf of the university.
 - (2) "Investigator" includes the principal investigator, co-investigators, and other persons (e.g., technicians, students, research associates) responsible, in whole or in part, for the design, conduct, or reporting of the project; and for reporting purposes, includes the investigator's spouse and dependent children.
 - (3) "Significant financial interest" is anything of monetary value including, but not limited to, salary or other payments for services such as consulting fees or honoraria; equity interests such as stocks, stock options, or other ownership interests; and intellectual property rights such as patents, copyrights and royalties from such rights.

Not included in this definition are:

- (a) Salary, royalties, promotion in rank, or other remuneration from the university;
- (b) Income from seminars, lectures, or teaching engagements

sponsored by public or nonprofit entities;

- (c) Income from service on advisory committees or review panels from public or nonprofit entities;
- (d) Financial interest arising solely by reason or investment in a business by a mutual, pension, or other institutional investment fund over which the employee does not exercise control;
- (e) Equity interest that when aggregated for the investigator and the investigator's spouse and dependent children, does not exceed ten thousand dollars in value, as determined by public prices or other reasonable measures of fair market values, and does not represent more than five per cent ownership interest for any one enterprise or entity;
- (f) Salaries, royalties, or other payments that when aggregated for the investigator and the investigator's spouse and dependent children over the next twelve months, are not expected to exceed ten thousand dollars; and
- (g) The financial interest is an ownership interest in a business which is the applicant organization under phase I of a small business innovative research ("SBIR") program or phase I of a small business technology transfer ("SBTR") program and the university is a subcontractor under the business' application.
- (4) "Conflict of interest" means an action, omission, or situation that may or may reasonably appear to affect or compromise the objectivity or integrity of an investigator's design, conduct or reporting of a project. (A potential conflict of interest may exist if the director of grants and sponsored programs determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of a project.)
- (5) "Disclosure" is a written statement submitted by the investigator describing the nature of any significant financial interests and the relationship of such interests to the externally funded project.

(D) Parameters.

- (1) All faculty and staff members or other university-affiliated individuals who apply for, receive, or are currently working on a grant, contract, cooperative agreement, sub-grant, subcontract, or sub-cooperative agreement which is funded in whole or in part by federal funds or other external sources must adhere to this policy and its procedures.
- (2) The director of grants and sponsored programs associate vice president for research is designated to solicit and review financial disclosure statements from investigators.
- (E) Principles.
 - (1) Complex relationships among universities, government agencies, and industry require adherence to standards of conduct in federally funded and other externally sponsored activities. Application of these standards must serve both project requirements and the public interest. Protecting the integrity of cooperating entities requires that both real and perceived conflicts of interest be avoided.
 - (2) Faculty or staff members engaging in a federally or other externally sponsored project are subject to the provisions of federal and state laws and any requirements of the sponsoring or entity.
 - (3) To avoid bias in the design, conduct, or reporting of the sponsored project, full disclosure must be made when a faculty or staff member consults for a business, nonprofit agency, government agency, or other non-university contractor, in the same technical field as the externally sponsored project.
- (F) Procedures.
 - (1) Prior to submitting an application to conduct an externally funded project, the investigator shall disclose to the director of grants and sponsored programs associate vice president for research any significant financial interests or other possible conflict situations:
 - (a) That would appear to be affected by the project for which

the funding is sought; and

(b) In entities whose financial interests would appear to be affected by such project.

A conflict of interest statement form shall be included with within the proposal authorization form ("Blue sheet") routing form process and shall be circulated as part of the approval process for review and approval for all proposals.

- (2) During the course of an award <u>Throughout the duration of a</u> <u>sponsored research project</u>, investigators shall update the conflict of interest statement at least annually. If an investigator acquires a <u>new significant</u> reportable significant financial interest <u>in an entity</u>, the investigator shall submit a revised or new conflict of interest statement to the director of grants and sponsored programs <u>associate vice president for research</u> within five working days after acquisition.
- (3) The director associate vice president for research shall review the disclosure and make an initial determination whether a potential conflict of interest exists. If the disclosure is determined not to be a potential conflict of interest, director the associate vice president for research shall provide documentation of this determination that shall be retained with the other project records and shall so advise the investigator, the chair, and the appropriate college dean, and the associate provost for research and dean of graduate studies and research.
- (4) If the director determines that a potential conflict of interest exists, the director shall promptly notify the associate provost for research and dean of graduate studies and research in writing.
- (5)(4) The associate provost for research and dean of graduate studies and research If the disclosure is determined to be a potential conflict of interest, the associate vice president for research shall consult with the dean of the college and the university general counsel. They shall review the disclosure, consult with the investigator, and seek any additional information to determine whether a conflict of interest exists. If they determine that a conflict of interest exists, they shall determine a plan of action, consisting of and document

<u>in writing</u> the conditions or restrictions that shall be required by the university to manage, reduce, or eliminate such actual or apparent conflict of interest. If all parties accept the plan, the associate provost for research and dean of graduate studies and <u>vice</u> <u>president for</u> research shall notify all <u>involved</u> parties and the provost of the final determination in writing.

- (6)(5) If a mutually acceptable method for managing, reducing, or eliminating the conflict of interest cannot be agreed upon, the associate provost for research and dean of graduate studies and vice president for research shall refer the disclosure to the provost, who shall consult with the university general counsel prior to appointment a conflict of interest review committee for final determination.
- (7)(6) The provost shall notify the investigator, the investigator's chairperson and dean, and the associate provost for research and dean of graduate studies and vice president for research of the final determination.
- (8)(7) In addition to possible legal penalties <u>action</u>, the university may take disciplinary action against individuals who fail to file a disclosure statement or intentionally file an incomplete or misleading disclosure statement. Breaches of this policy may be referred to a conflict of interest review committee to investigate and recommend sanctions. If sanctions are necessary, they will be imposed in accordance with any applicable university policy, procedure, or collective bargaining agreement.
- (9)(8) Prior to the expenditure of any funds under a federally funded project award, the university will, as required by law, report to the appropriate federal agency the existence of a conflict of interest and assure that the conflict has been managed, reduced, or eliminated.
- (10)(9) When the university identifies a conflict of interest subsequent to the university's initial report under the federally funded project award, the university will report the conflict of interest to the appropriate federal agency and manage, reduce, or eliminate the conflict within sixty days of identifying the same.

- (11)(10) The director and the associate provost for research and dean of graduate studies and associate vice president for research shall ensure that the required records, identifiable to each award, are retained for a period of not less than three years after the termination of the award, or until three years after the resolution of any action taken by the sponsor involving these records, whichever is longer. Records for proposals that are not funded by sponsoring agencies will be retained for a period of one year after the decision of the sponsoring agency.
- (G) Note: Further information may be found in the "Guide to Sponsored Programs Development" and the office of grants and sponsored programs and 42C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94.

Replaces:

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