

**Guidance: Managing Conflicts of Interest  
When Investigators Have Financial Interests or Operational Roles  
in Companies Sponsoring University Research**

**PURPOSE**

Faculty or staff are sometimes among the key personnel on a research project that is funded by a business entity. The purpose of this document is to provide guidance regarding roles and relationships of key personnel with the business entity that are incompatible, or unlikely to be compatible, with sound conflict of interest management. As used here, *key personnel* are those having responsibility at the university for the planning, conduct, or reporting of the research.

**BACKGROUND ON DISCLOSURE AND MANAGEMENT OF CONFLICTS OF INTEREST**

Members of the faculty or staff may be involved in business activities that are separate from, and also related to, their scholarly work at the university. Such activities can be complementary to, and noncompetitive with, conduct of university research, teaching and service (see Rules and Procedures of the Faculty (R&P), Section 2.5) and can play a role in deriving social and economic benefits from the outcomes of university research.

The initial steps in managing conflicts of interest are their identification and disclosure. Conflicts of interest are defined in university policies, specifically the University Conflict of Interest Policy and the Policy on Disclosure of Investigator Significant Financial Interests Related to Sponsored Projects. This document should be read in the context of these policies. These policies have forms for the disclosure of conflicts of interest on an annual schedule and/or on a case-by-case basis as conflicts of interest arise. Pursuant to R&P Section 2.5, conflicts of interest must also be disclosed annually, and approval must be obtained prior to taking on a role of principal or officer in a company.

A conflict of interest exists whenever there is reasonable concern that a financial stake or operational role in a non-university enterprise could substantially affect a person's judgment in carrying out the responsibilities of planning, conduct, and reporting of research. A conflict of interest is considered to be *manageable* when, with practicable assistance and oversight, such reasonable concerns can be allayed. Whether a conflict of interest is considered manageable depends upon factors including the nature of the person's relationship with the business and role in its operation, as well as the nature of the research project.

Decisions about management of conflicts of interest in sponsored research are made by the University's Conflict of Interest Review Committee (CIRC). For each case, the CIRC works with investigators to arrive at a sound conflict of interest management plan. This document describes circumstances to be avoided in all cases because they will seldom, if ever, be deemed to be compatible with sound conflict of interest management. Additional limitations may be necessary to arrive at a sound management plan in a given case.

## CONSIDERATIONS

### Key personnel

Key personnel on a university research project are obligated to apply academic standards when making judgments regarding planning, conduct and reporting of research. The role of the Principal Investigator (PI) includes responsibilities in addition to those of other key personnel: The PI has responsibility for setting overall direction in accord with the aims of the project, for holding others accountable for their roles, for allocating and accounting for resources, and for meeting obligations to the sponsor such as reporting. As such, the PI can be more vulnerable to unmanageable conflicts of interest than are other key personnel.

### Fiduciary duty

Certain roles in the operation or management of a company carry with them *fiduciary duty*, i.e., a legal *obligation* to act in the best interests of the company. Having such an obligation can change the nature of a conflict of interest from one that might be manageable with appropriate discipline, support and monitoring, to one that cannot readily be managed.

Roles such as Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, and many other managerial roles carry with them a fiduciary duty. Some others, such as Chief Scientific Officer, if limited to, at most, only *advising* those making decisions on behalf of the company, and as such do not carry with them a fiduciary duty.

### Delineation of roles

By definition, a conflict of interest involves the potential for situations in which the interests of the company and the interests of the academy and the university may conflict. One key element of a manageable conflict of interest is that conflicted person is able to conduct one role at a time, carrying out each without compromise. As such, certain combinations of roles are to be avoided. For example, if a person with a fiduciary obligation to a company were to serve among the key personnel on a university research project sponsored by that company, there is significant risk of encountering situations in which the person is forced to compromise in performance of one role or the other.

### Ownership and other financial considerations

When a person is a substantial owner of the company, the person may reasonably feel obligated to act in the best interests of the company, as if having a direct fiduciary duty.

Similarly, a person who has undertaken substantial personal debt or transferred substantial personal funds, such that the ability to repay debt or recover funds is dependent upon the performance of the company, may reasonably feel obligated to act in the best interests of the company, as if having a direct fiduciary duty.

## **GUIDANCE**

The following roles in and relationships with a non-university entity are generally incompatible with service as one of the key personnel on a research project sponsored by the entity:

Area	Roles generally incompatible with service as key personnel*
Grant or contract oversight	Serving among the key personnel on behalf of the company on a grant or contract where funds from that same grant or contract provide for any portion of the company's support for the university research project.  Serving in any other role at the company which would reasonably be expected to include oversight of the university research project.
Fiduciary obligations	Chief Executive Officer, Chief Operating Officer, and equivalent roles in which the person is bound to direct operations, allocate resources and/or make commitments in the best interests of the company  Entering into any agreement by which the person is bound to act, without suitable exceptions, in the best interests of the company  Membership on the company board of directors with more than 49% of votes.
Ownership and other financial considerations	Controlling shares in the company, i.e., ownership interest exceeding 35% (or equivalent though convertible debt or other instruments) or giving rise to control of over 35% of shareholders' votes.  Placing personal assets exceeding \$10,000 at risk in the operation of the company.

\* Limitations apply collectively to the investigator and members of the investigator's immediate family. Members of the immediate family should not serve in the roles described, nor should the total among immediate family members of votes or ownership exceed the amounts shown.

## **OTHER DOCUMENTS**

- University Conflict of Interest Policy, Policy on Disclosure of Investigator Significant Financial Interests in Sponsored Projects and Addendum for projects sponsored by the U.S. Public Health Service <https://research.cc.lehigh.edu/research-integrity>

## **HISTORY**

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