

Individual and Institutional Conflict of Interest: Policy Review by Research Universities in the United States*

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ABSTRACT: *This paper is a discussion of efforts to manage real and potential conflicts of interest in university research in the United States. The focus is on the report by an Association of American Universities (AAU) task force that addresses both individual and institutional conflict of interest issues.*

Background

Issues of conflict of interest have assumed increasing importance for research universities in the U.S. as collaboration between those universities and business and industry has increased.

Funding for university-based research by business and industry has grown dramatically in recent decades. In 1970, industry investment in university research was \$61 million. By 1980, that figure had increased by nearly four-fold to \$236 million. Since then, it has grown even faster. In the year 2000, industry investment in university research stood at \$2.31 billion.

The adoption in 1980 of the so-called Bayh-Dole Act, named after the two sponsoring senators Birch Bayh and Robert Dole, has had a profound effect on universities' technology transfer activities.¹ Through this legislation, the federal government turned over to the universities the property rights for any discoveries or inventions resulting from research funded with federal dollars. The legislation was intended to ensure that the results of university research would not sit on the shelf but be developed into useful products, processes, and practices through knowledge and technology transfer.

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The Association of University Technology Managers (AUTM) reports that, prior to 1980, fewer than 250 patents were issued to U.S. universities each year; little was done to commercialize discoveries. By 1999, 3,914 new license agreements were signed, as reported by AUTM. Between 1991 and 1999, “annual invention disclosures increased 63% (to 12,324), new patents filed increased 77% (to 5,545) and new licenses and options executed increased 129% (to 3,914).”²

As the universities began to pursue possible patents and licensing arrangements, or taking equity positions in new ventures, members of the U.S. Congress began asking questions about conflict of interest. Among them was then-representative Albert Gore, Jr. AAU was asked to investigate the issue, and established the Clearinghouse on University-Industry Relations that operated between 1983 and 1986. The clearinghouse issued two reports: “University Policies on Conflict of Interest and Delay of Publication” (February 1985),³ and “Trends in Technology Transfer at Universities” (July 1986).⁴

Federal regulations governing conflict of interest in university research date to 1995, when the U.S. Public Health Service and the National Science Foundation issued joint rules. But the agencies do not regulate university conflict of interest directly. Rather, they leave it up to the universities to develop and administer their own conflict of interest policies. The Public Health Service requires universities, before they spend money from a federal research award, to report if there are any conflicts of interest and to assure the agency they have been managed, reduced or eliminated. The National Science Foundation requires universities to report conflicts of interest only if the university has not been able to manage, reduce, or eliminate them.

While these regulations apply only to funding from these two agencies, all universities have implemented standards and most apply these procedures to all of their federally and non-federally funded research projects.

But this flexibility in the process has raised new questions in recent years as technology transfer activity has grown.

The media have taken significant interest in conflict of interest, and so has the public.

The issues of conflict of interest have ended up dealing both with *real* conflicts of interest, and with *perceptions* of conflict of interest. In a situation where the universities’ roles are heavily dependent on public perception, and the way those perceptions can drive political action, it has become important to deal effectively with both reality and perceptions. The transparency of the safeguards against conflict of interest has become very important as well as the effectiveness with which those safeguards are actually applied.

Two years ago, the leading public and private research universities in the United States represented by the Association of American Universities (AAU) decided to address the issues of conflict of interest again. The word “again” is key because, as mentioned earlier, the issues have been on both national and institutional agendas at least since the 1980s. The leadership of the AAU felt that it was important for the universities themselves to continue to take a strong stand on conflict of interest, and to try to make sure that individual universities addressed the issues.

AAU has been working closely with the Association of American Medical Colleges (AAMC) in addressing the issues of conflict of interest. AAU's perspective has been the entire university research enterprise, and especially the role and responsibilities of the university presidents in ensuring that effective policies and procedures are adopted and implemented.

The Report of the AAU Task Force on Research Accountability

It is useful to consider an overview of the main points of the report on conflict of interest that was issued by AAU in October of 2001.⁵

The report was prepared under the auspices of a special task force, co-chaired by Presidents Steven Sample of the University of Southern California and Dennis Smith of the University of Nebraska. Presidents Mary Sue Coleman of the University of Iowa, George Rupp of Columbia University, and Harold Shapiro of Princeton University, and Chancellor Robert Dynes of the University of California, San Diego, also served on the task force as did a number of research and legal officers of AAU universities.

The task force divided its task into two parts: Individual conflict of interest and institutional conflict of interest. In regard to the former, since much has already been done on this topic, the task force offered some policy and procedural refinements, and reported on some practices that had proved useful in various universities. In regard to the latter topic, the task force provided a set of principles and guidelines. Further refinements of the recommendations concerning institutional conflict of interest will follow after a workshop for that purpose that took place on May 1, 2002.

Individual Conflict of Interest

The task force adopted a definition of individual conflict of interest that was based on one developed by the AAMC in 1990:

“The term conflict of interest in science refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's professional judgement 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.”⁶

The heart of the matter is: How can a university avoid having the financial interests of individuals influence the conduct and administration of research?

The task force further defined the scope of its analysis as follows:

- Conflict of interest will be considered across all academic fields, not just biomedical ones (though biomedical conflicts have some unique aspects and invoke a special intensity and interest);

- The analysis will center on financial conflicts of interest in research, and exclude conflicts of commitment and non-research and non-financial conflicts, which bear separate scrutiny;
- Conflict of interest for individuals primarily concerns faculty, but also addresses other officials and staff involved in research administration; and
- Financial conflicts of interest involving individuals in senior positions (such as presidents and chancellors, departmental chairs, deans, provosts, and trustees) have a somewhat different character, and will be addressed in the section on institutional conflict of interest.⁷

The task force took pains to emphasize that knowledge discovery and technology transfer are extremely important, not only to the individual investigator and institution but also to patients and their families, in the case of clinical research, to industry, and to society at large. The group stressed that conflict of interest arises in the context of the highly desirable goal of bringing the fruits of research to society, because it requires close relationships between universities and industry.

How big is the problem? Why is action needed?

In recent years, journal and news articles and statements and reports by government officials have raised questions about how well universities are managing their responsibilities regarding individual conflict of interest. As was mentioned earlier, these responsibilities were defined in regulations promulgated by two major federal agencies in 1995. One question is whether all arrangements that give rise to individual financial conflicts of interest can be *managed*, or if some should be *prohibited*. Another question is whether the interests of *human participants* in research should be integrated into financial conflict of interest policies and processes.

The task force answered these questions in this way: Many conflicts of interest can be managed, but conflicts of interest involving human participants in research should be prohibited, except under very special circumstances.

The task force summarized a set of operating guidelines:

- Financial conflicts of interest in research require robust campus management systems;
- Many financial interests are not conflicts, and many conflicts can be managed;
- Research involving human participants requires special scrutiny;
- Treat research consistently, regardless of funding source;
- Disclose financial information to the institution;
- Disclose financial information to publications;
- Disclose financial information in oral presentations;
- Disclose financial information to federal agencies;
- Disclose financial information in the human participant review process;
- Increase the resources available for enforcement.

The key is disclosure and effective systems for judging and managing the financial arrangements that are disclosed!

The task force also investigated and summarized a number of management practices that were reported as working well in some institutions, including some specific recommendations concerning:

- The appointment and use of committees with some outside representation; and
- The importance of educating participants in the research process about policies and procedures, and concerning various aspects of disclosure.

Institutional Conflict of Interest

Let me now turn to institutional conflict of interest, an area where the task force – by its own judgement – broke more new ground than in regard to individual conflict of interest, and where more work is needed and being undertaken.

The task force adopted the following definition of institutional conflict of interest:

“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 a related organization (such as a university foundation) 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.”⁸

There are thus two major categories of institutional conflicts of interest.

The first category involves university equity holdings or royalty arrangements, on the one hand, and the choice of research projects to be pursued and their actual pursuit on the other hand. This category includes a category of special concern: The potential bias in decisions concerning research where the university holds equity positions in, or has royalty arrangements with, corporations developing university inventions (perhaps start-up companies based on university inventions). The institutions financial gain can be pitted very directly against its research priorities.

The second category involves university officials who, on the one hand, have financial interests in corporations with which the university does business and who, on the other hand, make decisions with institution-wide implications. To some extent, this second category can be considered a hybrid between individual and institutional conflict of interest. Since the decisions being made are institution-wide, the category has been included under institutional conflict of interest.

What is at stake?

The task force believed that some of the most fundamental responsibilities of universities were at stake. These responsibilities include the commitment to educate students, the commitment to academic freedom, including open and timely communication of knowledge, and ultimately the fundamental responsibility of advancing knowledge and understanding of the natural world and our human condition free from financial (and of course also political, religious, and cultural) considerations.

The complexities of the task were somewhat simplified by adopting a three-fold mantra that went as follows:

- Disclose always.
- Manage the conflict of interest in most cases.
- Prohibit the activity when necessary to protect the public interest or the interest of the university (as defined by the responsibilities just mentioned).

The subject of institutional conflict of interest is not well developed. Once the task force had agreed on a definition of institutional conflict of interest, the group recommended a series of steps for universities to follow.

The first step for each university is to develop and publicize clear policies, and to establish administrative processes to address the issues. It is essential to designate a group at the university that would have authority to review the institution's, and its main administrative leaders', financial relationships with outside entities. Such a group may have outside representatives to increase its credibility. As disclosures are made to the group, it would assess potential conflicts, weigh risks and benefits, and take action regarding institutional conflicts that it identified. It would subject conflicts involving humans as patients and/or subjects of research to special scrutiny. It would also consider the degree of liquidity of the institution's financial holdings, since the less liquid they are the more the university's assets in a company can be affected by research and other decisions made by the institution.

The review groups play a major role, because that is where the proper judgement is going to have to be exercised. The options available to the review groups include:

- Modifying the financial arrangements;
- Establishing special monitoring procedures to ensure the integrity of the research;
- Establishing a "firewall" between the financial and the research decision making in the institution; and
- In extreme cases, simply prohibiting the proposed research.

In the end, the task force emphasized the importance to every university of establishing a proper atmosphere of openness and integrity. That is the only way to ensure the credibility of an institution. The policies and procedures are all a means to that end.

The task force also stressed the importance of continued dialogue between the major partners in the research enterprise, the universities and the federal government. As the research enterprise continues to develop with federal funding and collaboration between universities and industry, only continued vigilance will ensure that conflicts of interest can be managed properly, and the integrity of the research enterprise preserved.

Conclusion

In conclusion, let me repeat the task force's own conclusion and call to action:

- The Task Force was concerned that:
 - individual conflict of interest processes were not always achieving the highest standards, and
 - institutional conflict of interest policies had rarely been developed.
- The group concluded that the risks to the objectivity of research were large enough to require prompt action.
- The Task Force urges university leaders in the Association of American Universities to assess promptly the adequacy of their conflict of interest management systems, if they have not already done so.
- Today's ever-changing research environment requires continued vigilance to ensure that universities administer research as carefully as they conduct it. This is true for conflicts of interest as well.
- Finally, the partnership between research universities and their principal research sponsors, including the federal government, must be based on the conviction that universities are accountable for the research they perform.
- If research universities do not demonstrate their ability to maintain accountability for individual and institutional conflict of interest, more prescriptive approaches may well be pursued by either the executive or legislative branches of government, or both.
- The Task Force therefore urges universities to give prompt attention to reviewing and, where necessary, strengthening their conflict of interest policies and management processes.

REFERENCES

1. Public Law 96-517, the Patent and Trademark Law Amendments Act.
2. "Common Questions & Answers About Technology Transfer", Association of University Technology Managers report, November 13, 2000, http://www.autm.net/index_n4.html
3. *University Policies on Conflict of Interest and Delay of Publication*, Association of American Universities, Washington D.C., February 1985.
4. *Trends in Technology Transfer at Universities: Report of a Clearinghouse on University-Industry Relations*, Association of American Universities, Washington D.C., July 1986.
5. *Report on Individual and Institutional Financial Conflict of Interest*, Association of American Universities, Washington D.C., October 2001.
6. Ibid, p. 2
7. Ibid, p. 2
8. Ibid, p. 10