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ABSTRACT

This document provides a detailed assessment of the opportunities and challenges facing university-industry research collaborations. This report represents a synthesis of the work and findings of this initiative. It analyzes several of the critical issues facing research collaborations between industry and universities and offers suggestions to make these collaborations more effective. The Bayh-Dole Act of 1980 was passed to improve the transfer of university research to private companies capable of translating advances into new products and services for consumers. Research collaborations can offer direct benefits for university and company participants, but there are several barriers to collaboration, including practical considerations and the conflict of values. Of the many ingredients in successful negotiations between companies and universities, mutual trust is perhaps the most important. In addition, a balance must be found between the need of university researchers to share their findings and the need of companies to protect the value of their investments through confidentiality. Indirect costs are yet another issue that companies and universities must resolve. Appendixes list panel participants from the study of collaboration and provide tables of university research expenditures and licensing income tables. (SLD)

Working Together, Creating Knowledge

The University-Industry Research Collaboration Initiative

BUSINESS–HIGHER EDUCATION FORUM

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Co-Chairs' Foreword

Developments during the past decade highlight the reality that we are living in a time of truly historic transformation–one that is rooted in the rise of a knowledge society based largely on the collaborative generation and use of information. With the end of the Cold War, the emergence of globalization, and the evolution of the Internet and the "new economy," the creation, application, and free flow of new knowledge have never been more important drivers of change. Enabling this transformation is an explosion of scientific and technological advances across disparate fields. This progress is opening an exciting era of basic exploration that also promises to address age-old human problems of disease, poverty, and international security, as well as growing concerns about our global environment. In the long run, only more scientific and technologically driven innovation can provide the new, more powerful tools required to help ensure a better future for all.

Fostering collaborative partnerships in scientific research has emerged as a critical imperative to sustaining this innovation. The increasing volume and accelerating pace of knowledge creation has transformed the research process to the point where no one scientist, institution, or even nation can sufficiently conduct wholly independent research programs; rising costs, driven by increasingly complex research, make resource-sharing an imperative. Changes in the nature of innovation largely depend on multidisciplinary approaches and use tools from a range of seemingly unrelated fields.

Although collaboration among all parties involved in the research process is critical, the relationship between academic investigators and industry researchers has emerged as a particularly central driver in the decades since the passage of the Bayh-Dole Act of 1980. Intended to encourage the application of publicly funded research findings to produce economic and social benefits for American society, this act and subsequent public policies have encouraged a marked upsurge in university-industry research collaborations. These partnerships have contributed to America's resurgent competitiveness in the global economy while promoting economic growth at regional and national levels—effectively leveraging, rather than replacing, the more extensive federal and state support of fundamental research on the nation's campuses.

Yet if the opportunities for and benefits from conducting university-industry research collaborations have soared, so have concerns about their effects and implications. The rising number, pervasiveness, variety, and importance of these partnerships have heightened their impact while raising the stakes involved. As universities pursue additional funding sources and companies seek continued competitive advantage—and as both try to keep up with the accelerating pace of change—these partnerships have become an increasingly critical means toward achieving key objectives. Yet they also threaten to distort the traditional role of universities as arbiters of knowledge and guarantors of objectivity in the public interest. As our economy evolves and its growth occurs at a more regional level by new, knowledge-fueled businesses and industries in a more entrepreneurial environment, the impacts of collaboration extend well beyond the direct partners. Underlying changes in science and technology raise new problems and hurdles. From ownership of and access to intellectual property to potential conflicts of interest in a world where once-clear lines now seem blurred, these issues have swelled in prominence and importance.

Some research collaborations have experienced serious, high-profile difficulties, with participants voicing frustration over complex issues that impede advancing research and realizing its benefits. Certain observers have voiced concerns about the broader implications of university-industry partnerships, suggesting that they be curtailed to avoid the destruction of core missions, particularly on the academic side.

Two years ago, the Business-Higher Education Forum decided to undertake a detailed assessment of the opportunities and challenges facing university-industry research collaborations. Our goals were to understand better the issues involved, to highlight best practices and lessons learned, and to provide practical guidance to those involved in such partnerships—particularly the new, inexperienced practitioners who are now entering into research collaborations. Our underlying premise was that thoughtful, balanced, and useful guidance would increase the number and quality of research collaborations. We approached this assessment knowing that other parties already have focused substantial attention on this topic; in fact, the Forum itself played an important role in the early development of thinking in this field. Given the opportunities and challenges now facing these critical research partnerships, the Forum's Research Collaboration Initiative (RCI) provided a unique venue for pulling together many perspectives and synthesizing these views into a common voice. At the same time, we sought to increase mutual understanding across sectors by enabling study participants to hear how others view these issues.

With these goals in mind, we sought to collaborate with those active in this field, from research-driven federal agencies and the National Academies of Science and Engineering, to associations such as the Council on Governmental Relations, to public policy groups including the Council on Competitiveness. We also reached outside the Forum's membership to involve leading research universities and innovation-driven companies. We conducted our work using a variety of tools, including surveys and workshops on specific issues, participation in external meetings, case studies of actual partnerships and institutions, and periodic deliberations of the RCI Task Force and the full Forum membership.

This report represents a synthesis of the work and findings that have occurred during this initiative. Given both the scope of issues involved and speed of ongoing developments, it is necessarily incomplete—indeed, since the beginning of this two-year effort, the prominence and urgency of these issues has increased. We also realistically appreciate that this initiative has identified concerns and has stemmed thinking in critical areas that will require further work, and that not all problems can be resolved in all partner relationships. Yet it is our hope that beyond giving practical guidance and insights, this report also will provide a foundation and framework for sustaining an ongoing dialogue among academia, industry, and government. This dialogue must occur if we are to ensure a balanced, pragmatic approach toward establishing and conducting university-industry research collaborations. Such a continued dialogue and approach will allow our nation and the world to realize the promise of innovation through the benefits that these partnerships can offer, without undermining the basic strengths or compromising the core missions and values of the parties involved.

On behalf of the RCI Task Force and the Forum Membership, we would like to thank the Office of Naval Research, along with the Kellogg and Hewlett Foundations for their financial support of this effort. Our gratitude also goes to the American Council on Education and the National Alliance of Business for providing staff, office, and logistical support to the RCI. Special

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Table of Contents

Co-Chairs' Foreword 3
RCI Task Force Members 6

Executive Summary 11
Summary of Recommendations 16

Chapter One
Introduction 19
University-Industry Interactions 21
Why Collaborations Are Important 21
What the RCI Is and Is Not Studying 24

Chapter Two
Two Cultures: Barriers to University-Industry Research Collaborations 27
University Barriers 27
Corporate Barriers 29
Maintaining a Balance 30
SPOTLIGHT: Washington University–Monsanto: Two Decades of Success 32

Chapter Three
Conflicts of Interest and Commitment 35
Conflicts of Interest and Commitment 35
Conflict Prevention and Control 38
SPOTLIGHT: Berkeley-Novartis: A Rough Road to Success 44

Chapter Four
Negotiating Agreements 47
Laying the Groundwork 47
Contracts 48
Confidentiality 50
Publication Delays 52
Indirect Costs 53
Intellectual Property 55
Licensing Terms 57
Background Rights 60
Research Tools 63
SPOTLIGHT: Biolex, Inc.: What a Technology-Transfer Office Can—and Can't—Do 68

Chapter Five
University Best Practices: Building a Research Collaboration Team 71
Organizing for Success 71
Motivating Faculty 73
Protecting Students 74
Marketing the University 74
Management and Support Assistance 75
Working as a Team 77
University Structure and Leadership 78
SPOTLIGHT: Office of Naval Research: A Government–Academia–Industry Collaboration ... 80

Chapter Six
Corporate Best Practices: Making Collaborations a Core Competency 83
Leadership and Vision 83
Managing Research Collaborations 87
SPOTLIGHT: Ribozyme Pharmaceuticals, Inc.: The View from a Smaller Company 93

Appendices
A. Panel Participants and Interview Subjects 97
B. University Research Expenditures and Licensing Income Tables 106

Executive Summary

This paper analyzes several of the critical issues facing research collaborations between industry and universities and offers suggestions to make these collaborations more effective. It is not intended to provide an exhaustive analysis of every issue confronting these collaborations, but it should be useful to inexperienced as well as experienced practitioners in both sectors.

Universities and companies in the United States have worked together to advance the frontiers of knowledge and incorporate that knowledge into new products, processes, and services since the Morrill Act of 1862 established the land-grant college system. For many years, however, the results of university research were not always expeditiously transferred to private companies capable of translating advances into new products and services for customers.

The Bayh-Dole Act of 1980 was passed to rectify this situation. Since the Act's passage, the commercial environment has markedly changed. Today, the extraordinarily successful growth of the "new economy" has transformed the way business is performed and economic growth is generated, placing even more emphasis on the pursuit, development, and integration of new knowledge. In 1998, corporations sponsored nearly $2 billion in research at universities, or about 9 percent of all research performed at U.S. colleges and universities. Many local and state governments are also pursuing the economic development benefits of industry-university partnerships. At the same time, concerns have been raised that these partnerships may threaten the integrity, objectivity, and core mission of academic research.

Research collaborations can offer direct benefits for university and company participants. Even when potential partners have the resources and knowledge to accomplish individual goals, working with outside experts can greatly improve the quality and comprehensiveness of the research and can help reduce its costs. Furthermore, many scientific advances are now occurring at the intersection of traditional fields. Industry-sponsored research also allows the university to obtain financial support for its educational and research missions, although the licensing of university technologies has not proven to be a substitute for federal research funding.

Barriers to University-Corporate Research Collaborations

Corporations and universities are not natural partners. Their cultures and their missions differ. Companies' underlying goals—and the prime responsibilities of top management—are to make a profit and build value for shareholders by serving customers. Universities' traditional missions are to develop new knowledge and educate the next generation.

For the university, four factors can prevent research collaborations with industry from being established or successfully accomplished: the practical difficulties of negotiating and managing a collaboration; possible deleterious effects on faculty and students; possible impact on the mission, reputation, and financing of the university; and state or local officials' expectations of university contributions to regional economic development. Hurdles that companies must overcome to foster greater numbers of collaborations include respecting the value of research collaborations; incorporating university research into product development; and management barriers.

Some university leaders (and many faculty) are concerned that collaborations with industry could threaten the essence of what it means to be an academic institution. While universities must compete to attract collaboration partners, they must also guard against devolving into contract research organizations, indebted to their sponsors and dependent upon revenues from sponsored research and licensing fees.

Conflicts of Interest and Commitment

The evolution of science—particularly biomedical science—over the past two decades has dramatically increased the possibility of conflicts of interest on the part of university researchers. Therefore, virtually all research universities now have policies aimed at monitoring and managing such relationships to prevent abuses, and many entities are asking whether these policies should be updated.

The mere *appearance* of a conflict of interest does not constitute wrongdoing, and conflict of interest does not automatically lead to scientific misbehavior. The purpose of conflict-of-interest policies is to prevent or control situations that might lead to inadvertent and unacceptable bias, to suspicions of wrongdoing, or to actual wrongdoing. At the same time, because our national innovation system demands close cooperation to succeed, potential conflicts can never be fully eliminated and must be managed.

Financial conflicts of interest arise when scientists' private financial interests and their research converge in a way that might call into question their ability to make unbiased decisions related to their work. Perceptions of a conflict of interest can damage the research enterprise by weakening public trust—a particular concern for research universities, which heavily depend on federal research funding.

Conflicts of commitment are generally defined as anything that might interfere with a faculty member's full-time duties. Many universities have formal policies limiting the amount of time that a faculty member can spend engaged in outside activities.

Institutional conflicts of interest, also called conflicts of mission, are a newly emerging source of concern. Some universities invest in start-up firms or accept equity in lieu of royalties on university-held patents, raising concerns that they might become beholden to a company in which they have a financial stake. Ultimately, developing multiple funding sources can help protect universities from becoming indebted to any one entity.

Most current conflict-of-interest policies at U.S. universities follow the patterns of federal regulations, although they significantly vary in the depth of the disclosures they require and in their thresholds for examining potential conflicts. Strategies for managing a conflict usually depend on the details of each case. Options can include divesting troublesome assets, ending consulting arrangements, withdrawing the researcher from the project, independent review, and disclosing significant financial assets in any published report on the research. A useful strategy for preventing potential conflicts involves ongoing education, aimed both at faculty members and at graduate students who hope to become practicing scientists.

Clinical trials are a special case, because lives are at stake. While many procedures exist to safeguard these trials, the array of protections is now being reassessed in many areas. Conflict-of-interest policy is only one element of the human-subject protections that surround clinical trials, but it is a particularly important element. Clinical trials depend on the willingness of patients to take part in those trials, which in turn, depends on the patients' trust in the clinical researchers who are running the trials.

As university officials, researchers, and the companies with which they collaborate study these conflict-of-interest issues, they should recognize several basic principles: The core values of academic freedom must be maintained; industry funding cannot, and should not, be viewed as a substitute for adequate, long-term public financing of basic scientific research; universities and companies should seek transparency, clarity, and consistency in identifying actual and potential conflicts of interest; and all research participants should continue their adherence to the scientific method in order to preserve public support for academic research.

Negotiating Agreements

Of the many ingredients in a successful negotiation between companies and universities, mutual trust is perhaps the most important. Negotiations generally proceed more quickly and easily when both sides are familiar with each other's needs and desires and don't worry that their partner may try to take advantage of them. Involving experienced people in the negotiation can also smooth and expedite the process. A master contract can be an effective way to avoid plowing the same ground when two long-time partners negotiate agreements covering individual projects. Model agreements can also speed the negotiation process, although they are difficult to develop and implement because business practices in different industry sectors—and even within the same company—demand disparate agreements.

Confidentiality

The ability of faculty researchers to discuss their work with colleagues and to publish their results is a cornerstone of the academic enterprise and supports the creation of new scientific knowledge. Nothing should be done to put this at risk. At the same time, companies have a legitimate need—and fiduciary responsibility to their shareholders—to protect the value of their investments.

Companies recognize that universities are not the best places to try to keep secrets. To that end, various strategies are used to protect confidential information. Individual researchers may be asked to sign confidentiality agreements, while sometimes institutional signatures are used. The challenges and consequences of maintaining confidentiality are particularly acute in the case of students, and universities differ in their ability to manage this process. Ultimately, responsibility for maintaining confidentiality lies with both sides.

Reasonable publication delays to secure intellectual property protection are usually acceptable to universities. Since much university research is actually performed by graduate students, it also is important to keep their academic needs in mind. The "standard" publication delay is 60 to 90 days, but universities report that they are under increasing pressure to extend such delays. The advent of the Internet and e-mail may significantly alter the terms and conditions of publications.

Indirect Costs

Now called Facilities and Administrative (F&A) costs, indirect costs are the university's research costs over and above researchers' salaries and the costs of new materials. A July 2000 RAND Corporation report concluded that, over the past decade, universities had only been recovering between 70 and 90 percent of their federal F&A costs. Despite this, universities often face pressure from both companies and faculty to charge less than their federal rate.

Universities contend they have little flexibility because the federal government is pressuring them to charge all customers the same rate. Nevertheless, a university may negotiate with a company on indirect costs when, for instance, a company joins a university research center, or when the modest size of the research project allows the university to use standardized contracts, and thus save on administrative costs.

Intellectual Property

The most nettlesome area of negotiations is usually the ownership, value, and use of the intellectual property arising from the sponsored effort. When federal funding is involved, the Bayh-Dole Act vests ownership with the university, not with any corporate participants. In other cases, companies often want ownership so that they might manufacture, use, and sell products that emanate from the research. Universities often desire ownership to allow their faculties and graduating students to continue to work in the area, meet joint sponsorship obligations, ensure commercialization, meet federal tax regulations, and license the technology on a non-exclusive basis. In most cases, it is possible to construct arrangements that can serve the commercialization needs of companies while still vesting intellectual property ownership with the university. This situation does not necessarily hold true in the case of copyrights.

When collaboration negotiations are combined with a contentious licensing negotiation, they can be much more arduous. Therefore, collaboration partners often try to resolve commercialization terms quickly or, if that is not possible, to defer the negotiation of licensing royalty rates until the research is complete.

Background Rights

Background rights are the licensing rights provided to an industry partner by a university for "background intellectual property"—intellectual property developed by the university using funds from other sponsors, including the federal government. Companies seek rights to use these inventions to complete their intellectual property portfolios so that they have sufficient licensing rights to commercialize the results of the sponsored research.

Universities have a number of problems with providing background rights. Many faculty members strongly believe that the intellectual property of one faculty member should not be mortgaged for the benefit of another, or even to permit the institution to get sponsored-research funding. Merely identifying intellectual property that might be relevant is both time-consuming and expensive. Agreements on background rights usually include provisions that the university offer a good faith or reasonable effort to find potential conflicts, although these phrases can be open to legal interpretation. For these and other reasons, universities rarely sign binding agreements on background rights. Until now, there have been few instances in which background rights have become a major problem, but the issue may have a chilling effect in the future.

Research Tools

Research tools can be highly complex entities that themselves require research to develop, and access to publicly funded research tools is becoming one of the most contentious areas of university-industry relationships. The issue is whether these research tools will be licensed broadly or exclusively to one company, frequently a faculty start-up. The friction generated by this conflict poses a serious risk of souring the relationship between universities and companies that would like to see these tools licensed broadly.

In December 1999, the National Institutes of Health issued a set of guidelines for universities that develop tools with the help of federal funding. The guidelines discouraged patenting unless patent protection was necessary to attract investment needed for full development, urged that tools be licensed with as few encumbrances as possible, and argued against reach-through royalties—a practice in which the owner of a research tool seeks royalties on any product that might be developed through its use. Tool developers—often emerging biotechnology firms—argue that reach-through royalties are an alternative to charging high up-front user fees or restricting access.

Best Practices for Universities

The success of university research collaborations with industry sponsors depends above all on the interest and enthusiasm that faculty scientists bring to the joint research effort. But university administrations can promote collaborations by motivating their faculties to take part and by creating a customer-friendly environment for would-be corporate partners.

The administrative components of a successful program go by different names on different campuses, and their duties are sometimes combined at smaller universities. But they carry out the same missions wherever they appear. These key offices are: the Office of Sponsored Programs or Office of Research Administration, to establish and manage collaborations; the Office of Technology Transfer or Office of Technology Licensing, to decide when to seek patents and to negotiate patent-licensing agreements; the Office of Development, responsible for university fund raising; and the Office of Corporate Relations, which oversees the overall management of the university's relations with industry.

University researchers operate as independent contractors in selecting and accomplishing their research goals. Motivating and helping researchers locate potential collaboration partners require a sophisticated understanding not only of how researchers operate but also of individual researchers' focus areas, and of the companies that share their research interests. When technology-transfer, sponsored programs, or corporate relations officials are knowledgeable about faculty research interests, they can play a key role in pre-screening companies with which faculty might wish to collaborate. Deans, department chairs, and vice presidents of research are well-positioned to coordinate these efforts.

Finding new partners may be a promising tactic for universities that want to increase their industry collaborations. A corporate relations office can be particularly well-suited to the task of marketing the niche strengths of the university. The university president can play a constructive role in fostering greater numbers of collaborations. Proposing a well-thought-out plan, and providing specific ways in which the company can work with the institution, can be an effective sales pitch.

Communication is perhaps the most critical management issue in collaboration. Exchanges between corporate and university partners should be clear and direct. They should also be frequent. Meeting company deadline expectations is a recurring challenge. Although university administrative offices provide some help, ultimate responsibility for managing the university's participation in the collaboration lies with the researcher.

Traditional university hiring, tenure, and promotion practices do not always make allowances for industry-sponsored projects, and faculty who take part may risk weakening their academic career prospects. Universities should consider giving appropriate credit to university researchers who collaborate with industry.

Best Practices for Industry

Industry support for collaborations with universities has to start at the top—with a company's top executives. A research collaboration must meet business objectives, be specified in financial terms, and ultimately be accountable to the firm's stockholders. For this reason, the company—not the university researcher—will often select research priorities.

Some companies have established internal matching-fund programs to encourage a culture change toward external research. A supportive corporate culture also is important in deciding whether to engage in a specific collaboration. Establishing and maintaining an effective collaboration are time-consuming, and company decision makers should recognize that effective collaborations require the substantive involvement of key personnel.

Most university and industry research coordinators understand what type of research could be mutually beneficial. It should be ethical, publishable, basic, or slightly applied, and it should pair university expertise with company interests. University scientists' curiosity-driven basic research often opens lines of inquiry that—although still fundamental in nature—can help lead to therapies and technologies of value to society. Well-matched projects are usually non-proprietary and often have a longer lifespan than is typical in a corporate research lab.

The first and most important issue is establishing a research agenda that the company wants to support and the faculty member wants to perform. Managing a partnership requires scientists in both the university and the company to draw heavily on their team-management skills and puts a premium on clear communication, openness, and forthrightness. It heavily relies on the strength of personal relationships. When the partners are making roughly equal financial and/or intellectual contributions, decision making is almost always by consensus.

Tying university research to company schedules is essential to a successful collaboration. The company, the university, and the researcher should pay close attention to any timelines before agreeing to a project. At the same time, integrating research results into a company's strategic processes poses a major challenge.

The involvement of graduate students can both enhance and impede a collaborative industry-university research project. At the same time, graduate students and occasionally undergraduates are almost always going to be involved in university-industry collaborations. The biggest challenges posed by student involvement arise during negotiation of confidentiality and intellectual property terms. In most cases, however, a university-industry collaboration gives the company a chance to evaluate graduate students on the job as potential employees.

Frequent turnover of company project managers is the most disruptive personnel change that affects collaborative teams. However, personnel changes are a part of corporate life, so researchers must expect changes to take place and should plan accordingly.

To ensure success, a university-industry collaboration needs an "end-user champion"—someone within the sponsoring company who is dedicated to making the partnership work. This person must have the support of senior company research officials—and ultimately the CEO—to pursue external research opportunities.

Universities and their corporate partners must always keep in mind that research collaboration is not an end in itself. It is a means by which academic and industry scientists can advance their research and companies can quickly move new products into the marketplace—serving the interests of both participants, the pursuit of new knowledge, and society at large.

SUMMARY OF RECOMMENDATIONS

Negotiating Agreements

- When a university-industry research relationship is of sufficient magnitude, collaboration partners should consider negotiating master contracts. Universities also should consider developing model agreements for single research projects and ensure that the terms do not unduly disadvantage small and medium-sized companies.
- Confidentiality agreements, when necessary, should be signed by the company, the university, and the researchers involved. The company and the university must take responsibility for safeguarding confidential information. Publication delays to protect intellectual-property rights should generally be no longer than 60 to 90 days. Any publication delays should be carefully monitored both to preserve academic freedom and to protect against any early disclosure that might invalidate patent claims.
- Indirect costs are a legitimate expense of performing university research. In most cases, companies should expect to pay at least the negotiated federal Facilities and Administrative charge for the research they sponsor in universities.
- Although ownership and control of intellectual property resulting from a collaboration must be decided by the collaboration part-

ners, it usually will be appropriate for the university to retain ownership. Both parties should remain flexible during negotiations, and the key measure should be whether the corporate partner has the ability to commercialize the fruits of the research to the benefit of the public. Universities should update their copyright policies to allow industry sponsors to be granted licensing terms on a basis similar to that provided with patents.

- Collaboration partners should avoid engaging in contentious licensing negotiations during a collaboration negotiation, while preserving the ability of the university and its faculty to share in the benefits of successes. Should the partners agree to preset a royalty rate or range, the university should be mindful of federal tax regulations governing commercialization terms for sponsored research that takes place in buildings or uses equipment funded by tax-exempt bonds.
- Companies have legitimate reasons for requesting background rights to sponsored projects and, as part of their due diligence, should assist universities in locating potential conflicts. Universities have legitimate reasons for not providing background rights, but they should make a strong effort to do so when appropriate and feasible. Universities should closely consult with faculty and confirm that all contractual obligations can be met before signing binding agreements.

Best Practices for Universities

- Research collaborations must be based on the willingness and enthusiastic participation of individual faculty members. A university can assist faculty in finding new collaboration partners, but should do so based on faculty interest, the research strengths of the university, and industry research opportunities. Hiring, tenure, and promotion processes should give appropriate credit to university researchers who collaborate with industry.
- Universities should coordinate the efforts of the various offices that support university researchers in their work with companies and, where appropriate, should consider co-locating them. The university campus president should establish a cooperative tone toward university-industry research collaborations and should align incentives to encourage teamwork and promote research collaborations.

Best Practices for Industry

- Companies should encourage internal champions of research collaborations to identify potential university partners based on shared research priorities. To expedite this process, companies should make it as easy as possible for potential university partners to communicate with the company research organization, and should consider establishing a central coordinating unit for this purpose.
- Companies should strive to integrate university research collaborations into their product and service development process where appropriate. They should involve their business units in this process, manage the collaborations appropriately, and plan for the turnover of key company personnel. Wherever possible, the company should involve students in the collaboration. The company should modify its personnel evaluation systems as necessary to reward the establishment of internal and external interdisciplinary teams. To achieve results, company leaders must make a long-term commitment.

1

"We seek cooperative research relationships with industry not simply to generate royalty revenue and stimulate economic growth, but to create relationships with industry that will help faculty in pursuing their own research and in training graduate students.[1]"

—Richard Atkinson, president of the University of California

Introduction

Universities and companies in the United States have worked together to advance the frontiers of knowledge and incorporate that knowledge into new products, processes, and services since the Morrill Act of 1862 established the land-grant college system. The land-grant colleges gave rise to agricultural extension offices, designed to bring new agricultural methods and technologies to farm operations, and business–academia cooperation expanded early in the 20th century with close relationships between companies and engineering schools.

Prior to World War II, most of the best university research was performed in European universities, and much of the best fundamental research was performed in corporate research laboratories. During the war, however, the federal government began to provide significant funds for university research, and afterward, Vannevar Bush, science advisor to both Presidents Franklin D. Roosevelt and Harry S Truman, urged that the government should continue investing in university research. Bush's report, *Science: The Endless Frontier,*[2] led eventually to the establishment of the National Science Foundation in 1950.

Not until the Soviet Union launched the first Earth satellite, Sputnik, in 1957 did the level of federal funding for university research begin to match the rhetoric. From 1960 to 1966, driven largely by the space program, federal nondefense research spending grew from approximately $6 billion to nearly $35 billion* a year,[3] a sizable portion of which was spent on university research. After peaking in 1966, federal funding for nondefense research to this day has never dropped below $20 billion annually,[4] while substantially declining as a percentage of overall federal spending.

The results of this research, however, were not always expeditiously transferred to private companies capable of translating advances into new products and services for customers. A significant problem was that each federal agency had its own policies regarding patent ownership and the licensing of federally sponsored research performed in universities.

The Bayh-Dole Act of 1980 was passed to overcome this difficulty. In addition to setting a uniform federal invention policy, the act permitted universities to retain ownership of patents generated through federally funded research and encouraged universities to work with industry to commercialize university inventions.[5] As one measure of success, the Association of University Technology Managers estimates that university licenses helped generate more than $40 billion in economic activity in 1999.[6]

Since the passage of the Bayh-Dole Act, the commercial environment has changed markedly. Beginning in the early to mid-1980s, the United States became increasingly concerned about its international economic competitiveness. Today, the extraordinarily successful growth of the new economy has transformed the way business is performed and the means by which economic growth is generated, placing even more emphasis on the pursuit, development, and integration of new knowledge. As national leaders in the performance of advanced research, universities are collaborating with companies to advance both parties' common research agendas. Federal Reserve Chairman Alan Greenspan recently noted, "In a global environment in which prospects for economic growth now depend importantly on a country's capacity to develop and apply new technologies, our universities are envied around the world. The payoffs—in terms of the flow of expertise, new products and start-up companies, for example—have been impressive."[7]

* Figures are in constant FY98 dollars.

The rate of growth of industry-sponsored research at the nation's universities also has been impressive. Industry research spending at colleges and universities in 1997 was more than seven times greater (in constant dollars) than in 1970. During that period, industry spending on its own research and development (R&D) more than tripled, federal funding of R&D at colleges and universities more than doubled, and federal funding of government-conducted R&D stayed relatively constant.

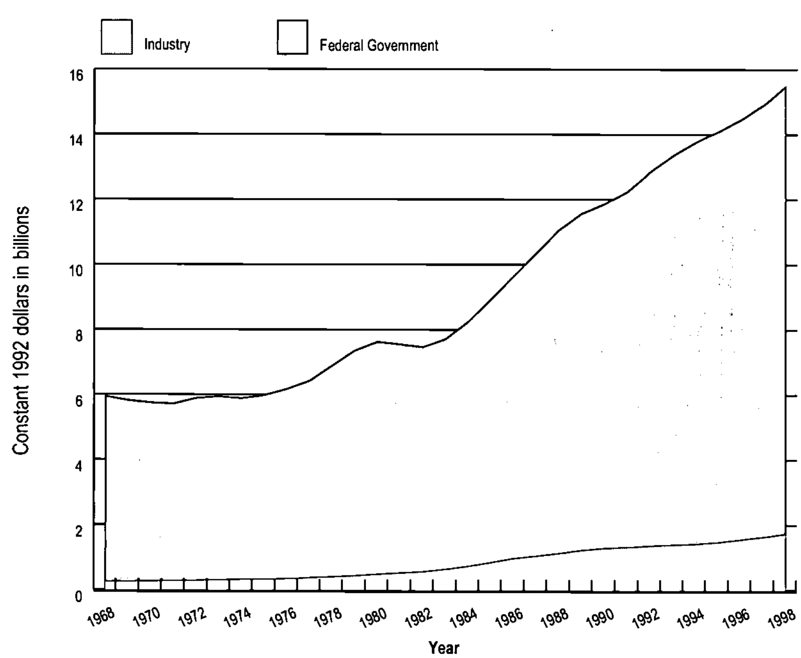
In 1998, corporations accounted for nearly $2 billion in sponsored research at universities, or about 9 percent of all research performed at U.S. colleges and universities. The federal government sponsored well over $13.5 billion in university research that year.[8] That same year, industry spent a total of $145 billion on its own R&D, more than $100 billion of which went to development activities. The remainder—a little less than $40 billion—was spent on basic and applied research,[9] a more likely area for university involvement. The Industrial Research Institute projects that industry funding of university research will more than double over the next 10 years.

Federal programs requiring collaboration and cost-sharing also are encouraging universities and companies to work together more closely.[10] Many federal programs now include industrial cost-sharing and collaboration—for example, the Advanced Technology Program of the National Institute of Standards and Technology, the dual use programs of the Department of Defense, and the Technology Reinvestment Program of the Department of Commerce. James MacBain, director for research relations at the University of Michigan College of Engineering, observed that the federally funded centers that include industrial liaison groups are "changing the way we do business."[11]

These closer research ties between academia and industry, and the connection between innovative research and regional economic development, have led many communities to promote academic research as a key component of their economic development strategies. Elected officials increasingly expect universities and community colleges to participate in regional economic development plans.

In 1998, corporations accounted for nearly $2 billion in sponsored research at universities, or about 9 percent of all research performed at U.S. colleges and universities.

Industry support for academic R&D has grown, but it is still dwarfed by federal support



Source: Association of American Universities, National Science Foundation.

UNIVERSITY-INDUSTRY INTERACTIONS

Research relationships are a subset of many different interactions between universities and companies. The Council on Governmental Relations has listed six research mechanisms through which universities and companies can work together:

- **Sponsored research:** The most frequent form of research relationship, which involves companies directly funding university research.
- **Collaborative research:** University-industry research partnerships that are encouraged through partial federal funding.
- **Consortia:** Groups of companies and universities engaged in various research efforts of common group interest.
- **Technology licensing:** Licensing of university patents (usually stemming from federally funded research) to companies for commercialization.
- **Start-up companies:** Usually involving university faculty, they often obtain licensing agreements to access university technologies.
- **Exchange of research materials:** Used to expedite the performance of research and accomplished through material transfer agreements.[12]

Of these six mechanisms, only the first three are fully *collaborative* in nature; the others involve the licensing of already-completed research for commercialization purposes. Interestingly, it is the licensing of university technology that is usually referred to as *technology transfer;* but true technology transfer is accomplished through all of these mechanisms, as well as through the use of faculty consultants and extension services. Even continuing education and graduate and undergraduate education can be considered a form of technology transfer, and the hiring of students by companies has long been considered one of the most important forms of technology transfer.

Within the area of research collaborations, there are additional distinctions based on the type of research performed. Ralph Christoffersen, president and chief executive officer of Ribozyme Pharmaceuticals Inc., pointed to one significant distinction: "[It is important to] distinguish between collaborations that are *research* collaborations, i.e., basic research carried out at a university in an area of interest to the industry partner, and collaborations that are highly *focused* and *applied* [collaborations], i.e., clinical trials."[13] Large clinical trials are so focused on the testing of already-developed technology that some practitioners barely consider them collaborations at all, and some do not consider them to be research.

Often, however, the distinction between basic and applied research is less stark. University scientists' curiosity-driven basic research frequently opens lines of inquiry that, although still fundamental in nature, are aimed at helping develop valuable new therapies and technologies. Thus, much research that might be considered "applied"—because it has a specific target—involves original investigations along paths that branch out from basic studies and are quite appropriate to a university's mission.

WHY COLLABORATIONS ARE IMPORTANT

Research collaboration is not an end in itself. It is a means by which academic and industry scientists can advance their own research and companies can move new products more quickly into the marketplace—serving the interests of both sides, the pursuit of new knowledge, and society at large.

Even when potential partners do have the resources and knowledge to accomplish individual goals, working with outside experts can greatly improve the quality and comprehensiveness of the research and can help to reduce its costs. "Joint technology development simply yields results neither group could have achieved alone," said Randolph Guschl, director of corporate technology transfer at DuPont Central Research and Development.[14] Or, as Hank McKinnell, chairman of the board and CEO of Pfizer Inc, observed, "All of us are smarter than any of us."[15]

Furthermore, many scientific advances are now occurring at the interfaces between traditional fields, heightening the rationale for collaborations.[16] "One principle that has become very evident from recent progress in molecular and cellular biology is that many of the most exciting discoveries involve teamwork requiring complementary sets of technical skills," wrote Nobel laureate Michael Smith of the University of British Columbia.[17] Universities are well positioned to contribute to this kind of interdisciplinary research. University researchers can tap many other funding, scientific, and humanities resources, on their campuses and elsewhere, that companies do not offer.

Another benefit that can flow from research collaborations is exchange of personnel. Just as one of the benefits to companies of research collaborations can be the recruitment of students, the partners may find university participants going to work for corporate sponsors and vice versa. During 20 years of collaboration between Washington University in St. Louis and the former Monsanto Company (now Pharmacia Corporation), each has "lost" employees to the other, and several researchers have moved from the university to key positions in other companies. Such exchanges provide each organization with valuable insights about the other's procedures and afford students the opportunity to learn from faculty with real-world experience. Michael Montague, director of research operations at Pharmacia Corporation, said that the greatest benefit of that company's relationship with the university was the move of Philip Needleman from the university's faculty to the company.[18] Prior to the Pharmacia-Monsanto merger, Needleman was Monsanto's chief scientist.

Industry Benefits

For companies, another major benefit of research collaborations is the opportunity to leverage research resources to gain access to external sources of expertise in a cost-effective fashion. In a 1995 report, the Industrial Research Institute cited the following motives for industry to pursue cooperative research agreements with universities:

- To access expertise not available in corporate laboratories.
- To aid in the renewal and expansion of a company's technology.
- To gain access to students as potential employees.
- To use the university as a means of facilitating the expansion of external contacts for the industrial laboratory.
- To expand precompetitive research, both with universities and with other companies.
- To leverage internal research capabilities.[19]

University research can be useful to a company even if it does not lead directly to new products. "Many [of our] research and development activities have been accelerated very substantially by the information flow that has come about through the interface with outside parties," said Theodore Tabor, former manager of external research at Dow Chemical Company. "It enhances our own core competencies, and that has led to new business and technology platforms by opening up entirely new fields for [us] to pursue. Whether we use that technology right now or not, it's often very, very important to us."[20]

University Benefits

For universities, working with companies allows them to gain access to external sources of expertise and funding. The 1995 Industrial Research Institute report identified these motives for universities to enter cooperative research agreements with companies:

- To obtain financial support for the university's educational and research mission.
- To fulfill the university's service mission.
- To broaden the experience of students and faculty.
- To identify significant, interesting, and relevant problems.
- To enhance regional economic development.
- To increase employment opportunities for students.[21]

University faculty members benefit from the opportunity to be involved in exciting new businesses and the challenges of market-relevant areas of research. Many university researchers also find that corporate sponsorship imposes a smaller administrative burden than the voluminous grant applications required by the federal government. The additional visibility that research collaborations bring can also lead to peer recognition and, in some cases, future consulting opportunities.

Many state governments recognize that university-industry collaborations can play a central role in economic development efforts, by spinning off new high-technology start-ups and by attracting other R&D companies to high-tech corridors around universities.

Collaborations also provide university students with support during their education, opportunities for internships or employment afterward, and specific research knowledge along with real-world experience. This prepares them more effectively for their future careers and can be a recruitment draw for students and junior faculty.

In the 1980s, faculty entrepreneurs began to appear in large numbers in universities. They were interested both in cutting-edge science and in working with new or existing companies to develop their discoveries. Since their arrival, these faculty entrepreneurs have trained a whole generation of graduate students to seek entrepreneurial opportunities. Often, these newly minted researchers will "interview" a university's technology transfer office when they are being considered for faculty positions.[22]

Research collaborations also can elevate the university's prestige and create valuable connections between the university and its surrounding community. Carolyn Sanzone, assistant vice chancellor for strategic technology alliances at the University of Massachusetts, said the payoffs include identifying corporate advocates for the university in state-sponsored economic development efforts and establishing advisory councils to create a local atmosphere that encourages collaborations. In addition to the direct benefit for collaborations, these groups can enhance competitiveness for federal funding opportunities.[23]

In addition, many state governments recognize that university-industry collaborations can play a central role in economic development efforts, by spinning off new high-technology start-ups and by attracting other R&D companies to high-tech corridors around universities. Within the past few years, at least 21 states have committed or have been considering research and technology initiatives totaling $7.7 billion to enhance university research and to lure new high-tech investment, according to Rich Bendis[24], president of the Kansas Technology Enterprise Corporation, a state-sponsored agency that promotes new high-technology investment in Kansas.

Photograph Copyright University of Notre Dame

University of Notre Dame Professor Hsueeh-Chia Chang, standing left, Associate Professor David T. Leighton Jr., standing right, graduate student Jason Keith, kneeling, and undergraduate researcher Eric Sherer have developed an automotive catalytic converter that ignites faster than current models.

Financial Situation

As it became increasingly difficult for university faculty to secure federal research funding in the early 1990s, industry-sponsored research collaborations supplemented the number of research opportunities available to university faculty and students. From the financial perspective of the university and faculty, when the sponsor pays its share of the university's indirect costs, funding from industry-sponsored research is identical to that from federally sponsored research.

In addition, universities have an opportunity to create new revenue sources by licensing the technologies they develop. Universities receive more than three times as much revenue from corporate-sponsored research as they do from licensing income.[25] But licensing revenue is uncommitted income that the university can use to support its research and education mission in any way it chooses.

For all but a handful of institutions, however, income from research licenses amounts to a very small percentage of the support they receive from federal, industry, foundation, and state and local government sources. In 1998, U.S. universities' licensing income averaged 2.7 percent of their total research sponsorship from all sources. Research hospitals' licensing income averaged 5.9 percent of their total research sponsorship.[26] "License income is not a substitute for federal funding of research," said Lori Pressman, chair of the Survey, Statistics, and Metrics Committee at the Association of University Technology Managers.[27] In fact, Louis Tornatzky, senior fellow, Southern Technology Council, reported in 2000 that "less than 50 percent of universities realize enough royalty income to cover the costs of running their technology-transfer office."[28]

Licensing revenue is not inconsequential, of course. The University of California system, the top recipient of such revenue in 1999, earned more than $80 million from its patent portfolio that year, 95 percent of which was generated from biomedical-related patents.[29] Such income, however, often depends on a single "blockbuster" patent, and it can be highly inconsistent. "In 1996 we had about $20 million from our intellectual properties," reported George Rupp, president of Columbia University. He expected intellectual property earnings to grow to $75 million in 2000 "and then suddenly [to] drop to $49 million just on the basis of one 'home run' [discovery] going into the public domain."[30]

For most institutions, success at generating licensing revenue is a function of size and serendipity. According to a survey by the Association of University Technology Managers, eight of the top 15 universities generated more than $9 million of research-related licensing income in 1999. The remaining seven universities generated less than $9 million. Of 124 other universities that responded to the survey, seven received more than $9 million, while 117 received less. The success of the high earners was largely due to a small number of blockbuster patents or copyrights.[31] "Our success with Taxol [the anti-cancer drug] shows it's better to be lucky than good," said Sandy D'Alemberte, president of Florida State University.[32] The unpredictability of licensing income is another reason why it cannot substitute for long-term federal support of research funding, even at universities where the amount of licensing revenue is comparatively high.

WHAT THE RCI IS AND IS NOT STUDYING

This report focuses primarily on sponsored-research relationships involving individual university and company researchers working together. Understanding the mechanisms of individual sponsored-research arrangements provides a critical foundation for understanding the issues raised by more complex collaborative arrangements. Furthermore, these individual relationships are the most common and yet the most pressing. The report addresses important aspects of other mechanisms, particularly technology licensing, to varying degrees, because they can affect the overall research relationship and the establishment of research collaborations.

Although this report is designed for inexperienced practitioners on both sides, it should be useful to experienced partners as well. It does not assume that the experience level of potential partners is always the same. "The relationship is not necessarily symmetrical," said Nils Hasselmo, president of the Association of American Universities. "It's not inexperienced universities negotiating with inexperienced companies, but it may well be very experienced companies negotiating with inexperienced universities or very experienced universities negotiating with inexperienced companies."[33]

Because of budgetary and time constraints, this report does not address many closely related topics. It does not consider how research collaborations contribute to regional economic development, or influence the university curriculum, or affect faculty tenure and career development. It does not discuss the technique (adopted by some universities) of establishing university-affiliated, nonprofit research foundations as a home for some university business collaborations, because this report focuses on collaborations involving university researchers in their official capacity. This report does not explore in depth the particular circumstances that may face small companies and small universities—or even community colleges—that do not have extensive research-administrative staffs. (However, the challenge of simultaneously maintaining institutions' core academic values and corporations' bottom-line fiscal prudence is the same, whether a collaboration involves just one research project or a multimillion dollar partnership.) Nor does the report discuss national security and international competitive implications or any antitrust concerns that may arise from the increasing similarity between research in the corporate and university sectors. Rather than touching upon all these areas only briefly, we opted to study the areas we selected in sufficient depth to analyze them thoroughly within the time we had allotted for this particular initiative.

NOTES

[1] Richard Atkinson, "The Future Arrives First in California," *Issues in Science and Technology 16*, (Winter 1999/2000), 45–51.
[2] Vannevar Bush, *Science: The Endless Frontier* (Washington, DC: United States Government Printing Office, 1945).
[3] American Association for the Advancement of Science, *Trends in Non-defense R&D by Function, FY 1960–99* (Washington, DC: AAAS, 2000), based on historical tables in the Budget of the United States Government, FY 1999.
[4] Ibid.
[5] Council on Governmental Relations, *Review of University-Industry Research Relationships* (Washington, DC: CGR, 1995), 1.
[6] Association of University Technology Managers, *AUTM Licensing Survey: FY 1999, Survey Summary* (Washington, DC: AUTM, 2000), 1.
[7] Alan Greenspan, remarks at the National Governors' Association summer meeting, State College, PA, 11 July 2000.
[8] Association of University Technology Managers, *AUTM Licensing Survey: FY 1998, 1999* (Washington, DC: AUTM, 2000), 71.
[9] Industrial Research Institute, *Industrial Research and Development Facts* (Washington, DC: IRI, 2000), 4.
[10] *Case Study Final Report*, Lakeville, MN, 7 September 2000, 4.
[11] James C. MacBain, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report*, 7 September 2000, 35.
[12] Council on Governmental Relations, *Review of University-Industry Research Relationships* (Washington, DC: Council on Governmental Relations, September 1995), 7–9.
[13] Ralph Christoffersen, letter to Project Director, 15 July 2000.
[14] Randolph Guschl, "Technology Transfer: Too Many Options?" *Chemtech* (July 1997): 7.
[15] Hank McKinnell, remarks at Business–Higher Education Forum summer 2000 meeting, Mystic, CT, 29 June 2000.
[16] Rita Colwell remarks at Business–Higher Education Forum winter 2000 meeting, Tuscon, AZ, 11 February 2000.
[17] Michael Smith, "Perspectives," *Northwest Science and Technology* (Spring 1999): 50.
[18] Michael Montague, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report*, 7 September 2000, 9.
[19] Industrial Research Institute, *A Report on Enhancing Industry-University Cooperative Research Agreements* (Washington, DC, 1995), 1.
[20] Theodore E. Tabor, remarks at *"Making Collaborations a Corporate Core Competency"* teleconference, 15 October 1999, 35.
[21] Industrial Research Institute, *A Report on Enhancing Industry-University Cooperative Research Agreements* (Washington, DC, 1995), 1.
[22] Louis Tornatzky, Paul Waugaman, and Denis Gray, *Industry-University Technology Transfer: Models of Alternative Practice, Policy, and Program* (1999), 10.
[23] Carolyn Sanzone, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report*, 7 September 2000, 33.
[24] Rich Bendis, president, Kansas Technology Enterprise Corporation. *KTEC News*, January–February 2001.
[25] Association of University Technology Managers, *AUTM Licensing Survey: FY 1998, Survey Summary* (Washington, DC: AUTM, 1999), 36, 71.
[26] Analysis of Association of University Technology Managers *Licensing Survey: FY 1998*, 36–37.
[27] Lori Pressman, Association of University Technology Managers, conversation with Mike Champness, 5 January 2001.
[28] Louis Tornatzky, *Building State Economies by Promoting University-Industry Technology Transfer*, for the National Governors' Association, 2000.
[29] University of California Technology Transfer Program, *Annual Report, 1999* (UCTTP, 2000), 15.
[30] George Rupp, proceedings of *A Dialog on University Stewardship: New Responsibilities and Opportunities*, Government-University-Industry Research Roundtable (1999), 23.
[31] Analysis of AUTM *Licensing Survey FY 1999*, 35–39.
[32] Sandy D'Alemberte, remarks at the Business–Higher Education Forum summer 2000 meeting, Mystic, CT, 29 June 2000.
[33] Nils Hasselmo, remarks at meeting to review the updated RCI interim report, 30 August 2000, 8.

2

Corporations and universities are not natural partners; their cultures and their missions differ. Established corporations are hierarchical, with clear chains of command; they are not democracies. Universities are organized more loosely, with significant authority dispersed among individual schools and departments. Universities aren't democracies, either, but similar to medieval feudal states, they have multiple power centers. Companies' underlying goals—and the prime responsibilities of top management—are to make a profit and build value for shareholders by serving customers, whereas universities' traditional missions are to develop new knowledge and educate the next generation. These differences must be understood and accommodated if university-corporate research collaborations are to succeed.

TWO CULTURES:

Barriers to University-Industry Research Collaborations

UNIVERSITY BARRIERS

On the university side, four factors can prevent research collaborations with industry from being successfully established: the practical difficulties of negotiating and managing a collaboration; possible deleterious effects on faculty and students; possible impact on the missions, reputation, and financing of the university; and state or local officials' expectations of the contribution a university can make to regional economic development.

Among the potential practical barriers are university officials' lack of understanding of how companies operate, the differing time horizons of the two sectors, and institutional reward structures—such as tenure criteria—that do not take account of faculty participation in collaborations.[1] In addition, many universities are not organized in a way that fosters collaborations. They lack structures to find compatible collaboration partners, manage collaborations, and coordinate university support services.

Finally, some university faculty members and officials remain skeptical of the idea that research collaborations should be a permanent addition to the menu of research options. "In the view of more traditional academic administrators and faculty . . . industry involvement in university research is viewed as a temporary instrumentality or aberration, not as a permanent shift in how research should get done,"[2] said Louis Tornatzky of Batelle Memorial Institute, and the Southern Technology Council.

Handling Conflicts of Interest and Commitment

The financial incentives and opportunities presented by collaborative research, particularly the quest to find a major breakthrough that could bring wealth to faculty researchers, also raise difficult issues of conflicts of interest and conflicts of commitment. These conflicts are discussed in chapter three.

Preserving Academic Freedom

Some critics question whether it is appropriate for universities to perform industry-sponsored research. They warn that the proprietary nature of some sponsored work, manifested in confidentiality restrictions and delays in publication requested by industry partners, counters the university's traditional ideal—an atmosphere of free and open inquiry. Critics also suggest that involvement in industry research collaborations may unduly influence tenure and promotion decisions. "Will faculty whose research has potential commercial value be given favored treatment over their colleagues whose research does not?" asked Robert Rosenzweig, former president of the Association of American Universities.[3]

Opportunities for faculty members to acquire equity in companies supporting their research can cloud their reputations as independent and unbiased truth-seekers and call into question their professional commitments to protect the well-being of both their institutions and their students. More subtle is the question of how corporate-sponsored research is designed or selected for funding. Might research collaborations unduly influence the research agenda of the university, pushing the focus from fundamental to applied research? Richard Florida of Carnegie Mellon University investigated this concern and found mixed results:

- Studies by Diane Rahm and Robert Morgan at Washington University in St. Louis found a small association between greater faculty involvement with industry and more applied research.[4]
- Statistics from the National Science Foundation show that the amount of basic research performed in academia has remained relatively stable since 1980.[5]
- Diana Hicks and Kimberly Hamilton of CHI Research categorized research according to the journal in which it appears, and found that the percentage of basic research being

performed in universities was unchanged from 1981 to 1995.[6]

These findings would seem to contradict the concern that industry support overwhelms the university research agenda. In addition, Hicks and Hamilton also reported that the number of times that other papers cite university-industry papers is higher than the number of citations of single-university papers, indicating that university researchers actually may be able to enhance their scientific impact by collaborating with industry partners.[7] Similarly, a national survey of researchers found that academic researchers who received a portion of their funding from industry published more often, in equally prestigious journals, and were involved in more academic service activities, than their peers who did not receive industry support.[8]

Maintaining Intellectual Property and Confidentiality

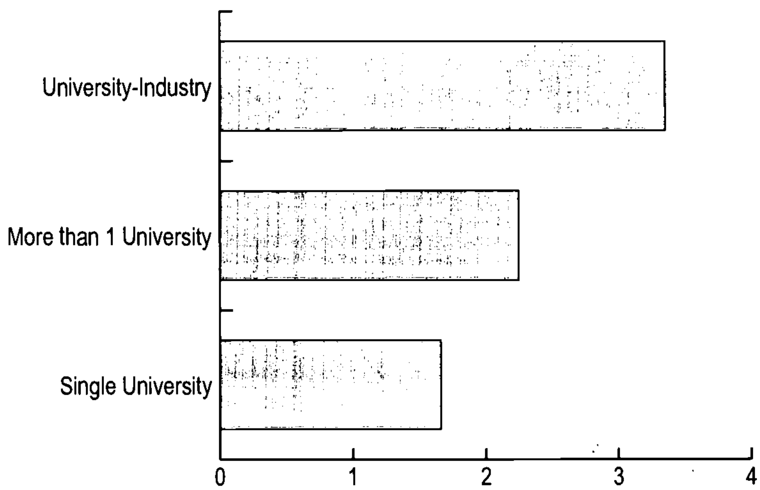
Intellectual property issues—the ownership and use of patents resulting from the collaboration—often are the first hurdle encountered by potential collaboration partners. Some companies express concern that universities are trying to patent more intellectual property than necessary, particularly in the area of research tools. Differences also arise over whether the university can or should provide rights to use background intellectual property.

Dissemination of research results can be a particular area of friction. Companies characteristically want to keep valuable data out of the hands of their competitors; university scientists want to publish quickly. Most collaboration agreements permit companies to delay submission of a university researcher's paper for 60 to 90 days, in order to prepare and file patent applications, and this restriction is now widely accepted. But companies also are concerned about less formal disclosures such as discussions among faculty researchers, and they worry that proprietary corporate information shared with a university scientist in a collaborative project might leak to the public—or to competitors.

Monitoring the Impact on Students

The potential impact on students is a hidden consequence of university-industry collaborations. Universities and faculty must ensure that collaborative research efforts do not hinder students' academic work by inappropriately involving them in confidential research or imposing restrictions on publication. For example, it is not unusual for a student involved in an industry-sponsored project to take six months longer to earn a Ph.D. than would be the case in a purely academic research effort.[9] As a result, it is impor-

University-industry collaborative papers are more likely to be highly cited



Between 1981 and 1992, 3.3 of every 1,000 papers published by university-industry collaborations were among the 1,000 most cited in other scientific publications over the next four years. By contrast, 2.2 of every 1,000 multi-university papers, and only 1.7 of every 1,000 single-university papers, landed among the top-cited publications.

Source: Diana Hicks and Kimberly Hamilton, CHI Research Inc., Haddon Heights, NJ tant for all parties (especially the students) to have realistic expectations of the commitment necessary to accomplish the effort.[10]

More importantly, faculty advisors must be sure they do not pressure a student into a thesis topic that reflects the priorities of a corporate research sponsor rather than the student's best interest. Faculty also must guard against a situation in which a Ph.D. candidate finds that his or her thesis research is unpublishable because it is wrapped in corporate secrecy constraints.

Although companies have long sought to meet and potentially hire students through research, the increasing relevance of collaborations to corporate research strategies may tie the efforts of the students more closely than ever to corporate research policies. Moreover, collaborations might adversely affect the academic schedules of students, and faculty-owned companies might hire students as consultants, blurring the distinction between student and employee.[11]

Dealing with Financial Challenges

Industry research funding carries other risks for universities. Research departments that attract substantial sponsored-research revenue may elude the supervision and evaluation of centralized faculty.[12] State legislatures may cut support for publicly funded universities that also draw significant industry funding, on the assumption that the universities can get along with less state funding. And universities may face pressure to shift internal resources to support industry work.[13] This cost shifting could have a significant effect upon the financial and organizational structures of a university. If corporate interests were to shape a university's budget, to whatever extent, the university would lose some of its independence and risk becoming captive to those interests. The financial opportunities of research collaborations also might tempt universities to allocate so much of their internal resources to attracting and managing collaborations that they fund other departments insufficiently.

Maintaining the university's tax-exempt status also is a major concern. Income derived from a regular trade or business that is not substantially related to the university's tax-exempt function is subject to unrelated business income tax, known as UBIT. Although university research is specifically excluded from UBIT, product testing is not. Certain restrictions also apply to the use of buildings and/or equipment that were financed by tax-exempt bonds.[14]

Encouraging Economic Development

Elected officials are increasingly interested in using university research, as well as community colleges, to help spur regional economic growth. Unfortunately, they are not always familiar with the university research process or the seminal role of individual faculty members in selecting research targets. When economic development becomes a top priority, these officials may try to force universities into industry collaborations that are inappropriate or premature—prompting resistance on the university side and making collaborations more difficult. Conversely, some state officials are suspicious of industry ties and have tried to restrain research collaborations lest they become corporate giveaways. "Legislatures in many states had made it very difficult for public universities to transfer technology because they feared that they would be vulnerable to charges of using state money to enrich the private sector," said Malcolm Gillis, president of Rice University, at a government-university-industry forum in 1999.[15]

Universities and faculty must ensure that collaborative research efforts do not hinder students' academic work by inappropriately involving them in confidential research or imposing restrictions on publication.

CORPORATE BARRIERS

Although many of the university barriers to establishing effective research collaborations involve fundamental university missions, corporations do not face this concern. None of the potential barriers to corporate involvement in collaborations questions the role and mission of the company itself.

Respecting the Value of Research Collaborations

At the most basic level, the establishment of a productive collaboration requires that potential partners understand and appreciate the value each brings to the relationship. Company officials, however, are not always predisposed to see universities as a source of relevant ideas. Many do not believe that university researchers have valuable insights. They contend instead that such insights are gained only through direct, "real-world" experience in specific areas of application—that is, in business. In addition, corporate R&D vice presidents are sometimes biased against collaborations. These executives are used to operating independently, and they often view university research as an expense without a return. Thus, external research collaborations usually require an internal champion to rally support within the company.

Competition among different parts of the company can also work against research collaborations. In 1997, Christopher Galvin, chief executive officer of Motorola, ordered an end to fierce intracompany struggles over funding. In a *Wall Street Journal* interview, Galvin said that a culture of "warring tribes" had made Motorola "unable to collaborate successfully inside or outside of the company."[16] Randolph Guschl, director of corporate technology transfer at DuPont Central Research, wrote in 1997: "Many scientists and managers do not want to work with others; they prefer to work alone. This cultural issue is probably the biggest barrier we've come up against. At DuPont, we had to work out this problem internally before we could reach out and follow up on the good leads. This is a never-ending challenge."[17]

Incorporating University Research into Product Development

Integrating university research into the product development process is a complex task. It is difficult enough to keep internal research relevant to business needs, but the challenge is magnified in a collaboration with an outside organization that lacks experience in keeping research relevant to specific goals and has no direct incentive to do so. If companies are not able to integrate outside research results into their product or service development processes, the utility of external collaborations will be limited and support from corporate management tepid.

Overcoming Management Barriers

The level of corporate support for research collaborations depends on factors such as cost, time to complete, and the risk of losing control of proprietary information. Other management barriers include lack of understanding of how universities operate, inability to appreciate the different time horizons of the two sectors, and an incompatible institutional reward structure for researchers who participate in collaborations.[18]

Frequent turnover of industrial program managers, whether because of merger activity or company promotions and reassignments, also can be a problem in long-term collaborations.[19] And in some cases, companies may need help navigating the internal bureaucracy of a university partner.

Some companies do not have the necessary tools or processes to make collaborations work effectively. This can be particularly true for small- and medium-sized companies, which often do not have the personnel to manage, or the money to fund, outside relationships of much magnitude and complexity.

MAINTAINING A BALANCE

Some university leaders (and many faculty) are concerned that collaborations with industry could threaten the essence of what it means to be an academic institution. Because industry funds the sponsored research, universities need to compete to attract collaboration partners. At the same time, they have to guard against devolving into contract research organizations, indebted to their sponsors and dependent on revenues from sponsored research and licensing fees.

"You don't want your faculty members constructing their research program to maximize the transfer of results out into the marketplace," observed Cornelius Pings, former president of the Association of American Universities. "They ought to be pursuing fundamental knowledge for the sake of knowledge."[20]

NOTES

[1] *Overcoming Barriers to Collaborative Research: Report of a Workshop,* Government-University-Industry Research Roundtable (Irvine, CA: National Academy Press, 1999), 8–9.
[2] Louis Tornatzky, Paul Waugaman, and Denis Gray, *Industry-University Technology Transfer: Models of Alternative Practice, Policy, and Program* (August 1999), 9.
[3] Robert Rosenzweig, "Universities Change, Core Values Should Not," *Issues in Science and Technology* (Winter 1999).
[4] Richard Florida, "The Role of the University: Leveraging Talent, Not Technology," *Issues in Science and Technology* (Summer 1999).
[5] Ibid.
[6] Diana Hicks and Kimberly Hamilton, "Does University-Industry Collaboration Adversely Affect University Research?" *Issues in Science and Technology* (Summer 1999).
[7] Ibid.
[8] Steven Stralser, *Faculty attitudes and perceptions about technology transfer,* unpublished dissertation, University of Michigan, Center for the Study of Higher and Postsecondary Education, Ann Arbor, MI, 1997, as cited in *Industry-University Technology Transfer: Models of Alternative Practice, Policy, and Program,* by Louis Tornatzky, Paul Waugaman, and Denis Gray (August 1999) 23.
[9] Pramod Khargonekar, University of Michigan, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 36.
[10] Robert L. Carman, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 19.
[11] *Overcoming Barriers to Collaborative Research,* 10.
[12] Robert Berdahl, University of California at Berkeley, proceedings of *A Dialog on University Stewardship: New Responsibilities and Opportunities,* Government-University-Industry Research Roundtable, National Academy Press, 1999, 24.
[13] George Rupp, proceedings of *A Dialog on University Stewardship: New Responsibilities and Opportunities,* Government-University-Industry Research Roundtable, National Academy Press, 1999, 22.
[14] Mark Crowell, presentation at Association of University Technology Managers convention, workshop C-7, 27 February 1998.
[15] Malcolm Gillis, proceedings of *A Dialog on University Stewardship: New Responsibilities and Opportunities,* Government-University-Industry Research Roundtable, National Academy Press, 1999, 27.
[16] Gene Allen and Rick Jarman, *Collaborative R&D: Manufacturing's New Tool* (New York, NY: John Wiley and Sons, 1999), 10.
[17] Randolph Guschl, "Technology Transfer: Too Many Options?" *Chemtech* (July 1997): 8.
[18] *Overcoming Barriers to Collaborative Research,* 8–9.
[19] Pramod Khargonekar, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 37.
[20] Cornelius Pings, remarks at meeting to review the updated RCI interim report, Washington, DC, 30 August 2000, 56.

Washington University–Monsanto: *Two Decades of Success*

One of the oldest and most successful university-industry collaborations is the 20-year pact between Monsanto Co. (now Pharmacia Corporation) and Washington University in St. Louis. Since 1981, this agreement has provided the Washington University Medical School with more than $100 million in research funding, produced 180 to 190 patents, and even fostered some personnel trades—including most prominently Philip Needleman, who left the faculty to join Monsanto in 1989 and who is now Pharmacia's chief scientific officer.

Although Monsanto merged with Pharmacia-Upjohn to create Pharmacia Corporation in 2000, the future of the Washington University collaboration apparently was never in serious doubt. The partners renewed the pact for another five years, at $5 million a year, beginning in January 2001. A similar agreement, totaling $15 million over seven years, has been worked out between the university and the new agricultural sciences subsidiary that Pharmacia established after the merger.

Originally, the collaboration was the brainchild of Howard Schneiderman, a former dean at Case Western Reserve University and the University of California at Irvine who had come to Monsanto to build a life-sciences department. Noting that Monsanto's St. Louis headquarters was virtually next door to the nation's third largest research medical school, Schneiderman approached his corporate CEO and Washington University officials with the idea of a research partnership; officials on both ends told him to see what he could work out.

"Howard and I hit it off very well," recalls David Kipnis, then head of the medical school's department of medicine, who worked with Schneiderman to shape the collaboration. "We spent three or four months dreaming of what we would like." Then Schneiderman and Kipnis brought in four senior scientists from each side to discuss ideas, and later took 20 scientists from each side on a weekend retreat to forge a detailed plan.

"One of the things we wanted to make certain was that nobody could accuse us of diverting the essential elements of our research to corporate science," Kipnis says. "The corporation was very agreeable to that."

At first, Schneiderman and Kipnis swore the group to secrecy. "Academic communities are like firewood" once rumors start, Kipnis explains. But once an agreement had been worked out, they went public. They made presentations to both company and faculty scientists, complete with overheads detailing the 20-page contract, and put it up to a faculty vote. Faculty members unanimously voted "yes." Schneiderman and Kipnis mailed copies of the contract to *The New York Times* and *The Washington Post*. They explained the pact at a public hearing of a House science subcommittee chaired by then Representative Al Gore. "And we have never had any negative reaction," Kipnis says.

"We wanted no secrecy," says Kipnis. "We wanted everything above board, which tends to be unusual sometimes in university-corporate relationships. I think you get in more trouble by keeping secrets."

Initially, Monsanto provided $2 million per year, a figure that grew to $9 million by 1988. In the meantime, partly because of the arrangement's success, Monsanto expanded its pharmaceutical business by acquiring G.D. Searle & Co. in 1985. Then the medical school decided that no single corporation should fund more than 5 percent of the school's research budget, and Monsanto gradually scaled its contribution back to $5 million annually. Presently, the medical school's total research budget is about $230 million per year.

Each year, the company identifies research areas in which it is interested and issues a "request for applications" modeled after the Request for Applications (RFAs) issued by the National Institutes of Health. Medical school researchers who are interested submit short, 10-page grant applications, which are reviewed by boards of senior scientists from both the company and the university. During the two decades of this collaboration, the company and university boards have had "a correlation coefficient greater than 0.85," says Kipnis—a level of agreement that surprises even him.

Every three years, a panel of outside scientists reviews the research conducted under the agreement; until recently Nobel Prize-winning molecular biologist Daniel Nathans of The Johns Hopkins University School of Medicine led this panel. The panel routinely asks graduate students—without any faculty members present—whether they felt that corporate funding had distorted their research. Most students don't even realize that corporate funding was involved.

"From the very beginning," Kipnis says, "we said that the company's supposed to develop drugs. We develop ideas and develop basic science, and we ought not to mix the two. That's something that has been carefully adhered to."

The medical school also tracks how the grants are distributed, and it is pleased with the result. Generally, about 40 percent of the money has gone to young assistant professors, about 35 percent to associate professors, and about 25 percent to the most senior researchers, and almost every department is represented.

In return, the company gets the right of first refusal to license and develop any discovery that it helped fund. Company researchers also gain access to an academic environment that enables them to discuss ideas and explore new developments with a far broader group of scientists than any single company could support. Company scientists attend Washington University seminars, and university scientists attend company seminars. Both sign agreements not to release information until it is published or patented.

The Monsanto–Pharmacia arrangement hasn't scared other companies away from collaborations with Washington University. Chancellor Mark Wrighton says other corporate research support to the university totals about $20 million per year.

What's the secret of making such a collaboration work? A top priority, Wrighton says, is that the people involved on each side "articulate to each other what their goals are." A company and a university have different goals, and each must be able to "credibly and demonstrably benefit from the relationship in the sense of achieving a goal." In addition, he says, "make sure that there are good and open lines of communication with the people who are responsible for the program." And keep in mind: It's not just about the money.

"There's a lot more to these relationships than money," Wrighton says. "Major corporations hire our graduates. They have people enrolled in our continuing education programs, in our MBA programs. They have influence over the decisions of other companies—not directly, but through the visibility of such a relationship and how they speak about it."

He offers the same advice to other companies that might be interested in such an arrangement with any university. "It's not merely about how much money, but what are the other elements of the partnership that bring them benefits? Is it routine and good access to the people of the university? To networking opportunities that bring them together with exciting people?"

"I think it's more than just a simple contract," says Wrighton. "It's a partnership."

3

"Objectivity lies at the heart of science, and it must not be compromised in any way, by financial considerations, nor in the pursuit of fame, nor for the desire to produce an important insight into the processes of life.[1]"

—Ruth Kirschstein,
acting director of the National Institutes of Health

Conflicts of Interest and Commitment

The evolution of science—particularly biomedical science—during the past two decades has dramatically increased the possibility of conflicts of interest on the part of university researchers. University scientists are more likely than ever before to participate in joint research projects with their industry counterparts, or to be funded by industry. Basic research, traditionally the province of academia, and applied research aimed at developing a product are no longer separated by rigid boundaries. The time it takes to transform a basic-science discovery, such as the shape of a protein, into a commercial product—in other words, to bring a discovery from the laboratory to the bedside—has narrowed, at least in some cases. And the stunning growth of the biotechnology industry has been based on moving academic-research discoveries—and often the academic researchers, too—off campus and into entrepreneurial start-up companies earlier in the discovery process.

"It has usually been the case that [university] researchers have hoped for a favorable outcome from their work, followed by wide recognition," observed Ruth Kirschstein, acting director of the National Institutes of Health (NIH), at a government-sponsored conference on conflict of interest in clinical research in August 2000. "It is only recently that immediate—and quite possibly substantial—financial gain became a possibility."

CONFLICTS OF INTEREST AND COMMITMENT

With growing interactions and closer ties between industry practitioners and university scientists, it should be no surprise that there are increasing opportunities for ties that are, or may seem to be, *too* close. Therefore, virtually all research-performing universities now have policies aimed at monitoring and managing such relationships to prevent abuses. Government, industry, and university officials—including members of the Business-Higher Education Forum—are reexamining whether existing policies should be updated.

When discussing conflict of interest, it is important to be clear just what is—and isn't—being talked about. Potential conflicts arise in many forms. Furthermore, the mere *appearance* of a conflict of interest is not wrongdoing, and conflict of interest does not automatically lead to scientific misbehavior. The purpose of conflict-of-interest policies in many parts of society—in universities, in corporations, in government, and in the courts—is to prevent or control situations that might lead to inadvertent and unacceptable bias, to suspicions of wrongdoing, or to actual wrongdoing. At the same time, because our national innovation system demands close cooperation to succeed, we can never fully eliminate potential conflicts—and we must manage them carefully.

Financial Conflicts of Interest

Financial conflicts of interest arise when scientists' private financial interests and their research converge in a way that might question their ability to make unbiased decisions related to their work. Although a conflict does not equal misbehavior, even the *appearance* of a conflict can raise doubts as to whether a researcher allows personal or financial gains to influence professional decisions.[2] Thus, even the *perception* of a conflict of interest can damage the research enterprise by weakening public trust—a particular concern for research universities, which depend heavily on federal research funding.

"Public trust is what fuels public support for medical research," said Jordan J. Cohen, president of the Association of American Medical Colleges, at a recent meeting of the association. "We risk great peril if we fail to respond to the growing perception that financial conflicts of interest have gotten out of control."[3] On the industry side, this concern is shared by innovation-based companies that rely in part on using unbiased basic research in the public domain—research that must be supported by adequate public funding.

Intellectual Conflicts of Interest

Intellectual conflicts of interest are pervasive and unavoidable—in science as in any other profession. Scientists are human: They want their hypotheses to be proved right. They want their discoveries to be recognized as significant. And they don't enjoy admitting that in some earlier hypothesis, they were wrong. This type of overt conflict of interest is not easily hidden. In addition, longstanding scientific practices—including peer review and the long-held practice of replicating experimental results before fully accepting them—defend scientists against the possibility of biased experiments that stem from their own hopes that results will look a certain way.

"Conflicts of interest and commitment are ubiquitous in academic life and indeed in all professional life, and conflicting pressures are inherent in the academic milieu," said David Korn, senior vice president for biomedical and health sciences of the Association of American Medical Colleges, at the conference on conflict of interest sponsored by the U.S. Department of Health and Human Services (HHS) in August 2000. "For example, [there is pressure] for faculty advancement, obtaining sponsored-research funding, winning the acclaim of one's professional peers, competing for prestigious research prizes, and even the desire to alleviate human pain and suffering. All may be more powerful in influencing faculty behavior than the prospect for material enrichment."

"These intellectual conflicts tend to be amorphous and are not of much concern to the public," Korn added. "But they are widely recognized within the academy. Institutional policies and procedures, as well as scientific review procedures, have long been in place to try to manage them."

Conflicts of Commitment

Conflicts of commitment are generally defined as anything that might interfere with a faculty members' full-time duties; such duties include teaching, research, time with students, and service obligations to the university. Many universities have formal policies limiting the amount of time that a faculty member can spend in outside activities such as consulting—for example, setting a maximum of one day per week. Often these restrictions are part of a university's conflict-of-interest policy. While conflicts of commitment are less ambiguous, more easily quantified, and more straightforward to police than financial conflicts of interest, they still can be difficult to detect and monitor. It is not simply a matter of a university setting its own standard of allowable time for outside activities and then enforcing it. "What you have to watch for are faculty who teach a course or two, and then go off to worry about a company," said Steve Koonin, provost and vice president of the California Institute of Technology.[4]

Institutional Conflicts of Interest

Institutional conflicts of interest, also called conflicts of mission, are a newly emerging source of concern, at least in some quarters. "Like individuals, institutions have financial interests in the outcomes of research—with the same problems," said Kirschstein at the August 2000 conference.

Some universities invest in start-up entrepreneurial firms based on faculty members' discoveries, or accept equity in new companies in lieu of royalties on university-held patents. Might they become beholden to an emerging company in which they have a financial stake? Could they be tempted to tilt their research agenda to help such a company, or to make themselves seem more valuable to a major source of sponsored-research funds? These questions are only now beginning to be explored.

A university with a stake in a corporation also might be tempted to offer favorable licensing terms for university-owned technologies, or if a large investment were involved, it could find its

Policies of 235 Medical Schools and Other Research Institutions on Disclosure and Management of Conflicts of Interest

Item*	Institutions with policies that address item no.	(%)
Type of conflict		
Income	215	(91)
Equity interest	218	(93)
Intellectual property	171	(73)
Finder's fees	2	(1)
Fiduciary interest only	134	(57)
Appearance of conflict	156	(66)
Support of the research	79	(34)
Other in-kind support	104	(44)
Policy meets federal guidelines	215	(91)
Policy exceeds federal guidelines	20	(9)
Person (or entity) with interest requiring initial disclosure		
Investigator	235	(100)
Spouse or partner	210	(89)
Minor or dependent child	208	(89)
Another household member	75	(32)
Adult child	53	(23)
Parent	51	(22)
Grandchild	15	(6)
Another relative	36	(15)
Family (unspecified)	5	(2)
Trust	15	(6)
Party to which initial disclosure must be made		
Party within institution	235	(100)
IRB	3	(1)
Funding agency or sponsor	18	(8)
Research subjects	3	(1)
Journals	16	(7)
Collaborating researchers	1	(<1)
When disclosure is required		
Annually or semiannually	193	(82)
On material change creating new potential for conflicts	178	(76)
When conflict is anticipated	133	(57)
On application for funding	149	(63)
On award of funding	20	(9)

Item*	Institutions with policies that address item no.	(%)
How disclosure should be managed		
Divestment of interest	146	(62)
Withdrawal of investigator from project	143	(61)
Disclosure to IRB	0	
Disclosure to funding agency or sponsor	102	(43)
Disclosure to research subjects	0	
Disclosure to journals	5	(2)
Disclosure to collaborating researchers	2	(1)
Modification of research plan	139	(59)
Monitoring of project	156	(66)
Additional peer review	16	(7)
Public disclosure	139	(59)
Mandatory management method	1	(<1)
Discretionary management method	234	(>99)
Penalty for nondisclosure		
Termination	109	(46)
Suspension	47	(20)
Salary modification	29	(12)
Nonfinancial modification (e.g., research space)	29	(12)
Reprimand	65	(28)
Disqualification from future grant applications	44	(19)
Notification of funding agency, journal, or both of nondisclosure	98	(42)
Removal of investigator from project	11	(5)
Unspecified or nonspecific penalty	108	(46)
Mandatory penalty	0	
Discretionary penalty	235	(100)

*The items are not mutually exclusive. IRB denotes institutional review board. One institution applied criteria that were stricter than the federal guidelines to clinical research, but applied the federal criteria to basic-science research. This institution was considered to have exceeded the federal guidelines.

Source: McCrary et al., *New England Journal of Medicine*, 30 November 2000.

own financial resources inextricably linked with that company's prospects. Questions also may arise about how the university manages its equity, because selling a large stake in a young firm could significantly depress the company's stock.

University officers and government officials are just beginning to grapple with this question. No comprehensive data exist to document how widespread university equity holdings are in companies that have been—or might be—affected by the universities' own actions. But Kirschstein emphasized, at a December 2000 meeting of NIH's Advisory Committee to the Director, that the issue will get more attention.[5]

Ultimately, developing separate funding sources can help protect universities from becoming indebted to any one entity, observed Richard Atkinson, president of the University of California. "My own view is that one of the best ways to protect the independence of university research is to encourage a variety of funding sources: state government, federal agencies, private corporations, foundations, and individuals."[6]

CONFLICT PREVENTION AND CONTROL

Public concern over conflict of interest in research, particularly in clinical research involving human patients, escalated following the September 1999 death of Jesse Gelsinger, a teenaged patient in a gene-therapy clinical trial at the University of Pennsylvania. Now, universities, medical schools, and companies that sponsor university-based research are reexamining their policies to assess their effectiveness and to adopt more uniform standards.

Research free from vested interests is the hallmark of university-based scientific investigation. An important reason that companies wish to work with universities is to add legitimacy to the research results that the company might not achieve on its own. Maintaining a reputation for neutrality and objectivity is vital to the university. Similarly, companies working with universities desire high-quality, unbiased results to help make what are often very important, expensive, and risky investment decisions for their own R&D programs. These companies cannot afford to undercut their own credibility by associating with biased researchers.

Disclosure of Financial Ties

Today, virtually all U.S. research-performing universities have conflict-of-interest policies, most of which follow the pattern of a 1995 federal government regulation covering federally funded research institutions. The federal regulation requires researchers to disclose to university conflict-of-interest offices or committees any "significant" financial ties with companies that might be affected by such research. Then, these offices (or committees) must "manage, reduce or eliminate" any conflict.[7]

The federal regulation suggests that a reasonable threshold for disclosure is $10,000 in annual income, or $10,000 in equity holdings, or 5 percent ownership of a particular company. Researchers' financial disclosures generally are confidential and are not passed on to the federal funding agency, where they might be subject to public release under the federal Freedom of Information Act. Some disclosures by scientists at state universities, however, are publicly available under state freedom of information laws.

Most university policies follow this model, but they vary significantly in the depth of the disclosures they require from researchers and in their thresholds for examining potential conflicts, according to several articles published in scientific journals in late 2000.[8,9] Requirements for researchers evaluating drugs or medical devices in clinical trials with human volunteers generally are more demanding than the rules for laboratory researchers—but again, they vary significantly among the nation's top medical schools.[10]

Determining the appropriate threshold for disclosure—even if the disclosures are to be kept confidential in university offices—is no easy task.

"It is important that we are not so burdensome in our regulatory development . . . that we force conflicts underground."

–Kenneth Trevett, Schepens Eye Research Institute

"It is important that we are not so burdensome in our regulatory development . . . that we force conflicts underground," said Kenneth Trevett of Schepens Eye Research Institute. "This is a real issue, and when you get into issues where people feel as though their privacy interests are unreasonably jeopardized, you are going to force some of these conflicts underground."

Conflict Management

Strategies for managing a conflict usually depend on the details of each case, and the options are wide-ranging. Among the techniques that have been used by institutions such as Washington University in St. Louis and Johns Hopkins University in Baltimore—and that are offered as possible strategies in the federal rule—are:

- Divesting troublesome assets.
- Ending consulting arrangements.
- Withdrawing the researcher from the project.
- Designating another researcher to oversee the project.
- Monitoring of the research by independent reviewers.
- Disclosing significant financial assets in any published report on the research.

"There are some arrangements that carry unmanageable conflicts or too high a level of risk," said Julie Gottlieb at Johns Hopkins University. "These are rejected, forcing the investigator to choose between the financial interest and the research project."[12]

Successful strategies should encourage the practice of objective science in an environment of openness and trust, guard against unintentional bias and error, and, of course, punish scientific misbehavior whenever it is uncovered. Further, it is important to keep in mind that research misconduct—such as intentionally counterfeiting or distorting data—is a separate issue, and universities and the federal government have established separate regulations and procedures to investigate misconduct charges and to punish proven misconduct.

Education

A useful strategy for preventing potential conflicts of interest involves ongoing education, aimed both at faculty members and at graduate students who hope to become practicing scientists. For more than a decade, universities that receive research training grants from the NIH have been required to train graduate students in the responsible conduct of research, including conflicts of interest.[13] In December 2000, the HHS proposed expanding this training requirement to cover researchers themselves.[14]

As a result, many universities offer—and require attendance at—special courses on ethical principles of research and on institutional policies in such areas as conflict of interest and misconduct. For example, Stanford University provides an online guide called "Getting Started in Research at Stanford" for researchers new to the campus.[15] The web site includes information on research policies and regulations, information about funding opportunities, resources for researchers, and information about university offices and individuals who can answer questions about the research process. The University of Maryland College Park offers the "Sponsored Projects Management Program,"[16] a series of minicourses for faculty and staff that addresses specific aspects of contract and grant administration, including the university's conflict-of-interest policies.

Successful strategies should encourage the practice of objective science in an environment of openness and trust, guard against unintentional bias and error, and, of course, punish scientific misbehavior whenever it is uncovered.

40

Clinical Trials

Clinical trials are a special case in which scientists test the safety and effectiveness of drugs, vaccines, or medical devices in human volunteer patients. Lives are at stake, not just the validity of laboratory science, and an elaborate structure already exists to protect human research subjects in clinical trials. For example, at universities and medical schools that receive any federal funding, Institutional Review Boards (IRBs)—which include lay members of the community as well as scientists—must review and approve the plan for any clinical trial before it can get underway. Trial participants must give informed consent to the experimental treatment, and one task of an IRB is to ensure that the informed-consent forms are understandable and comprehensive. Approval of the U.S. Food and Drug Administration (FDA) is required before even an early-stage experimental drug can be given to a human patient. Many clinical trials require appointment of independent data and safety monitoring committees to halt the experiment if unexpected risks appear.

This array of protections, however, is now being reassessed in the federal government, in university medical schools and in industry—a reassessment that gained impetus following the gene-therapy trial death of Jesse Gelsinger in 1999.

Conflict-of-interest policy is only one element of the human-subject protections that surround clinical trials, but it is a particularly important element. Clinical trials, which are vital to the development of new therapies, depend first on the willingness of patients to take part in those trials. That willingness, in turn, depends on the patients' trust in the clinical researchers who are running the trial. A recent editorial in *The New England Journal of Medicine* by Greg Koski, director of the Office for Human Research Protections at the HHS, and Jeffrey Drazen, the journal's editor-in-chief, warned that if clinical researchers' motives become suspect, they may lose that trust.[17]

U.S. medical schools already have conflict-of-interest policies that, generally, are more stringent than institutions' policies covering laboratory research.[18,19,20] But these standards, too, vary among institutions. In late 2000, Joseph B. Martin, dean of the Harvard Medical School, and Dennis L. Kasper, executive dean for academic programs, assembled a meeting of leaders of the nation's top medical schools to begin reviewing and coordinating their policies.

The FDA offers an additional defense against the possibility that a conflict of interest might bias the results of a trial. When clinical-trial results are submitted as part of an application to market a new drug (or for approval of a new use for an existing drug), the agency requires the researchers to disclose whether they have a significant financial interest in the company. The agency may ignore the trial's results if it sees a conflict of interest. Clinical trials are expensive; the FDA rule gives companies a significant reason to avoid such situations.

Neither the FDA nor institutional policies question companies' reimbursements to physicians or their institutions covering expenses for conducting trials. Such payments are an unavoidable reality in the highly expensive and risky process of medical product innovation. The questions fall to the companies that are developing new medicines and devices; they must have the trials performed to understand the new therapeutics' properties and to obtain sufficient evidence to win regulatory approval for clinical use and marketing.

CONFLICT-OF-INTEREST POLICIES FOR INVESTIGATORS IN CLINICAL TRIALS

Conflict-of-Interest Policies at the Ten medical schools receiving the largest amount of funding from the National Institutes of Health

Variable	Medical School										
	A	B	C	D	E	F	G	H	I	J	TOTAL
Interest that must be disclosed											
Stock	Yes	Yes	Yes[1]	Yes[2]	Yes	Yes[2]	Yes	Yes[3]	Yes[2]	Yes	10
Stock option	Yes	Yes	Yes	Yes[2]	Yes	Yes[2]	Yes	Yes[3]	Yes[2]	Yes	10
Income	Yes	Yes	Yes[4]	Yes[4]	Yes	Yes[4]	Yes	Yes	Yes[4]	Yes	10
Loan or gift	Yes	Yes	Yes		Yes	Yes[4]		Yes	Yes[4]	Yes	8
Decision-making position	Yes	Yes	Yes		Yes			Yes	Yes	Yes	7
Person with interest requiring disclosure											
Faculty member	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Immediate family	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Selected research staff					Yes		Yes	Yes			3
All research staff		Yes				Yes			Yes	Yes	4
Trainees			Yes[5]	Yes[5]					Yes[6]	Yes[7]	4
Party to which disclosure must be made											
University official or committee	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Institutional review board			Yes	Yes	Yes	Yes	Yes	Yes			6
Research subjects					Yes			Yes			2
Professional community (in publications or presentations)	Yes	Yes							Yes	Yes	4
Prohibited interest											
Stock	Yes	Yes	Yes[1]	Yes[2]							4
Stock options	Yes	Yes	Yes	Yes[2]							4
Consulting fee	Yes		Yes[4]	Yes[4]							3
Decision-making position	Yes										1

[1] Disclosure was required only if the financial interest exceeded $10,000 per year for a publicly funded study, or $20,000 for a privately funded study.
[2] Disclosure was required only if the financial interest exceeded $10,000 per year or 5 percent ownership.
[3] Disclosure was required only if the financial interest exceeded $10,000 per year or 5 percent ownership for a federally funded study, or $1,000 per year for a nonfederally funded study.
[4] Disclosure was required only if the financial interest exceeded $10,000 per year.
[5] The disclosure requirement applied only to research fellows.
[6] The disclosure requirement applied to research fellows and students.
[7] The disclosure requirement applied only to students.

Source: Lo et al. *New England Journal of Medicine*, 30 November 2000.

Principles to Consider

This report makes no pretense of offering answers to all the questions that arise over conflict-of-interest concerns, nor of proposing a model policy for U.S. universities and medical schools. Almost certainly, one size will not fit all. But as university officials, researchers and the companies with which they collaborate study the issue, they would be wise to recognize several basic principles:

- Policies should preserve the core value of academic freedom of discourse, while recognizing the distinct but complementary roles of academia and industry. Academia, industry, and society all would lose if universities neglected fundamental basic research and became arms of commerce.
- Universities should seek diverse funding sources for their research. Industry funding cannot, and should not, substitute for adequate, long-term public financing of basic scientific research.
- Universities and companies should seek transparency, clarity, and consistency in identifying actual and potential conflicts of interest and in establishing procedures for managing or eliminating them.
- All participants in the research process should continue their adherence to the scientific method, and to other safeguards against bias, in order to preserve public support for academic research and to maintain public willingness to participate in clinical research.

Conflicts of interest, or at least potential conflicts of interest, never will be entirely removed from our modern and increasingly complex society. The goal for universities and companies should be to recognize and pragmatically manage conflict-of-interest issues in a way that preserves the core values of academia and fosters the benefits of innovation for all society.

NOTES

[1] Ruth L. Kirschstein, National Institutes of Health, Conference on Human Subject Protection and Financial Conflicts of Interest, 15 August 2000. The full transcript is available at http://www.aspe.hhs.gov/sp/coi/8-15.htm.

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Berkeley-Novartis: *A Rough Road to Success*

The plant-sciences research partnership between the Swiss pharmaceutical firm Novartis AG and the University of California at Berkeley offers a dramatic demonstration of how touchy such arrangements can be—even in a state where university-industry collaborations helped create Silicon Valley and the U.S. biotechnology industry.

When officials of Berkeley's College of Natural Resources announced Novartis' five-year, $25 million pact to fund research in the college's Department of Plant and Microbial Biology—in return for an option on about 30 percent of the department's research discoveries—they expected to hear cheers from funding-starved scientists. Instead, the November 1998 agreement became a poster boy for opponents of sponsored-research arrangements.

Many faculty members complained that the university hadn't consulted them about the prospect of such a partnership. Opposition was particularly fierce among the three-quarters of the faculty who worked in other college departments and among opponents of genetically modified crops. At the press conference announcing the deal, one anti-biotechnology protester threw a pie at then Dean Gordon Rausser, one of the architects of the agreement. Rausser ducked.

Even some advocates of university-industry scientific collaborations were uneasy about the prospect of one company's buying access to the research output of a whole college department. They were not reassured by Berkeley officials' calling the agreement an "experiment."

"What if the experiment were to succeed?" asked Robert Rosenzweig, former president of the Association of American Universities, in a Spring 1999 article in *National Crosstalk*. "What would be the next part of the university to be sold to a corporation?" In a January 11, 2001, editorial, *Nature* pointed to the Berkeley-Novartis agreement as a sign that the university-industrial complex may be "out of control."

Rausser is quick to point out that the *Nature* editorial and other critics misstate some of the contract's terms. But the controversy has not subsided.

"If you were to ask many of the faculty in the college, there is a lingering resentment about the process that was involved in generating this agreement," says Richard Malkin, who became interim dean when Rausser stepped down in July 2000. "One of the things I am trying to do is to sort of defuse this situation. It's very difficult, in the sense that it exists. The people [who] disagreed continue to disagree."

Under the November 23, 1998, pact, the Novartis Agricultural Discovery Institute in La Jolla, California—recently renamed Syngenta—offers $5 million a year to fund nontargeted research in the Department of Plant and Microbial Biology. One-third of the Novartis money goes toward infrastructure, including new research facilities, and other indirect costs. Faculty scientists write brief, one- or two-page proposals describing the research they want to conduct—a procedure aimed at spurring curiosity-driven, investigator-initiated projects. A research committee made up of three department researchers and two Novartis officials reviews the proposals and awards funding.

So far, all department researchers who choose to take part have won grants ranging from $60,000 to $200,000 per year. Only two of the 31 faculty members in the department—25 full-time and six adjunct professors—have opted out.

"Novartis is not driving the research agenda," says Malkin.

In return, Novartis gets a first look at virtually all discoveries produced by department scientists, including inventions that Novartis didn't fund, and a 90-day option to declare that it wants to negotiate licenses. (However, Novartis can claim only about 30 percent of the discovery-disclosures it sees. The percentage depends on how much of the department's total research budget Novartis provides, which currently is about 30 percent.) Critics say that Berkeley has given Novartis control of the faculty's most promising inventions. Rausser says Novartis' rights are "minimal."

"We weren't giving up anything," Rausser says. Most university patents, he notes, involve proof of concept, and at that early stage of the discovery process, "no one knows what's going to be commercially successful."

Roughly two years into the agreement, Berkeley has shown "several" invention disclosures to Novartis, and the company has signed options to negotiate licenses on two of them, according to Carol Mimura of Berkeley's Office of Technology Transfer. If Novartis doesn't pursue a license on an invention—or if the company and the university can't agree on a licensing fee—the university is free to offer it to other companies.

Mimura says Novartis won't get a special break in license-fee negotiations just because it provides a large share of the plant and microbial biology department's research budget. "We won't do a lenient deal with them," she says.

Rausser stayed on as dean one year longer than he had originally planned, at the request of university leaders and College of Natural Resources department chairs, and he says the pact "has worked very well." It has lived up to most of the principles that faculty leaders considered important when they decided to seek a sponsored-research agreement, he says.

For example, Rausser says, faculty members are free to set their own research goals and to publish their results. The university owns any patents. Novartis can request publication delays for patent-filing of up to 90 days. If Novartis asks Berkeley to file for a patent, the company pays the costs. Novartis knows that Berkeley scientists conduct fundamental, not applied research. And university oversight mechanisms are in place to ensure that the Novartis money enhances, rather than crowds out, curiosity-driven basic research.

Only one of the original goals hasn't been met, Rausser says. Faculty members had hoped to join forces with a company that held complementary intellectual property which they could use in their own research. Novartis does, in fact, own plant-genetics databases that Berkeley scientists would like to access. But in the final contract negotiations, the company demanded the right to reopen the question of patent ownership on discoveries that were made with the help of these databases. As a result, few of the Berkeley scientists have tapped into them.

Rausser notes that the college structured the main terms of the deal and negotiated with four companies before choosing Novartis. He insists that the process was, in fact, "transparent." He frequently briefed committees of the Academic Senate during the course of a year as the contract evolved. A week before the contract was final, Rausser recalls, at a lunch with 35 Academic Senate members, Berkeley Chancellor Robert Berdahl asked if anyone thought he shouldn't sign it. Not one person objected, Rausser says.

Research conducted under the pact will be reviewed by a committee of outside researchers at the contract's midpoint—that is, later in 2001. "The university wants to learn from this experiment," Rausser says. Perhaps the outside reviewers will help Berkeley, the College of Natural Resources, and the critics finally agree on just how good a deal the Berkeley-Novartis contract really is.

4

Negotiations between companies and universities form the crux of research collaborations; in this phase participants move from talking about working together to actually making it happen. Because no two universities and no two companies are alike, no two negotiations between different partners can be identical. But the concerns profiled in this chapter usually are the first ones voiced by frustrated partners, even if they are not necessarily the first problems that need to be solved.

Negotiating Agreements

LAYING THE GROUNDWORK

Of the many ingredients in a successful negotiation, mutual trust is perhaps the most important. Negotiations generally proceed more quickly and easily when both sides know each other's needs and desires and do not worry that their partner may try to take advantage of them. Ned Siegel of Pharmacia Corporation identified interpersonal communication and rapport as the first critical factor in a successful collaboration—and shared scientific interest as a close second.[1]

This familiarity comes naturally in situations where the partners have long-standing ties. "We try our best to make sure that we meet and get to know and develop good working relationships with the vice president for research at the universities we partner with," observed Theodore Tabor, manager of external research for Dow Chemical Company. "We have found this to be beneficial because we can discuss the philosophy each partner brings to our relationship. A lot of times, problems can disappear pretty quickly if you develop these kinds of relationships and a true, sound understanding of one another's position."[2]

Training and Experience

Not surprisingly, getting experienced people involved in the negotiation can smooth and expedite the process. Nothing slows discussions, or raises frustration levels, more than having an inexperienced negotiator who tries to insert unrealistic provisions into an agreement. The growth of collaborations during the past few years has created new positions for negotiators—particularly on the university side—many of which are filled by people with minimal experience and little training. "There are problems not only in the research disciplines, but also in the areas of technology-transfer personnel, intellectual property portfolio managers, negotiators, and properly trained legal talent," pointed out Bill Decker, associate vice president for research at the University of Iowa.[3]

Employees who have dual backgrounds in *both* universities and corporations bring unique skills to the negotiation process. This value is becoming more widely recognized; universities are beginning to consistently seek individuals with corporate backgrounds, and vice versa, to fill negotiator positions. The benefits are already apparent, particularly when the negotiations involve detailed technical issues. "When you have real technology-transfer professionals on both sides who understand these issues, they often aren't a problem," said Randolph Guschl, director of corporate technology transfer at DuPont Central Research.[4]

Some professional societies have instituted programs to provide their members with professional development opportunities as negotiators. Nevertheless, the ultimate responsibility for training and developing technology-transfer professionals lies with each government, university, and corporate office, said Edward Pagani, director of strategic alliances at Pfizer Global Research & Development. "Corporations and not-for-profit groups must invest time and money in training and retaining technology-transfer professionals and creating a rewarding environment for them to develop their skills."[5] Establishing and rewarding high-performance expectations will encourage more new personnel to take advantage of upcoming professional development courses, seminars, and conferences.

Importance of Speed in a Negotiation

Inexperience and turnover of involved staff also can affect how expeditiously collaboration negotiations are concluded. "We negotiated with one company that changed their counsel several times," observed John Schneider, assistant vice president for industry research at Purdue University. "It took us four years to negotiate that agreement."[6] Internal bureaucracy can take a toll. "We were finding that we weren't acting very businesslike in the way that we interacted with industry," observed Mark Crowell, associate vice chancellor for technology transfer and industry research at North Carolina State University (NC State). Now, he continued, "We have streamlined the process. We can essentially get comments back to a company on an agreement in a day."[7]

Wrangling over the terms of the agreement can consume a lot of time. Every industrial and research sector has a clock that ticks at a different rate. For instance, the information technology industry moves much quicker than industry. Emil Sarpa, manager of external research at Sun Microsystems, said that taking six to nine weeks to reach a negotiated agreement with a university is too long. To streamline the process, he often uses a mini-agreement with three to six months' funding to start a project while the negotiations with the university proceed.[8] His company has backed out of negotiations at a time when they had become overly prolonged because the industrial cutting edge was moving faster than the lawyers doing the negotiating.[9] Negotiation delays also have been known to frustrate university faculty members, causing them to take intellectual property "out the back door" by working directly with companies.[10] "The key is to not get bogged down in excessive details at the early stages of negotiation," observed James Merz, vice president for graduate studies and research at Notre Dame University. "It is much better to develop a partnership with high levels of trust, structure a broad agreement regarding intellectual property, and work out the details if valuable intellectual property results. This may be a bit idealistic but so far we have had some success."[11]

CONTRACTS

Master Contracts

For two partners that have already collaborated—and therefore, who already understand each other's cultural differences and organizational preferences—a master contract can be an effective way to avoid plowing the same ground when they negotiate agreements covering individual research projects. Partners also can use master contracts to formalize the relationship in strategic partnerships—arrangements under which a corporation sponsors a large number of projects at a particular institution. While the contents of master contracts vary, they usually contain provisions regarding intellectual property ownership, confidentiality, publication delays, and the process of researchers applying, and getting approval, for funding of individual projects under the overall agreement. These provisions allow negotiations on a specific project to focus on the scope of work, the time period, and the budget.

Because a master contract will cover many topics, partners need to establish a relationship of sufficient magnitude to justify the time and expense of negotiating it. Master contracts generally work well when a large company sponsors many recurring projects at a single university, and the research being performed adapts well to boilerplate provisions.[12] The major limitation of master contracts is that they do not always transfer well between different divisions of the same company, or between different research projects at a university.[13] In describing the situation at Washington University in St. Louis, which has a diverse research environment, Ted Cicero, vice chancellor for research, observed, "Defining the scope that will be covered by a particular master contract can be very, very difficult. When you have longstanding relationships . . . trying to carve out other areas of research that would be amenable to a master contract is sometimes quite difficult."[14]

Many universities are pleased with the results of master contracts.[15] Purdue University has a dozen master contracts with companies both large and small.[16] The University of North Carolina, Washington University in St. Louis, and the University of California, Berkeley, have similar master contracts with, respectively, GlaxoSmithKline (formerly Glaxo Wellcome), Pharmacia Corp. (formerly Monsanto Co.), and Novartis. A master contract for the Center for Innovative Product Development at the Massachusetts Institute of Technology (MIT), though written for a consortium, is another example of an effective master contract.[17] Each is a model that other practitioners could use in developing their own master contracts, although care must be taken. "Model contracts vary because of individual institutional policies and state policies," observed Lynne Chronister, director of sponsored projects at the University of Utah. "They're not directly transferable from one institution to another."[18]

The long-term effect of such agreements upon the willingness of other companies to sponsor work at those campuses remains unknown. It is an issue with which Washington University in St. Louis still struggles, even many years after having established its relationship with Monsanto (now Pharmacia). "I continually fight a perception that much of our research is funded by Pharmacia and therefore other companies need not get involved in funding our activities. Nothing could be further from the truth," said Cicero. "While the Pharmacia funding is very important to us in both the biomedical and now the plant sciences areas, it accounts for only a fraction of the research that is funded by industry."[19]

MIT, which has strategic arrangements with many companies, closely monitors this type of situation. "Companies that engage with us at the partnership level should not be the sole company in their industry or sector to have a presence at MIT," wrote Charles Vest, president of MIT. "So far, this has not emerged as a problem. Indeed, in some instances our partners have actively worked to engage other companies in the research efforts."[20]

Model Agreements

Model agreements are another approach used to speed the negotiation process. These agreements are challenging to develop and implement because business practices in different industry sectors demand disparate agreements, and because different companies in the same industry, and even different divisions within those companies, may present opposing views about how a collaboration should be structured and used. In addition, the sheer number of complex provisions in even simple collaboration contracts makes finding common ground extremely difficult. "Model research agreements have attempted to present uniform provisions, but the exceptions outnumber the rules," said Louis Tornatzky, senior fellow, Southern Technology Council.[21]

Over the years, many partners have attempted to develop model agreements. One of the first was an eight-page report prepared jointly in 1988 by the Government-University-Industry Research Roundtable and the Industrial Research Institute, called *Simplified and Standardized Model Agreements for University-Industry Cooperative Research*.[22] Neither it nor any of the other efforts have succeeded in fostering a widely effective model agreement. Most collaboration partners now believe that the primary value of a model agreement is as an initial point of departure for negotiating a specific agreement between two parties, rather than as the final agreement for all arrangements.[23] "Every single company we've signed a model agreement with has negotiated slight variations in the terms to suit their needs and the activities that are going on," said Carolyn Sanzone, assistant vice chancellor for strategic technology alliances at the University of Massachusetts.[24]

To be effective, a model agreement should include basic, agreeable terms that are designed to lead to quick consensus. While a model agreement should not be offered as a "take-it-or-leave-it" proposal, prospective partners should know that requesting changes could lengthen the time it will take to negotiate a deal and may affect the university's willingness to participate in the sponsored-research effort. "A standard agreement should constitute your best offer and should cover your basic needs," said NC State's Mark Crowell. "To ensure this, you should periodically review

To be effective, a model agreement should include basic, agreeable terms that are designed to lead to quick consensus.

and update your standard agreements to prevent 'language creep.'"[25]

For experienced universities, three variations of model agreements are beginning to emerge. "One is a very simple standard model agreement for single research projects, whether they're $10,000 or $100,000," said Karen Hersey, senior counsel, intellectual property at MIT. "Second are the master contracts for those companies that would like to fund multiple tasks over a period of time. The last are our strategic partnerships, which are usually five-year agreements with the companies committing about $20 million."[26]

Large companies are overwhelmingly more likely than small ones to enter into strategic arrangements or sign master contracts with universities. Small companies' involvement with universities usually is limited to a single research project, often of modest cost. Because universities may find it difficult to expend a great deal of effort negotiating a sponsorship agreement when the financial return is modest, smaller companies without their own legal staffs may need to pay special attention to model agreements.

Recommendation:

When a university-industry research relationship is of sufficient magnitude, collaboration partners should consider negotiating master contracts. Universities also should consider developing model agreements for single research projects and should ensure that the terms do not unduly disadvantage small- and medium-sized companies.

CONFIDENTIALITY

The ability of faculty researchers to discuss their work with colleagues and to publish their results is a cornerstone of the academic enterprise and forms the basis of how new scientific knowledge is created. Companies and researchers should do nothing to put this at risk. At the same time, companies have a legitimate need—and fiduciary responsibility to their shareholders—to protect the value of their investments.

Companies recognize that universities are not the best places to try to keep secrets. By carefully monitoring the information provided to university researchers, and by not sharing "crown jewels," companies can limit the exposure of key technologies to possible compromise. "We try to avoid disclosing anything that's confidential," said Pfizer's Pagani. "There's no way to monitor whether confidentiality is maintained, and there may not be a suitable remedy if our confidential information is inappropriately disclosed. The wise thing is, you only give what you have to, and if it's important to do it, you balance the benefit/risk ratio."[27]

This does not mean that university researchers (and under the proper circumstances, their students) can never access confidential company data. Sometimes it is vital to do so. "In those cases where we're doing engineering research, we really have to understand what the company's problem is," said Purdue's Schneider. "In order to work on the research problem, I've got to know some trade secrets, and in that case we do have to enter into confidential relationships."[28]

The strategic agreement between the University of California, Berkeley, and Novartis requires individual researchers to sign confidentiality agreements before they can gain access to Novartis' proprietary databases.[29] Other university-corporate arrangements use the same approach. "A lot of universities don't like to include company confidential information in the research agreement because they say it is so hard for them to police it with faculty and students," observed Dow Chemical's Tabor. "They say that if there's going to be confidential information exchanged, the agreements should not be with the university but with the individuals."[30]

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Faculty Signatures

Not all universities, however, share this view. MIT's Hersey said she is leery of allowing individual faculty members to sign nondisclosure agreements. She prefers the institution to sign, so that the faculty would not have to put personal assets at risk. "Researchers should not be encouraged to sign unless they have been made very aware of the risks they are assuming, and unless they understand what it is they are signing," she said. "These are legal documents and enforceable against the individual. They can also be misused by industry to muzzle individual investigators."[31] DuPont's Guschl also cautioned, "These are legal business agreements and a few people are going to get burned unless that's understood."[32]

Pfizer prefers institutional signatures, according to Pagani. "We're concerned about what remedies we may have if [only] a professor signs the confidentiality agreement. If he or she breaches it, there's not a lot we can do."[33] Sometimes, confidential information must be discussed before a project can even be negotiated. In this situation, faculty may sign exploratory confidentiality agreements, or provisions can be made in a master agreement between two strategic partners.[34]

The corporate partner has more legal remedies when the university has signed a confidentiality agreement. This also can cause the university to be concerned about its overall potential liability. "The university has the deep pockets, and the argument would be that the faculty member is an employee of the institution and we should be responsible for his or her behavior," observed Cicero of Washington University in St. Louis. "This might lead to universities becoming very reluctant to sign any confidentiality agreements if they have to make certifications to a sponsor."[35]

In fact, a university may find itself being sued whether or not it signs a confidentiality agreement. In any event, the predicament of the university being held responsible for faculty actions is not unique to the research collaboration setting. "The extent to which the university is responsible for faculty members' actions comes up in all kinds of contexts," said Nils Hasselmo, president of the Association of American Universities (AAU). "An example would be the use of the Internet."[36]

When an institution signs an agreement, it is legally binding; but this may not be the case when a faculty member tries to do so on behalf of the institution. "Faculty members generally cannot obligate the university, no matter what they sign," said Cornelius Pings, former president of the AAU.[37]

Nevertheless, some companies ask faculty to sign as individuals. "I ask researchers to sign everything that we send them. Not as a party to the agreement, but to say they at least read it," observed DuPont's Guschl. "They should understand what obligations they have, whether contractual or just with respect to being part of a collaboration."[38]

Impact on Students

The challenges and consequences of maintaining confidentiality are particularly acute in the case of students, and corporate officials say that universities differ in their ability to manage this process. "We find a lot of universities have a very clear understanding of what their graduate and undergraduate students can and cannot do with confidential information," said Guschl. "Then we find a lot of other universities that haven't even discussed these matters internally ... Each university needs to understand their positions in this area and tell us what they are, because usually the university sets the rules. Undergraduate research is growing, and there are sometimes very different rules about what undergraduates can and cannot talk about."[39]

Informal solutions range from requiring faculty disclosure of the possession of confidential information to relying on academic and corporate researchers to be discreet in their conversations. "We have one lab that has an informal policy of asking where the parents of the undergraduates work," observed Richard Stoddard, director of federal relations at Ohio State University. "If it's a limited industry, and if the parents work for company A and the student is doing research related to company B, the lab is concerned about the student going home and telling mom or dad what he or she has been doing."[40]

It is unlikely, however, that informal solutions alone will be sufficient. More fully developed policies probably will be needed in this area. "The exchange of proprietary information is necessary but should be kept to the minimum necessary to complete the project," wrote Notre Dame's Merz. "We may need to develop better ways to monitor the safeguarding of this information as the scope of industrial research increases."[41]

Ultimately, responsibility for maintaining confidentiality lies with both sides. The Washington University Medical School in St. Louis has an informal rule that faculty members are expected to obtain funding from one company for each research area, with an exception in the area of clinical research. At Purdue, some faculty members working with a specific company will not bother to submit proposals to others that they know might present a conflict. "The companies themselves monitor the professors somewhat carefully, [although] some of them are better than others. So there are mechanisms in both directions," Schneider observed.[42]

PUBLICATION DELAYS

Universities usually accept reasonable publication delays. "Prohibitions and excessive restrictions on universities publishing the results of their research are unacceptable and we should take a hard line on this," wrote Merz. "On the other hand, delays for securing intellectual property protection are usually OK with industry and acceptable to us."[43]

Since graduate students actually perform much of the university research, it is important to keep their academic needs in mind. "Many graduate students are held in bondage until they can get their thesis published and their final exam scheduled," observed Pings. "There should not be clouds on the content of the thesis or unreasonable delays in the release of a thesis and therefore scheduling of final examinations."[44]

For example, the Berkeley–Novartis arrangement allows for a 30-day review period, without editorial constraint, to enable Novartis to determine whether it wants the university to file for patent protection. Novartis can request a delay of up to 60 additional days for the university to file a patent application. The university can terminate any publication delay by filing for a patent. "Publication delays in the agreement do not delegate content control to Novartis but instead are designed to allow the university to protect its intellectual property rights and, if needed, delete any proprietary information provided in confidence to the university," said Gordon Rausser, who was dean of Berkeley's College of Natural Resources when the agreement was negotiated.[45]

Strict patent rules regarding the existing body of technological knowledge ("prior art") can strongly influence decisions to disclose research results. "If a patent is to be filed, it is essential that constraints are placed on public presentations by faculty and students until after patent filing, or the claims in the patent may be significantly narrowed or even invalidated entirely," observed Ralph Christoffersen, president of Ribozyme Pharmaceuticals Inc.* "This means that seminars or other presentations may be delayed or their content carefully controlled. Since such actions are potential infringements on academic freedom, the methods used to accomplish such controls must be carefully considered."[46] In the Washington University–Pharmacia relationship, the company reviews research results before presentations at meetings or in publications. The resulting delay occasionally causes difficulties, especially for meeting last-minute abstract submission deadlines.[47]

The "standard" acceptable publication delay is 60 to 90 days.[48] Universities report that they are receiving increased pressure to extend publication delays beyond this standard time frame. Timely publication also is one of the key criteria in meeting federal tax regulations regarding unrelated business income.

"We have faced substantial pressure to accept longer publication delays," wrote Charles Wethington, president of the University of Kentucky. "This trend seems most pronounced with clinical trial research agreements, but is also substantial with many engineering research agreements."[49] The reason usually cited for the

*Patents in the United States are based on the principle of "first to invent," while elsewhere in the world the prevailing principle is "first to file."

delay of publishing clinical trial results is that multiple sites are involved in the work and the sponsor does not want publication or disclosure until all studies are completed.[50] A 1994 survey of 210 life science companies conducted by researchers at Massachusetts General Hospital found that 58 percent required publication delays of six months or more. The NIH recommends that universities not accept publication delays of more than two months.[51]

Some companies have instituted novel approaches to resolve the issue of publication delays, even incurring additional cost to do so. Pfizer, for example, will provide compounds similar to the confidential compound under study for simultaneous evaluation by the university. "The data collected on the analogues or on a patented chemical series can be published immediately; the data on the unpatented compound may be published as soon as the patent issues or the structure of the compound is made public by Pfizer," said Pagani. "If this solution is acceptable to the university, the research plan is modified and the budget is increased appropriately to cover the direct and indirect costs to conduct the additional research."[52]

Ultimately, the balance between academic freedom and intellectual property ownership is a delicate one. When one party tries to designate one goal as always taking precedence, trouble can begin. "We've had a recent contract change that funds research in a number of universities where there is language throughout the contract that makes protecting patent rights always more important than academic freedom and publishing," said MIT's Hersey. "This language basically says the most important thing is protecting patent rights, no matter how long it takes."[53]

The advent of the Internet and e-mail may significantly alter the terms and conditions of publications. In his book *The Elegant Universe,* Brian Greene, professor of physics and mathematics at Columbia University, describes a frantic week of effort to meld the work of three researchers working on superstring theory.* One researcher posted the original idea on the web, and the next day the other two downloaded it. By the time the original researcher was ready to depart for a conference, the three had managed to coauthor a significant scientific paper and to post it on the web. By early the next afternoon, it became clear that the response to their work was enthusiastic.[54] Such Internet-based collaboration and publication has become common in the field of high-energy physics. It is uncertain whether this approach will spread to other areas of science, particularly those that present greater commercial potential, such as biomedical research.

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Recommendation:
Confidentiality agreements, when necessary, should be signed by the company, the university, and the researchers involved. The company and the university must take responsibility for safeguarding confidential information. Publication delays to protect intellectual property rights should generally be no longer than 60 to 90 days. Any publication delays should be monitored carefully both to preserve academic freedom and to protect against any early disclosure that might invalidate patent claims.

INDIRECT COSTS

Facilities and Administrative (F&A) costs, also called indirect costs, are those that the university expends in performing research over and above researchers' salaries and new materials costs. F&A costs cover the costs of maintaining and operating university facilities, complying with health and safety practices, disposing of hazardous wastes, providing campus security, and accounting for the expenditure of sponsored-research funds. F&A costs also help finance the debt incurred to construct university research facilities, but they do not contribute to reserve funds to build new facilities.[55] F&A costs also cover expenses for heating and cooling, library usage, and the salaries of departmental and central office staff.[56]

The university and the federal government periodically negotiate the F&A rate based on documented costs that both independent and government auditors have reviewed. The rate

*"Superstring theory" is the latest attempt by physicists and mathematicians to develop a unified theory of both large celestial bodies and subatomic particles. This quest for a "unified field theory" eluded Albert Einstein during the last 30 years of his life.

varies significantly among universities but averages about 50 percent of direct costs.[57] Within the total F&A rate, the federal government has imposed a 26 percent cap on administrative costs; this cap affects mostly private universities located in large, expensive metropolitan areas.[58]

In July 2000, a RAND Corp. study concluded that, during the past decade, universities had only been recovering between 70 and 90 percent of their federal project F&A costs.[59] The report also said that F&A spending as a percentage of total project cost had remained level for at least a decade, and that university F&A rates generally were slightly lower than at other types of research institutions, such as federal laboratories and industrial research laboratories.[60]

Many universities do not include all of their allowable costs as part of their negotiated federal F&A rate because either they do not wish to prolong the negotiation, they do not want to incur the expense of documenting the cost, or they want to maintain an F&A rate that is competitive with peer institutions. "We've actually done an internal calculation to figure out by how much the federal F&A rate underpays our costs," said Washington University's Cicero. "We found that for each dollar of federal research support we receive, it costs the university 25 cents."[61]

When preparing research proposals for industry, universities appropriately include their F&A costs. Occasionally, a university may try to charge more than the federal F&A rate when the federal cap on administrative costs is lower than its actual costs.[62] But universities often face pressure from both companies and faculty to charge less than their federal rate. "In most negotiations with industry, the company research director calls the university principal investigator (or vice versa) and an amount is agreed upon," observed Russ Lea, interim associate vice president for research and sponsored programs at the University of North Carolina. "The principal investigator then wants the institution to waive a portion of the F&A rate so he or she can perform more research. This situation is legion among most corporate projects."[63]

As for corporate sponsors, "the larger and more sophisticated industries understand indirect cost rates," observed Hersey. "It's when you start dealing with the smaller companies, and especially the start-ups, that you run into the real discussions on negotiating your F&A rate."[64]

"We think that it is fair and reasonable to pay a university what it actually costs to do the work," wrote Ed Shonsey, president of Novartis Seeds.[65] In addition, Pfizer's Pagani noted that paying the full federal F&A rate protects a company's interests. "If we don't pay it, others can argue that they did, and we can become embroiled in disputes about rights in the research results," Pagani said. "By paying all direct and indirect [F&A] costs to perform the research at university laboratories, we minimize or eliminate claims by others, particularly the federal government under the Bayh-Dole Act."[66]

Universities contend that they have little flexibility. "The federal government looks at all of our sponsored-research projects and would take a very dim view if we're charging other people a different rate than we're charging the federal government," said Washington University's Cicero. "If you're underpricing contracts to get research contracts from industry, that will weigh very heavily against you [when the F&A rate is up for renegotiation]."[67] Nevertheless, a university may negotiate with a company on F&A costs when, for instance, a company joins a university research center, or where the modest size of the research project allows the university to use standardized contracts, thus saving on administrative costs. This flexibility can be especially important for smaller companies that cannot afford to pay the fully burdened rate. "Universities approach this the way companies do, in that the university has to decide at what price it wants to do this," said AAU's Hasselmo. "There are areas of research the university wants to pursue and it may be willing to accept a lower indirect cost rate simply because this is a critical investment and in the total picture is something it really wants to do."[68]

Despite the difficulties faced by universities, some potential corporate sponsors continue to ask universities to reduce the F&A rate. In the vast majority of cases, the university refuses to do so. "I ask the sponsoring divisions to look at the total cost of getting the research performed, put aside the overhead rates, and tell me if they want to pay this much," said DuPont's Guschl.

"By paying all direct and indirect [F&A] costs to perform the research at university laboratories, we minimize or eliminate claims by others, particularly the federal government under the Bayh-Dole Act."

–Edward Pagani, director of strategic alliances at Pfizer Global Research & Development.

Sometimes deals "evaporate" because of indirect-cost disputes, but often DuPont executives conclude that "what matters is what they're paying and what they're getting in return," he says.[69]

Interestingly, negotiations about F&A rates are virtually nonexistent in the area of industry-sponsored clinical trials. Most major medical centers have established non-negotiable F&A rates, which industrial sponsors have come to accept. Although no formal agreement exists among the centers regarding a uniform F&A rate, its consistent application (and the fact that it averages about half of federal on-campus rates) explains why both sides seem satisfied with the situation.[70]

Consider the situation in Iowa. State universities there have collaborated with Iowa state agencies to adopt consistent F&A policies. The rates are non-negotiable, and the verbal agreement is enforced by peer pressure among the universities. The allure of removing F&A costs as a contentious negotiation item has led some universities to talk about trying to use a similar model with industry research collaborations on a national scale.[71]

A final technique used by some universities is simply to present to potential industry sponsors fixed-price contracts with the F&A costs integrated into each line item instead of broken out separately.[72] This technique removes the F&A costs as a visible target and helps focus the corporate sponsor on weighing the importance of the proposed research against its cost.

Recommendation:
Indirect costs are a legitimate expense of performing university research. In most cases, companies should expect to pay at least the negotiated federal Facilities and Administrative charge for the research they sponsor in universities.

INTELLECTUAL PROPERTY

The most nettlesome area of negotiations is usually the ownership, value, and use of the intellectual property arising from the sponsored effort. The opening position during negotiations for both sides customarily begins with assertions that each will "own or have access to" intellectual property arising from the collaboration. (When a specific project includes federal funding as well as industry sponsorship, however, federal law requires that the university retain ownership of any resulting patents.)[73]

Patent Ownership

Companies usually want to secure patent ownership in order to manufacture, use, and sell products that result from the research; however, the importance of intellectual property ownership and patents differs among industry sectors. For example, in the information technology sector, short product life cycles elevate the priority of time-to-market issues over that of patent protection. Process-intensive industries that present high risk of development failure, such as the chemical and pharmaceutical industries, often secure patent protection before investing in costly new manufacturing facilities or engaging in expensive drug development activities.[74]

Universities, on the other hand, are driven by different incentives. They often desire ownership to allow their faculty to be unencumbered as they work, publish, and collaborate with colleagues. Universities often avoid granting restrictive rights to the sponsoring company, because they do not want to preclude students from working in that particular research area after they graduate.[75]

In addition, universities may have to meet obligations to other research sponsors, including the federal government. Universities are ethically—and in some cases, legally—responsible for ensuring that their discoveries are made available for use, potential development, and application by society, through commercialization, within a reasonable amount of time (rather than being shelved for competitive reasons).

Patent ownership enables them to monitor the development activities of their licensees; it also allows universities to license the technology on a nonexclusive basis to more than one company, potentially increasing the licensing-revenue stream, and to meet federal tax regulations to protect the nonprofit status of the university.[76]

Universities generally are willing to recognize joint intellectual property ownership if the university and industry researchers coauthor a paper or coinvent a product or process, or if federal funds or federally sponsored research are intermingled with the collaboration. As long as both sides remain flexible, it is usually possible to construct arrangements that can serve companies' commercialization needs while still vesting intellectual property ownership with the university. In many cases, a nonexclusive license affords the company sufficient access to pursue its commercialization plans, and the university usually can provide exclusive licenses when needed. "In almost every case, we don't object to the university owning the intellectual property as long as we get a nonexclusive license to practice and use it," observed Pfizer's Pagani.[77]

An effective negotiation remains focused on the long-term goals of patent ownership and requires flexibility from both sides. At Dow Chemical, for example, the company's Cooperative Research staff works to identify those areas where patents are likely to occur and can then tailor the boilerplate agreement with the university to fit the situation.[78]

Copyrights

Patents are the predominant mechanism of intellectual property ownership in most of the research collaborations studied for this report. But in some collaborations, such as those involving educational materials, *copyrights* (not patents) are the major form of intellectual property ownership. The ownership relationship between the university and its faculty is very different in the two cases, and this can have significant implications for negotiating intellectual property use agreements with industrial sponsors. Because faculty often control the copyright on their course materials, universities cannot license the materials to industrial sponsors as they do with patents. "We have a difficult time explaining to the sponsor why we cannot assure them that we can grant them all of the rights to copyrighted materials that they would like because, quite frankly, we're not sure we own them," said MIT's Hersey.[79]

The contrast between the sharply defined legalities of patents and the ambiguity and internal strife regarding copyrights has led many universities to update their copyright policies. "Universities should be looking at clarifying how copyrights are handled in a sponsored-research agreement funded by a private company," said NC State's Crowell. "From the standpoint of ownership, the copyright should essentially be treated like a patent, so the university can be in a position to convey negotiated licensing rights to the sponsors."[80]

After a recent update of its copyright policy, Columbia University now allows researchers to retain copyrights for books, monographs, articles, and so forth, but declares that the university will own the rights when the works are supported directly or commissioned by the university, receive more than the normal financial or logistical support, or are subject to contractual obligations.[81] Columbia will share copyright revenues with the authors just as it shares patent licensing revenues with faculty discoverers.

Recommendation:

Although ownership and control of intellectual property resulting from a collaboration must be decided by the collaboration partners, it usually will be appropriate for the university to retain ownership. Both parties should remain flexible during negotiations, and the key measure should be whether the corporate partner can commercialize the fruits of the research to the benefit of the public. Particularly when federal funds are involved, universities are responsible for ensuring that promising discoveries are made available for their potential commercialization or use within a reasonable time. Universities should update their copyright policies to allow industry sponsors to be granted licensing terms similar to those terms provided with patents.

LICENSING TERMS

Because the financial stakes are high, it is not surprising that many collaboration negotiations are conducted as if each could result in the next blockbuster patent. No university president wants to be invited to explain to the governing board, or to a state legislative committee, how the latest Cohen-Boyer patent* managed to slip through. But patents with such broad application and high value are uncommon, and their use still does not consider the substantial downstream costs and risk of developing and marketing actual products. As a result of these expectations and countering realities, collaboration negotiations can become more arduous when combined with a contentious licensing negotiation.

To avoid combining these negotiations, collaboration partners either try to resolve the issue of commercialization terms quickly (perhaps by agreeing to a royalty-free license), or if that is not possible, defer the negotiation of licensing royalty rates until they complete their research. Examples of universities and companies negotiating a firm, nonzero, commercialization royalty rate at the beginning of a collaboration are rare, but they do exist: In 1999, the Arizona Board of Regents proposed changing its intellectual property policies to institute a windfall provision that would trigger payments based on a mutually agreed-upon net sales threshold or event.[82] "Negotiating rates on a hypothetical, unknown invention is risky for both parties, and tends to lead to generally unneeded friction between the parties," wrote University of Kentucky President Charles Wethington. "It also substantially complicates negotiations."[83]

Universities will sometimes grant royalty-free licenses to faculty start-up companies. Since faculty start-ups are chronically short of operating funds, the university may grant royalty-free licenses to existing university patents in return for an equity stake in the company. In these cases, the license is usually exclusive, because an exclusive license is usually necessary for the start-up company to attract venture capital funding. At the same time, investing an equity stake in a faculty start-up company can lead to potential conflicts that must be monitored closely; therefore, many public universities are unable or unwilling to use this approach. When a faculty start-up receives an exclusive license for the results of publicly funded research, other companies that may wish to license the technology cannot do so. This can potentially confer a public subsidy for private gain and lies at the heart of the dispute over research tools.

Collaboration negotiations can become more arduous when combined with a contentious licensing negotiation.

Establishing Upfront Fees

As an alternative, a university may grant a royalty-free license (usually nonexclusive) in return for an upfront fee, often in the form of support for additional, undirected research. While it may be advantageous for the university to do this, it may not always be in the best interest of the faculty. In 1996, a jury awarded Jerome Singer and Lawrence Crooks, two University of California researchers who performed research in the area of magnetic resonance imaging, $2.3 million because the university had discounted the patents it licensed to manufacturers in exchange for more than $20 million in research funding—reducing the licensing revenues in which the researchers would have shared.[84]

The payment of an upfront fee** can be particularly useful in the area of information technology, where the improbability of blockbuster patents can lower the financial risk to universities of accepting upfront payments in lieu of royalties. However, not all information technology companies will agree to the payment of an upfront fee. Many prefer to receive a nonexclusive, royalty-free license without further financial consideration for any technology that may arise from research that they sponsor.[85]

Although some information technology companies will not let the lack of a royalty-free, nonexclusive license stop them from sponsoring university research, others will. Many information

*Awarded in 1980 to Herbert Boyer of U.C. San Francisco and Stanley Cohen of Stanford, the Cohen-Boyer gene-splicing patent became a seminal patent for the emerging biotechnology industry. Cohen continued performing research at Stanford, while Boyer later founded Genentech. The patent was licensed to several hundred biotechnology start-ups and eventually earned U.C. and Stanford almost $200 million in licensing revenue.

**This upfront fee is not to be confused with the payment universities receive for performing sponsored research. The former is paid in lieu of downstream royalty income that might arise from the results of the research, while the latter covers the university's costs (including indirect costs) for performing the research.

technology companies have long insisted on getting nonexclusive, royalty-free licenses to the results of their sponsored-research efforts, and some are becoming even more adamant about it.[86] "My experience has been that many companies in this field do insist on a nonexclusive, royalty-free license up front in the research agreement—and many will, in fact, walk if they can't get it," observed NC State's Mark Crowell.[87]

The forces driving information technology companies to insist on nonexclusive, royalty-free licenses stem from the structure of their industry and the speed at which it moves. "In addition to the fact that there probably are fewer 'blockbuster' patents in this area as compared with biotechnology or pharmaceuticals, I think the main reason for this difference is the different way this industry uses patents," observed Crowell. "They see patents as 'chits,' to be traded for other patents in cross-licensing arrangements with their competitors in order to ensure freedom to operate. Additionally, given their tendency to stockpile licenses under cross-licenses or otherwise, it becomes increasingly difficult to define a basis for calculating a royalty—and a party insisting on a royalty may just find that the company would prefer to do without a certain patent, or engineer around it."[88] Gary Weber, assistant vice president for research and director of technology transfer at Pennsylvania State University, said, "The 'electronic' companies, both software and hardware, maintain that things are changing too fast for anything which has been patented to be of any value to them. If you had time to patent it, it must be obsolete."[89]

Deferring the Royalty Issue

Potential partners sometimes finesse the issue by agreeing to defer setting a royalty rate. "A lot of companies, including some of the bigger ones, are becoming more comfortable with deferring it until the invention is made so that we are not having to hold up the research process for something that may never happen," said MIT's Hersey.[90] No consensus exists, however, on mechanisms to protect each side's interests when the decision is deferred. "Experience from our membership indicates that few industries actually prefer pre-set royalties," wrote Kate Phillips, then vice president of the Council on Governmental Relations. "The majority is willing to defer and agree that [deferral] speeds up the negotiation process."[91]

One method is to specify, in the contract, how the partners will decide the rate once the research is complete. "If the concern is assuring that the university is reasonable, expanded contractual provisions on how the parties will reach an agreement could be included," said University of Kentucky's Wethington.[92] He also observed that it would be possible to include terms requiring the university to agree to generally acceptable rates.

Arbitration is another option, but probably not widely adaptable. "I don't think we're geared for going through an extensive, true, triple-A arbitration proceeding," said Joyce Brinton, director of Harvard University's Office for Technology and Trademark Licensing.[93] Texas prohibits its universities from even sending disagreements to arbitration.[94] Mediation by "a skilled, experienced mediator" or nonbinding arbitration "could help assure both parties that subsequent royalty rates would be commercially reasonable," Wethington suggested.[95]

The parties sometimes agree to substitute a range of royalty rates that would be subject to future negotiation, depending on the type of product developed and its success in the market. But this approach is not always popular with universities. "In select areas where the invention is anticipated and market rates are well established, it might not be objectionable to set royalty ranges, but in most instances we believe this approach is harmful," wrote Wethington.[96]

To work around this problem, some universities and companies with longstanding ties have relied on the strength of their relationships and on artfully constructed language. "Eighty percent of the time, I think we get there," said NC State's Crowell, "but there still are problems often enough to have it register as a concern in my book."[97] An example of the language sometimes used by NC State follows:

"Sponsor shall have an option to negotiate an exclusive, royalty-bearing license on terms which are based on the value of the technology, which are fair and equitable, and which are based on standard industry practice. Royalty rate shall take into account the follow-

ing factors: (i) extent to which the innovative features covered by the patents must be combined with the IP rights owned by the sponsor or others; (ii) scope of the patents and degree of novelty; and (iii) the costs borne by the parties in securing the patents.'[98]

But some companies just say "No" to the idea of deferring the royalty-rate issue. "I believe that most commercial organizations will balk at the idea due to the significant unknown financial risk associated with the approach," wrote Ribozyme's Christoffersen. "In the case of a biotechnology company, addition of the risk of an unknown royalty obligation to all the other risks associated with biotechnology research would probably make the collaboration a 'non-starter'."[99]

Preserving Tax-Exempt Status

In some cases, federal tax regulations make it impossible to set licensing royalties in the initial collaboration agreement. When the research is performed in buildings or uses equipment that was financed by tax-exempt bonds—which is often the case in university research—the Internal Revenue Service (IRS) requires that the sponsor pay a competitive rate determined at the time when the discovery "is available for use."[100] These regulations "specifically prohibit the establishing of a royalty rate or royalty range or royalty cap in a research agreement," said Crowell. "So if you have those kinds of bonds that you're worried about, you literally can't do it without putting that tax status in jeopardy."[101]

IRS procedure 97-14 "sets forth conditions under which a research agreement does not result in private business use under the Internal Revenue Code of 1986."[102] A taxpayer's gross income does not include interest on state and local bonds, but does include interest on private activity bonds. In addition, if more than 10 percent of the proceeds of a public bond issue are used for private, nongovernmental use, the bond qualifies as a private bond, and the income from the use of the facilities or equipment it finances is subject to tax.[103] The IRS guideline follows:

SECTION 5. OPERATING GUIDELINES FOR RESEARCH AGREEMENTS

.01 *In general.* If a research agreement is described in either section 5.02 or 5.03 of this revenue procedure, the research agreement itself does not result in private business use.

.02 *Corporate-sponsored research.* A research agreement relating to property used for basic research supported or sponsored by a sponsor is described in this section 5.02 if any license or other use of resulting technology by the sponsor is permitted only on the same terms as the recipient would permit that use by any unrelated, non-sponsoring party (that is, the sponsor must pay a competitive price for its use), with the price paid for that use determined at the time the license or other resulting technology is available for use. Although the recipient need not permit persons other than the sponsor to use any license or other resulting technology, the price paid by the sponsor must be no less than the price that would be paid by any non-sponsoring party for those same rights.

.03 *Cooperative research agreements.* A research agreement relating to property used pursuant to a joint industry-governmental cooperative research arrangement is described in this section 5.03 if:

(1) Multiple, unrelated sponsors agree to fund governmentally performed basic research;

(2) The research to be performed and the manner in which it is to be performed (for example, selection of the personnel to perform the research) is determined by the qualified user;

(3) Title to any patent or other product incidentally resulting from the basic research lies exclusively with the qualified user; and

(4) Sponsors are entitled to no more than a nonexclusive, royalty-free license to use the product of any of that research.[104]

In some cases, federal tax regulations make it impossible to set licensing royalties in the initial collaboration agreement.

The IRS regulation was promulgated in 1997. It is designed to ensure that companies do not benefit from universities' tax-exempt status and that universities do not take advantage of that status to generate revenue. Changing the tax status of these bonds would disrupt the investment expectations of the bondholders and could damage the credit rating of the university.[105]

It is unclear how aggressively the IRS will enforce these relatively new regulations. It usually takes some time for the agency to set up educational programs and involve district offices.[106] Universities will be reluctant to push the boundaries of this regulation until there is some track record of how it is being enforced. Collaborations with information technology firms may be particularly affected. These companies generally insist on nonexclusive, royalty-free licenses at the outset. Even though identical terms are available to all participants, the IRS still may deem them unacceptable.

Other opportunities for university-industry collaborations also could be at risk unless the IRS eases its requirements. "The major global businesses that we have would be much more prone to work with academia on projects that have a stronger commercial component than they do now," said Frank Knoll of Dow Chemical Co. "This would really open the door to a lot more product-related research that is very challenging and very interesting, which I think could be beneficial to many universities. It would open them up to the marketplace and the actual product problems more than you see now."[107]

The dilemma of tax-exempt status has captured the attention of corporate CEOs. "We need to be concerned about [this problem]," wrote Novartis' Shonsey. "As a company, we have been trying to negotiate [royalty] caps—which also apparently presents a problem and could jeopardize the university tax-exempt status."[108] Ribozyme's Christoffersen noted, "There is a problem with tax exempt bonds and it needs to be solved."[109]

Recommendation:

Collaboration partners should avoid engaging in contentious licensing negotiations during a collaboration negotiation, while preserving the ability of the university and its faculty to share in benefits from successes. Should the partners agree to pre-set a commercialization royalty rate or range, the university should be mindful of federal tax regulations governing commercialization terms for sponsored research taking place in buildings or using equipment funded by tax-exempt bonds.

BACKGROUND RIGHTS

Background rights are the licensing rights that a university provides to an industry partner for "background intellectual property"—intellectual property developed by the university using funds from other sponsors, including the federal government. Background intellectual property may already exist when the sponsored agreement begins, but other researchers, students, or other corporate sponsors also can develop it separately as the collaboration proceeds.[110] Companies seek rights to use these inventions to complete their intellectual property portfolios so that they have sufficient licensing rights to commercialize the results of the sponsored research.

Requests for universities to provide background rights began with consortia such as the Semiconductor Research Corporation, SRC/SEMATECH (a government-industry manufacturing technology collaboration in the semiconductor industry), and the Electric Power Research Institute (EPRI). Their standard agreements require that the university will license to the consortia any background rights deemed necessary on a nonexclusive basis.[111] Today, individual companies (particularly in the information technology arena) increasingly seek background rights for the research they sponsor.[112, 113]

Universities have a number of problems with providing background rights. Most important is the effect on faculty members who are not part of the sponsored-research agreement. Because most universities consider faculty to be co-holders of intellectual property, universities cannot unilaterally make one faculty member's work "background" to another sponsored-research project. To do so would have a chilling effect on professorial collegiality and on the willingness of faculty to work together.[114] So central is collegiality to the culture of academic freedom that providing background rights can be a deal-breaker to many universities.[115]

The University of Kentucky recently walked away from a deal with a large industrial sponsor that demanded not just access to three patents already held by the university but also rights to future inventions that had not yet been invented. "These applications involved a variety of inventors, a variety of funding sources, and were important to the various researchers' on-going and future research," said Katherine Adams, associate general counsel of the university. "We ultimately concluded that we could not work with this potential sponsor."[116]

"What the faculty have said is that it is inequitable and unfair," said MIT's Hersey. "They say in the very harshest terms [that] for the intellectual property of one faculty member to be mortgaged for the benefit of another, or even for the benefit of the institution to get sponsored-research funding, is not the best and highest use of the background intellectual property."[117] Former AAU President Pings, who also is a former provost of the University of Southern California, said, "I wouldn't want to be a provost going before a faculty trying to defend signing away rights of individual faculty members."[118]

In addition, providing background rights, even to license technology at commercially reasonable rates, can complicate and even limit researchers' ability to pursue lines of inquiry or the university's ability to license the technology to another firm.[119] This can affect the ability of the university to attract future sponsored research and can dull patent incentives for start-up companies to participate in regional economic development plans.[120]

Patent Searches

Merely identifying intellectual property that might be relevant is both time-consuming and expensive. "All of the proposed methods for scrutinizing and including background technology are extremely time-consuming, and as a practical matter, out of reach for most universities, whose technology-transfer offices are minimally staffed to begin with," observed the University of Kentucky's Adams.[121] The task becomes even more complex because background rights requests typically are made at the beginning of the research program, long before anyone knows the results and the background rights implications.[122]

Identification of background intellectual property also has become more difficult because of the increasingly collaborative environment within the university and the mobility of faculty members. "You have multiple authorship papers now, four to six authors on a paper, and you have to go back five, six, seven years," said Washington University's Cicero. "You may be dealing with 10 to 15 different individuals who now have scattered throughout the university. Very often, we also have postdoctoral fellows and faculty members who are part of a patent at our university but now are at different institutions. Does the burden fall upon me to contact the other institutions if I want background rights, to get the consent of that faculty member?"[123]

Agreements on background rights usually include provisions that the parties offer a "good faith effort"[124] or use "reasonable efforts to disclose in the field of use"[125] in order to identify potential background conflicts. These are legal terms whose interpretation will require the involvement of legal counsel and could hold the university liable for any oversight. "The only way you should even begin down that path is to have a full-blown infringement opinion done looking at your entire portfolio within a certain area of technology," said NC State's Crowell. "And if anybody here has ever paid the cost to have an infringement opinion done, you're talking about a pretty scary proposition."[126]

For all these reasons, universities rarely agree to sign binding agreements on background rights.[127]* "There is an obligation on the part of the university to try to know its wares and what it is holding in a certain area and be prepared to

Universities have a number of problems with providing background rights. Most important is the effect on faculty members who are not part of the sponsored-research agreement.

* A public midwestern university has recently experienced this firsthand. The university agreed to provide a research sponsor the right to negotiate background rights for a reasonable royalty rate on a nonexclusive basis. The sponsor has since used this clause to prevent the university from granting an exclusive license for pre-existing technology to a local start-up company. The university and the sponsor disagree on whether the technology should be considered background technology, and they have not been able to resolve the issue after many months of discussion.

disclose this," observed Pings. "But on the other hand, in general, industry should not expect universities to sign formal, sweeping background rights agreements. They're probably going to find that this will not be done."[128]

On the industry side, managers say that they appreciate the difficulties facing university officials and faculty, but they quickly become less sympathetic when other university faculty assert their rights to profit from the commercialization of company-funded research. "Background rights became important because companies would be looking at a situation of unacceptable risk," said David Peyton, director of technology policy at the National Association of Manufacturers. "They would go into a project, put their people and their money in, and at the end find this patent they didn't know about that prevents them from exercising the technologies they thought they were going to be able to exercise."[129]

Until now, background rights rarely have become a major problem. But the inability of universities to grant background rights may begin to negatively affect collaborations. At a major chemical company, some research managers may rethink their decision to fund research if they cannot be assured of obtaining background rights.[130] As sponsored research and commercialization efforts become more intertwined, the level of uncertainty increases and companies may become less enthusiastic about engaging in future joint research efforts.

Corporate Responsibility

Much of the responsibility for addressing this problem lies with the corporate partner that desires to commercialize the research. Companies often need to perform a "freedom to practice" assessment or to solicit a full-blown patent infringement opinion, which should identify any potential blocking patents within the university. At Tulane University, officials will discuss any patent rights that such a search by the company uncovers—provided these rights are unlicensed at the time.[131]

Identifying possible intellectual property conflicts that might result from ongoing university work is an even more complex issue. Should universities disclose pending patent claims to potential industry partners? University officials do not agree on the answer. Tulane officials say no. "[First], there is no assurance that those claims will issue as a patent in the form written, and second, it provides a hunting license to the work of other faculty," said Tulane President Scott Cowen in a recent memorandum.[132] But other university officials say they would consider at least reviewing applications for patents that have been filed but have not yet been granted. "The university might be willing to take a look at pending patents, which the company can't know about," said NC State's Crowell. "We may be able to identify university efforts that might conceivably generate blocking patents, and then we can decide which rights we want to make available."[133]

The generic project agreement of the National Center for Manufacturing Sciences (NCMS) lets each participant decide if and how it will contribute background technology to a project. Participants are not obligated to license background technology to other participants, but they are required to make a good-faith effort to identify the existence of any background technology they may possess.[134]

MIT has implemented a specific background rights checking procedure to search for potential conflicts; this procedure involves six steps and seven decision points. MIT consults each faculty member before entering into background rights negotiations. The procedure is used at the beginning of the sponsored-research effort and at well-defined intervals during the course of the research collaboration.[135]

MIT recognizes, however, that it cannot guarantee it will find every related patent. "[There is] always some risk that a 'surprise' patent will be found later to which an industrial sponsor may require rights in order to practice intellectual property resulting from work they funded," observed Lori Pressman, then assistant director of MIT's Technology Licensing Office.[136] She also pointed out that universities hold only a small percentage of all the patents that might potentially block a sponsor's commercialization plans. Other university officials echoed this view. "In over 99 percent of the cases, the university won't be the party that holds background technology," said the University of Kentucky's Adams, "yet we

Concern about the loss of potential collaborations, and a desire to be good, responsive partners to industry, have led many universities to do their best to provide background rights, but clearly the administrative burden is heavy.

talk as if the university that does the work is going to be the entire limiting factor."[137]

Concern about the loss of potential collaborations, and a desire to be good, responsive partners to industry, have led many universities to do their best to provide background rights, but clearly the administrative burden is heavy. "[It moves the university] from proactively licensing unencumbered intellectual property to correctly identifying that which needs to be held in reserve," said MIT's Pressman. "The continuous surveillance obligations are an administrative burden."[138]

Of course, universities have other good reasons to track their intellectual property portfolios:

- Ensuring that the technology is licensed appropriately.
- Better managing risk.
- Building a broader-based, interdisciplinary research program.
- Marketing to potential collaboration partners.
- Instituting an organized, proactive program to license their technology. [139]

Recommendation:

Companies have legitimate reasons for requesting background rights to sponsored projects, and as part of their due diligence they should assist universities in locating potential conflicts. Universities have legitimate reasons for not providing background rights, but they should make a strong effort to do so when appropriate and feasible. Universities should consult closely with faculty and confirm that all contractual obligations can be met before signing binding agreements.

RESEARCH TOOLS

Scientific investigators need reliable tools to help them perform their research. Although this definition could include objects such as microscopes or magnetic resonance imaging machines, in this context it means laboratory discoveries or products that are useful in the course of conducting additional scientific research. With the sophistication of modern science, research tools can be highly complex entities that themselves require research to develop. An example is strains of mice that are genetically predisposed to contract specific forms of disease. Scientists then use the mice to understand the disease process and to aid in the search for treatment agents.

The research tool itself is rarely a necessary component of the resulting product; for example, researchers will hone the structure and properties of a new aircraft wing using a wind tunnel, but the wind tunnel is no longer needed once they have designed the wing.

Limiting Access to Research Tools

Access to publicly funded research tools is becoming one of the most contentious areas of university-industry research relationships. The issue is whether universities will license these research tools broadly or exclusively to one company, frequently a faculty start-up. This concern is not directly related to matters of university-industry collaborations. The friction generated from this conflict, however, may sour the relationship between companies that would like to see these tools licensed broadly and their university partners. Limiting access can also affect universities by impairing the ability of faculty to conduct research.[140]

At the heart of the research-tool problem, of course, is the fact that one person's research tool can be another person's key strategic product. Tool developers, which often later emerge as biotechnology firms, claim that without exclusive licenses, they cannot secure venture capital funding, thus stifling innovation.

Requesting Reach-Through Royalties

As recently as 20 years ago, academic researchers freely shared new research tools such as laboratory reagents and even animal models of disease. But now, because universities and their researchers have learned the value of patenting such discoveries—and because research tools can be expensive to develop—users of research tools often can expect to pay a significant amount for their use. During the past few years, both industry and university researchers have complained that in some cases, the cost is too high. In fact, sometimes the cost may even be indeterminable. The owner of a research tool, whether a company or a university, sometimes asks for royalties on any product that might eventually be developed through use of the tool—a concept known as reach-through royalties. On occasion, universities have asked other universities for such downstream rights, even though they themselves would balk at signing such a deal. In other cases, the discoverers of a patented research tool hold onto it for their own internal use, to give themselves a competitive advantage. Another significant concern is universities' exclusive licensing of publicly funded research tools to private companies, which in turn license the tools to other private companies and universities, often with reach-through royalties.

Companies that use a research tool understandably object to reach-through royalties because the tool developer does not share the financial risk in getting the product to market, and the contribution of the research tool may have been a small component of the entire product development process. Moreover, critics say the prospect of royalty-stacking—encumbering a potential product such as a new drug with several reach-through royalty obligations—may lead companies to abandon otherwise promising lines of research. But because tool developers are often emerging biotechnology firms, they often have few, if any, other revenue-producing products on the market. These firms argue that reach-through royalties are an alternative to charging high upfront user fees or to restricting access.

NIH Actions

NIH has been concerned for several years about the effect of research-tool licensing and royalty arrangements on the pace of fundamental biomedical research. In December 1999, the agency issued a set of guidelines on research-tool access for universities that develop tools with the help of federal funding. The guidelines discouraged patenting unless patent protection is necessary to attract investment needed for full development, argued against reach-through royalties, and urged that universities license tools with few encumbrances and at reasonable fees.[141] But these guidelines did not have the force of law. One year later, Maria Freire, director of NIH's Office of Technology Transfer, reported that although NIH had made significant progress, scientists still had problems accessing research tools, particularly in negotiations between academia and industry.[142]

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Biolex Inc.: *What a Technology-Transfer Office Can—and Can't—Do*

When plant molecular biologist Anne-Marie Stomp wanted to launch North Carolina State University's first biotechnology spinoff company, the university's technology-transfer staff did "really a terrific job" for her. They were "extraordinarily encouraging," she recalls. They offered advice, suggested outside contacts, opened doors, and best of all, "those guys will always make time for you. I could sit down and say, 'This is what I'm wondering about; am I on the right track?' You can use them as a sounding board. That's a fantastic resource to have."

But Stomp—who launched her company, Biolex Inc., in 1998—cautions that a university technology-transfer office can do only so much.

"Their mandate—and I think correctly so—is not actually to spin you off," she says. "That's not their job. That last step, where you take your little backpack and your little machete and you go out into the corporate jungle and start hacking your way, is a solo trip."

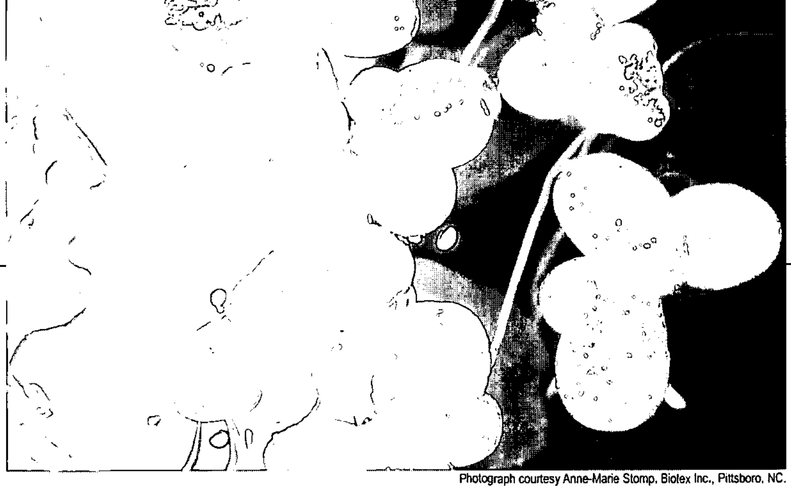
So far at least, Stomp's solo trip into the corporate world is on course. Two years and a few months after it received its first venture capital infusion, Biolex is still in the technology development phase, she says. With 37 employees, it is still living on invested capital—it has received about $9 million in venture funds—not on earnings. But unlike most biotechnology start-ups of its age, it already has some paying customers. And "we are deep into conversations with a number of major corporations that are very interested in our technology."

Biolex's technology is based on processes that Stomp discovered for inserting foreign genes into the smallest flowering plant in the world: lemna, commonly known as duckweed. Duckweed is a disk-shaped aquatic plant, ranging from less than one-fifth to about one-quarter of an inch across, that forms "a beautiful, jade green mat" on water surfaces such as ponds and water traps on golf courses. (It is not to be confused with the algae that form pond scum on stagnant water. "Nobody calls my plants 'pond scum,'" Stomp says with a laugh. "Those are fighting words.")

Duckweed has other characteristics that make it scientifically and commercially enticing. Similar to yeast or bacteria, it reproduces swiftly and clonally: Mature plants bud off tiny daughter disks that are genetically exact copies, doubling the size of a duckweed mat in two days or less. It has an exceptionally high protein content, offering potential as a biological factory for producing medicinal or industrial proteins. Some municipal water systems already use duckweed for tertiary water treatment—removing phosphates and nitrogen from partially treated wastewater—raising the prospect of someday combining pollution cleanup with the manufacture of high-value proteins, and transforming wastewater into a production asset instead of a problem.

Stomp, then an associate professor at NC State's College of Natural Resources, found duckweed because she had gone looking for something very much like it. In the early 1990s, she was familiar with research that studied the use of trees for water cleanup by discharging wastewater into forest plots, but she believed that an aquatic plant might be better suited to the job. Certainly, a small, fast-growing plant would be better suited to laboratory research than a stately, slowly maturing tree. "Trying to do genetic engineering and biotechnology on trees is very similar to doing genetic research and biotechnology on whales," she observes.

As she learned about duckweed's properties, Stomp realized that only one element was needed to turn it into a versatile biotechnology platform—the ability to genetically engineer it to produce a desired protein or to help researchers identify the protein that was encoded by an unfamiliar gene. "That was the critical missing link on the technology that could launch the whole thing," she says. Supported by a series of grants from the Environmental Protection Agency, the U.S. Department of Agriculture, and the National Science Foundation, Stomp set out to develop such a method, succeeded, and in 1995 filed for a patent. The patent was issued in March 2000. NC State now owns it, and Biolex has an exclusive license.



Photograph courtesy Anne-Marie Stomp, Biolex Inc., Pittsboro, NC.

"That idea, that was a three-point shot," Stomp says. "That was a keeper, and I knew that I had one." In science, she notes, "if you're really creative, you throw the ball a lot. You've got to just be gutsy enough to throw a lot, to get those ones that really hum."

Now it was time for Stomp to become a high-tech entrepreneur. She had worked with NC State's technology-transfer office in the past; she not only had industry funding for her earlier forestry research but also had filed several patents on forest pine genetic engineering. So she turned to her friends in the technology-transfer office again.

"They were extraordinarily encouraging," she says. "And I had many productive discussions with them because, again, as an academic, what did I know about starting a company?"

For the most part, however, NC State officials could only listen, advise, make some contacts, and cheer her on. Too many academics don't realize that there's a limit to what a university can do for them, Stomp says.

"Most academics have a childlike relationship with their administrators. They look to the administrators as if the administrators are parents and they are but baby birds, so they look for the administration to feed them," she says. But she warns, "If you interact with the administration that way, the administration really can't help you, because their job is not to feed you but to facilitate for you."

Stomp incorporated her company in 1997 and spent the next year planning its structure, mapping out its finances, and trolling for venture capital support. "I did lots and lots of listening to people in the private sector, and if it made sense to me, I gave it a try."

Along the way, NC State was, in fact, able to provide some tangible support: At the urging of Larry Tombaugh, dean of the College of Natural Resources, the college's N.C. Forestry Foundation invested $25,000 in Biolex—Stomp's very first capital commitment. That's a small number, but "it really helped. If you have a dollar, you can leverage it, you know?"

Charles Moreland, NC State's vice chancellor for research and graduate studies, helped, too. For example, at the contract-closing for Stomp's initial round of venture capital funding, one of her investors suddenly wanted to know what the indirect cost rate would be on a sponsored-research agreement that Stomp planned to work out with her former lab. She telephoned Moreland. He thought for a moment, and gave her the rate. Stomp recognizes that her relationship with the technology-transfer office helped speed up the process. "It can take months to negotiate these things through the bureaucracy," she says.

Moreland also quickly agreed with Stomp's suggestion that she take a leave of absence from the university to avoid any appearance of conflict of interest, even though there was no precedent for that at NC State. "Charlie is willing to make a decision," she says. "Some people in the system won't, but Charlie will. And that's a terrific resource."

Biolex started actual operations after receiving its first capital infusion, $1 million, in October 1998. A year later, the company moved from Raleigh, North Carolina, to the small town of Pittsboro, about 45 minutes from Research Triangle Park. (Stomp, who grew up in a small town in Connecticut, also is interested in bringing high-tech industry to rural areas.)

Although Stomp is the company's founder, she didn't claim the titles of chairman or CEO. Instead, she's listed as vice president of research and development. She's a scientist, she explains, not a business manager with lots of experience in running a company.

She seems to have the right instincts, though. "I'm always thinking, OK, now we've made this technological advance, how do I spin it, package it? Is there a need in the marketplace for this kind of technology, and can I find a partner to start making this pull its weight?"

Stomp's professional insights will ring true to many researchers: "You don't have to be named the CEO to be the power broker."

Lemma, also known as duckweed, is the world's smallest flowering plant—even smaller than a penny.

5

At universities, the success of research collaborations with industry sponsors depends most of all on the interest and enthusiasm that faculty scientists bring to the joint research effort. But university administrations can promote collaborations by motivating their faculties to take part and by creating a customer-friendly environment for would-be corporate partners.

University Best Practices: Building a Research Collaboration Team

ORGANIZING FOR SUCCESS

"There needs to be a *total* . . . institutional strategy for industry partnerships, not the piecemeal approach that is currently being done on a department and college basis," said an industry official interviewed as part of this study. "This is a problem . . . at many large universities."[1] In other words, universities must provide the organizational support to attract, negotiate, and carry out research collaborations with industry—and the various parts of their administrative structures must work together smoothly rather than seizing up in bureaucracy.

The administrative components of a successful research partnership program go by different names on different campuses, and smaller universities sometimes combine the diverse duties involved. But these components accomplish the same missions wherever and however they appear. The key offices (and functions) of effective collaborations are:

- Office of Sponsored Programs or Office of Research Administration—establishes and manages collaborations.
- Office of Technology Transfer or Office of Technology Licensing—decides when to seek patents and when to negotiate patent-licensing agreements.
- Office of Development—coordinates university fund raising.
- Office of Corporate Relations—oversees management of the university's relations with industry.

Office of Sponsored Programs or Office of Research Administration

Within the university setting, the sponsored-programs office coordinates the upfront activities required to establish collaborations as well as tasks related to their management. Responsibilities include obtaining and overseeing external research funding, developing collaborative ventures with other organizations, and ensuring compliance with federal policies and regulations.[2] The sponsored-programs office also usually negotiates the terms of a collaboration agreement, with assistance from university counsel.

Research administrators traditionally have helped faculty members identify funding opportunities and develop proposals. They also run interference for faculty to ensure that research projects meet federal obligations. As a result, the typical sponsored-programs office has earned a reputation for knowing the expertise of university faculty and is becoming more involved in developing internal and external cooperative arrangements.[3]

The negotiation of licensing terms is usually not the responsibility of the sponsored-programs office. Except at smaller universities, the technology-transfer office usually handles the license negotiations.[4]

Office of Technology Transfer or Office of Technology Licensing

The technology-transfer office manages the activities that occur at the end of a collaborative effort. This office decides whether and how patents will be filed on the new technology and, with assistance from university counsel, negotiates the terms of a licensing agreement. As a result, the technology-transfer office is best known for helping faculty become wealthy—or for telling them they will not. "It's very difficult to explain to faculty members that their ideas aren't commercially viable," observed Ted Cicero, vice chancellor for research at Washington University in St. Louis.[5]

As a result of its duty to select companies that will license university technologies, the technology-transfer office has direct, frequent contact with industry. Although a step removed from the actual research, this office is familiar with the expertise of the university faculty and tracks potential industrial research opportunities. It plays a central role in support of university researchers. Despite the already-supportive role this office plays, faculty members often would like to see the technology-transfer office adopt an even more service-oriented focus. Some researchers believe that this office makes it difficult for them to commercialize their work, leading them to evade university regulations and market their discoveries on their own.

In terms of revenue, perspectives vary depending on the party involved. University presidents frequently want to know how much revenue the office is generating for the university. Faculty inventors, on the other hand, want to know how much revenue the office is generating for them. And some university faculty members want to know why the university is even pursuing revenue at all for its academic work.

Issues such as service to the university and revenue generation are not looked upon lightly by technology-transfer offices. But these offices usually are very busy and often understaffed, and staff members do not always possess sufficient expertise to deal with the myriad issues that arise. "Well-staffed offices generally have one full-time-equivalent position for every $15 million to $25 million of research expenditures," wrote Louis Tornatzky, senior fellow, Southern Technology Council. "Professional staff will usually have advanced degrees in a scientific or engineering discipline and comparable degrees and/or experience in business or law."[6] Offices that work with faculty entrepreneurs also need staff members who are experienced in launching a business, perhaps including an individual who has been involved in a successful technology start-up venture. In addition, a successful technology-transfer office requires a significant commitment of resources. Tornatzky suggested that state governments provide up to five years of financial support in order to build university technology-transfer capacity.

Office of Development

The Office of Development is responsible for university fund raising. It solicits gifts from corporations and foundations, runs major fund-raising campaigns, and solicits donations from alumni. In recent years, as corporations have become more selective in their philanthropy, development offices have tried to identify common university-industry priorities when they seek contributions. Technology development is high on this list, and development offices have become more involved in university-industry research collaborations.

"Where a natural match between an institution's research strengths and corporate priorities can be found, many opportunities exist to gain corporate support," said Carolyn Sanzone, assistant vice chancellor for strategic technology alliances of the University of Massachusetts. "The corporate agenda for support to educational institutions has moved further away from personal interests and affiliations of CEOs and is more likely to be managed within the overall corporate structure."[7]

Office of Corporate Relations

As university development offices have adapted to this new reality, many universities created an Office of Corporate Relations to manage the university's relationships with industry. At some universities—such as Pennsylvania State University, Ohio State University, the Georgia Institute of Technology, and the Massachusetts Institute of Technology—it is called the Industrial Research Relations office.* The corporate-relations office also serves as an advance team for new relationships and sometimes matches companies with faculty experts. But its role is so new that it does not exist on many university campuses.

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–Louis Tornatzky, Southern Technology Council

*This report will discuss the role of corporate-relations offices in encouraging research collaborations, even though they do not exist at all universities. Where they do not, the reader should assume the report is referring to the elements of the development offices that have adopted these responsibilities.

Administration

University administration officials must reinforce the efforts of these offices. Those most frequently involved in research issues are the vice president for research, deans, department chairs, and their staffs. "Much can be done within large influential units without the involvement of the [university] president," observed Tornatzky. "Correspondingly, the best intentions of presidents can easily be undone—particularly in terms of explicit or informal reward systems—at the unit level."[9]

Collectively, these university officials are responsible for establishing and implementing university and departmental research policies, allocating resources, and coordinating with other entities on campus. Deans and department chairs often operate by themselves in smaller universities and wield considerable influence in larger universities. Their positions often give them access to senior corporate research officials, and their knowledge of the research strengths of the university, and ability to understand corporate research priorities, enable them to identify fruitful areas for collaboration. They are well positioned to coordinate the efforts of the faculty, the sponsored-programs office, the technology-transfer office, and the corporate-relations office in support of research relationships with industry.

MOTIVATING FACULTY

University researchers operate as independent contractors in the selection and accomplishment of their research efforts. As a result, establishing university-industry research collaborations requires attracting the interest and involvement of individual faculty members. Neither partner can sustain a collaboration without this foundation.

Faculty members' level of independence also depends on the manner in which they are paid. Faculty who are in a research-track position often do not draw a university salary. If they do not attract outside research funding, such as federal grants, they will not get paid.[10] Faculty who are in a tenure-track position draw a university salary, and outside research revenue usually does not supplement their base salary.[11] Instead, it supplants a portion of their university salary, and the amount saved goes to their academic department. Students working on a sponsored-research effort generally are considered university employees, but they receive lower pay and benefits than a regular, full-time employee. All, however, can share in licensing revenue should their name be cited on a patent or copyright.

Industry collaborations offer researchers new funding for their labs and varied research endeavors.[12] Researchers who pursue such projects usually are interested both in the fundamental science of their disciplines and in how to use that new knowledge. They tend to be skilled at the networking and relationship-building necessary to find potential partners.

"Many of our research collaborations develop in more ad hoc or informal ways," wrote Bill Decker, associate vice president for research at the University of Iowa. "We would not want to interfere with that."[13] Lynne Chronister, director of sponsored projects of the University of Utah, observed, "We're very successful with university-industry relationships and have almost zero central coordination of any of that . . . And so I think what we have here is something that is very individually based. There's a very strong culture here and very good policies that promote it, but it's really up to the individual faculty, not even the deans and chairs."[14]

Many faculty members who are most effective at collaborating are already oversubscribed, so encouraging them to do more will probably not greatly increase the number of university-industry partnerships.[15] Generating and sustaining the interest of those who have not yet collaborated extensively with industry is the challenge for university officials. "We would like to engage in more research collaborations," wrote the president of a private, West Coast university. "The limiting factor is the relatively small number of faculty members interested in attracting industrial sponsors for their research projects."[16]

Motivating and helping researchers locate potential collaboration partners requires a sophisticated understanding not only of how university researchers operate but also of individual researchers' focus areas, and of the companies that share their research interests. When technology-

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transfer, sponsored-programs, or corporate-relations officials are knowledgeable about faculty research interests, they can play a key role in prescreening companies with which faculty might wish to collaborate.[17]

The University of Massachusetts Office of Strategic Technology Alliances looks at faculty as clients and goes out of its way to assist them.[18] At Purdue, "we consider our office to be a service organization," said John Schneider, assistant vice president for industry research. "We want to help our faculty through the university's bureaucracy and facilitate them in developing relationships with industry. We want them to succeed and to make it as easy as possible."[19]

Once initial interest is generated, the next challenge is maintaining it. George Moellenbrock, director of corporate and foundation relations at Pennsylvania State University, observed that, "It's not difficult to get them [faculty] to the table . . . The tricky part is getting them to keep coming back to the table, [particularly when] not everything you put out in front of a company lands somewhere and moves forward."[20] To overcome this, an East-Coast public university has instituted a series of roundtables between research faculty and corporate research officials. At these meetings, the participants can informally discuss common research interests.

Follow-up to these initial informal sessions is important. "Faculty members have a lot of other things on their plate, and you need to almost make it happen for them in many ways when these relationships start to develop. So we try to jumpstart new opportunities through aggressive marketing and corporate contacts," said Sanzone.[21]

PROTECTING STUDENTS

University-industry collaborations offer attractive opportunities to graduate students working toward master's or doctoral degrees in university laboratories. An increasing proportion of students now move on to careers in private industry, and sponsored research can give them a better understanding of the private-sector environment, help them make contacts that might lead to job offers, and perhaps even enable them to work in corporate laboratories on promising projects that they began while pursuing their degrees.

But sponsored research also may pose risks. Universities should not divert graduate students toward efforts that will not advance their education or their thesis research. If students' work is hemmed in by corporate confidentiality requirements, they may find themselves barred from presenting their work at scientific meetings—or, even worse, unable to publish a Ph.D. thesis.

University officials and researchers must make clear to industry research partners that graduate students, and sometimes undergraduates, who work on industry-sponsored projects are not university employees—even though company-funded fellowships may be supporting their research. These young men and women are, first of all, students, and the university is responsible for ensuring that their interests are not damaged because of participation in sponsored research.

MARKETING THE UNIVERSITY

Most collaboration partners have worked together before. All of the major partnerships at a private, East-Coast university and 80 to 90 percent of nonfederal sponsored projects at a public Midwestern university are with existing partners. At a private, West-Coast university, only about one-third of new collaborations are with prior partners, but prior partners account for almost two-thirds of sponsored research there.[22] Thus, finding new partners may be a promising tactic for universities that want to increase their industry collaborations.

Although technology-transfer and sponsored-programs offices can promote new collaborations, a corporate-relations office can be particularly well suited for this task. The corporate-relations office is generally more outward oriented, usually has high-level connections, and is experienced in marketing the strengths of the university. "[Universities] should do a critical self-analysis to identify the specific niche strengths your institution has for the corporate sector in the areas of workforce development, workforce education, and technology development," wrote Sanzone. Local companies are the best initial targets, simply because they are nearby. But national corporations can be good prospects, too, because they share the same concerns. "Think locally. Act globally," Sanzone wrote.[23]

Some industry sectors are more open to collaborations than others. Life sciences companies spend a high percentage of their research budgets on campus. Electronics and computer firms are also heavy users of university research—particularly smaller companies. But chemicals and materials companies tend to spend less than 5 percent of their research budgets in universities. They try to develop work in house after culling good ideas from universities.[24]

The president of a university can play a constructive role in fostering greater numbers of collaborations; however, he or she must be well informed. Industry heads usually know all elements of the existing relationship between the organizations, and they usually expect university presidents to be equally familiar with the totality of their interactions.[25]

It is not necessary to secure full support for a research initiative from one corporate sponsor. Universities can leverage corporate support with public funding, alumni contributions, or foundation support. They also can use internal resources, where available, to seed initiatives. The goal is to offer the company a winning scenario, not a risky investment. As the relationship grows, it can be leveraged for other contributions, including non-monetary support. Proposing a well-thought-out plan, and providing specific ways in which the company can work with the institution, can be an effective sales pitch.[26] "An institution that establishes, promotes, and acts to implement a strategic plan is almost irresistible to the corporate sector," wrote Sanzone.[27]

The $25 million, five-year collaborative agreement between the University of California at Berkeley and Novartis Seeds grew from just such a plan. Gordon Rausser, then dean of the College of Natural Resources, analyzed the market needs of firms for which UC Berkeley's research would be relevant, and then the university sought out potential partners. "Typically, the university and its faculty wait passively until they receive a request for proposals (RFP) from governmental agencies or private companies and then generate a response to the other parties' terms," Rausser said. "By contrast, the Berkeley/Novartis agreement resulted from the university staking out its strategic advantage, taking the central position in the bargaining process, and inverting the typical protocol . . . The research agreement was structured by Berkeley, and the corporate candidates were asked to compete among each other to meet its conditions."[28]

MANAGEMENT AND SUPPORT ASSISTANCE

Successful research collaborations require myriad support activities above and beyond the work of the researcher. These include negotiating the contract, providing administrative and financial management assistance, and offering intellectual property advice. "There needs to be collaboration 'teaming,' using skilled people who bring their expertise to the enterprise," said Karen Hersey, senior intellectual property counsel at the Massachusetts Institute of Technology. "The administrators 'facilitate' . . . providing the hands-on experience to get the research collaboration buttoned down."[29]

But bureaucratic delays are a deal-killer. North Carolina State University has taken steps to coordinate and, where possible, streamline its relations with industry partners. Charles Moreland, vice chancellor for research and graduate studies, has a firm rule: A company should only have to make one call to Moreland's office to get what it needs.[30]

Almost every case study subject contacted for this report identified communication as the most critical management issue in a collaboration. As in any project involving different scientific disciplines, jargon can be a problem. Ralph Hutcheson, president of Scientific Materials Corporation (a university-based start-up company) said that early in his collaboration with a public western university, "clear communication among the physicists, chemists, [and] chemical and electrical engineers was prevented by disciplinary jargon." But the scientists learned to communicate across specialty borders, and "after five years' practice, the group can now talk across the former divides."[31]

Exchanges between corporate and university partners should be clear and direct. They also

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should be frequent, ideally every week to every month informally, with more formal presentations or write-ups every six to twelve months.[32] Timing visits to company sponsors to coincide with the company's internal budget process can help secure ongoing support.[33]

Good communication helps the participants work out disagreements without resorting to legal intervention. "If at all possible, disagreements should be resolved by frank discussions, rather than be put on paper with all the legal ramifications," observed David Kipnis, distinguished university professor of medicine at Washington University School of Medicine in St. Louis.[34] At the same time, researchers must know when to involve legal counsel. Ron Iacocca, formerly associate professor, Pennsylvania State University, now research scientist, Eli Lilly & Co., said that if a project required a significant shift in direction, he would seek legal assistance and amend the contract to avoid being legally bound to an outdated agreement.[35]

Meeting company-established deadlines is a recurring challenge to universities and researchers.[36] Industry officials often complain that university researchers lack management expertise and fail to respect contractual deadlines.[37] University researchers often say that meeting schedules is most difficult when the project has commercial applicability, which is also when corporate pressure is the greatest. University administrative offices provide some help in this situation, but responsibility for managing the collaboration from the university side ultimately is the researcher's.

But, some forms of research are not amenable to timetables, and university researchers and officials should make certain that their corporate partners recognize the difference. For example, clinical researchers can reasonably be asked to keep a large clinical trial on schedule (although even here, some factors—such as recruitment of patients—are not entirely in their control). But at the other extreme, basic, fundamental research—such as an effort to determine the function of a newly discovered protein—often cannot be run on a deadline basis.

Evaluating and Rewarding Faculty Involvement

Research collaborations are usually considered part of the faculty member's official duties and almost always result in research that can be published. Nevertheless, traditional university hiring, tenure, and promotion processes do not always allow for industry-sponsored projects, and faculty who take part may risk weakening their career prospects. "A promotion packet can contain industrial letters of support, but these must be in addition to the requisite academic support letters," said Pramod Khargonekar, chair of the Department of Electrical Engineering and Computer Science at the University of Michigan, who warns younger faculty against letting their scholarly output drop. "At the level of promotion to full professor, industrial collaboration can have a more positive impact as senior faculty are viewed with a different value system," said Khargonekar.[38]

Universities should not completely overhaul their faculty performance measures to require closer ties with industrial partners. Doing so would threaten the basic mission of the university and lead to faculty resentment. Tulane University, for example, believes that hiring and tenure decisions should be based on merit, institutional needs, and the anticipated productivity of the individual, not on the pursuit of industry-sponsored research.[39] One reason: Industry interests might change.

But some researchers have suggested special incentives or other compensation for participating in university-industry research collaborations,[40] and some universities have agreed. "[Our] administration has set up systems to give faculty research-proposal credit for participating in multidisciplinary proposals," said John Schneider of Purdue. "In addition, publication credit for patents is granted."[41] At the Georgia Institute of Technology, faculty may receive one-third of any licensing royalties and may hold equity in start-up companies that have licensed their technology.[42]

"Too frequently we have a culture that penalizes faculty for working outside the university," observed Dennis Smith, president of the University of Nebraska. "We need to change that."[43]

"Too frequently we have a culture that penalizes faculty for working outside the university. We need to change that."

–Dennis Smith, president of the University of Nebraska

Recommendation:

Research collaborations must be based on the willingness and enthusiastic participation of individual faculty members. A university can assist faculty in finding new collaboration partners but should do so based on faculty interest, the research strengths of the university, and industry research opportunities. Hiring, tenure, and promotion processes should give appropriate credit to university researchers who collaborate with industry.

WORKING AS A TEAM

Most universities could improve the way their administrative offices work together to promote collaborations with industry. "There needs to be a better integration between the staff working in contracts and grants and in technology transfer," said Richard Attiyeh of the University of California. Attiyeh suggests that the dean's office could be the central point. "That person, that office, is uniquely situated to take into account both the administrative imperatives and the academic imperatives and integrate those in a meaningful way in this process."[44]

Sanzone suggests that the corporate-relations office must play a major role. To do so, it "needs strong and effective linkages with all areas in the institution that directly interact with companies, including grants and contracts offices, student placement services, offices which deal with vendors, etc. In addition, the corporate-relations officer can be a key player in encouraging new faculty liaisons across academic disciplines."[45]

At Penn State, the development office compiles a short profile of the various research, recruiting, and vending relations it maintains with industrial partners. This profile includes information about campus visits, interviews, alumni, philanthropy, and key contacts.[46] "This becomes a starting point for us to understand the extent of a relationship and see where there are gaps . . . and how we might fill them," said Moellenbrock. "We share this knowledge with other offices at the university."[47]

In a case study prepared for this report, the administration of a public, Midwestern university suggested a "team approach" that would require faculty, deans, and administrative offices to understand the university's position and work together in negotiations with industry. But Gene Allen, director of collaborative development for MSC Software, cautioned, "However the university is organized, its efforts should be structured to minimize bureaucracy."[48]

Measuring Success

Devising university-wide performance measurements that do not force the various offices to compete for credit can promote better coordination. Ralph Christoffersen, president of Ribozyme Pharmaceuticals Inc. and a former university president, cautioned against measuring the success of research efforts by the amount of money they generate. "If revenue is not the primary measure of success, then issues such as competition for fund-raising credit between corporate-relations offices and technology-transfer offices completely disappear."[49]

Devising university-wide performance measurements that do not force the various offices to compete for credit can promote better coordination.

Much of the bureaucratic rivalry within universities over industry collaborations has dissipated in recent years. "I don't see the competition between technology-transfer offices and corporate-relations offices that much anymore," observed Molly Broad, president of the University of North Carolina System. "Both are usually working very closely with the appropriate deans."[50]

At the University of Massachusetts, the performance of the Office of Strategic Technology Alliances is measured in several ways. One is revenue generated from industry, but others are the level of university-industry partnerships, the initiation of new faculty projects, and whether a company is visible on campus beyond recruiting efforts. This sort of multifaceted performance assessment will likely be necessary to gauge the performance of other university offices.

UNIVERSITY STRUCTURE AND LEADERSHIP

Participants at the 1997 University of California Presidents Retreat identified four challenges facing universities in their interactions with industry. They are:

- Basing decisions on "how to make it work," as opposed to following rules.
- Granting greater autonomy (with accountability) to decision makers.
- Ensuring that faculty and administrators better understand the principles that should guide decisions about industry agreements.
- Better communication and teamwork among university personnel involved in negotiations with industry.[52]

Some universities have encouraged teamwork by co-locating related university offices. About 10 years ago, Penn State decided to cluster the administrative activities that engaged industry into one facility. This has fostered cooperation, rather than competition, for establishing relationships with companies and sharing information.[53] North Carolina State has incorporated its Office of Industry Research Relations and Office of Technology Transfer into a combined Office of Technology Transfer and Industry Research.

When faculty and staff express reluctance to work with industry, the university president may need to build a consensus in support of balanced research collaborations. It will be important that he or she understand the issues well enough to be able to speak the same language as staff collaboration experts. Where necessary, the university president also should develop new procedures and performance measures that encourage teamwork. "The arrival of a new chancellor prompted centralization of the research collaboration programs at our eight schools," observed Ted Cicero of Washington University in St. Louis. "He has provided very important support."[54]

Recommendation:

Universities should coordinate the efforts of the various offices that support university researchers in their work with companies and, where appropriate, should consider co-locating them. The president of a university campus should be responsible for establishing a cooperative tone toward university-industry research collaborations and should align incentives to encourage teamwork and promote research collaborations.

NOTES

[1] Katherine Adams and Richard Schwartz, *A Case Study of the University of Kentucky,* quoting an industry contact (Lexington, KY: 1999), 4.

[2] *The Role of Research Administration,* National Council of University Research Administrators, April 2000, 2.

[3] Ibid., 6–7.

[4] Lynne U. Chronister, e-mail to Project Director, 20 September 2000.

[5] Ted Cicero, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 46.

[6] Louis Tornatzky, *Building State Economies by Promoting University–Industry Technology Transfer,* prepared for the National Governors' Association (Washington, DC: Batelle Memorial Institute, 2000).

[7] Carolyn Sanzone, *Securing Corporate Support: The Business of Corporate Relations* (1999).

[8] John A. Schneider, conversation with Project Director, 14 July 2000.

[9] Louis Tornatzky, e-mail to Project Director, 14 August 2000.

[10] Lynne Chronister, e-mail to Project Director, September 2000.

[11] OMB Circular A-21, http://www.whitehouse.gov/OMB/circulars/a021/a021.html.

[12] Memo to Judy Irwin, from the office of Scott Cowen, 8 August 2000.

[13] Bill Decker, e-mail to Mary Sue Coleman, forwarded to Project Director, 2 August 2000.

[14] Lynne Chronister, remarks during *Building an Effective University Technology Transfer Team* teleconference, 17 December 1999, 21.

[15] *Case Study Final Report,* Lakewood, MN, 7 September 2000, 30.

[16] Confidential response to BHEF RCI Survey, April 1999.

80

[17] *Case Study Final Report,* Lakewood, MN, 7 September 2000, 30.
[18] Carolyn Sanzone, remarks during *Building an Effective University Technology Transfer Team* teleconference, 17 December 1999, 16.
[19] John A. Schneider, e-mail to Project Director, 17 July 2000.
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[21] Carolyn Sanzone, remarks during *Building an Effective University Technology Transfer Team* teleconference, 17 December 1999, 20.
[22] Confidential responses to BHEF RCI Survey, April 1999.
[23] Sanzone, *Securing Corporate Support,* 1999.
[24] Randolph Guschl, e-mail to Project Director, 29 September 2000.
[25] Reynold Levy, remarks at *Collaborations and Partnerships Conference, 1999,* Duke University, 15 November 1999.
[26] Sanzone, *Securing Corporate Support,* 1999.
[27] Ibid.
[28] Gordon Rausser, unpublished letter to the editor of *The Atlantic Monthly,* 19 May 2000.
[29] Karen Hersey, e-mail to Project Director, 2 August 2000.
[30] Charles Moreland, conversation with Project Director, April 1999.
[31] Ralph L. Hutcheson, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 9.
[32] *Case Study Final Report,* Lakewood, MN, 7 September 2000, 3.
[33] Alan Lesser, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 2.
[34] David M. Kipnis, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 3–4.
[35] Ron Iacocca, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 31.
[36] Pramod Khargonekar, interview by Beth Starbuck, Calyx, Inc. *Case Study Final Report,* 7 September 2000, 36.
[37] Diana MacArthur, response to BHEF RCI Survey, April 1999, 6.
[38] Pramod Khargonekar, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 37.
[39] Memo to Judy Irwin, from the office of Scott Cowen, 8 August 2000.
[40] Katherine Adams and Richard Schwartz, *A Case Study of the University of Kentucky* (Lexington, KY: 1999), 4.
[41] John A. Schneider, e-mail to Project Director, 17 July 2000.
[42] Louis Tornatzky, case study of Georgia Tech for the Southern Growth Policies Board, 30 July 2000, 14.
[43] Dennis Smith, remarks during Business–Higher Education Forum summer 2000 meeting, Mystic, CT, 29 June 2000.
[44] Richard Attiyeh, Group 8, "Facilitating UC-Industry Relationships, Organization and Structure," *Proceedings of the President's Retreat,* 1997. The full report is available at http://www.ucop.edu/ott/retreat/tabofcon.html.
[45] Sanzone, *Securing Corporate Support,* 1999.
[46] George Moellenbrock, remarks during *Building an Effective University Technology Transfer Team* teleconference, 17 December 1999, 10.
[47] Ibid.
[48] Gene Allen, conversation with Project Director, 18 July 2000.
[49] Ralph Christoffersen, letter to Project Director, 15 July 2000.
[50] Molly Broad, comments during Business–Higher Education Forum summer 2000 meeting, Mystic, CT, 29 June 2000.
[51] Carolyn Sanzone, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 33.
[52] Scope of Advisory Group 8, "Facilitating UC-Industry Relationships, Organization and Structure," *Proceedings of the President's Retreat,* 1997. This section of the report is available at http://www.ucop.edu/ott/retreat/report8.html.
[53] *Case Study Final Report,* 7 September 2000, 29.
[54] Ted Cicero, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 46.

Office of Naval Research: *A Government-Academia-Industry Collaboration*

The Power Electronic Building Block (PEBB) program, one of the most extensive collaborative research efforts undertaken by government, academia, and industry, began in 1994 under the leadership of the Office of Naval Research (ONR), and the radical impact of PEBB technology on naval systems has sparked new interest in the power electronics field.

Power electronic building blocks—electrical connectors that use software to sense what other devices are plugged into them—are essential parts of all naval ships, aircraft, ground vehicles, and most weapons and sensors. They act as super-efficient switches, converters, inverters, circuit breakers, power supplies, generators, and motor controllers. Their use in a high-power electrical system greatly increases the system's efficiency while dramatically reducing its size, weight, and cost. PEBB technology is the key factor that will enable the "All Electric Concept" for ships, aircraft, and ground vehicles.

"Research in high-power electrical systems had dribbled off in the 1960s and '70s," says Dave Rossi, head of Industrial and Corporate Programs at ONR. With research efforts and budgets focused on solid-state electronics for computers, communication systems, and sensors, research for generating and transmitting electrical power was almost nonexistent. The military demands of the 1990s, however, began to pose new requirements for electrical power sources with increased efficiency and reduced size, weight, and cost. "The military needs shifted," Rossi says, "and solid-state electronics for power was in demand."

Today, the PEBB program's mission is to harness the potential richness of government-industry-university partnerships by involving all entities at every stage of the technological innovation process. Currently, ONR devotes more than $10 million per year to PEBB research through more than 100 contracts and grants involving 200 or more researchers. Industry partners devote more than $40 million to PEBB research each year, and the amount is growing. Being involved with the PEBB program is "a once in a lifetime opportunity" for researchers, says Terry Ericsen, program officer of the PEBB program.

But building the program wasn't simple. The partners had to overcome several challenges along the way.

By the 1990s, the Department of Defense, and in particular the Navy, needed to quickly and efficiently design and produce new electronic power platforms. The Navy was interested in a range of concepts including high-energy weapons, hybrid electric engines, communications, and stealth technologies. This "all-electric" ship concept, however, would require the very same electronics research that had diminished in the 1970s.

At the same time, industry was beginning to tackle power electronics issues for civilian products. ONR, working with the Department of Energy's Partnership for a New Generation Vehicle program, identified demands for PEBB technology within the automotive industry. "There was a lot of cross-talk," says Rossi. Commercial automakers, in partnership with government, teamed up with Virginia Polytechnic Institute and State University (Virginia Tech) and began work on the Science and Technology Power Electronics program. This government-sponsored program includes such partners as ONR, the National Science Foundation, and the state of Virginia.

As technological discoveries were spun out of university laboratories, government laboratories standardized the processes involved to satisfy the engineering requirements of both the Navy and industry partners. Automobile companies used these standards to move into commercial product development. Then, because military requirements were embedded in the systems, the technologies could be spun back to the Navy, and the systems could be purchased off the shelf at commercial prices.

Examples of these collaborative efforts include Rockwell International's PowerFlex-700 motor drive, which will be used in shipboard motor controllers, ABB Inc.'s PEBB devices for the international utility market, and high-power applications such as electromagnetic propulsion in naval platforms.

To end up with dual-use products, industry had to be drawn into the process early, and the Navy mounted an aggressive outreach effort. "We would ask industry, can you use this technology?" Rossi says. The answer often was yes, but the technology was often too risky for industry to undertake.

Knowing that the technology would have a commercial application, the Navy pursued the innovation process in partnership with academia. As the technologies advanced, all industry partners and potential suppliers were updated on the outcomes. With the risk diminished, industry became an active partner, bringing the new discoveries into commercial product development.

Eventually, PEBB technology may lead to a tenfold increase in investments by the commercial market, and because the technology is so pervasive, its potential profitability is enormous. The technology may revolutionize the business of supplying commercial electrical power. PEBBs could provide a wide range of essential devices that are significantly more efficient and cost-effective than existing power-generating and transmission components. PEBB technology also is a crucial part of the Partnership for a New Generation Vehicle's hybrid electric car initiative.

"These products would not have been realized if industry did not have the incentive to build them and universities were not partners in the research effort," Ericsen says.

Moreover, the Navy couldn't have funded PEBB development on its own, Rossi says. "If we had to rely upon only government investment, it would be impossible to build these systems," he says.

The PEBB collaboration effort was not always smooth sailing and did not always enjoy full support from the partners. The challenges included overcoming cultural differences, recruiting new partners, and capitalizing on the dual-use concept.

The greatest hurdle was changing cultural perspectives. During the 1980s, the defense industry and government often distrusted one another, and suspicions were exacerbated by frequent charges of waste, fraud, and abuse. The Navy had to convince the industry partners that it was an honest broker in the process. Industry needed assurance the technologies to be developed would indeed be available to the civilian sector. Shifting this cultural perspective took a long time and depended heavily on open communications among the partners. "Part of the art of collaboration is learning the best way to interact," Ericsen says. "The collaborative effort has to be pulled as much as it is driven."

Another challenge was bringing nontraditional suppliers into government collaborations. Companies outside the defense sector did not have the long history of government interaction that the defense sector had. "The commercial sector was worried that the military would require them to change their business practices, like using military accounting systems," Rossi says. These issues were worked out by such steps as changes in procurement requirements.

Collaborative efforts such as the PEBB program will not work across the board. The technologies must have a true dual use to be of interest to the private sector. Of course, military platforms will not be dual-use, but many of the subsystems can comprise dual-use technologies. "At the platform level the systems are solidly military in design, but at the subsystem level the commercial products, with embedded Navy requirements, can be used," says Rossi.

Benefits of the PEBB program have been tremendous. "The cost and time savings for the production of new power electronic systems are immeasurable," Rossi says.

In addition, "by bringing industry in at the beginning of the process to determine the commercial viability of a technology, the Navy was able to secure a buy-in by its industry partners," Rossi says. "This greatly reduced the government's development and procurement costs. In the past, a military subsystem was developed and produced for the customer with commercial applications as an afterthought."

University research in heavy electrical power technologies also has been reinvigorated.

Periodically, the PEBB program brings in outside experts to conduct reviews and evaluations. "During this review process all the partners are involved," says Narian Hingorani, former vice president of the Electric Power Research Institute. The outside experts advise the project manager on possible areas of emphasis and suggest improvements or new methods as the technology advances. "As the stages of technological discovery continue, industry begins to buy in to the process," Hingorani adds. "It works very well."

As the PEBB program has matured, ONR has initiated "technology working groups" to move the collaborative approach even more deeply into the R&D process. The working groups include researchers and technology experts from government, university, and industry, organized around particular technologies and open to all who want to participate. These integrated teams have allowed all the partners to meet around the table and build on continued product development. The technology working groups look at different applications of the technologies and "solve common problems," Ericsen says. The teams collaborate to determine areas of critical technology development, build technology concepts, and begin the standardization process. In addition, research performed at the university level is guided by requirements and issues developed in the technology working groups.

Today, the program has grown to include smaller companies that participate in the Small Business Innovation Research (SBIR) program, which sets aside a percentage of all federal research funding for research grants to smaller companies. ONR also has reached out to other government agencies that might benefit from a similar process to share the lessons it has learned about making such collaborations work. With more than 100 contracts and grants per year, the program has created a viable model for the inclusion of all partners—government, academia, and industry—at all levels of the innovation process.

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"Technology transfer is people to people. You have to commit the people to make it work."

—Hank McKinnell, Chairman and CEO, Pfizer Inc

Corporate Best Practices: Making Collaborations a Core Competency

LEADERSHIP AND VISION

While the impetus for initiating specific new projects typically is driven by the research needs of company scientists, industry support for collaborations with universities generally must start at the top or it will never start at all. In every company, no matter what the product or sector, the chief executive officer (CEO) and senior leadership team establish the priorities and operating tone. "The climate is set from the top," observed Hank McKinnell, chairman of the board and CEO of Pfizer Inc.[1]

"Our CEO doesn't sign off on every collaborative project we do," said Rick Jarman, collaboration manager for Eastman Kodak Co. "At the same time, it is important to have support from the top to create the fertile ground throughout the company to collaborate effectively."[2] This is particularly true in smaller companies. "In a small company, CEO support of collaborative research is critical," observed Ralph Hutcheson, president of Scientific Materials Corporation, a start-up company in Bozeman, Montana.[3]

University presidents and administrations play a more limited role. They have no direct control over how faculty will perform specific duties, despite the fact that the actions of faculty define how effectively the university accomplishes its missions of education, research, and service.

This dichotomy has important implications for university-industry research collaborations. Private sector companies are results-driven; they cannot afford to be unfocused when it comes to making research investments. A research collaboration must meet business objectives, must be specified in financial terms, and ultimately must be accountable to the firm's stockholders.

For this reason, the company—not the university researcher—often will select the research priorities. But the interest of the university scientist must be engaged, too, because in most cases, university researchers choose their own research topics. In effect, this means that corporate management and university faculty ultimately must agree on the vision and goals for the collaboration.

The support required from the CEO for any project varies with its complexity and its proximity to meeting specific operational and broader strategic goals. "Corporate support for research collaborations needs to match the project, with higher level support required for those projects connected to emerging products and for those requiring a more complex team," observed Robert Carman, program manager, advanced programs in propulsion and power at Boeing Rocketdyne.[4] The biomedical partnership agreement between Monsanto (now Pharmacia) and Washington University in St. Louis required approval at the CEO and chancellor levels, as did Boeing Co.'s participation in building a wind tunnel at the California Institute of Technology.

Some companies have established internal matching-fund programs to encourage a culture change toward external research. A chemical company used this approach in the early stages of its research collaboration program.[5] "Company support for collaborations at [our company] draws upon the vision of the chief technology officer," observed Emil Sarpa, manager of external research at Sun Microsystems. "[It] is institutionalized in our decentralized organization by top-level discussions and by enticing, 50-50 matching fund programs."[6]

A supportive corporate culture also is important in deciding whether to engage in a specific collaboration. Establishing and maintaining an effective collaboration is time-consuming at many levels of a company, particularly for corporate research departments. Company decision makers should recognize that effective collaborations require the substantive involvement of key personnel. "Technology transfer is people to people," observed McKinnell. "You have to commit the people to make it work."[7]

Choosing Appropriate Research Topics

The first decision a company must make is whether a prospective research effort is a good candidate for outside collaboration. "Technology selection evolves into budgetary discussions that lead to eventual winners in the decision on what technologies will be developed by the company," wrote Gene Allen and Rick Jarman in *Collaborative R&D: Manufacturing's New Tool*. A collaboration is not "an odds-on favorite" to be chosen, they said, because of "the shortage of true believers in collaboration and the natural tendency to take a good, or funded, idea and rush to develop it alone," in order to be first to market.[8]

Once company officials decide to pursue a collaborative research program, they must next determine whether to work with a university, a government laboratory, a partner company, or a contract research organization. Analyzing the proposed collaboration's purposes can help in selecting partners. In an article in the January–February 2001 issue of *Research Technology Management*, Beth Starbuck, president of Calyx Inc., described six goals that a company might wish to achieve in a collaboration with a university:

- Provide a window on the future.
- Complement internal expertise.
- Augment internal capacity.
- Track development of potential competing technology.
- Try new analytical techniques.
- Identify prospective employees.[9]

Most university and industry research coordinators share an understanding of what type of research is mutually beneficial. It should be ethical, publishable, basic or slightly applied, and it should pair the expertise of the university with the interests of the company.[10] Michael Montague, director of research operations for Pharmacia Corp., said that basic research into new methods, processes, and fundamental enabling knowledge fits best with the mission of a university. Slightly more applied research into a well-defined problem, such as analytical testing of a new compound, can be a good "starter" project or summer project for a graduate student, Montague said. But highly applied projects, such as synthesis and screening of compounds against an assay, don't belong in a university. With the exception of clinical trials of new drugs or medical devices at academic medical centers, this kind of research usually should be performed in an industrial setting or a contract laboratory.[11]

Larger companies are more likely to sponsor fundamental research on campus. "At least in the larger relationships, companies seem to be backing away from the targeted, focused applied project and are moving to support more basic, broad-based programs," observed Karen Hersey, senior intellectual property counsel of the Massachusetts Institute of Technology. "They are no longer interested in just incremental improvements. They want major new ways to do things. Companies are looking at us to move them ahead . . . [to] give them that leg up on the competition."[12]

At Boeing Rocketdyne, Carman said that although nearly all of his basic research is collaborative, 20 to 50 percent of the university research that Boeing sponsors is of a more applied nature. "The amount is based on the business phase, with less involvement of a university in the short-term phase."[13]

Smaller companies tend to view somewhat applied research as appropriate for university collaborations.[14] Either a large or small company can use its relationship with the university to explore new directions before developing a product or process in house, although small companies may try to use the university to provide all their research needs. Large, technology-driven companies often find it cost-effective to work with universities for long-term (three to five years), complementary research projects. Short-term research needs of large companies generally do not match university goals or timeframes. Commodity companies, by and large, rely on in-house research and are not frequent consumers of university research.[15]

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Alan Lesser of the University of Massachusetts, who also is editor of the *Polymer Composites Journal,* observed that well-matched projects are usually nonproprietary and often have a longer time horizon than is typical in a corporate research laboratory. "Both for large and small technology-driven companies, long-term, exploratory projects that complement university efforts are the best match," he said.[16]

Ultimately, each collaboration partner must seek to meet its own needs through the collaboration. "For collaborations to work, each participant needs to benefit from the effort," Allen and Jarman wrote. "All parties need to be selfish in this respect. The collaborative program has to be in line with the development that each organization would otherwise be pursuing as part of its core business," whether it be product development or research, education, and service.

Finding Partners

Finding research partners is a multilayered process. Strategic planning may identify technological areas of interest or specific projects that might be appropriate for university collaboration. Often, company researchers who closely follow external developments in their fields identify potential projects and likely university partners. The faculty member and/or institution most suitable for a partnership also can be drawn from a company researcher's professional networks, alumni connections, databases of experts (such as the Community of Science or ScienceWise.com), or through a central coordinating office's experience of campuses. Sometimes, university researchers propose collaborative research projects to companies, and some companies use an open RFP format to encourage proposals in areas of strategic interest.[18]

Boeing Rocketdyne selects potential external partners as part of its annual strategic planning process, identifying projects that might lead to a competitive advantage or to developing potential employees. The strategic plan also may define technological areas that the company may wish to develop, and the planning exercise may even design programs to support university exploration in these areas. "When a decision is made to move into that new technology, the company is then positioned to move and ready to hire," said Carman. "Defining which university will be the partner usually results from networking, publications, consortia, or which schools known students select."[19]

Company researchers complement this process. They define an area in need of exploration and draw on personal contacts or professional networks to identify experts. "I then introduce myself to the selected faculty member and discuss whether their interests might relate to our identified problem," said Ray Edelman, a senior technical fellow at Boeing Rocketdyne. "With most of the advanced technology problems, we need fundamental information to answer practical questions, although I prefer that a faculty member appreciate the possible application and relevance of the results."[20]

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Sun Microsystems provides logistical support for its matchmakers.[21] It identifies potential collaborators through the advice of company engineers, seminars, visits of the collaboration coordinator to universities, and university-initiated contacts. Then, its technology sponsors use a template to describe proposed projects to potential collaborators, alerting them to the company's interests.[22] Beth Starbuck noted that if a company's first choice for a faculty partner is unavailable, it may approach the department's most recent graduate who stayed in academe. It also may consider funding a start-up grant to attract new faculty members to areas of interest.[23]

Unlike others in the information technology industry, Sun Microsystems does not use RFPs to solicit proposals from universities. The office of the collaboration coordinator screens institutions and unsolicited proposals, using criteria similar to those that Sun Microsystems uses to manage internal research projects. The criteria are:

- Is the appropriate engineering group willing to be the technical sponsor?
- Does the university have the appropriate expertise?
- Does the university have a reputation for negotiating deals expeditiously?
- What are the outcomes from using the template?[24]

Universities' efforts to find compatible corporate partners provide another avenue for connecting industry and university researchers. From the corporate perspective, the number of potential university opportunities can be daunting. "A company cannot try to make every opportunity happen," wrote Randolph Guschl, director of corporate technology transfer at DuPont Central Research. "Too many options are available, and you must learn to pick the lucrative ones."[25]

At the same time, the company must give the outside world a point of entry into its research activities.[26] Sun Microsystems invites university researchers to e-mail a one-screen project-proposal abstract to Emil Sarpa, manager of external research. The company promises that an engineering group will evaluate the concept and tell the researcher whether Sun is interested. Then, negotiations with the researcher and his or her university will determine project terms and funding.[27]

DuPont, which is inundated with more than 1,000 project proposals per year, sorts them initially by analyzing whether a proposal fits its existing research agenda or provides an opportunity to branch into a new area. If DuPont expresses preliminary interest in a proposal, it sends an electronic abstract to a company panel of experts for review. If the project clears that hurdle, it moves to the scientist-to-scientist level for more detailed study.[28] The Sun and DuPont models stand in marked contrast to the federal grant process, which generally requires researchers to submit comprehensive, detailed grant applications without any indication that they might receive funding.

Companies sometimes pick a few key partners with whom they will work most often. DuPont has narrowed its list of preferred "technology partners" to about two dozen, although it will continue to work with different universities that are pursuing research areas of interest. Making the list of preferred institutions requires effort. "Our partners must accept the fact that they are competing with others," wrote Randolph Guschl. "We are going to work with people who are easy to deal with, can respond quickly and honestly, and keep the strategic focus on the partnership."[29]

Other companies have a central coordinating office to identify preferred faculty members and/or institutions and to maintain a list of universities with which the company has had good results.[30] Information about the best universities and researchers to work with also is shared through professional organizations such as the External Research Directors' Network of the Industrial Research Institute.[31] "The existence of the central coordinating organization was probably pivotal in making collaboration a core competency at [our company]," concluded Frank Knoll of Dow Chemical Co.[32]

An Internal "Champion"

To ensure success, a university-industry collaboration needs an "end-user champion"—someone within the sponsoring company who is dedicated to making the partnership work.[33] This individual must bridge the language gap between academia and industry, mesh university and industry cultures, reconcile the conflicting interests inherent in any collaboration, and ensure that the research is integrated into internal company processes so that it remains relevant. "The champion has to be senior enough in the company to be able to get resources committed," wrote Allen and Jarman. "The champion should also have enough confidence in the personnel and in the concept being developed to be willing to take risks in attempting new business processes and procedures."[34] He or she also must be able to draw strong support for the technology from company scientists working directly in that field. For the end-user champion to spend the time necessary to accomplish this, senior company research officials—and ultimately the CEO—must value external research.

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Management support also can be vital to keeping a collaboration afloat through changes in funding priorities. Nothing is more deadly to a collaborative program than financial cutbacks: When a company pares research expenses, research contracts with universities can be among the first to be cut. "Commitment from management to honor these programs is essential, because building technology-transfer relationships takes a long time," wrote Randolph Guschl. "Once the process has been started, it needs continuous support from all involved parties."[35]

Recommendation:

Companies should encourage internal champions of research collaborations to identify potential university partners based on shared research priorities. To expedite this process, companies should make it as easy as possible for potential university partners to communicate with the company research organization and should consider establishing a central coordinating unit for this purpose.

MANAGING RESEARCH COLLABORATIONS

The appropriate form of management oversight of a collaborative effort will depend on the type of research being performed and the objective sought. Research of a more applied nature, such as regulatory and problem-solving research, often can be managed like internal or external research contracts, because it often has well-defined goals and milestones. This type of research usually is a relatively small component of industry research performed in universities.

Fundamental, exploratory research, on the other hand, requires a partnership management approach. "Milestones that are appropriate for problem-solving and regulatory projects may limit creativity and progress in discovery research," wrote Beth Starbuck.[36] Managing an exploratory-research collaboration requires "flexible" oversight to work through "often unpredictable" turning points while keeping the project relevant to the company's R&D goals, she added. Companies generally have not developed skills at working with research partners in this manner.

Research goals and timetables can be mandated for a company's internal research or in an external, applied research contract. But timelines must be negotiated for an external project involving exploratory research—and both sides must recognize that it cannot be held to a timetable.

The first and most important issue is establishing a research agenda that the company wants to support and the faculty member wants to carry out. Ideally, the project will explore a research pathway that the company perceives as an important new direction for its R&D and that the university researcher believes is a promising route for advancing a given science or technology. "In the university-industry partner relationship, universities may gain access to technology necessary for further advances in fundamental understanding, while industry may be able to improve a technology in preparation for eventual sale of products," said the House Science Committee's 1998 National Science Policy Study. "This type of symbiotic relationship is at the heart of successful partnerships."[37]

Managing a partnership requires scientists in both the university and the company to draw heavily on their team-management skills and places a premium on clear communication, openness, and forthrightness.[38] It relies heavily on the strength of personal relationships. "[You need] someone on the other end who cares as much as you do," said Ron Iacocca, formerly associate professor, Pennsylvania State University, now research scientist, Eli Lilly & Co. "Where that doesn't exist . . . the project dies."[39] In addition, in a collaboration no one person or organization controls all the resources necessary to accomplish the program.[40] When the partners are making roughly equal financial and/or intellectual contributions, decision making occurs primarily by consensus.

The contract should clearly define the distinction between applied and exploratory research. "Since research relationships between corporations and universities can take many different shapes—ranging from true collaboration to the purchased provision of services—partners should mutually acknowledge the form of relationship they intend to enter and should structure any formal agreements to be consistent with the

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nature of the relationship," cautioned Bill Decker, associate vice president for research of the University of Iowa.[41]

Both sides should choose their words carefully. Some company officials tend to call all their external research "contract research." After all, it is all contracted out. University officials usually prefer to call university-industry collaborations "sponsored research."[42]

More is involved here than political correctness or hurt feelings. Conventional "contract research" is often based on a company protocol and follows company-mandated work schedules and methodology. Company officials expect to be able to give orders to the contractor performing the research. But "sponsored research" may involve a topic proposed by a university researcher and may draw long-term support from several funding sources.[43] In such cases, the researcher and university have obligations to the other funders as well as to the company. In addition, university faculty members fiercely guard their academic independence. Using a term—"contract research"—that connotes a subordinate relationship will feed their apprehension that industry research collaborations mean the loss of academic freedom.

Nevertheless, company officials have the right to remind university researchers that a contract is a contract. "No matter what you call it, university partners do have to understand that industry-sponsored research is not NIH- or NSF-sponsored research," said Diana MacArthur, president of Dynamac Corp. "There are obligations to fulfill and timetables to be met."[44]

Tying university research to company schedules is essential to a successful collaboration. The company, the university, and the researcher should pay close attention to any timelines before agreeing to a project. "I want to confirm that the goals and objectives of the research plan are realistic in light of the subject matter, timeline, and expectations of the scientists," said Edward Pagani, director of strategic alliances for Pfizer Global Research & Development. "We then make a determination whether Pfizer should enter into a collaboration for the proposed research."[45]

However, Boeing Rocketdyne's Carman suggested that integrating research results into a company's strategic processes is "the major problem with U.S. industry in general."[46] Beth Starbuck urges that companies stay in touch with university researchers and students while "their" research results are being integrated into the product or service development process. They can consult as experts and advise during the troubleshooting phase. Such continued contacts offer the added benefit of maintaining the relationship, even during interruptions in funding.[47]

Because the company collaboration manager is such a key part of the collaboration team, his or her departure can present difficult challenges. Experienced university and company officials say that frequent turnover of company project managers is the most disruptive personnel change that affects collaborative teams.[48] University researchers may interpret such personnel changes as evidence of lack of commitment by the company.[49] Even experienced faculty can become frustrated when personnel changes bring less-skilled replacements.

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Personnel changes are a part of corporate life, particularly in an era marked by corporate mergers and acquisitions, and in a high-tech world where often the best strategy for a young, entrepreneurial firm is to join forces with a larger company. But Boeing Rocketdyne's Ray Edelman suggested, "Always have a backup in mind."[50]

The Role of Students

The involvement of graduate students can both enhance and impede a collaborative industry-university research project. One of the major reasons that research-oriented companies began engaging in such collaborations was to meet, evaluate, and possibly hire bright graduate students. But many of the obstacles that collaborations encounter stem from the need to protect students' academic interests.

In either case, graduate students and occasionally undergraduates will nearly always be involved in university-industry collaborations. Education is a key mission of the university. And graduate students perform much of the laboratory work in any university research project.

The biggest challenges posed by student involvement arise during negotiation of confidentiality and intellectual property terms. The university needs to ensure that students are not negatively affected by the collaboration or by any financial and professional conflicts. Chapters 4 and 5 of this report address these concerns in greater depth. But companies should keep some additional considerations in mind.

For example, the students should be informed at the outset of any confidentiality and intellectual property expectations, particularly if the company has shared proprietary data with the university laboratory. Of course, even if graduate students are funded by a company fellowship, they work directly for their university mentor, and their future careers can depend on that scientist's guidance and goodwill. Therefore, the mentor—who presumably is the researcher involved in the collaboration—and the university are responsible for informing students of any confidentiality restraints. But companies should make certain that confidentiality warnings are impressed upon them. If students join the project mid-term, the company project manager should promptly educate them regarding these matters.[51]

Because graduate students are important members of laboratory teams, companies that propose or issue an RFP for a collaborative project might consider timing it to fit the academic cycle. University researchers who might otherwise be interested may not participate if an unfortunately timed request does not allow them to secure student assistance.[52] Ideally, a student would begin working on a project after he or she has taken a few courses, and perhaps the Ph.D. qualifying exam, but before getting too far in his or her research. The student should have enough time before graduation to become deeply engaged in the project.[53] All parties, but especially the student, should have a realistic understanding of the commitment necessary to accomplish the collaboration.[54]

Corporate sponsors should be prepared to hear, from time to time, that a particular student cannot work on a project—or even that the university won't accept a project—because of confidentiality constraints. A common nightmare for university professors is the thought that a student may complete his or her thesis research and then find that it is unpublishable because it contains confidential corporate information.

In most cases, however, a university-industry collaboration gives the company a chance to evaluate graduate students on the job as potential employees. To this end, the company should build relationships directly with them. Steve Hahn of Dow Chemical Co. believes the goal should be to "get to know the students well enough that they call you directly."[55] Hahn values informal, telephone, or e-mail contacts with university partners—including graduate students or postdoctoral fellows.[56] But some university researchers mentor their students before letting them talk directly to company representatives.[57]

Ultimately, what separates university-industry collaborations from other opportunities to meet promising students is the expectation that the project will generate important results for the company. Involvement of students is important not only because they perform much of the actual research but also because their fresh insights sometimes can identify solutions to problems that elude faculty researchers. "I have seen where a student went ahead and accomplished what the professor said wouldn't work," said Hahn.[58]

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Reporting Requirements

Formal reports from university researchers provide the industry sponsor an important, detailed, written account of the status of the collaborative effort. The Industrial Research Institute suggests that a formal annual report "allows for a reasonable level of oversight, considering both the flux of new people entering the university and the rapidly changing array of consulting, publishing, and research activities of a faculty member."[59] Annual reports also provide exposure for the project to company officials beyond the project monitor.[60]

Informal monthly reports and a campus visit about six months into the project also are useful tools that keep a project on track.[61] "If you just send a check at the beginning of the year and hope you get the results at the end of the year, you're going to be very disappointed," said McKinnell.[62]

In addition, the project monitor at the company often provides internal profiles at the beginning of the effort, at the point when a patent should be considered, and at the end of the year.[63] The company integrates these reports into research summaries and uses them in project planning and personnel evaluation. Reporting requirements in a strategic university-industry relationship can become quite complex, but the system at smaller companies is usually more informal.[64]

Measuring Success

Metrics for evaluating a collaboration's success can be applied at the project, personnel, and organization level. Assessing the integration of collaborative research results into product and service development, however, is something that most companies do not do well.[65]

Companies can improve project evaluation by creating, and sharing, a matrix of measurements to evaluate various types of projects. The matrix should differentiate among problem-solving, exploratory, and regulatory research, and should recognize that different factors will be important at various stages in the project. "Raising a short set of generally accepted standards to high visibility corporation-wide develops a culture of careful assessment of external projects," wrote Starbuck.[66]

Project assessment also can benefit from peer review in publications or through presentations at scientific meetings. Funding by third parties—such as the federal Small Business Innovative Research (SBIR) program or Department of Defense research-funding programs—offers additional external assessments.[67] The president of one start-up company consciously uses the SBIR sponsoring agencies as a source of external review.[68]

With appropriate metrics, project evaluations can also be used to assess the company project manager. When expectations have been met, the manager can be rewarded. These metrics should be established during the project definition phase.[69] The same concept also can apply to company researchers. "The annual performance evaluation of our scientists should include a review of the goals and objectives of external collaborations that they support," said Pagani. "They are reviewed with that in mind as opposed to just having everything reviewed on their internal activities and what's done on the outside is ignored."[70]

Companies also should periodically evaluate collaborations with strategic partner universities. Rather than just reviewing the results of specific projects, however, these assessments should rate the efficiency and effectiveness of the entire relationship, including the university legal team, faculty cooperation, and any change in the relationship over time. Selection and continuation of a university as a "preferred provider" should be based on a track record of success.[71]

Evaluation of master agreements and strategic alliances generally is a formal process, which includes regular reviews of both the research results and the collaborative process. It questions whether new projects and individuals are involved in the relationship and whether academic freedom is impaired. The University of Massachusetts and Pennsylvania State University include this review process in their master agreements, and the partnerships between Washington University in St. Louis and Pharmacia,[72] and between U.C. Berkeley and Novartis, do the same.

Success isn't easy. "We made our External Technology Program a core competency just in the fall of 1998," observed Theodore Tabor, manager of External Research for Dow Chemical Co. "What is interesting is that we've had this program in place for nearly 20 years now. It took a lot of work."[73]

Recommendation:

Companies should strive to integrate university research collaborations into their product and service development process where appropriate. They should involve their business units in this process, manage the collaborations appropriately, and plan for the turnover of key company personnel. Wherever possible, the company should involve students in the collaboration. The company should modify its personnel evaluation systems as necessary to reward the establishment of internal and external interdisciplinary teams. To achieve results, company leaders must make a long-term commitment.

Broadening the Collaboration

Research-intensive companies involved in collaborations with universities also might find it worthwhile to join hands with universities in some areas outside the laboratory. For example, joint examination of potential ethical issues involved in the research could provide a wider perspective and help arm companies against disruptive surprises—not just in clinical research, but also in exploratory areas such as stem-cell research, tissue engineering, and genetically modified organisms. Moreover, such expanded collaborations might enhance the abilities of both sides to improve public understanding of the actual scientific issues involved and of the opportunities and benefits, as well as the challenges, of technological innovations.

NOTES

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[4] Robert L. Carman, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 18
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[6] Emil Sarpa, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 27
[7] Hank McKinnell, remarks at Business–Higher Education Forum summer 2000 meeting, Mystic, CT, 29 June 2000.
[8] Gene Allen and Rick Jarman, *Collaborative R&D: Manufacturing's New Tool* (New York, NY: John Wiley and Sons, 1999), 91–92.
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[10] *Case Study Final Report,* 7 September 2000, 5.
[11] Michael J. Montague, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 23.
[12] Karen Hersey, remarks during *Building an Effective University Technology Transfer Team* teleconference, 17 December 1999, 33 and 35.
[13] Robert L. Carman, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 18.
[14] *Case Study Final Report,* 7 September 2000, 9.
[15] Alan J. Lesser, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 34–35.
[16] Ibid., 3.
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[21] *Case Study Final Report,* 7 September 2000, 11.
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[40] Gene Allen and Rick Jarman, *Collaborative R&D: Manufacturing's New Tool* (New York, NY: John Wiley and Sons, 1999), 204.
[41] Bill Decker, through Mary Sue Coleman, e-mail to Project Director, 2 August 2000.

[42] Council on Governmental Relations, letter to Project Director, 8 March 2000.
[43] Memo to Judy Irwin, from the office of Scott Cowen, 8 August 2000.
[44] Diana MacArthur, memo to Project Director, 27 July 2000.
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[59] *A Report on Enhancing Industry-University Cooperative Research Agreements,* Industrial Research Institute, Washington, DC, 1995, 5.
[60] Steve Hahn, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 22.
[61] Ibid., 22.
[62] Hank McKinnell, remarks at Business–Higher Education Forum summer 2000 meeting, Mystic, CT, 29 June 2000.
[63] Steve Hahn, interview by Beth Starbuck, Calyx, Inc., *Case Study Final Report,* 7 September 2000, 22.
[64] Ibid., 3.
[65] Ibid., 7.
[66] Elizabeth Starbuck, "Optimizing University Research Collaborations," *Research Technology Management* (January-February 2001): 44.
[67] *Case Study Final Report,* 7 September 2000, 7.
[68] Ibid.
[69] Elizabeth Starbuck, "Optimizing University Research Collaborations," *Research Technology Management* (January-February 2001): 44.
[70] Edward Pagani, remarks during *Building an Effective University Technology Transfer Team* teleconference, 17 December 1999, 30.
[71] Elizabeth Starbuck, "Optimizing University Research Collaborations," *Research Technology Management* (January-February 2001): 44.
[72] *Case Study Final Report,* 7 September 2000, 7.
[73] Theodore E. Tabor, remarks during *Making Collaborations a Corporate Core Competency* teleconference, 15 October 1999, 21.

Ribozyme Pharmaceuticals Inc.: *The View from a Smaller Company*

When Ribozyme Pharmaceuticals Inc. (RPI) was in its start-up stage—a small biotechnology venture aimed at developing therapies from the Nobel prize-winning discoveries of University of Colorado researcher Tom Cech (pronounced "check")—RPI President and Chief Executive Officer Ralph Christoffersen made the university an offer it couldn't refuse: a $500,000, five-year research grant, to be used for anything the university wanted to do.

"I used to be the president of a university, Colorado State, and I was an academic for 20 years," Christoffersen says, "so I had a pretty good idea of what kinds of things would be of interest to the university. And one of the things that's most difficult to get, for a university president, is unrestricted dollars." State funding generally isn't unrestricted, Christoffersen notes, and federal research grants certainly aren't. "So I thought this would be a powerful thing for the university president's office to have."

In return, RPI got an exclusive option to license any ribozyme-related discovery made in University of Colorado laboratories—whether or not RPI funding had been involved. The company already had an exclusive license to the university's broad patents on ribozyme manufacture or use, and it licensed another Colorado patent during the five-year grant period. It also forged friendly ties with Colorado University scientists in collaborative projects, in seminars at RPI's labs or on the university's nearby Boulder campus, and by recruiting Cech and other Colorado researchers to its Scientific Advisory Board.

"Tom Cech invented this technology, and the university had made substantive investments in RNA chemistry and biochemistry, and we were an RNA company, so for us to have a connection to that set of expertise was very valuable, especially in the early days," Christoffersen says.

RPI was founded in 1992 to develop Cech's discovery that segments of RNA—once thought to have no function beyond a role in translating genes' blueprints into proteins—can act as enzymes and cleave other RNA molecules. Dubbed ribozymes, these small segments of RNA offer the prospect of marvelously selective drugs to block the body's production of damaging proteins or to chew up the genomes of RNA viruses. They could add a whole new class of weapons to medicine's arsenal. Cech, who now is president of the Howard Hughes Medical Institute, and Sidney Altman of Yale University shared the 1989 Nobel Prize in Chemistry for the discovery.

Christoffersen's half-million-dollar grant to the University of Colorado was a huge bet for a young start-up company, amounting to 5 to 10 percent of its research budget. The significance of the stake dramatizes what Christoffersen calls "the biggest conceptual difference" between small start-ups and large pharmaceutical companies when it comes to university-industry research collaborations: Large pharmaceutical companies can take more chances, and can do so with substantially more money.

"Large companies can and do create a collection of interactions with universities, multiple ones, because they can afford it," says Christoffersen, who was senior vice president and director of U.S. research for SmithKline Beecham Pharmaceuticals from 1989 to 1992. "Therefore, the importance of any one collaboration is less than is typically the case for a small company . . . .[where] resources are limited, you only have so many bets you can make, and you have to pick them far more carefully."

A smaller company does have some advantages over an industry giant in a university collaboration, however. It can move more quickly. For example, although RPI's agreement with the University of Colorado included the usual provisions for publication delays to let the company evaluate a discovery, the company never had to hold things up for long or to ask for an extension. "We can look at something in a week, and have a patent written in a month," Christoffersen says. "So in practice, it's not a real problem."

Whatever a company's size, Christoffersen says, the trickiest part of any university-industry research collaboration involves balancing "the university's need and requirement for academic freedom, collegiality, and openness, with the company's need for confidential information."

For example, if a company wants its university partner to file for a patent on a particular invention, secrecy is essential—at least for a while. Disclosure of the information in a published report or a presentation at a scientific meeting before the patent application is filed could limit or even invalidate the patent claim.

But students and postdoctoral fellows who are working on the discovery in the university inventor's lab need to write papers and theses, and they must have the opportunity to present their work at seminars and scientific conferences.

"There is an inherent conflict of interest between what you need to do to keep the information nonpublic in order for it to be valid in a patent, and the way you go about having students give seminars," Christoffersen says. "It's a very tricky thing for a university, because once they decide they want to patent something, the principal investigator—most of the time—has to be careful about what kind of information is made public when."

Now, six years after going public, and having grown from 15 to about 120 employees, RPI has four candidate drugs in or about to enter clinical trials. An anticancer drug that inhibits the formation of tumor-feeding blood vessels by blocking production of a key receptor, and a ribozyme designed to destroy the hepatitis C virus as it attempts to multiply in liver cells, are in Phase 1 safety trials and should enter Phase 2 trials, aimed at assessing efficacy, this year. By year's end, a drug to block breast-cancer cells' production of a protein that spurs tumor growth, and an antiviral aimed at hepatitis B are expected to enter Phase 1 trials.

"These are real designer drugs," says Christoffersen. "You can design a ribozyme so that it will find and bind only to its target, and nothing else. And on a statistical basis, the particular sequence of 15 nucleotides in the target will appear only once in the entire [human] genome." So ribozyme-based drugs also should have low side effects, "and that's in fact been the case," he says. "Both in animal studies and in our human clinical studies thus far, we've seen an extremely benign side-effect profile."

The company also continues to maintain smaller-scale research collaborations with the University of Colorado as well as other universities.

Appendix A
Panel Participants and Interview Subjects

Appendix A
Panel Participants and Interview Subjects

RESEARCH COLLABORATION INITIATIVE PANELS

BUSINESS–HIGHER EDUCATION FORUM MEETINGS
February 1998–February 2001

FEBRUARY 1998 WINTER MEETING
hosted by the Florida International University

Session: **Investment in Research and New Knowledge**

Moderator: Dennis O'Connor
Provost, The Smithsonian Institution, and 1996-98 Forum Chair

Framing the Issues: Henry A. McKinnell
Executive Vice President, Pfizer Inc, and President,
Pfizer Pharmaceuticals Group

JULY 1998 SUMMER MEETING
hosted by the University of Nebraska

Session: **Pros and Cons of Industry and University Research Partnerships**

Moderator: Dennis O'Connor
Provost, The Smithsonian Institution, and 1996-98 Forum Chair

Panelists: Cornelius J. Pings
Past President, Association of American Universities

Dennis Smith
President, University of Nebraska

Michael Emmi
Chairman of the Board and Chief Executive Officer,
SCT Corp.

Session: **Consideration and Discussion of Proposed Initiative**

Co-Chairs: Henry A. McKinnell
Executive Vice President, Pfizer Inc, and President,
Pfizer Pharmaceuticals Group

Cornelius J. Pings
Past President, Association of American Universities

Session: **Plan to Move Forward**

Convener: Dennis O'Connor
Provost, The Smithsonian Institution, and 1996–98 Forum Chair

JANUARY 1999 WINTER MEETING

hosted by the University of Arizona

Session: **The Role of Research and Innovation in a New Era—The Research Collaboration Task Force Sets Forth Its Agenda**

Speakers: Henry A. McKinnell
Executive Vice President, Pfizer Inc, and
President, Pfizer Pharmaceuticals Group (Co-chair)

Nils Hasselmo
President, Association of American Universities (Co-chair)

Mike Champness
Project Director, Research Collaboration Initiative

Session: **Intellectual Property and the Use of Research Tools—What Can Be Learned from the NIH Experience?**

Moderator: L. Dennis Smith
President, University of Nebraska

Speaker: Maria C. Freire
Director, Office of Technology Transfer
National Institutes of Health

JUNE 1999 SUMMER MEETING

hosted by the California State University and California State University–Long Beach

Session: **Project Update, Key Issues, and Survey Outcomes**

Speakers: Nils Hasselmo
Co-chair, RCI
President, Association of American Universities

Mike Champness
Project Director, Research Collaboration Initiative

Session: **University-Industry Research Collaborations: Setting the Stage**

Moderator: Mark S. Wrighton
Chancellor, Washington University in St. Louis

Panelists: Karen Hersey
Intellectual Property Counsel, Massachusetts Institute of Technology

Mark Crowell
Associate Vice Chancellor and Director, Office of Technology Transfer and Industry Research
North Carolina State University

Michael Dierks
Senior Attorney, Microprocessor Products Group, Intel Corporation

Gene Allen
Director, Collaborative Development
The MacNeal-Schwendler Corporation

Session: **The UC Berkeley–Novartis Sponsored Research Agreement**

Moderator: L. Dennis Smith
(Forum Vice Chair)

Speakers: Edward T. Shonsey
President and CEO, Novartis Seeds, Inc.

Gordon Rausser
Dean, College of Natural Resources
University of California, Berkeley

FEBRUARY 2000 WINTER MEETING

Tucson, Arizona

Session: **The Research Collaboration Initiative Report: Putting the Pieces Together**

Speakers: Henry A. McKinnell
President and COO, Pfizer Inc

Nils Hasselmo
President, Association of American Universities

Mike Champness
Project Director, Research Collaboration Initiative

Session: **Important Themes from the National Science Policy Study**

Moderator: Nils Hasselmo
President, Association of American Universities

Speaker: The Honorable Vernon Ehlers (R-MI)
Vice Chairman, House of Representatives Committee on Science

Session: **Scaling the Institutional Barriers to Effective University-Industry Technology Transfer**

Moderator: Charles T. Wethington Jr.
President, University of Kentucky

Panelists: Frank Knoll
Project Manager, Cooperative Research, Dow Chemical Company

Michael Greis
Director, University Relations, IBM

Carolyn S. Sanzone
Assistant Vice Chancellor for
Science and Technology Advancement
Corporate and Foundation Relations, University of Massachusetts

Richard W. Schwartz, M.D.
Professor, Department of Surgery, College of Medicine, University of Kentucky

Session: **University-Industry Research Collaborations: The NSF Perspective**

Moderator: Nils Hasselmo
President, Association of American Universities

Speaker: The Honorable Rita R. Colwell, Director, National Science Foundation

JUNE 2000 SUMMER MEETING
hosted by Pfizer Inc in Mystic, Connecticut

Greetings: The Honorable Joseph I. Lieberman (D-CT) (via video)
Ranking Member, Senate Governmental Affairs Committee

Session: **Status and Discussion of Interim Report**

Speakers: Henry A. McKinnell
President and COO, Pfizer Inc

Nils Hasselmo
President, Association of American Universities

Mike Champness
Project Director, Research Collaboration Initiative

Session: **Balancing Conflicting Collaboration Demands Within the University**

Moderator: Mark Wrighton
Chancellor, Washington University in St. Louis

Speakers: The Honorable Arthur Bienenstock
Associate Director for Science
White House Office of Science and Technology Policy

Richard Koehn
Vice President for Research, University of Utah

Elizabeth Starbuck
President, Calyx, Inc.

Session: **Clusters of Innovation**

Moderator: John Yochelson
President, Council on Competitiveness

Speaker: Randall Kempner
Senior Consultant, Monitor Group

Commentator: Molly Corbett Broad
President, University of North Carolina

FEBRUARY 2001 WINTER MEETING

Tucson, Arizona

Session: **Research Collaboration Initiative Report Summary and Follow-up**

Speakers: Henry A. McKinnell
President and Chief Executive Officer, Pfizer Inc

Nils Hasselmo
President, Association of American Universities

Project Overview: Mike Champness
Project Director, Research Collaboration Initiative

Session: **Research Collaboration and Regional Economic Development**

Moderator: Peter Likins
President, The University of Arizona

Research Collaboration Initiative Interviews Case Studies and Spotlights

CASE STUDIES

(interviews performed by Elizabeth Starbuck, Calyx, Inc.)

Corporate

Boeing Rocketdyne

- Robert Carmen
- Ray Edelman

Dow Chemical

- Frank Knoll
- Steve Hahn

Pharmacia (formerly Monsanto)

- Mike Montague
- Ned Siegel

Scientific Materials

- Ralph Hutcheson

Sun Microsystems

- Emil Sarpa
- Mick Jordan

University

Pennsylvania State University

- Gary Weber
- Art Heim
- George Moellenbrock
- Ron Iacocca

University of Massachusetts

- Carolyn Sanzone
- Alan Lesser

University of Michigan

- Jim MacBain
- Pramod Khargonekar

Washington University–St. Louis

- Ted Cicero
- David Kipnis

SPOTLIGHTS

(interviews performed by Bruce Agnew)

Washington University-Pharmacia: *Two Decades of Success*
- Mark Wrighton, Washington University in St. Louis
- David Kipnis, Washington University in St. Louis

UC Berkeley-Novartis: *A Rough Road to Success*
- Gordon Rausser, UC Berkeley
- Ignacio Chapela, UC Berkeley
- Richard Malkin, UC Berkeley
- Carol Mimura, UC Berkeley

Biolex Inc.: *What a Tech Transfer Office Can—and Can't—Do*
- Anne-Marie Stomp, Biolex Inc.

Ribozyme Pharmaceuticals: *The View from a Smaller Company*
- Ralph Christoffersen, Ribozyme Pharmaceuticals
- Stephen O'Neil, University of Colorado

(interviews performed by Carolyn Hanna)

Office of Naval Research: *A Government-Academia-Industry Collaboration*
- Terry Ericsen, Office of Naval Research
- Dave Rossi, Office of Naval Research
- Narian Hingorani, Electric Power Research Institute

B

Appendix B
University Research Expenditures and Licensing Income Tables

University Research Expenditures, Technology Transfer and Licensing Activities, Fiscal Year (FY) 1999
(Ranked by FY 1999 Total Research Expenditures)

U.S. Universities: Name of Institution	Year That 0.5 Professional Full-Time Equivalent Devoted to Technology Transfer	Total Research Expenditures	Invention Disclosures Received	Total U.S. Patent Applications Filed	Licenses & Options Executed
University of California System	1979	$1,864,901,000	818	670	219
Johns Hopkins University	1973	$1,010,088,334	250	256	106
Mass. Institute of Technology (MIT)	1940	$725,600,000	381	341	95
University of Michigan	1982	$499,722,000	158	147	42
University of Washington/ Washington Research Foundation	1983	$479,654,994	226	114	115
University of Pennsylvania	1986	$477,000,000	244	151	57
W.A.R.F./Univ. of Wisconsin-Madison	1925	$421,600,000	278	162	106
University of Minnesota	1957	$417,556,493	219	99	71
Stanford University	1970	$417,037,000	236	237	147
North Carolina State University	1984	$413,369,278	148	62	83
SUNY Research Foundation	1979	$405,238,284	201	123	46
Texas A&M University System	1992	$402,203,000	145	85	53
Harvard University	1977	$401,849,500	109	186	48
Penn State University	1989	$393,462,000	188	231	40
Cornell Research Foundation, Inc.	1979	$376,784,000	172	147	150
Univ. of Illinois at Urbana–Champaign	1993	$358,247,000	104	53	39
Duke University	N/A	$334,505,814	115	111	41
Washington University	1985	$333,196,000	104	78	114
University of Colorado	1993	$331,579,000	79	63	10
University of Arizona	1988	$320,244,777	97	40	11
Yale University	1982	$315,953,000	70	110	23
University of Pittsburgh	1992	$311,200,000	107	70	16
University of Florida	1983	$280,408,217	136	127	10
Columbia University	1982	$279,275,674	182	109	98
University of Iowa Research Foundation	1975	$259,514,262	79	83	21
University of Texas at Austin	1988	$258,122,000	81	49	31
Ohio State University	1990	$257,950,000	100	35	26
University of Southern California	1971	$254,811,651	156	101	57
Purdue Research Foundation	1988	$253,018,364	102	81	76

*Reports prior to FY 1998 reflect Gross License Income Received

Source: Association of University Technology Managers Licensing Survey: Selected Facts and Figures for FY 1999

Adjusted (*) Gross License Income Received	Licenses & Options Yielding License Income	Legal Fees Expended	Legal Fees Reimbursed	U.S. Patents Issued	Start-up Companies Formed
$74,133,000	715	$12,500,000	$7,500,000	281	13
$10,353,453	137	$3,288,453	$1,344,461	111	7
$16,131,334	346	$5,933,157	$2,284,627	154	17
$3,472,671	90	$2,764,309	$1,116,081	56	2
$27,878,900	185	$1,338,024	$457,327	36	N/A
$2,984,000	55	$1,677,000	$1,399,000	82	6
$18,011,400	191	$2,850,000	$1,677,000	79	4
$5,662,088	153	$1,940,733	$1,091,233	55	5
$27,699,355	339	$2,674,594	$958,879	90	19
$7,761,000	60	$936,145	$735,545	30	8
$13,538,619	149	$1,671,656	$133,999	53	3
$5,180,510	155	$879,302	$457,362	19	0
$9,886,404	166	$3,150,532	$2,298,884	72	2
$2,830,448	64	$897,517	$458,299	46	3
$6,070,000	199	$2,900,000	$2,200,000	70	4
$2,856,207	84	$578,089	$8,116	14	4
$1,566,195	73	$1,241,331	$565,312	43	2
$6,999,971	107	$1,168,144	$939,485	39	4
$3,127,303	10	$329,300	$26,778	27	1
$314,299	31	$118,494	$116,028	8	3
$40,695,606	28	$1,186,852	$322,924	37	3
$608,851	23	$1,636,874	$421,008	30	3
$21,649,577	45	$2,937,299	$793,876	58	2
$89,159,556	212	$4,030,556	$1,152,913	77	5
$3,464,565	80	$1,530,469	$728,514	32	2
$1,929,390	24	$553,213	$330,953	17	1
$1,626,000	34	$545,000	$112,000	18	0
$450,568	55	$650,668	$190,757	13	4
$2,149,000	201	$1,070,000	$548,000	24	4

University Research Expenditures, Technology Transfer and Licensing Activities, Fiscal Year (FY) 1999
(Ranked by FY 1999 Total Research Expenditures)

U.S. Universities: Name of Institution	Year That 0.5 Professional Full-Time Equivalent Devoted to Technology Transfer	Total Research Expenditures	Invention Disclosures Received	Total U.S. Patent Applications Filed	Licenses & Options Executed
Baylor College of Medicine	1983	$239,000,000	89	39	35
University of Georgia	1979	$237,493,000	72	44	32
Northwestern University	N/A	$236,668,615	80	71	14
Georgia Institute of Technology	1990	$223,641,675	127	143	18
University of Missouri System	1987	$212,238,803	62	37	16
Indiana University (ARTI)	1991	$209,154,093	59	38	14
Michigan State University	1992	$207,912,000	85	82	33
University of Massachusetts, all campuses	1995	$206,382,231	112	N/A	19
Emory University	1985	$205,600,000	89	50	13
University of North Carolina/Chapel Hill	1985	$198,081,333	116	74	70
University of Virginia Patents Foundation	1977	$197,046,500	154	155	25
Iowa State University	1935	$186,700,000	160	106	163
University of Rochester	1980	$185,488,000	85	53	5
University of Maryland, College Park	1987	$185,036,200	84	113	61
University of Utah	1968	$182,753,466	172	98	25
Univ. of Texas Southwestern Med. Center	1990	$179,709,069	80	63	23
Case Western Reserve University	1986	$176,519,336	59	37	10
University of Miami	1989	$175,600,000	27	9	9
University of Illinois at Chicago	1985	$175,093,000	61	35	20
University of Alabama/Birmingham	1987	$171,831,840	121	113	40
University of Tennessee Research Corp.	1983	$170,896,000	75	54	7
Virginia Tech Intellectual Properties, Inc.	1985	$169,250,000	65	58	41
Carnegie Mellon University	1992	$167,675,342	104	36	23
University of Kansas	1994	$167,575,000	67	22	7
Rutgers, The State University of NJ	1989	$165,872,573	112	103	60
Vanderbilt University	1990	$165,200,000	87	51	31
University of Chicago-ARCH Dev. Corp.	1986	$162,805,000	65	74	14
University of South Florida	1990	$161,300,000	48	53	13
University of Hawaii	1987	$151,809,406	41	36	0

*Reports prior to FY 1998 reflect Gross License Income Received

Source: Association of University Technology Managers Licensing Survey: Selected Facts and Figures for FY 1999

Adjusted (*) Gross License Income Received	Licenses & Options Yielding License Income	Legal Fees Expended	Legal Fees Reimbursed	U.S. Patents Issued	Start-up Companies Formed
$12,280,879	110	$621,363	$117,324	25	0
$3,208,427	64	$878,682	$681,680	21	5
$2,758,450	38	$416,895	$264,301	35	0
$2,038,078	46	$833,832	$106,136	23	3
$1,544,985	21	$399,971	$231,806	22	1
$1,040,092	39	$632,995	$201,458	18	1
$23,711,867	48	$1,187,038	$245,446	63	1
$4,105,000	41	N/A	N/A	32	2
$15,257,565	35	$915,425	$500,948	44	4
$1,696,786	47	$956,393	$564,159	41	0
$4,185,446	62	$569,024	$179,877	23	6
$1,812,870	298	$854,852	$335,317	49	2
$2,994,170	17	$329,000	$33,000	14	1
$968,144	109	$430,190	$196,120	12	3
$3,257,026	58	$939,807	$256,946	40	8
$4,856,751	57	$996,890	$422,397	27	1
$505,192	16	$284,243	$24,463	17	3
$432,937	22	$211,404	$66,344	8	0
$1,839,290	45	$355,451	$209,792	13	2
$1,560,587	58	$804,313	$150,935	24	2
$602,053	24	$612,123	$81,813	17	1
$1,328,343	74	$180,830	$42,396	37	3
$5,892,284	51	$1,183,217	$35,600	30	5
$885,000	39	$129,000	$65,000	10	1
$4,304,616	73	$1,026,345	$801,421	31	3
$1,100,579	44	$440,251	$216,718	17	2
$1,868,392	40	$1,635,106	$746,700	33	1
$490,408	18	$385,579	$84,444	24	8
$171,877	19	$235,501	$17,269	11	0

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(Ranked by FY 1999 Total Research Expenditures)

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California Institute of Technology	1978	$150,000,000	143	212	21
New York University	1989	$149,000,000	50	N/A	N/A
Univ. of New Mexico/Sci. & Tech. Corp.	1995	$148,600,000	47	53	3
Colorado State University	1970	$147,664,283	30	17	9
Wayne State University	1988	$147,000,000	39	18	3
Oregon State University	1980	$145,665,138	38	25	17
Boston University	1976	$142,515,956	56	52	17
Florida State University	1996	$132,664,855	23	15	8
University of Maryland, Baltimore	1989	$131,484,606	62	44	7
University of Nebraska-Lincoln	1996	$131,046,000	32	28	8
Mount Sinai School of Medicine of NYU	1991	$123,404,735	36	35	12
University of Cincinnati	1983	$115,025,000	47	36	15
Virginia Commonwealth University	1994	$113,000,000	88	68	17
Univ. of Texas Houston Health Sci. Ctr.	1985	$107,035,788	20	12	8
University of Connecticut	1987	$105,800,000	45	32	12
Princeton University	1987	$102,000,000	60	61	14
Clemson University	1987	$99,340,766	29	7	7
Tufts University	1978	$98,567,533	51	32	12
Oklahoma State University	1995	$88,900,000	19	9	1
Tulane University	1985	$87,324,000	13	17	9
Oregon Health Sciences University	1989	$86,822,525	32	45	11
University of Oklahoma, all campuses	1984	$85,584,836	30	45	6
Thomas Jefferson University	1984	$85,400,000	87	80	17
University of Texas Medical Branch	1988	$85,000,000	30	38	4
Univ. of Kentucky Research Foundation	1984	$83,743,077	65	32	9
Medical University of South Carolina	N/A	$81,246,129	40	24	5
Dartmouth College	1985	$81,055,083	18	26	7
Auburn University	1988	$80,544,000	25	13	5
Utah State University	1987	$80,539,784	27	7	4

*Reports prior to FY 1998 reflect Gross License Income Received

Source: Association of University Technology Managers Licensing Survey: Selected Facts and Figures for FY 1999

Adjusted (*) Gross License Income Received	Licenses & Options Yielding License Income	Legal Fees Expended	Legal Fees Reimbursed	U.S. Patents Issued	Start-up Companies Formed
$6,500,000	35	$1,150,000	$33,000	62	7
$10,700,000	18	$1,000,000	$700,000	30	2
$400,200	9	$374,500	$85,200	15	2
$386,990	18	$98,177	$32,258	13	4
$458,000	12	$106,000	$15,000	18	1
$825,283	45	$201,382	$117,569	6	1
$263,095	18	$764,966	$422,999	22	7
$57,313,014	14	$160,282	$104,883	5	1
$116,681	16	$281,886	$93,120	12	2
$796,894	24	$253,173	$0	9	2
$1,012,061	14	$781,672	$51,168	9	0
$3,905,945	16	$145,033	$29,687	6	4
$459,200	21	$131,124	$63,005	14	3
$343,050	9	$223,230	$0	6	0
$481,134	10	$304,600	$6,000	11	2
$1,480,000	20	$1,650,000	$1,265,000	26	2
$4,648,141	10	$72,274	$0	2	1
$506,149	21	$625,216	$299,375	11	0
$154,946	7	$141,088	$52,726	4	0
$7,572,483	19	$235,000	$130,215	7	0
$291,131	32	$359,302	$187,466	15	1
$110,265	7	$281,455	$181,981	8	2
$742,515	24	$338,970	$91,867	27	1
$108,857	10	$376,655	$258,549	21	0
$2,496,786	N/A	$520,270	$63,016	24	2
$121,627	11	$272,517	$69,718	8	3
$491,302	47	$173,977	$117,601	20	0
$186,738	6	$213,994	$53,200	12	0
$227,929	15	$84,884	$16,634	6	1

University Research Expenditures, Technology Transfer and Licensing Activities, Fiscal Year (FY) 1999
(Ranked by FY 1999 Total Research Expenditures)

U.S. Universities: Name of Institution	Year That 0.5 Professional Full-Time Equivalent Devoted to Technology Transfer	Total Research Expenditures	Invention Disclosures Received	Total U.S. Patent Applications Filed	Licenses & Options Executed
Univ. of Texas Health Sci. Ctr., San Antonio	1990	$80,020,875	21	41	14
Wake Forest University	1985	$78,351,866	36	19	6
Brown University Research Foundation	1983	$76,330,000	40	36	4
University of South Carolina	1993	$69,819,000	36	26	7
University of Delaware	1997	$64,872,678	20	29	4
University of Arkansas, Fayetteville	1990	$63,110,717	26	21	2
New Mexico State University	1990	$63,037,606	12	10	3
West Virginia University	1999	$62,000,000	9	3	1
Arizona State University	1985	$60,091,584	49	47	11
University of New Hampshire	1997	$60,015,544	6	5	6
University of Oregon	1992	$58,616,598	9	11	10
University of Louisville	1996	$53,258,000	30	9	3
Kansas State Univ. Research Foundation	1942	$52,597,214	28	16	7
University of Vermont	1998	$52,500,000	25	11	6
Idaho Research Foundation/Univ. of Idaho	1986	$50,345,178	18	7	2
Montana State University	1980	$49,741,400	15	12	7
Temple University	1986	$45,456,670	19	N/A	5
North Dakota State University	1995	$44,696,000	23	6	7
Rice University	1998	$44,500,000	20	33	8
Louisiana State University, Agric. Center	1989	$44,318,252	17	7	7
University of North Dakota	N/A	$43,131,073	2	1	0
Brandeis University	1982	$42,666,882	17	18	6
New Jersey Institute of Technology	1990	$42,500,000	35	8	2
University of Houston	1996	$42,002,331	40	7	5
University of Maine	N/A	$41,453,000	6	3	2
University of Rhode Island	1991	$41,400,000	12	7	11
San Diego State University	1998	$40,624,000	7	3	4
Syracuse University	1989	$39,500,000	10	4	1
University of Dayton	1984	$37,039,132	28	9	2

*Reports prior to FY 1998 reflect Gross License Income Received

Source: Association of University Technology Managers Licensing Survey: Selected Facts and Figures for FY 1999

Adjusted (*) Gross License Income Received	Licenses & Options Yielding License Income	Legal Fees Expended	Legal Fees Reimbursed	U.S. Patents Issued	Start-up Companies Formed
$3,660,638	32	$516,571	$38,768	13	0
$2,788,987	9	$798,320	$130,239	3	1
$1,009,516	13	$157,041	$93,222	17	1
$175,187	12	$88,264	$10,813	4	0
$470,303	8	$122,683	$7,910	3	2
$259,883	21	$187,862	$38,423	13	1
$1,792	3	$115,770	$17,031	2	0
$41,800	5	$83,500	$0	2	0
$1,274,145	18	$547,472	$172,444	12	1
$34,696	5	$14,336	$0	0	0
$232,000	20	$86,858	$90,000	5	1
$48,632	4	$30,869	N/A	2	1
$258,063	31	$216,370	$135,589	12	2
$338,000	3	$182,000	$88,000	2	0
$140,500	6	$299,413	$199,388	3	0
$243,700	18	$203,630	$159,890	7	1
$493,947	16	$213,892	$0	N/A	0
$1,059,797	38	$93,041	$6,596	4	0
$21,000	4	$117,000	$9,000	1	1
$1,091,787	17	$153,265	N/A	3	1
$0	0	$8,578	$0	0	0
$120,126	21	$184,820	$180,411	9	3
$22,500	3	$175,000	$0	4	0
$120,831	8	$294,601	$71,072	5	0
$0	0	$30,301	$0	4	0
$823,385	10	$123,447	$666	3	0
$82,000	2	$50,000	$0	1	2
$112,529	16	$181,628	$129,483	5	0
$567,535	5	$246,160	$129,197	8	1

114

University Research Expenditures, Technology Transfer and Licensing Activities, Fiscal Year (FY) 1999
(Ranked by FY 1999 Total Research Expenditures)

U.S. Universities: Name of Institution	Year That 0.5 Professional Full-Time Equivalent Devoted to Technology Transfer	Total Research Expenditures	Invention Disclosures Received	Total U.S. Patent Applications Filed	Licenses & Options Executed
George Mason University	1996	$32,376,000	13	11	0
Loyola University Medical Center	N/A	$29,778,103	4	3	10
Michigan Technological University	1988	$28,073,860	20	11	11
St. Louis University	1998	$27,817,000	19	15	3
University of South Alabama	1995	$27,252,916	5	11	0
Creighton University	1992	$25,700,000	17	3	2
Lehigh University	N/A	$25,312,458	N/A	N/A	N/A
Southern Illinois University/Carbondale	1993	$23,655,654	15	6	6
Kent State University	1989	$23,472,249	12	5	3
University of Montana	1995	$22,996,357	5	2	3
New York Medical College	1994	$22,821,758	16	3	3
Wright State University	N/A	$22,753,000	2	1	4
University of New Orleans	1999	$22,297,000	6	6	1
Univ. of Maryland, Baltimore County	1994	$21,854,000	26	9	1
Univ. of Maryland Biotech Institute	1995	$20,387,312	17	14	4
Brigham Young University	1986	$17,226,876	71	12	21
Ohio University	1991	$16,492,896	13	8	0
University of Northern Iowa	1998	$13,148,015	0	2	0
Medical College of Ohio	1983	$11,895,179	7	2	0
Portland State University	N/A	$11,735,117	3	0	0
California State Polytechnic University	1999	$11,575,000	1	2	2
University of Akron	1995	$10,193,500	29	20	7
East Carolina University	1995	$8,360,000	10	6	1
TOTAL U.S. UNIVERSITIES		$23,565,568,068	10,052	7,612	3,295

*Reports prior to FY 1998 reflect Gross License Income Received

Source: Association of University Technology Managers Licensing Survey: Selected Facts and Figures for FY 1999

Adjusted (*) Gross License Income Received	Licenses & Options Yielding License Income	Legal Fees Expended	Legal Fees Reimbursed	U.S. Patents Issued	Start-up Companies Formed
$753	1	$10,360	$0	3	0
$567,500	10	$86,252	$0	0	0
$222,272	18	$174,275	$2,500	2	0
$788,472	22	$160,157	$83,590	6	0
$7,178	3	$131,031	$0	6	0
$123,717	4	$27,779	$0	2	0
$117,661	7	$26,000	$0	N/A	N/A
$48,245	9	$149,877	$30,163	N/A	0
$147,159	7	$221,087	$119,488	4	1
$67,000	4	$54,422	$0	2	0
$87,589	8	$43,133	$25,030	3	2
$18,525	6	$6,254	$0	1	0
$13,770	2	$39,881	$5,000	2	0
$39,117	2	$100,525	$0	6	0
$335,000	2	$367,328	N/A	4	0
$3,961,971	51	$215,310	$29,633	4	1
$617,805	3	$174,515	$119,272	4	0
$1,268	1	$13,364	$0	2	0
$22,991	6	$75,664	$21,701	6	0
$0	0	$0	$0	0	0
$10,000	2	$47,000	$0	1	0
$244,056	15	N/A	N/A	11	1
$76,000	0	$46,836	$3,984	2	0
$641,000,108	**6,663**	**$100,438,800**	**$42,438,911**	**3,079**	**275**

116

Hospitals and Research Institutes Research Expenditures, Technology Transfer and Licensing Activities, Fiscal Year (FY) 1999
(Ranked by FY 1999 Total Research Expenditures)

U.S. Hospitals & Research Institutes Name of Institution	Year That 0.5 Professional Full-Time Equivalent Devoted to Technology Transfer	Total Research Expenditures	Invention Disclosures Received	Total U.S. Patent Applications Filed	Licenses & Options Executed
Massachusetts General Hospital	1976	$247,034,000	174	170	40
Mayo Foundation	1986	$240,500,000	119	72	31
Brigham & Women's Hospital	1986	$196,289,000	81	70	28
M.D. Anderson Cancer Center	1987	$155,126,396	67	36	17
Fred Hutchinson Cancer Research Ctr.	1988	$141,372,000	26	12	21
Beth Israel Deaconess Medical Center	1997	$117,327,557	63	41	21
Sloan Kettering Institute for Cancer Res.	1981	$100,982,132	36	24	22
Dana-Farber Cancer Institute	1990	$94,477,120	47	22	21
Children's Hospital, Boston	1991	$85,000,000	75	82	13
Health Research, Inc.	1986	$75,800,000	19	7	7
St. Jude Children's Research Hospital	1995	$73,778,337	32	16	16
Medical College of Wisconsin	1984	$72,500,000	10	6	9
City of Hope National Medical Center	1986	$65,890,000	40	31	0
Woods Hole Oceanographic Institute	1993	$62,118,319	1	0	0
Children's Hospital of Philadelphia	N/A	$58,348,000	21	15	4
Children's Hospital, Cincinnati	1996	$55,419,771	20	12	3
Fox Chase Cancer Center	1984	$54,242,489	31	23	37
Salk Institute	1969	$51,416,000	45	38	23
National Jewish Med. and Res. Center	1994	$34,234,123	9	12	3
Wistar Institute	1991	$23,974,000	10	33	15
Oklahoma Medical Research Foundation	1990	$23,777,502	17	19	2
Hospital for Special Surgery	1996	$18,515,000	8	5	0
Institute of Paper Science and Tech.	1997	$15,599,000	17	11	2
New York Blood Center	1975	$14,000,000	9	N/A	6
California Pacific Medical Ctr. Res. Inst.	N/A	$12,751,706	4	1	0
Schepens Eye Research Institute	1997	$10,599,003	6	7	0
Torrey Pines Inst. for Molecular Studies	1997	$5,386,000	2	2	8
St. Elizabeth's Medical Center of Boston	1995	$4,500,000	6	5	3
Cleveland Clinic Foundation	1989	N/A	111	29	3
TOTAL U.S HOSPITALS & RESEARCH INSTITUTES		$2,110,957,455	1,106	801	355

*Reports prior to FY 1998 reflect Gross License Income Received

Source: Association of University Technology Managers Licensing Survey: Selected Facts and Figures for FY 1999

Adjusted (*) Gross License Income Received	Licenses & Options Yielding License Income	Legal Fees Expended	Legal Fees Reimbursed	U.S. Patents Issued	Start-up Companies Formed
$6,603,343	60	$3,547,170	$1,801,539	85	4
$4,361,548	124	$994,627	$261,310	31	0
$3,149,675	70	$1,067,008	$617,477	26	4
$3,169,420	60	$682,882	$443,687	20	0
$2,103,483	75	$253,336	$67,712	14	2
$1,171,033	32	$1,137,489	$916,925	29	3
$43,065,502	44	$816,603	$140,000	7	1
$2,268,182	65	$865,000	$257,201	33	0
$2,616,923	30	$1,191,938	$389,981	27	1
$6,996,742	35	$266,619	$22,771	14	0
$619,921	43	$391,634	$168,050	6	0
$469,265	20	$89,735	$59,383	3	1
$23,752,074	24	$0	$0	10	0
$118,300	2	$9,920	$9,800	0	0
$101,160	7	$131,051	$39,557	2	0
$315,459	9	$401,060	$71,949	2	0
$331,676	26	$314,522	$0	2	1
$2,521,687	68	$1,700,056	$1,220,374	21	0
$510,864	18	$113,724	$47,845	7	0
$2,482,000	53	$290,391	$73,526	7	0
$586,988	20	$461,711	$64,819	5	0
$5,587,603	9	N/A	N/A	2	0
$0	0	$110,977	$87,223	4	0
$35,000,000	30	$600,000	$100,000	14	0
$0	0	$87,696	$47,450	0	0
$125,375	3	$252,830	$54,119	3	0
$125,000	1	$41,300	$33,000	3	0
$0	0	$83,000	$61,500	1	0
$1,995,522	29	$458,321	$74,029	20	0
$150,148,745	957	$16,360,600	$7,131,227	398	17

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