Approaches to Developing an Institutional Conflict of Interest Policy - Section One

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SECTION ONE: Defining Institutional Conflicts of Interest (What is It?)

In its examination of financial conflicts of interest, the AAU defined conflicts of interest as:

The term individual financial conflict of interest in science refers to situations in which financial considerations may compromise, or have the appearance of compromising, an investigator’s professional judgment in conducting or reporting research. The bias such conflicts may conceivably impart not only affects collection, analysis, and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants, and the use of statistical methods.

In discussing institutional conflicts of interest AAU sets its definition in the context of how these conflicts may occur:

An institutional financial conflict of interest may occur when the institution, any of its senior management or trustees, or a department, school, or other sub-unit, or an affiliated foundation or organization, has an external relationship or financial interest in a company that itself has a financial interest in a faculty research project. Senior managers or trustees may also have conflicts when they serve on the boards of (or otherwise have an official relationship with) organizations that have significant commercial transactions with the university. The existence (or appearance) of such conflicts can lead to actual bias, or suspicion about possible bias, in the review or conduct of research at the university. If they are not evaluated or managed, they may result in choices or actions that are incongruent with the missions, obligations, or the values of the university.

Taking a similar approach of identifying where conflicts may occur can assist a university in determining how to begin the development of policies and procedures that address institutional conflicts of interest. It can help suggest what constituent groups should be represented on a policy committee, who should be consulted or should review drafts of policies, and how to build a university process of approval.

The areas described below do not make an exhaustive list. It is offered to encourage a broad consideration to help inform the policy development process. Conflicts can occur as a result of the following:

a. Major Gifts from Commercial Sponsors.
   Significant gifts to the University or to any of its departments, colleges, research institutes, etc., from a commercial sponsor of research may raise questions about the influence of the company on the University’s research
programs and how they are managed. Other similar concerns arise when individual companies sponsor research or provide significant consulting income to a significant number of faculty members within a single department.

i. Gifts, or promise of gifts, in exchange for favorable terms on a technology license, or first look at IP may also pose a problem.

ii. Alumni venture funds that provide that a portion of revenue be “contributed” to the university must be carefully scrutinized for creating ICOI conditions – whether real or perceived.

b. Financial Interests acquired in connection with the Licensing of University Technology

The University has an active program to license its inventions to commercial entities. Under these licenses the University typically acquires a financial interest in successfully developed products and, sometimes, in the developing entity itself. These financial interests can be of concern when they may appear to influence decisions about the conduct of research, teaching or patient care activities. For example, even where individual investigators do not have a personal stake, knowledge that the University stands to gain financially from successful development of a licensed technology can influence the direction of related research, the objectivity of research, the dissemination of results and the allocation of University resources among competing projects. The potential for conflict increases where the licensee sponsors research at the University. In such situations the University’s financial interests under the license may appear to alter decisions concerning the terms or conduct of the sponsored research. Special cases include allowing specific departments or colleges to invest in technology development directly.

i. Non-Endowment Equity Interests in Start-up Companies. In licenses to start-up companies the University often accepts equity in lieu of licensing fees, or in exchange for reduced royalties. From a financial viewpoint, the potential gain from holding equity may far exceed the potential return from a royalty-only license. The potential for significant gain, and the possibility that it may be realized long before any product comes to market, increases the possibility that such an equity interest may influence or may appear to influence University decisions about research that could affect the value of the University’s equity position. Such arrangements must be carefully evaluated and managed to insure that research decisions are not influenced by the University’s potential for realizing financial gain.
ii. The proper role of university employees hired specifically to encourage faculty start-ups and to advocate for start-up companies as well as broker financial relationships with fledgling enterprises. These employees and functions create special exposure for universities and the perception of ICOI.

c. Master Agreements with a Company Sponsor:
   Because of the research strengths at certain universities, companies have offered long-term funding support for research conducted by a department or college. This support, often governed by a master agreement, may give special preferences to the company. Some universities build advisory committees or collaborative arrangement with companies through membership associations that provide special access to research results. These arrangements and the contracts or agreements that support them may include provisions that will create the appearance of conflicts.

d. Research Involving the Use of Human Subjects
   The University has special responsibilities to patients and participants in human subjects research and must ensure that its financial relationships do not compromise its primary obligations to them. For this reason, some Universities will not accept or engage in certain specified financial relationships involving human subject research or patient care, and will subject other types of relationships to close scrutiny to assess whether the particular financial relationship may affect or may reasonably appear to affect either human subjects research or patient care conducted at or under the auspices of the University.

   i. Clinical trials or human subjects research sponsored by companies in which the institution has an equity or proprietary interest in the company, e.g. a license even though no royalty stream has yet been realized (NPV of the potential royalty stream).

e. Procurement of Goods and Services from Corporations in which the University has a Financial Interest.
   Purchasing goods and services from companies that sponsor research at the University, or who are licensees of University technology, can sometimes raise issues similar to those raised by large gifts from commercial sponsors.

f. University Participation in Economic Development Corporations or Venture Capital Funds.
   Universities sometimes establish entities or participate in organizations designed to support or fund new business ventures or to promote local economic development. When such organizations support companies that are a licensee of University technology or in which University faculty members have significant involvement, conflicts can arise between the
interest in promoting economic development and the University’s primary interests in research and teaching. Active investment by the University in ventures that are developing University technologies can raise significant concerns about whether research agendas and the conduct of related research at the University may be improperly influenced by the desire to protect the University’s investment.

g. Roles of Trustees and Officers
Advisory Board or Board of Trustee members (or other university officials), in the course of meeting their obligations and duties to the university may get early knowledge of university technologies. Some of these same members may hold a management role or board seat on companies’ Board of Directors looking to license technology or sponsor research at the university.

Depending on the local context, not all of the situations described above will be determined to be a situation that leads to institutional conflicts of interest. However, a thorough review of the areas where institutional financial conflicts of interest may occur will help frame the next steps in the development of an effective policy.