

Managing Conflicts of Interest

In recent decades, industry and academia (I/A) have increasingly forged research partnerships. Universities and their scientists have benefited from private-sector contracts, financial support, equipment donations, and the entrepreneurial ventures of faculty members. For corporations, these agreements have provided sustained access to trained students and to academic fonts of knowledge and creativity. One recent study of I/A partnerships found that up to 90% of biomedical-research companies had relationships with academia (New Engl. J. Med., 1996, 334 (6), 368). Another showed that companies in I/A partnerships had greater productivity than companies that did not have them (Coopers & Lybrand, L.L.P. Trendsetter/Barometer, Jan. 26, 1995).

This growing network of academic institutions and companies has raised questions about potential conflicts of interest (COI) and the objectivity of scientific research sponsored by corporations. "There is a growing indication that COI may be the Achilles heel of I/A partnerships," says physicist Thomas H. Moss, executive director of the Government-University-Industry Research Roundtable (GUIRR), which the National Academy of Sciences established in 1984 to facilitate a dialogue among federal, industry, and academic leaders on issues of mutual concern. "Though COI issues are not new," adds Moss, "they have reached a new level in the current context of multimillion-dollar research contracts, high-stakes intellectual property issues, complex financial dealings, and fast-paced technology development."

I/A partnerships experienced their strong growth after Congress passed the Bayh-Dole Act in 1980. The law permits government grantees and contractors to retain title to discoveries made with federal money and encourages universities to license discoveries made with federal funds to private industry. Bayh-Dole was enacted amid concern about declining U.S. productivity and competition from Japan.

From 1980 to 1998, corporate funding for academic research increased at an annual rate of more than 8% and reached

\$1.2 billion in 1998, according to preliminary numbers obtained from the National Science Foundation's Science and Engineering Indicators 2000 (<http://www.nsf.gov/sbe/srs/seind00/start.htm>). Before the Bayh-Dole Act, universities obtained about 250 patents a year; in fiscal year 1998, the number totaled more than 4,800.

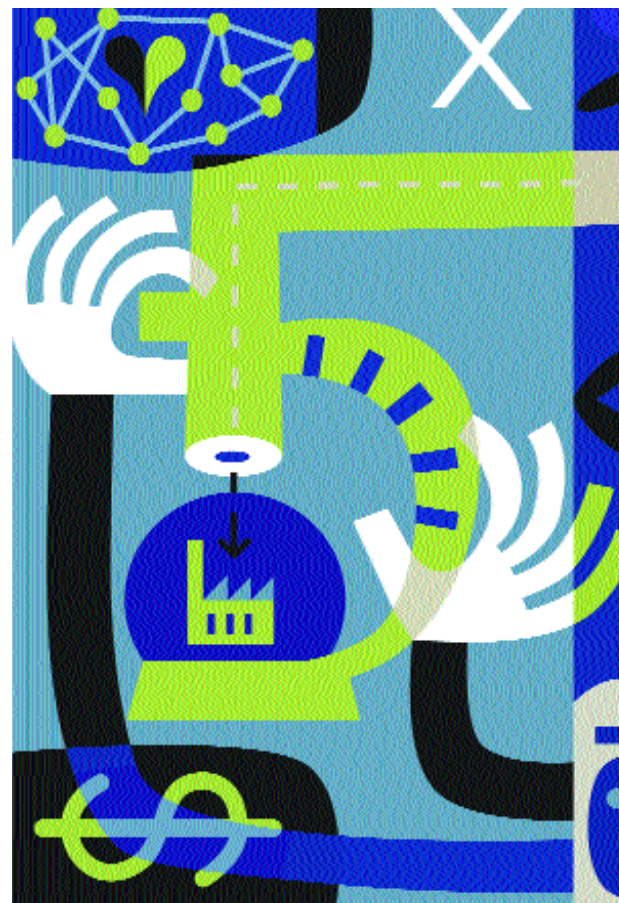
Partnership types

Today, most universities have a technology transfer office, and many participate in incubators and/or venture funds to help faculty convert their discoveries into companies; some even take equity in these companies. I/A partnerships take several forms. A company may fund a particular science or engineering project or compensate an individual investigator as a consultant. A consortium of companies may contribute to university-affiliated research or technology centers; or corporate, state, and federally funded academic investigators may collaborate on short- or long-term projects. There are also I/A-funded, university-based research parks, research grants from industry, partnerships in student training, exchanges of faculty and industrial employees, joint-use facilities, and sometimes, industry involvement in faculty recruiting.

California recently announced the California Nanosystems Institute, a partnership between the state, industry, and the University of California, Los Angeles, and Santa Barbara. The institute will receive \$100 million from the state over four years, and the two schools are expected to raise another \$200 million from other sources. Thirty companies, including Hewlett-Packard, Sun Technology, and the biotechnology firm Sequenom have pledged nearly \$50 million to support the venture. Another example is the Center on Polymer Interfaces and Macromolecular Assemblies (Palo Alto, CA), an R&D partnership involving Stanford University, the University of California, Davis, and IBM's Almaden Research Center.

The benefits of I/A relationships are

many. For example, universities can gain access to industrial facilities and databases, financial support for research that helps both partners, opportunities to tap into private-sector expertise, and the long-term benefits of experience and contracts. They also benefit from the technology and knowledge generated by focused, well-capitalized industrial research. Companies have proprietary technology and organized teams of scientists to address problems that univer-



sities might find difficult or inappropriate for graduate students in an academic setting. Universities also gain financial stability and exposure of their faculties and students to real-world problems. In addition, there is the hope of patent income.

Private-sector partners benefit from collaborative discoveries and the academic knowledge base. They also gain a window on the future of technology. I/A partnerships have been good for the country. A

recent article in *Science* (2000, 291, 553) reported that technology transferred from universities to industry in 1999 contributed \$38 billion to the economy and created more than 300,000 jobs and hundreds of new companies.

Concerns

I/A relationships have a downside, however. Some critics contend that universities risk endangering their primary role as

Ellen Sheridan, assistant vice president for research at the University of Chicago. Sheridan serves on the board of the Council on Governmental Relations, an organization of more than 140 U.S. research universities that is studying how to manage I/A COI.

Ethical conflicts can take various forms. For example, company-sponsored university scientists might show a bias in favor of reporting positive experimental results on company projects when publishing. The

research priorities of a department or an institution could be skewed toward the product needs of a company, focusing on areas that yield a quick payoff instead of on ideas that have no obvious or immediate commercial value. An academic department at the University of California, Berkeley, recently entered into an agreement with a large multinational corporation that gives the company the first chance at licensing any inventions it sponsors. The corporation's \$25 million in funding now accounts for more than one-third of the department's entire research budget. Some faculty and students have protested, contending that the agreement gives the company too much influence in departmental policies and decisions.

It is also possible for a professor or others in a university holding equity in a company to skew research to benefit the price of the company's stock.

Indeed, the U.S. Securities and Exchange Commission recently charged Dale Lange, a Columbia University professor of neurology, with insider trading after he made a \$26,000 profit from stock he bought in a company about to market a new drug. Lange had conducted the confidential clinical trials of the medication.

The biomedical sciences are not alone in the potential for I/A ethical risks. "I am aware of several situations, not all necessar-

ily at the University of Chicago, in which academic physicists with interests in companies committed to commercial development of their discoveries were confronted with problems concerning COI," says Sheridan. "Typical problems are choices in when to delay publication while companies establish their market edge; distraction of students and postdocs in the academic lab while they or their mentor are focused on problem-solving issues pertaining to the commercial product; assignment of projects to students that indirectly relate to the company's agenda for research leading to product development; the sharing of preliminary information with a specific company rather than openly sharing research results; and so on."

Endangering core values

An overemphasis on I/A relationships on campus may compromise core university values, such as the primacy of the educational mission, the role of the humanities, and the freedom to publish one's results or freely discuss them. Intellectual property can also become a problem and a source of tension in I/A partnerships. In one instance, the University of South Florida and an industrial sponsor accused a student of stealing the rights to a discovery the student had made as an undergraduate. The university spent 10 times the amount of the original research grant on outside legal counsel. In 1996, a state court found the student guilty and sentenced him to prison.

"What arises most frequently at MIT is that a faculty member may be a founder or part owner of a company based on MIT technology and would like the company to sponsor his academic research. We have specific policies prohibiting this," says physicist David Litster, vice president for research at the Massachusetts Institute of Technology. A COI also arises when faculty uses university- or government-paid time, resources, or facilities for for-profit activities.

Sometimes faculty can be pressured by a company to put off prompt publication of research results. Standard I/A agreements require delaying publication of research



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places of impartial scholarship, research, and social critique by aligning themselves with industry's priorities. Others say the biggest danger lies in the erosion of public trust in the objectivity of corporate-sponsored academic scientists and research.

"Where there is a link between discovery and commercial products—and these relationships exist in all disciplines—there also exists the potential for financial interests to conflict with academic values," says Mary

involving what could be considered proprietary information for one or two months, and some companies have even asked for delays of three to six months. A COI may occur when an investigator engaged in industry-sponsored research receives stock options or shares in the company, serves on a company's board of directors, or starts a

company and serves as its president. Undeclared consulting benefits, undetected data manipulation, unauthorized transfer of university intellectual property, or directing students toward fields that help a company also may constitute COI.

"The potential COI problem is growing rapidly in size and complexity, as many pro-

fessors have the 'Let's start a small company' bug," says John Rowell, an industrial physicist at Northwestern University and former chair of the American Physical Society's Forum on Industrial and Applied Physics.

Managing COI

The growth of I/A relationships may put universities on the horns of a dilemma. With all the inherent risks, should universities limit I/A collaborations, even when public funding of science and engineering research is declining? And if they do not, will I/A relationships get out of control and diminish public trust in the validity of scientific research? What about the growing tendency of academic institutions to measure their success in terms of their direct contribution to economic development instead of their educational responsibility to the public?

Any I/A collaboration carries the risk of ethical conflicts. In general, companies pay for research that benefits them and their shareholders. "The key issue here is finding the proper balance between appropriate entrepreneurship by academic inventors and the maintenance of the public trust in the responsible conduct of scientific research," says Sheridan.

For I/A relationships to succeed without incurring improprieties, they must be monitored and managed properly. One way to do this is "through the development of consistent guidelines and expectations for individuals, given the wide range of complex situations that arise," says Arthur Sanderson, vice president of research at Rensselaer Polytechnic Institute. "It's important to realize that COI does not, in itself, imply some wrongdoing. In fact, promoting entrepreneurial activities on campus creates COI as a consequence of success because exploitation of research ideas will make COI inevitable. The challenge is to manage the COI rather than to eliminate it."

Rensselaer is revising its existing guidelines covering intellectual property and other issues related to COI, and currently requires annual disclosure of any I/A involvement. Sanderson says the hard part is implementing guidelines in a detailed and comprehensive manner, "given the complexity of

technical, financial, and legal issues that may arise.” Most research universities and professional scientific and engineering societies have long-set policies for dealing with COI. “The problem is that many of the existing policies were not designed to handle the sort of complex situations that arise today, and they must be updated,” declares GUIRR’s Moss.

“The principal way we have of controlling COI at MIT is through transparency,” says Litster. “Every year, everyone is required to make a complete disclosure to their department head describing all outside professional activities, compensated or voluntary. This includes any financial interests they may have in companies sponsoring departmental research or involving their students in outside activities.”

Where guidelines are not current, too vague, or inadequately monitored, other solutions exist. A university could establish a separate research institute with its industrial partners that would isolate commercially sponsored research from academic work while allowing scientists and students to engage in both. One such example is the Center for Electronic Imaging Systems, a partnership between the University of Rochester (NY) and Eastman Kodak, Inc.

Help from outside

Another approach could be to create a new entity outside the university to hold equity and receive royalties. The ownership of equity by individual scientists in companies involved in I/A partnerships, especially when the research may have a direct impact on the stock price, is one of the more problematic COI issues. The new entity might correct this problem by holding and controlling equity in companies funding research at the university and making all decisions concerning that equity.

Other answers include enhanced oversight of potential COI and the setting of guidelines by an impartial, outside organization, such as GUIRR (<http://www4.nationalacademies.org/pd/guirr.nsf/>), the Association of University Technology Managers (<http://www.autm.net>), or the National Council of University Research Administra-

tors (<http://www.ncura.edu>). Guidelines allow university administrators to recuse themselves from formulating policies that affect their institutions financially, such as prohibiting faculty from holding equity in a company sponsoring research on campus or forbidding the universities to invest in these companies. Another solution would be to

prohibit university scientists from consulting and collaborating with the same company, thus more sharply delineating the boundary between industrial and academic work.

COI may be inevitable in university life, but if an institution sets, manages, and enforces a clear policy on these issues, I/A partnerships can be a boon to all. 