

UNIVERSITY OF OKLAHOMA

INSTITUTIONAL CONFLICT OF INTEREST IN RESEARCH ACTIVITIES

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I. Statement of General Policy

The University of Oklahoma is responsible for handling public funds in a manner that ensures that all University activities reflect its mission of providing the best possible educational experience through excellence in teaching, research, creative activity and service to the state and society. As the University's collaboration and interaction with the private sector increases, so does the potential for institutional conflicts of interest. These conflicts involve situations in which the integrity of research, the University's educational mission, and/or the University's reputation may be compromised, or may appear to be compromised, by the University's financial interest.

Institutional conflicts of interest can occur whenever the external financial interests or business relationships of the University or of one of its officials are such that their actions could affect, or could reasonably appear to affect, the conduct review or oversight of the University's research.

It is the policy of the University of Oklahoma that all institutional conflicts of interest, whether real or perceived, must be fully disclosed. The reported conflict must be properly identified and either managed or eliminated prior to initiating any contract, sponsored project, dedicated gift or transaction that might appear to be influenced by the conflict. This policy can be implemented by using a three-step approach:

1. Disclose always
2. Assess the potential for institutional conflicts of interest
3. Manage the conflict in most cases, and prohibit the activity when necessary to preserve the University's mission or protect the public's interests

This policy has been developed to protect the integrity of the research and development process at the University of Oklahoma. It is not intended to supersede or modify other Conflict of Interest policies, including those found in the Norman Campus Faculty Handbook (Sections 3.6, 3.83, 4.20.2, and 5.10) and those found in the OU Health Sciences Center's Faculty Handbook Appendix E.

II. Disclosing and Identifying Institutional Conflicts of Interest

What to disclose

All institutional conflicts of interest, whether perceived, potential, or actual must be disclosed. Institutional conflicts of interest may occur when the institution, any of its senior management or regents, or a college, department, school, or other sub-unit, has an external relationship with, or financial interest in, a company that itself has an interest in a University research project.

Information to disclose

- Financial interests of all Board of Regents members and executive officers
- Single corporate or private donations exceeding \$1 million or cumulative gifts of \$5 million

- Changes in University equity or royalty holdings
- New University-held licenses

Who must disclose

- Individual disclosures of financial interest should be filed by:
 - Executive officers
 - Members of the Board of Regents
- Other disclosures are event-based, and include:
 - New licenses and royalty or equity holdings, which should be disclosed by the Office of Technology Development
 - Business contracts for goods or services in which the University generates revenue in excess of \$1 million, which should be disclosed by college or department generating such revenue
 - All single donations to the University exceeding \$1 million or cumulative donations exceeding \$5 million in value which should be disclosed by the Office of University Development

How to disclose

Annual disclosures of Significant Financial Interests (as defined in the University's Individual Conflict of Interest policies) must be filed by executive officers, vice presidents and members of the Board of Regents. Disclosure forms required of those individuals by the state ethics commission should also be submitted to the respective campus Provost by June 18th of each year. The provost for each campus is responsible for collecting and maintaining records of such disclosures.

Event-base disclosures such as corporate donations exceeding \$1 million in value, contracts by which the University generates in excess of \$1 million in revenue and new licenses or equity holdings should be reported by the appropriate Dean or Vice President in sufficient detail to the appropriate Provost. Such disclosures should be made within a reasonable time after their occurrence, but in no event later than sixty (60) days following the acceptance of funds or change in equity or royalty status. The Provost for each campus is responsible for maintaining records of such disclosures.

Identifying Institutional Conflicts of Interest

Institutional conflicts of interest may be identified by cross referencing potential research engagements against the conflict of interest information disclosed. The Vice Presidents for Research on each University campus are responsible for cross referencing University research opportunities against the institutional conflict of interest information maintained by their respective Provost. If a potential institutional conflict of interest is identified, the Vice President(s) for Research shall notify the appropriate Provost, who shall evaluate and act upon the potential conflict in accordance with this policy.

All other employees shall promptly disclose any perceived, potential, or actual institutional conflicts of interest of which he or she becomes aware to his/her unit head(s) (chair, center director and/or dean) or supervisor in writing. The unit head(s) will notify the Provost, who will evaluate and act upon the potential conflict in accordance with this policy.

III. Managing Institutional Conflicts of Interest

While there should be presumption against allowing research to proceed when an institutional conflict of interest exists, such as presumption can be overcome if a management plan is developed that can appropriately address the conflict. The following steps are recommended for developing a management plan, and are described in greater detail below:

- Factual inquiry performed by Provost
- Factual report and recommendation to either eliminate or manage the conflict made by Provost to an ad hoc committee
- Ad hoc committee review of Provost's report and recommendation
- Ad hoc committee's adoption of a management plan that allows for complete elimination of the conflict, or acceptable management of it
- Implementation of the management plan

Upon receipt of a notice of a potential institutional conflict of interest, the Provost shall oversee an initial inquiry as to the facts of the situation. The inquiry shall include information regarding related individual conflicts of interest, if any. A report containing these facts as well as a recommendation to either eliminate or manage the institutional conflict of interest shall then be made to an ad hoc committee.

The ad hoc committee should be comprised of two executive officers of the University of Oklahoma appointed to serve by the President, a representative from the Office of Legal Counsel, from each campus office of the University Senior Vice President and Provost, and two member from outside organizations appointed to serve by the Chair of the Board of Regents. The ad hoc committee shall be called to meet by either the Norman campus or Health Sciences Center Provost as needed.

Upon receipt of the factual report and recommendation from a Provost, the committee shall consider the recommended plain to either eliminate or manage the institutional conflict of interest with the following considerations in mind:

- The welfare of any human participants involved in the research
- The integrity of any research process involved
- The effect of the institutional conflict of interest on the University's reputation
- The effect of the institutional conflict of interest on the individual researcher's reputation

Additional considerations may be provided for the ad hoc committee's perusal, such as those articulated in Appendix B for management plans involving intellectual property. The ad hoc committee shall review all considerations when developing the management plan.

The committee's adopted plan should provide sufficient detail to allow for complete elimination of the conflict, or acceptable management of it. Such a management plan may include, but is not limited to, potential actions set forth in the University's Individual Conflicts of Interest Policies.

Plans for eliminations of the conflict should be provided to the Provost for implementation. If the Provost disagrees with the ad hoc committee's recommendations, the Provost may, after consultation with the President, appeal the committee decision to a subcommittee of the Board of Regents for the University, which shall be specifically formed for this purpose.

The subcommittee of the Board of Regents may review the written materials associated with the potential institutional conflicts of interest and make any investigation that it deems necessary. After considering all the facts and circumstances presented, the subcommittee may take any action that it believes necessary to preserve the integrity of the University, including an outright prohibition of the proposed research.

Plans for management of the conflict should be implemented in the following manner:

After development of a final, acceptable management plan and commencement of the activity,

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the appropriate individuals with oversight responsibility will regularly report, in writing, to the appropriate Provost on the effectiveness of the plan. The frequency of such reports shall be determined by the ad hoc committee, but generally shall be made at least annually.

If, during the conduct of the activity, the appropriate Provost determines that the conflict has not been properly managed or has become unmanageable, he/she will then determine if the activity should cease, require further modification, or require employee divestment of the conflict. If outside agencies require notification of conflict resolution and management, they will notified in accordance with their requirements.

IV. Additional Considerations

Representing the University as a whole

Any individual representing the University as a whole in any activity shall make reasonable efforts to avoid institutional conflicts of interest. This includes identifying, acknowledging, and mitigating any institutional conflicts of interest that may arise when representing the University's interest.

Institutional conflict of interest database

The respective Office of the Provost should compile all event-based disclosures into a searchable database. This database should be made available to the respective campus office(s) of research administration, the College of Continuing Education and other offices at the discretion of the respective Senior Vice President and Provost. The database should be referenced and used when considering any new sponsored research agreement.

V. Sanctions

Disclosure of institutional conflicts of interest-apparent, potential, and actual-.is required for all persons who engage in activities that may involve such conflicts. Among other acts or omissions, failure to fully disclose conflicting relationships and/or interests or to follow a prescribed management plan may be a serious breach of this policy and may be itself considered research or ethical misconduct.

Persons who violate this policy shall be subject to applicable University policies relating to research or professional misconduct by faculty and staff. With due regard to inadvertent violations, University sanctions may include, without restriction: reprimand, restitution, loss of pay suspension or dismissal.

Furthermore, persons who violate this policy also may be subject to civil and criminal penalties for violations of state or federal law, e.g., civil penalties for willful violations of state laws may reach \$50,000.00 or more per violation.

Allegations against an employee for breach of this policy should be reported in a confidential writing to the appropriate Provost and, if against a staff employee, the appropriate executive officer.

VI. Appendix A

For all management plans involving intellectual property developed at the University, the following considerations, if applicable to the situation, should be addressed by the ad hoc committee:

- Any research agreement with a company may not contain any restrictions on publication, including student theses or dissertations, other than those sanctioned by the Faculty Handbook;

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- All individuals working on research project should be provided prior written notice that the research is being sponsored by a company in which a faculty member has an ownership interest, fiduciary relationship, and/or serves as a scientific officer or is on the board;
- Faculty members should provide the Provost and any other appropriate committee or University office a written description of the proposed research and a written assurance of his/her compliance with the restrictions set forth above;
- Faculty members should provide the Provost and any other appropriate committee or University office written reports on the progress of the research, listing related peer-reviewed publications and grants at least annually;
- Faculty members shall follow all management measures required under the management plan and as deemed appropriate by the Provost.

