

Fact Sheet: Academia-industry-government relations in research

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Relationships between academia, industry, and government have grown due to many factors, including legislation and technological advances.

- Competitive pressures in the U.S. in the 1970s provided an impetus for legislation aimed at stimulating collaborative R&D efforts between the public and private sectors (1).
 - The Bayh-Dole Act (1980) gave universities the right to own intellectual property developed from federally funded research and, as a result, benefit economically from commercialization of its knowledge.
 - The Federal Technology Transfer Act (1986) created Cooperative Research and Development Agreements (CRADAs) that allow a private company and a government agency to work together on a project.
- The biotechnology revolution, that produced new commercially important DNA technologies, also sparked industry-academia relationships (2).
- Agency initiatives encourage public-private ventures:
 - The National Science Foundation (NSF) has multiple programs, including the Science and Technology Centers program that has established more than 50 active industry-university cooperative research centers since 1984 (3).
 - The National Institutes of Health (NIH) identified public-private partnerships as an important component of the NIH Roadmap, aimed at accelerating medical discovery to improve human health (4).
 - The Small Business Technology Transfer Program was created in 1992 to stimulate cooperative R&D and technology transfer involving small businesses and nonprofit organizations, including universities and Federally Funded Research and Development Centers (FFRDCs).
- The expectations of states are for universities and research centers to contribute to the growth of local economies.

The increase in academia-industry-government relationships is evident in the rise of university patents, collaborative publications, and collaborative research agreements.

- According to the Association of University Technology Managers (AUTM) survey of 198 U.S. universities, teaching hospitals, research institutes and technology investment firms, 7,921 new U.S. patent applications were filed and 3,933 patents issued in FY 2003 (5). Prior to the passage of the Bayh-Dole Act, university-generated patents were approximately 250 per year (6).

- Increases in the number of cross-sector co-authorships (articles with authorship affiliations in more than one of the following sectors: academia, industry, Federal Government, nonprofit institutions, FFRDCs, and state and local government) were steeper in biomedical research than in engineering, biology, chemistry, physics and mathematics (7). In biomedical research, the share of cross-sectoral articles increased from 18 percent in 1988 to 23 percent in 2001, equating to 5,010 cross-sectoral articles in 1988 and 7,991 in 2001 (3)—*See Appendix 1: Scientific collaboration and co-authorship.*
- The number of CRADAs increased dramatically after authorization in 1986 to 3,500 in 1996. Newly executed CRADAs have been stable at about 1,000 annually since FY 1997.—*See Appendix 2: CRADAs.*

Many different types of financial relationships exist between industry, academia, and government.

- Companies provide direct support for research projects at universities:
 - Of 210 life science firms surveyed in 1994, 90 percent had some relationships with academia. Of those, 59 percent provided research support and 38 percent supported the education of students and fellows through grants (8).
 - One-quarter of biomedical research faculty at major U.S. universities received direct research support from industry in 1995 (9).
 - Industrial R&D support to academic institutions has grown more rapidly (albeit from a small base) than support from all other sources during the past 3 decades (3). Although it remains a relatively small share compared to federal support, industry provided approximately \$2.3 billion to academic R&D in 2001 (3)—*See Appendix 2: Industry funding of academic R&D.*
- Technology transfer to industry and university spin-off companies: Since 1980, 4,081 new companies have been formed based on a license from an academic institution. In FY 2003, 120 institutions reported at least one start-up company for a total of 374 new companies that year (5).
- Academic investigators translate their knowledge to industry via consulting and advisory board membership:
 - The 1994 survey of life science companies revealed that of the 90 percent that had a relationship with academia, 88 percent of those retained faculty as consultants, the most prevalent relationship (8).
 - Research faculty at top U.S. universities reported that 50 percent had consulted for industry in 1995 (10).
 - Disclosure forms at a single institution (UCSF) found that 34 percent had speaking engagements, 33 percent had provided consulting, and 32 percent had advisory board positions for companies (11).
- Industry provides research-related gifts and materials independent of research contracts. Almost one-half of academic investigators at top research universities surveyed in 1994 and 1995 had received research-related gifts in the previous 3 years, including equipment,

biomaterials, discretionary funds, student support, or travel funds. The most frequently received gift was biomaterials. Sixty-four percent of the scientists that received gifts reported that they were important to the progress of their research (12).

- Equity relationships: Equity is an important mechanism for small companies to provide compensation for services. There are no comprehensive publicly available data regarding the personal financial benefits for individual scientists (13). However, disclosure forms at a single institution (UCSF) found that 7.6% of investigators had financial ties with sponsors of their research and 14% held equity (11).
- Government researchers also engage in relationships with industry, although there is a lack of data on the extent of these relationships (13).

Many important benefits and consequences are derived from scientific collaborations between academia, industry, and government.

- The worldwide public benefit and its access to the availability of new products and services that are developed from joint research collaborations. The role of university research has been found to be especially critical to the biotechnology and pharmaceutical industries (14, 15). Collaboration between industry and academia has led to many important therapies and research tools such as gene splicing technology that initiated the biotechnology industry, diagnostic tests for breast cancer and osteoporosis, and vaccines. AUTM reported that 2,230 products were made commercially available through institutional licensing activities from FY 1998-2003 (5).
- More student and faculty research projects are focused on “real” industry and societal problems.
- There are more consortium research programs at universities that have as participating researchers from several institutions, industry and often from different agencies in the federal government.
- AUTM reported that 188 institutions total FY 2003 sponsored expenditures were \$38.525 billion that was up by 10.1 percent from fiscal year 2002 (5). Of the reported 10.1 percent increased in sponsored research expenditures, expenditures on federal government supported projects increased 14.8 percent from FY 2002 and expenditures of industry-funded projects rose 5.2 percent in FY 2002. (5, pg. 3).
- Academic laboratories benefit by increased resources for research funding, materials, and equipment to support on-going projects. Although not the most prevalent type of relationship, direct funding from industry was viewed as the most important to academic institutions because they provided resources to support ongoing investigations by faculty and trainees (9).
- Of the institutions reporting data for AUTM’s FY 2003 survey, these institutions incurred approximately \$200 million in legal fees in addition to the expenses each of the

institutions incurred for the staffing and operations of their technology transfer offices (5). Net license income received in FY 2003 by 194 institutions was \$1.310 billion and running royalties on product sales were \$1.125 billion for 189 institutions (5). Any royalties that are retained by the institution are required by Bayh-Dole to be used to support the research programs at the institutions. Often these revenues are used to support students, purchase equipment, and provide seed funding for new research projects.

- According to AUTM, the U.S. universities reported cumulatively 25,979 licenses and of these 151 are generating more than \$1 million (5). In addition 65 percent of licenses to large companies from U.S. universities are non-exclusive; 57 percent of the licenses with small companies are non-exclusive; and 6 percent licenses with start-up companies are exclusive (5).
- Consulting relationships with the inventor of a licensed technology is often beneficial in order to facilitate the development of the technology into a product. The drug industry, for example, rates consulting and informal channels of communication just as important as patents and contract research (16).

However, these relationships are increasingly faced with serious challenges, including financial conflicts of interest, which may have negative consequences.

- A commonly cited definition of conflict of interest is: “set of conditions in which professional judgment concerning a primary interest (such as a patient’s welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)” (17)—a circumstance and not behavior.
- There is evidence supporting the belief that deepening commercial ties can undermine academe’s commitment to openness. For example, industry-funded results may be less likely to be published (18) or delayed even longer than that required to file a patent (9). Other restrictions include denial of access to research data or biomaterials (18, 19).
- Financial relationships between academic institutions and industry have raised doubts as to the ability of institutions to monitor faculty conflicts of interest objectively (20, 21)
- Financial interest in or funding by a company with activities related to an investigator’s research is associated with pro-industry conclusions (22). Industry funding may cause bias, or it may be that industry selectively funds research likely to yield favorable conclusions. There is a bias towards positive outcomes more generally in all biomedical research irrespective of sponsorship.
- Graduate student progress may be inhibited. Surveys of university faculty (23) and trainees (24) described several types of problems that are encountered when students are involved in industry-sponsored research, including suppression of data, fewer

publications or delays in publications of manuscripts and dissertations, and constraints in the type of research that is conducted.

- The most intense scrutiny of academia-industry and government-industry relations focuses on risks to human patients. High profile cases, such as the death of Jesse Gelsinger in a gene therapy trial at the University of Pennsylvania, highlight the need for protection of human research participants. However, the number of scientific misconduct accusations submitted annually to the Office of Research Integrity has not risen dramatically and none since 1994 have involved academia-industry interactions (25).

Conflict of interest is regulated by the federal government,...

- Code of federal regulations (5 CFR Part 50 Subpart F) established standards for institutions to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be biased by any conflicting financial interest of an investigator. PHS guidelines provide *de minimus* standards for disclosure while allowing research institutions the discretion in managing conflicts. The threshold for disclosure is \$10,000 in annual income or equity in a relevant company or 5 percent ownership of such a company.
- The Food and Drug Administration (FDA) regulations state that investigators that receive compensation in excess of \$25,000 from a corporate sponsor of a trial in which the investigator is engaged must disclose to the FDA at the time of filing for a new drug application.
- NIH has requirements for grantees and their institutions based on the PHS regulations (26), while NSF (27) and other scientific grant-making agencies have separate policies.

...academic institutional policies,...

- Surveys show that institutions' conflict of interest policies vary widely but most are more extensive than federal regulations (28, 29, 30).
- Federal requirements are flexible to allow institutions to implement them in ways that meet their individual needs. However, the lack of uniformity and clarity in academic institutional conflict of interest policies may lead to unnecessary confusion among investigators and industry partners (28).

...and biomedical journal policies.

- Journals, major gatekeepers of research results, began adding disclosure requirements in their instructions to authors in the 1980s. Biomedical journals were among the earliest to implement these in their instructions to authors.
- A 1998 survey (31) of conflict of interest disclosure policies of top journal found:

- Thirty-three percent of medical journals had policies requiring disclosure of conflicts of interest from authors.
- From all journals that responded, 72 percent of editors reported that they always or almost always publish disclosures
- Seventy-seven percent share financial interest disclosures contained in the manuscript with reviewers and 54 percent expect reviewers to evaluate the manuscript
- Thirty-six percent request financial conflict of interest information from reviewers and 49 percent from editors
- Journals varied in the specific types of financial relationships that required disclosure.

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Appendix 1: Scientific collaboration and co-authorship

Co-authorship of science and engineering (S&E) articles reveals the changing social structure of the conduct of scientific research. In most fields, articles are increasingly authored by research teams that span academic departments or institutions, cross-sectoral boundaries, or include international collaborators. Collaboration on S&E articles, as measured by articles with more than one institutional author, has increased significantly in the past 2 decades.

Scientific collaboration across institutional boundaries in the United States is extensive and has continued to intensify. The share of coauthored articles increased from 48 percent of all U.S. articles in 1988 to 62 percent in 2001. The level of institutional collaboration by field, in terms of the share of coauthored articles, was highest in clinical medicine, biomedical research, the earth and space sciences, and physics, and lowest in chemistry, psychology, the social sciences, and the professional fields.

Cross-sectoral collaboration: Government policies have reinforced collaboration by requiring or encouraging collaboration as a condition of research funding and by announcing programs targeted to encouraging cross-sectoral collaboration.

As Table 1 illustrates, articles with authors from different institutional sectors accounted for more than one-third of the academic sector's coauthored articles and more than three-fourths of those of the other sectors in 2001. The academic sector was at the center of cross-sectoral collaboration, represented in more than 80 percent of the articles originating in other sectors.

U.S. cross-sectoral collaboration, 2001

(Percent)

All fields				Federal	Nonprofit		State/local
Sector	All sectors	Academic	Industry	Government	institutions	FFRDCs	government
Academic	37	na	26	32	37	11	6
Industry	76	83	na	17	17	6	3
Federal Government	80	87	15	na	15	5	4
Nonprofit institutions	79	91	13	13	na	2	4
FFRDCs	80	85	14	14	7	na	0
State/local government	92	86	12	20	23	1	na
Biomedical research				Federal	Nonprofit		State/local
Sector		Academic	Industry	Government	institutions	FFRDCs	government
Academic		na	22	34	45	7	4
Industry		86	na	16	19	4	2
Federal Government		90	11	na	14	4	2
Nonprofit institutions		93	10	11	na	3	2
FFRDCs		81	13	18	15	na	2
State/local government		86	11	18	18	2	na

na not applicable, FFRDC federally funded research and development center

NOTES: Shares based on whole counts of publications, where each institutional author on a coauthored article is assigned a whole count. This counting methodology results in the sum of sector shares exceeding 100 percent because some coauthored articles involve collaboration across more than two sectors.

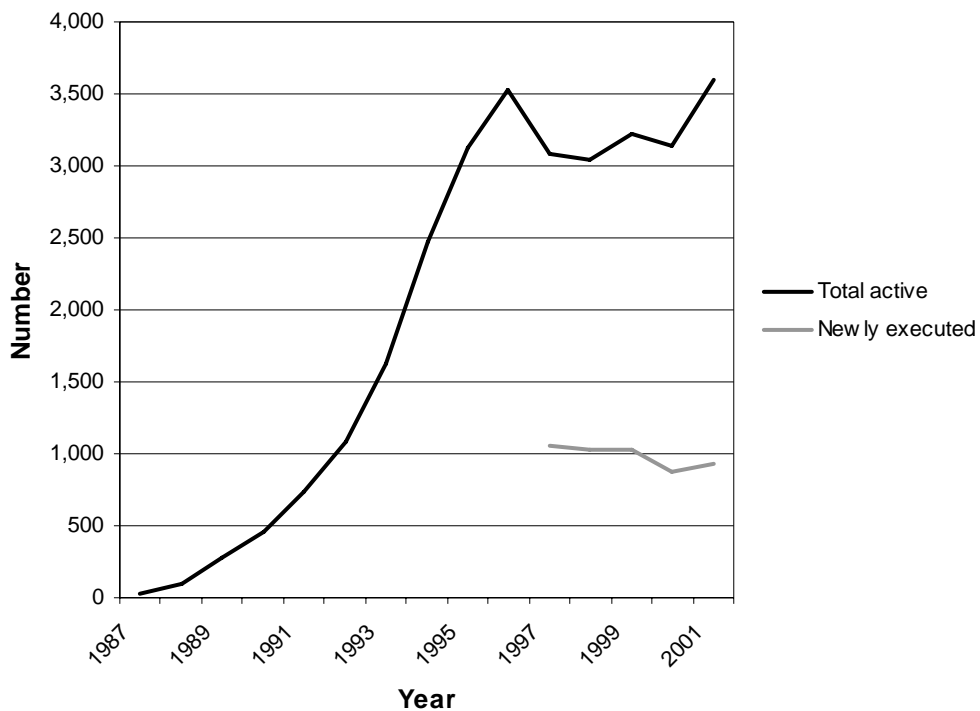
SOURCES: Institute for Scientific Information, Science Citation Index and Social Sciences Citation Index; CHI Research, Inc.; and National Science Foundation, Division of Science Resources Statistics, special tabulations. See appendix table 5-42.

Science & Engineering Indicators – 2004 (Table 5-41)

Appendix 2: CRADAs

In Cooperative Research and Development Agreements (CRADAs), Federal laboratories may share or provide personnel, services, equipment, or facilities, but not funds, with or to a private organization as part of a joint R&D project with the potential to promote industrial innovation consistent with the agency's mission. Private partners may retain ownership rights or acquire exclusive licensing rights for the developed technologies.

Federal Laboratories in Collaborative Research Agreements: Two indicators of Federal laboratories' participation in research alliances show selected features of these activities: the first identifies their industrial focus, and the second describes Federal agency participation in CRADAs. The 10 Federal agencies reporting technology transfer activities to the Department of Commerce executed 926 new CRADAs with industrial and university partners in FY 2001, bringing the number of active CRADAs to 3,603. Three agencies accounted for more than 80 percent of active CRADAs in FY 2001 include DOD (54.5 percent of all CRADAs), DOE (15.4 percent), and HHS (13.6 percent). The FY 2001 increase in active CRADAs was driven by increases in DOD and HHS CRADAs.



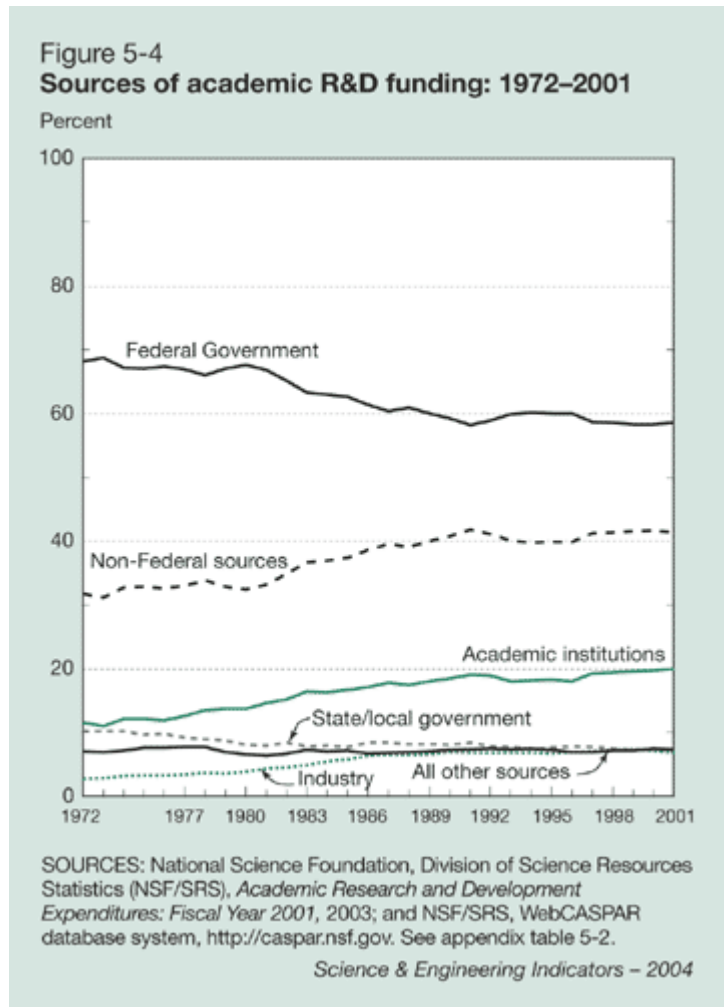
Compared with other forms of technology transfer activities, cooperative research activities, both CRADAs and non-CRADA joint R&D projects, involve a number of additional managerial and organizational requirements for both agency and company.

Source: NSF Science & Engineering Indicators 2004

Appendix 3: Industry funding of academic R&D

The academic sector relies on a variety of funding sources for support of its R&D activities. Although the Federal Government continues to provide the majority of funds, its share has declined over the past 3 decades, with most of the decline occurring during the 1980s. In 2001, the Federal Government accounted for 59 percent of the funding for R&D performed in academic institutions, compared with 68 percent in 1972.

In 2001, industry provided 6.8 percent of academic R&D funding-- approximately \$2.3 billion dollars-- to academic R&D, compared with 2.8 percent in 1972. Despite the recent decline, the funds provided for academic R&D by the industrial sector grew faster than funding from any other source during the past 3 decades. However, industrial support still accounts for one of the smaller shares of funding, and support of academia has never been a major component of industry-funded R&D.



Corporate R&D Strategies in an Uncertain Economy: The Industrial Research Institute (IRI), a nonprofit association of more than 200 leading R&D-performing industrial companies, has surveyed its U.S.-based members on their intentions for the coming year with respect to R&D expenditures, effort allocation, personnel, and other items. Because IRI member companies carry out as much as three-fourths of the industrial R&D in the United States, the results from these surveys help identify broad trends in corporate R&D strategies. The most recent survey (2002), suggests that many companies are shifting the focus of their R&D spending from directed basic research and support of existing business to new business projects. This reported shift in R&D priorities also is reflected in how responding companies intend to spend their R&D budgets. IRI survey respondents reported the following strategic shifts:

- Decreased outsourcing of R&D to other companies
- Increased outsourcing for university R&D and Federal laboratories

- Increased participation in alliances and joint R&D ventures
- Increased acquisition of technology capabilities through mergers and acquisitions

Overall, these strategic moves are consistent with responses suggesting tighter R&D budgets and lower targets for R&D/sales ratios. In the midst of an uncertain economy and technology market, companies are moving to leverage the value of their R&D spending through alliances and collaborations as opposed to contracting out their R&D to other companies.

Source: NSF Science & Engineering Indicators 2004