

Academic-Industry Collaboration under Federal Grants and Cooperative Agreements: Financial, Administrative, and Regulatory Compliance

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ABSTRACT

Federal sponsorship of collaboration between academic institutions and industry is on the rise. Many government programs emphasize cooperation between universities and the commercial sector as a means to merge basic and applied research, promote economic development, and enhance knowledge dissemination. The intersection between academia and industry on federal research projects yields financial, administrative, and regulatory complexities related to cost accounting, program income, audits, equipment, transparency, the distinction between subawards and sub-contracts, and other items. This article discusses foundational compliance issues associated with participation of for-profit firms in grants and cooperative agreements.

INTRODUCTION

Academic-industry interaction has received considerable attention in recent years. A lot of attention has focused on conflicts that arise when commercial organizations support and fund research or

services provided by, or to, an academic investigator.¹ This article focuses on a different but important subject: the financial, administrative, and regulatory challenges in federally funded academic-industry collaboration.

When institutions and companies collaborate on research projects, often these projects are funded by the industry participant. But academic-industry cooperation is not funded exclusively by industry. The federal government recognizes the value of these collaborations and has demonstrated a growing willingness to fund them.

In today's research environment, for-profit firms increasingly partner with colleges, universities, and research institutions on scientific projects. These collaborations grew under the American Reinvestment and Recovery Act of 2009, which opened new doors to industry participation in grants for energy research, broadband development, and medical research, among other areas. Academic-industry collaborations also have grown as more government funds become available for "translational" research, that is, studies designed to turn scientific discovery into practical application. The congressional ban on earmarks to for-profit companies is another factor that makes academia—with its relatively steady stream of federal funds—an ever more attractive research partner (*Chronicle of Higher Education*, 2010).

Strong ties between institutions and industry are not new; however, the infusion of federal funds into these relationships has increased in quality and quantity. The research community is well-acquainted with the strings attached to government grants for research. Yet for-profit firms may find this terrain unfamiliar, long experience

in research and development notwithstanding.

Take, for example, "Company ABC" (a pseudonym) that teamed with a university to apply for a medical research grant from the U.S. Department of Health and Human Services (DHHS). Upon notice that DHHS would fund the proposal, Company ABC engaged counsel to negotiate these terms for the project:

- A 10% fee charged to the grant, as a condition to Company ABC serving as a subgrantee to the prime grantee university.
- Direct reimbursement of various Company ABC indirect costs.
- Company ABC to have sole discretion over income generated with grant funding (i.e., program income).
- Confidentiality of all Company ABC research results.

The problematic nature of these terms is apparent to the seasoned research administrator. Not only would the terms contravene federal grant policies, but there is also some question about whether the terms are legally permissible.

Broad challenges associated with academic-industry collaborations are already familiar to the research community. This article highlights special compliance issues associated with federally funded projects, and focuses on financial, administrative, and regulatory issues. The article begins with an inventory of models for industry participation in federal research awards. Next, it provides examples

of specific compliance matters. Finally, it identifies additional subjects not unique to government-funded collaborations but nonetheless relevant to them.

The items discussed in this paper are basic compliance issues that arise when two sectors—*for-profit* and *nonprofit*—combine to undertake federal research. By its nature, this paper comes into contact with myriad items and provides only a “*nutshell*” treatment of each. Although the paper covers a broad spectrum of subjects, it does not exhaust, even remotely, the compliance particulars and peculiarities that arise in academic-industry relationships. Every subject identified here warrants further consideration in the context of particular collaborations. The author designed this paper to serve as a reminder of principles and concepts that prompt day-to-day judgment in academic-industry relationships funded by grants and cooperative agreements.

FORMS OF COLLABORATION

Academic-industry interactions take various forms. Collaborations may involve, for example, industrial affiliate programs; clinical trial agreements; research equipment loans; material transfer; spinoff companies; research parks; joint ventures; consortia; and consultations. These arrangements reflect the diverse missions and expectations that each entity brings to the collaboration.

In federally funded collaborations, an observer could “*follow the federal money*” and learn a lot.² For example, on one end of

the spectrum, a biotechnology company and a medical school might together, or as part of a consortium, apply to an agency for an interdisciplinary clinical research grant; both the company and the medical school could be true project “*partners*” (though probably not “*legal*” partners), by splitting research responsibility, clinical sites, and grant funds. On the other end of the spectrum might be a research institute that contracts out a small set of commercial services under a grant to a local high-tech firm; collaboration could be minimal and the firm may not be identified in the grant application. Somewhere in the middle could be a paid consultative relationship between an academic laboratory and a commercial organization on a particular issue in a federal project. There are many variations to each of these arrangements.

As the examples suggest, “*collaboration*” need not be a joint undertaking in which a university and a firm undertake truly cooperative scientific activity. Rather, academia looks to industry for a variety of commercial goods and services that are critical to the research mission, and sometimes these relationships are also deemed “*collaborations*”. Perhaps the most common form of industry participation in grants and cooperative agreements is for a company to serve as a “*contractor*” to a prime academic awardee. The word “*contract*” is a term of art in federal grants lexicon; it refers to an agreement between a prime awardee and a third party through which the prime awardee procures routine commercial

goods or services for the sponsored project. (This paper uses the word “contract” and “sub-contract” synonymously.)

This is in contrast to a “subaward”, which is another term of art. A “subaward” refers to an agreement between a prime awardee and a third party through which the prime awardee transfers federal financial assistance to the third party for substantive scientific activity under the sponsored project.

When an academic institution is the prime awardee under a grant or cooperative agreement, the characterization of a commercial firm as either a “contractor”, on the one hand, or a “subawardee”, on the other, has a profound effect on compliance obligations. The next section provides a more expansive explanation of the distinction between contractors and subawardees.

Note that casting a company as either a contractor or a subawardee is not intended to imply that companies are always subordinate to the academic institution. Commercial firms often are eligible to be direct, prime recipients of competitively awarded grants and cooperative agreements, especially in Recovery Act programs.³ Nevertheless, it is increasingly common for companies to be subawardees under federal research grants and cooperative agreements. As explained below, many of the compliance issues associated with commercial subawardees will be one and the same for commercial prime awardees. Thus, both prime

recipients and subrecipients will benefit from the distinctions drawn in this section.

THE DISTINCTION BETWEEN SUBAWARDEES AND CONTRACTORS

Research awards to academic institutions almost always involve some flow of funds to the commercial sector. A simplistic and often-used question at the outset of a federally funded relationship between a prime awardee institution and a company is this: will the company’s relationship with the institution be one of true research collaboration, or one of vendor-customer? If the former, then normally a subaward is issued to the firm. If the latter, then normally a sub-contract is issued. The reality is that relationships between institutions and commercial entities are multifaceted arrangements that take any number of shapes and are difficult to categorize neatly. Relevant sources of guidance follow, and even this guidance is not conducive to mechanical application in each situation.

Office of Management and Budget (“OMB”) Circular A-110 (codified at 2 C.F.R. Part 215) and the DHHS Grants Policy Statement recognize a general distinction between a “subaward” and a “contract” (or sub-contract) under an award:

A subaward is the transfer of financial assistance for substantive programmatic work under the federal award; it does not include the procurement of commercial goods and services from a vendor.⁴

A contract is a grantee's agreement with a third party in order to procure commercial goods and services for a project.⁵

The Federal Demonstration Partnership ("FDP") Statement on Subawards (September 18, 2000) also provides guidance.⁶ The FDP interprets a subaward to be an arrangement "in which two (or more) qualifying legal entities/institutions are working collaboratively on a sponsored project. Each institution has its own principal investigator/project director; however, one of the collaborating institutions takes on the role of prime awardee with the sponsoring federal agency" (Federal Demonstration Partnership, 2000, p. 1). The FDP Statement also notes that a subawardee "is conducting its own scope of work and is not providing goods or services, such as simply executing lab tests or constructing experimental instrumentation. In a subaward situation, the principal investigator/project director of the subrecipient may be a co-author on publications or the subrecipient may seek patent protection for inventions and otherwise function in much the same manner as if the award came directly from a federal sponsor" (Federal Demonstration Partnership, 2000, p. 2).

To distinguish between subawards and contracts, the substance of the relationship between the two entities is more important than the form of agreement.⁷ Cognizant of this admonition, which is stated clearly in OMB Circular A-133, the research

community often uses guidance drawn from Circular A-133, as follows.⁸

Characteristics reflective of a "subaward" relationship between an academic institution and a firm include those where the firm:

- (1) has its performance measured against the federal award's objectives;
- (2) can make, and has responsibility for, substantive programmatic decisions;
- (3) has responsibility for complying with applicable federal program compliance requirements; and
- (4) uses the federal funds to carry out its program's objectives as compared to providing goods or services for a grantee's program.

In contrast, characteristics indicative of a "contract" relationship between an academic institution and a firm are when the firm:

- (1) provides the goods and services to the institution within normal business operations;
- (2) provides similar goods or services to many different purchasers;
- (3) operates in a competitive environment;
- (4) provides goods or services that are ancillary to the operation of the federal program; and
- (5) is not subject to compliance requirements of the federal program.

Admittedly, these traditional distinctions between subawards and contracts have eroded over time as academic-industry interactions take new and diverse forms. For purposes of compliance obligations, however, the distinction remains significant. The implication of the distinction is described in the next section.

IMPLICATIONS OF THE CONTRACTOR/SUBAWARDEE DISTINCTION

Commercial Entities that are “Contractors”

Conventional wisdom suggests this: One way to limit the compliance obligations of companies that participate in federal research, and to limit the subrecipient monitoring obligations of academic institutions that award federal funds to those firms, is to make an appropriate determination that the company is a contractor and not a subawardee. By and large, the conventional wisdom holds true. Contractors generally are not tethered to award programmatic requirements; are not subject to the financial and administrative pre-award and post-award requirements of OMB Circular A-110; are allowed, unlike most subawardees, to make a profit from their work under grants and cooperative agreements; and have few obligations in regard to cost accounting, property accountability, procurement processes, audits, and project reports.

It would be a mistake, however, to assume that agreements with contractors

under grants and cooperative agreements are no different from other contracts to procure goods and services in the commercial marketplace.

First, OMB Circular A-110 prescribes standards applicable to the prime awardee’s selection of a contractor. “These standards are furnished to ensure that such materials and services are obtained in an effective manner and in compliance with the provisions of applicable Federal statutes and executive orders.”⁹ Included among these standards are requirements for the prime awardee to ensure “open and free” competition in the selection of a contractor; maintain written procurement standards; release clear and accurate solicitations; include a preference for firms that offer products and services that conserve natural resources, protect the environment, and are energy efficient; include a preference for small businesses, minority-owned firms, and women’s business firms; undertake and document cost or price analysis in connection with every contract; and document a justification for lack of competition when competitive bids or offers are not obtained.⁷

“... the prime awardee is expected to flow down, and the selected contractor is expected to comply with, all applicable laws and regulations listed in Appendix A of OMB Circular A-110.”

Second, the prime awardee is expected to flow down, and the selected contractor is expected to comply with, all applicable laws and regulations listed in Appendix A of OMB Circular A-110. ("All contracts, awarded by a recipient including small purchases, shall contain the following [Appendix A] provisions as applicable.")⁸ Included among these provisions are laws on equal employment opportunity, lobbying, construction, environmental protection, and intellectual property.

Third, some sponsors apply specific public policies and appropriations law mandates to contractors under federal awards. As an example, the DHHS and NIH Grants Policy Statement collectively identify over forty public policy obligations that, based on the nature of the contractor's work, may apply to commercial contractors under grants and cooperative agreements.⁹ Some examples include the following:

- Public Health Security and Bioterrorism Preparedness and Response Act: regulates the use or procurement of select agents and toxins.¹⁰
- Pro-Children Act: imposes restrictions on smoking in facilities where federally-funded children's services are provided.¹¹
- Restrictions on Abortions: prohibits use of federal funds for abortions.¹²

These and other federal policies may seem peculiar to contractors who view themselves as routine vendors in the commercial marketplace. However, these policies demonstrate that, on some level, the

government holds these contractors to a higher standard than that which would otherwise apply in the commercial marketplace.

Commercial Entities that are "Subawardees"

To deem a company a subawardee under a federal award presents critical compliance obligations. Generally, funds provided to subawardees retain their full federal character. For-profit subawardees are expected to comply with almost all the pre-award and post-award requirements set forth in OMB Circular A-110, as well as sponsor policies and procedures that supplement the same. For instance, DHHS's implementation of Circular A-110, at 45 C.F.R. Part 74, specifically applies to DHHS grants and subawards to "commercial organizations".¹³ The difficulty is that commercial firms seldom are familiar with Circular A-110's provisions on management of funds, program income, property accountability, procurement processes, intellectual property, and audits, and few such firms have the financial or administrative controls in place to swiftly comply with such provisions.

Some sponsors maintain separate policies and regulations that apply to for-profit awardees and for-profit subawardees. The U.S. Department of Defense (DoD), for example, issues "Administrative Requirements for Grants and Agreements with For-Profit Organizations". These provisions apply to all direct awards and subawards to for-profit firms.¹⁴ These special regulations are not entirely

consistent with the provisions of OMB Circular A-110. For example, DoD indicates that for-profit firms must prepare “monthly” personnel activity reports (e.g., time and effort reports) to support salary and wage charges to awards.¹⁵ Circular A-110 does not speak to effort reporting, and the cost principles applicable to educational institutions, OMB Circular A-21, would not require monthly effort reports for all personnel. DoD changes or supplements several other familiar A-110 grant administration requirements.

Note that some private firms are reluctant to make the representations and certifications that federal sponsors expect subawardees—even for-profit subawardees—to make. These certifications include the “assurances” enumerated in Standard Form 424B, which pertain to compliance with myriad statutes and policies, including nondiscrimination laws, human subjects regulations, and laboratory animal welfare.¹⁶ Noncompliance with these laws or a false certification of compliance can generate serious consequences for the prime awardee and the subawardee, including potential False Claims Act liability.

To Receive—or Not to Receive— Federal Funds

Some companies ask this question: Can we continue to participate in a federal project and also remain free of the foregoing compliance obligations if we avoid the direct or indirect receipt of federal funds? In other words, can the company serve as an uncompensated collaborator or consultant

on an academic institution’s government funded project and legally avoid these obligations?

At first glance, this arrangement would appear to permit a company to avoid compliance infrastructure, maintain a profile on important federal projects, and thereby enhance the company’s reputation. It may also leave open the possibility of co-authorship or generation of intellectual property.

However, to use this strategy as a means to avoid compliance often is unavailing. Many requirements apply to a firm’s involvement in federally sponsored research, regardless of the direct or indirect receipt of federal funds. Consider these examples:

- *Financial Conflicts of Interest (FCOI)*: The Public Health Service (PHS) regulations that address financial conflicts of interest apply to recipients of federal research funds, and also to each “Investigator” that participates in the research.¹⁷ Thus, if a commercial firm’s personnel participate in the research as “investigators”—i.e., they are responsible for the design, conduct, or reporting of research—then the firm’s investigators may be subject to parts of the FCOI regulation, which generally require disclosure of financial conflicts of interest and steps to manage, reduce, or eliminate a conflict.¹⁸ Ordinarily, a prime awardee would flow down the FCOI regulation through its

subaward agreement, and obligate the subawardee to abide by the prime institution's FCOI policies, or require the subawardee to make certain assurances on conflicts of interest.¹⁹

- *Research Misconduct:* Regulations that govern research misconduct in federal projects apply to "allegations" of research misconduct, regardless of whether the accused or the accused's employer receives federal funds.²⁰ When there is a nexus to a federal project, an allegation against a company's employee may trigger an inquiry, a requirement to resolve the allegation in accordance with applicable regulations, and a requirement to report the investigation to the sponsor.
- *Human Subjects:* As a general principle, federal research that involves human subjects is subject to the "Common Rule" (45 C.F.R. Part 46). The Common Rule may apply in some situations in which a firm participates in research but does not receive federal funds. Companies may be familiar with Food and Drug Administration (FDA) regulations that cover clinical research related to investigational drugs and devices. However, the Common Rule is not identical to the FDA regulations.²¹ The Common Rule defines human subjects research more broadly than the clinical investigations covered by

FDA regulations. For example, the Common Rule often applies to analysis of private information, such as medical information, even where there is no direct intervention or interaction with a subject, and even in some circumstances where the information is coded and not immediately identified with a human subject.

- *Animal Research:* The PHS Policy on Humane Care and Use of Laboratory Animals applies to "all PHS-conducted or supported activities involving animals, whether the activities are performed at a PHS agency, an awardee institution, or any other institution and conducted in the United States, the Commonwealth of Puerto Rico, or any territory or possession of the United States."²² The actual receipt of federal funds by the organization engaged in animal activity under a federal project is not a precondition to application of the requirement.

Several other regulatory items, such as intellectual property policies, follow this general pattern.

The balance of this article focuses on selected compliance obligations associated with for-profit firms that serve as subawardees on government grants and cooperative agreements, or as direct recipients of such funds.²³

Prohibition on Profit

Companies have obligations to shareholders and others to show a return on

the investment of time and effort in research and development. In contrast, almost all federal sponsors explicitly prohibit payment of “profit” or “fees” to commercial recipients and subrecipients that participate in a federal grant, except under specific and authorized conditions.

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For example:

- “HHS policy allows the payment of fee on SBIR/STTR grants, but HHS will not provide profit or fee to any other type of recipient under any other grant program. A fee may not be paid by a recipient to a subrecipient/consortium participant, including a for-profit organization. However, a fee (profit) may be paid to a contractor [e.g. vendor] providing routine goods or services under a grant in accordance with normal commercial practice” (*HHS Grants Policy Statement*, II-30).
- “Except for grants awarded under the SBIR/STTR programs, under an NIH grant, no profit or fee will be provided to a for-profit organization, whether as a grantee or as a

consortium participant” (*NIH Grants Policy Statement*, p. IIB-248).

- “Payment of fees (profit) are allowable only if specifically permitted by a program solicitation and only to the extent that it does not exceed the amount negotiated by the Grants and Agreements Officer and specified in the award letter” (*National Science Foundation [NSF] Proposal and Award Policies and Procedures Guide*, p. V-12).
- “Fee or profit or other increment above cost may not be paid on Department of Commerce financial assistance awards [grants] unless there is statutory authorization to do so. Requests for fee or profit by recipients of any type should be referred to [Commerce] for review” (*Department of Commerce Grants Manual*, chap. 9).
- “Grants and cooperative agreements may not provide for the payment of fee or profit to recipients or subrecipients, except for awards made pursuant to the Small Business Innovation Research or Small Business Technology Transfer Research programs” (*Department of Energy Financial Assistance Rules*, 10 C.F.R. § 600.318).

These policies may come as an unwelcome surprise to companies with little experience in federal research projects. Firms that build profit and fee into labor charges or otherwise “load” their billing

rates may need to disconnect elements of cost from their standard charge schedules.

Cost Accounting Principles and Systems

Institutions of higher education and nonprofit organizations are quite familiar with the cost accounting principles of OMB Circulars A-21 and A-122, respectively. In many cases, these institutions have accounting systems centered around, and tailored to, tracking reasonable, allowable, and allocable costs. These costs are identified with unique accounting codes and institutional policies define appropriate documentation for each cost. However, few commercial organizations have systems that are designed to track costs in this manner, unless the company is a prior recipient of cost-reimbursement government contracts.

Commercial firms are subject to the *Cost Principles for Commercial Organizations* in the Federal Acquisition Regulation ("FAR") at 48 C.F.R. Part 31. It can be expensive and time-consuming for a firm to newly establish the accounting infrastructure needed to comply with the FAR cost principles and other financial requirements applicable to the receipt of federal funds.

Take, for example, the documentation of salary and wages charged to grants. The NIH makes clear that cost accounting for commercial firms means that these firms must document salaries and wages charged to grants "by maintaining a labor distribution system for all employees regardless of function. The labor

distribution system must account for **total** hours and charge direct and indirect labor to the appropriate cost objectives"²⁴ in order to accurately identify labor costs charged to direct activities, indirect activities, and included in the base to which indirect costs are allocated (emphasis in original). Some for-profit firms are surprised to learn that to serve as a direct awardee or subawardee under a grant demands this type of accounting infrastructure.

Note that the FAR cost principles are not fully consistent with the OMB Circular cost principles that apply to educational and non-profit institutions. For instance, the FAR cost principles permit for-profit awardees to incur "precontract costs" to the extent such costs would be allowable if incurred after the effective date of the award.²⁵ This is in contrast to the Circular A-21 cost principles, which indicate that "Costs incurred prior to the effective date of the sponsored agreement, whether or not they would have been allowable thereunder if incurred after such date, are unallowable unless approved by the sponsoring agency."²⁶

Also, recovery of indirect costs under grants and cooperative agreements can be a challenge for commercial firms. Indirect cost recovery usually is based on a negotiated indirect cost rate. For-profits that already receive government awards may have a negotiated indirect cost rate with specific agencies.²⁷ Such rate agreements, unlike nonprofit rate agreements, may contain highly confidential commercial and proprietary information; often they will not

be released to a collaborator entity or even to a prime awardee. When a for-profit firm has no indirect cost rate or other known general and administrative rate upon award, special difficulties may arise. In these situations, if the firm is to be reimbursed for indirect costs, potential options, among others, would be for the firm to: (a) negotiate a rate with the sponsor agency, if it is otherwise eligible to have a rate agreement; (b) negotiate an appropriate rate with a prime awardee, based on the FAR cost principles; or (c) establish some other agreement with the sponsor agency or prime awardee about reimbursement of indirect costs.

Program Income

Numerous grants and cooperative agreements have the potential to generate “program income”, and the likelihood of program income may increase when a commercial firm collaborates with a nonprofit institution. Broadly, any revenue generated directly by a grant-supported project, program, or activity, potentially is program income. Circular A-110 defines program income as “gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the award”.²⁸ Examples of program income include fees for services performed; charges for the use or rental of real property, equipment, or supplies acquired under the federal award; the sale of commodities or items fabricated under the award; and license income on patents and copyrights. A classic example of program income is admission fees charged to participants for a

workshop or conference sponsored by an award.

Even though program income may be maintained by the organization that generates the revenue, usually program income must be reported to the sponsor agency. More importantly, the government regulates the use of the revenue, which can make commercial organizations uncomfortable. In general, sponsors will require one, or a combination, of these uses of program income:

- Additive use: program income is added to the award funds and must be used to further the award purposes.
- Deductive use: program income is deducted from the government’s total share of costs under the award.
- Matching use: program income is applied toward an awardee’s cost share requirements.²⁹

Ambiguous program income situations are plentiful when commercial organizations participate in federal research. For example, if both government funds and private funds are contributed to produce a revenue-generating event in the course of a project, are all the revenues considered program income? Or could a percentage of revenue remain with the firm? Some sponsors permit proportional distribution, but not all do.

Three additional observations on program income are important to commercial firms. First, recipients have no obligation to the government for program income earned *after* the end of the project

period, unless the award terms and conditions provide otherwise.³⁰ Second, if authorized by the sponsor agency, the costs incidental to the generation of program income may be deducted from gross income to determine program income, provided these costs have not been charged to the award.³¹ In other words, program income can be “net” income. Finally, although program income includes royalties and other income earned from a copyrighted work, patents, trademarks, or inventions, typically such income is exempt from the program income requirements, though it is subject to the other intellectual property terms of the award.

Federally Funded Equipment

Rules on ownership, management, and disposition of equipment purchased with grant assistance may be different for nonprofit and for-profit organizations. The Federal Grant and Cooperative Agreement Act of 1977 permits agencies to vest title to grant-funded equipment in nonprofit organizations without further obligation to the government.³² Such property is considered “exempt property”—it is generally excused from the equipment management and accountability rules set forth in Circular A-110.³³

However, a commercial organization has much less flexibility when it acquires equipment under federal awards or subawards. Such equipment is “nonexempt property” and, unless otherwise specified in the award, subject to a spectrum of acquisition, use, management, and disposition requirements, which include a

requirement to mark, tag, and segregate the equipment.³⁴ Some agencies reserve title to equipment purchased by commercial organizations. NSF is one example: “[T]itle to equipment purchased or fabricated with NSF grant funds by a small business or other commercial firm will vest in the government. Such equipment will be acquired and used in accordance with [NSF Conditions for Acquisition and Use of Equipment] and [NSF Property Management Standards].”³⁵ Commercial organizations should not assume, therefore, that property acquired under a project will be unencumbered by federal requirements.

Audits and Access to Records

Commercial firms involved in federal research sometimes are surprised to learn of the government’s sweeping audit rights. Any company, as a direct or indirect recipient of award funds, automatically agrees to the authority of the federal sponsor, the U.S. Inspector General, the U.S. Comptroller General, and any of their authorized representatives, to have timely and unrestricted access to the company’s books, documents, papers, or other records pertinent to the award.³⁶ The government’s rights include access to the firm’s personnel for discussion related to such records, and these rights are not limited by the record retention period, which generally is three years from the date of submission of the final financial report under the award. For-profit firms that are unaccustomed to federal business may be uncomfortable with such broad audit and interview rights. Academic institutions, on the other hand,

have long had policies and procedures that are consistent with the government's rights.

If an academic institution wanted to appraise the financial or other risk of engagement with a specific subawardee, normally the institution could review the subawardee's annual Circular A-133 audit report, which is publicly available.³⁷ This risk assessment is considered a component of a prime awardee's subrecipient monitoring obligations. However, Circular A-133 does not apply to for-profit organizations, and prime awardees must look elsewhere to conduct an assessment of for-profit subawardees.³⁸

Audit requirements for commercial firms vary between federal agencies. For example, DHHS requires for-profit firms to have a non-federal audit if the firm, during its fiscal year, expended a total of \$500,000 or more under one or more DHHS awards, as a direct recipient and/or as a subrecipient. The firm either may have: (1) a financial-related audit, in accordance with Government Auditing Standards, commonly known as the "Yellow Book", or (2) an audit that meets the requirements contained in Circular A-133.³⁹ Even when the firm does not meet the \$500,000 threshold for the mandatory audit, the firm's "records must be available for review by appropriate officials of Federal agencies."⁴⁰ Academic institutions that work with for-profit subawardees must flow down the appropriate audit terms and secure compliance with the same. Also note that pursuant to HHS policy, foreign subawardees—whether for-profit or not—

are subject to the same audit requirements as for-profit organizations.⁴¹

Intellectual Property

The multiple intellectual property complexities in academic-industry collaboration are worthy of coverage in their own articles. For example, ownership of IP, protection of background IP, and rights to research data are particular challenges, as is the question of material transfer. Research institutions and commercial firms may be constrained, under federal law, from agreeing to terms that otherwise are customary in the broader marketplace. This section highlights a few fundamental observations in regard to federally funded inventions.

Collaboration between academia and industry arguably is written into the Bayh-Dole Act, which imposes an obligation on research institutions to commercialize government funded inventions.⁴² Nonprofit inventors and their institutions fulfill this "duty to commercialize" through license relationships with industry.⁴³

The Bayh-Dole Act, by its own terms, did not apply to for-profit firms that were not small businesses. However, in response to increasing commercial sector concerns about this lack of uniformity, a 1983 Presidential Memorandum and a 1987 Executive Order extended Bayh-Dole to all for-profit organizations, to the extent permitted by law.⁴⁴ As such, inventions by companies that are conceived or first actually reduced to practice in the performance of experimental, development, or research work under a grant or

cooperative agreement may be retained and protected by the company, subject to certain government rights and various inventor obligations.⁴⁵ The company must track and report inventions, and maintain a system to ensure that the government obtains its rights (Henderson & Smith, 2002).⁴⁶

The government's rights to inventions include a nonexclusive, nontransferable, irrevocable, paid-up worldwide license to practice or have practiced for or on behalf of the United States the invention throughout the world.⁴⁷ This is commonly known as "government-purpose" rights. The sponsor agency also maintains "march-in" rights, which allows the government to step into the shoes of the patent-holder and grant additional "compulsory" licenses to the invention upon investigation and certain findings. Grounds for march-in include a finding that such action is "necessary to alleviate health or safety needs which are not reasonably satisfied" by the patent-holder, its assignees, or licensees.⁴⁸ The government has not exercised these rights with any frequency, if at all, but the existence of the right must be understood by commercial organizations that participate in grants and cooperative agreements.

It would not appear, under the regulations that implement the Bayh-Dole Act, 37 C.F.R. Part 401, that companies are subject to all the same obligations familiar to nonprofit institutions, such as the obligation to:

- Seek approval from the sponsor agency prior to assignment of an invention;
- Share royalties collected on a subject invention with the inventor;
- Use royalties or income earned to support scientific research or education; and
- Attract small business licensees.⁴⁹

Other obligations unmistakably apply to for-profit firms. Among these is the preference for U.S. manufacture of inventions. Unless a waiver is obtained from the sponsor agency, products that embody the invention or that are produced through use of the invention must be manufactured substantially in the United States.⁵⁰ This preference presents a challenge to firms that have relationships and agreements with foreign manufacturers, often in countries where manufacturing is inexpensive. The penalty for omission to comply with this requirement could be steep—e.g., "march-in"—though it is unclear whether in this context a march-in ever has occurred.

On February 28, 2011, the United States Supreme Court heard oral arguments on the question of whether a university's statutory right under the Bayh Dole Act in inventions under federally funded research can be terminated unilaterally by an individual inventor through the inventor's separate agreement with a third party company that purports to assign the inventor's rights to that company. The outcome of the case, known as *Bd. of Trustees of Stanford University v. Roche Molecular Systems, Inc.*,

may considerably affect how research institutions and companies secure assignments from individuals who work on federal projects.⁵¹

Transparency and Open Government

The current presidential administration asserts a “commitment to creating an unprecedented level of openness in Government.”⁵² In this regard, organizations that participate in federal research have developed a heightened sensitivity to protection of confidential information that is generated, used, or submitted in a federal project. Generally, commercial firms have much more to lose from the unanticipated disclosure of proprietary and confidential business information.

New policies related to the Freedom of Information Act (“FOIA”)⁵³ have caused concerns among companies that participate in grants and cooperative agreements. The Justice Department has directed agencies to adopt a heavy presumption in favor of information disclosure, even for information that technically falls within the scope of a FOIA Exemption.⁵⁴ Broadly, FOIA requires federal agencies to disclose records requested in writing by any person. Agencies may withhold information pursuant to nine statutory FOIA exemptions. One exemption is for “trade secrets and commercial or financial information obtained from a person and privileged or confidential”, otherwise known as Exemption #4. Quintessentially sensitive information—such as an organization’s technical methodology and

price data, the release of which would cause competitive injury—typically is protected under Exemption #4. However, agency grant and cooperative agreement officials have been known to be less receptive to Exemption #4 and less likely than their procurement counterparts to withhold records from public disclosure. Commercial organizations would be wise to proactively and thoroughly identify, mark, document, and support the confidential nature of sensitive information that is used in federal research.

Two relatively new laws also contribute to heightened disclosure requirements:

- The Federal Funding Accountability and Transparency Act of 2006 (“FFATA”) requires disclosure, on a single publicly accessible website, of all entities and organizations that receive federal funds and payments.⁵⁵ Through this website, the public—including a firm’s competition—now have broad insight into federal awards secured by commercial firms, and insight into the partnerships and collaborations that commercial firms form with academic institutions.
- The Recovery Act (ARRA)⁵⁶ contains several transparency and accountability requirements. A firm that participates in an ARRA project should anticipate the public disclosure of project data, as well as firm-related information, including the names and compensation of the firm’s top officers.⁵⁷ Furthermore,

grantees and subawardees that participate in ARRA projects must “promptly refer to an appropriate inspector general any credible evidence that a principal, employee, agent, contractor, sub-grantee, subcontractor, or other person has submitted a false claim under the False Claims Act or has committed a criminal or civil violation of laws pertaining to fraud, conflict of interest, bribery, gratuity, or similar misconduct involving those funds.”⁵⁸ This affirmative obligation to disclose misconduct is a complicated and tricky legal scenario for any organization, and especially for a company.

CONCLUSION

The foregoing issues are merely illustrative. From these examples, though, perhaps research professionals can draw practical inferences on issues likely to arise when for-profit firms participate in grants and cooperative agreements. Other important issues that fall under the rubric of academic-industry collaborations include, without limitation, the following⁵⁹:

- Publication and rights in data
- Material transfer agreements
- Export control and fundamental research
- Confidentiality, nondisclosure, and noncompetition
- Conflicts of interest and commitment

- Faculty consulting agreements
- Third party reimbursement
- Liability, indemnification, and warranties
- Gifts or loans of equipment
- Tax-exempt bond-financed facilities
- University-affiliated research parks
- Equipment loans
- Commercialization
- Personnel sharing
- Research subject injury
- Visiting scientists

Collectively, these issues suggest that to nourish and expand academic-industry interaction is a delicate process. This should not imply, however, that such programs must meet with skepticism and pessimism. Rather, alliance between academia and industry is imperative in the modern research environment. Current economic conditions and other pressures on corporate budgets have companies paying increased attention to opportunities for federal funds. University-industry compacts are on the rise, and the government has shown willingness to support them with grants and cooperative agreements. As these relationships grow, alertness to the compliance matters entailed is today a permanent endeavor for research professionals.

ENDNOTES

1. On May 21, 2010, the U.S. Department of Health and Human Services (DHHS) issued proposed rules on the identification and management of financial conflicts of interest. The proposed rules enhance the present financial conflict of interest management and reporting requirements for Public Health Service (PHS) grant recipients. See 75 Fed. Reg. 28687. The final rule is expected in 2011.
2. "Following the federal money" also could be deceptive. For many reasons, as described in this article, a commercial entity might forego federal funding and still cooperate as an uncompensated participant in a federal project.
3. Federal sponsors make a variety of grants available to commercial entities. For example, the U.S. Department of Commerce's Broadband Technology Opportunities Program (BTOP) made grant funds available to for-profit entities to support the deployment of broadband infrastructure. See <http://www2.ntia.doc.gov/>. The Department of Energy makes grant funds available to for-profit entities for education, outreach, and modernization of electricity delivery systems, renewable and efficient energy research and development, and a variety of other research programs. See <http://www1.eere.energy.gov/vehiclesandfuels/>. The Food and Drug Administration (FDA) makes grant funds available to for-profit companies for specialized drug and device research. See <http://www.fda.gov/forindustry/developingproductsforrareconditions/default.htm>.
4. See DHHS Grants Policy Statement (GPS) II-78 (2007); NIH Grants Policy Statement (GPS), p. I-25 (2010).
5. See DHHS GPS App. B-4; NIH GPS, p. I-12.
6. The Federal Demonstration Partnership (FDP) is a broad association of federal agencies, universities, and research organizations that work to streamline the administration of federally sponsored research. Materials can be found at <http://thefdp.org/>.
7. OMB Circular A-133 includes this caution in the course of presenting characteristics indicative of a subawardee versus a vendor. § __210(d).
8. See OMB Circular A-133 § __210(b).
9. Circular A-110 § __.40-48; 2 C.F.R. § 215.40-48.
10. Circular A-110 § __.40-48; 2 C.F.R. § 215.40-48.
11. Circular A-110 App. A; 2 C.F.R. § 215 App. A.
12. See Exhibit 3 in the HHS GPS and Exhibit 4 in the NIH GPS.
13. HHS GPS, p. II-9; NIH GPS, p. IIA-8.
14. HHS GPS, p. II-5; NIH GPS, p. IIA-8.
15. HHS GPS, p. II-6; NIH GPS, p. IIA-9.
16. 45 C.F.R. § 74.1.

17. Department of Defense Grant and Agreement Regulations (DoDGARS), 32 C.F.R. § 34.1(b)(2).
18. 32 C.F.R. § 34.11(a)(4) (“The recipient shall have a system to support charges to Federal awards for salaries and wages, whether treated as direct or indirect costs. Where employees work on multiple activities or cost objectives, a distribution of their salaries and wages will be supported by personnel activity reports which must: (i) Reflect an after the fact distribution of the actual activity of each employee. (ii) Account for the total activity for which each employee is compensated. (iii) Be prepared at least monthly, and coincide with one or more pay periods.”)
19. See Standard Form 424B, <http://www.grants.gov/techlib/SF424B.PDF>.
20. 42 C.F.R. § 50.602. The Public Health Service is a branch of DHHS that includes the National Institutes of Health (NIH) and other federal agencies. Note that FCOI regulations are on the verge of being revamped and reissued. See *supra* note 1.
21. 42 C.F.R. § 50.605. “Investigator” means “the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of the requirements of this subpart relating to financial interests, ‘Investigator’ includes the Investigator's spouse and dependent children.” 42 C.F.R. § 50.603.
22. 42 C.F.R. § 50.604.
23. 42 C.F.R. § 93.102.
24. 21 C.F.R. § 50, 56.
25. PHS Policy, available at <http://grants.nih.gov/grants/olaw/references/phspol.htm>.
26. The U. S. Departments of Defense and Energy have special authority to award TIAs to for-profit entities. See *supra* note 4. Some, but not all, of the compliance issues associated with grants and cooperative agreements will apply to TIAs.
27. “Time and Effort Reporting for Commercial Organizations,” NIH Office of Acquisition Management and Policy. See http://oamp.od.nih.gov/dfas/forproffittime_effort.asp.
28. FAR 31.205-32. In practice, however, many agencies will restrict or limit the incurrence of precontract costs.
29. OMB Circular A-21 J.36; 2 C.F.R. § 200 App. A J.36. In practice, many grantor agencies permit educational institutions to exercise “expanded authorities” that allow for the incurrence of pre-award costs.
30. For example, the NIH Division of Financial Advisory Services (DFAS), Office of Acquisition Management and Policy (OAMP), negotiates indirect cost rates with commercial organizations for purposes of grants and contracts awarded to for-profit entities. See NIH Manual Chapter 7610 dated 9/11/2006.
31. OMB Circular A-110 § __.2(x); 2 C.F.R. § 215.2(x).
32. OMB Circular A-110 § __.24(b); 2 C.F.R. § 215.24(b).
33. OMB Circular A-110 § __.24(e); 2 C.F.R. § 215.24(e).
34. OMB Circular A-110 § __.24(f); 2 C.F.R. § 215.24(f).
35. 31 U.S.C. § 6306.
36. Equipment management and disposition conditions are established in OMB Circular A-110 § __.34; 2 C.F.R. § 215.34.
37. OMB Circular A-110 § __.34; 2 C.F.R. § 215.34.

38. NSF Proposal and Award Policies and Procedures Guide, Pg. IV-4.
39. OMB Circular A-110 § __.53(e). *See also* 45 C.F.R. § 74.26(d)(2).
40. See <http://harvester.census.gov/sac/>.
41. "Since this part [Circular A-133] does not apply to for-profit subrecipients, the pass-through entity is responsible for establishing requirements, as necessary, to ensure compliance by for-profit subrecipients. The contract with the for-profit subrecipient should describe applicable compliance requirements and the for-profit subrecipient's compliance responsibility. Methods to ensure compliance for Federal awards made to for-profit subrecipients may include pre-award audits, monitoring during the contract, and post-award audits" OMB Circular A-133 § __210(e).
42. 45 C.F.R. § 74.26(d); HHS GPS Pg. II-90.
43. 45 C.F.R. § 74.26(d) (2).
44. Bayh-Dole University and Small Business Patent Procedures Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015-3028 (codified as amended at 35 U.S.C. §§ 200-211, 201-307 (1994)).
45. See Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy, Pub Papers 248 (Feb. 18, 1983) and Executive Order 12591.
46. With respect to work that is subject to copyright protection, normally a firm may freely copyright works developed under a federal grant or cooperative agreement. The sponsor agency receives an automatic, royalty-free right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so. OMB Circular A-110 § __.36(a); 2 C.F.R. § 215.36(a).
47. 35 U.S.C. § 202(c)(4); 37 C.F.R. § 401.14.
48. 35 U.S.C. § 203(a); 37 C.F.R. § 401.14(j).
49. 37 C.F.R. § 401.14(k).
50. 37 C.F.R. § 401.14(i).
51. *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems Inc.*, 583 F.3d 832 (Fed. Cir. 2009), cert. granted, 178 L. Ed. 2d 368 (2010).
52. White House Memorandum for the Heads of Executive Departments and Agencies, Transparency and Open Government, Jan. 21, 2009, *available at* http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment/.
53. 5 U.S.C. § 552.
54. Office of the Attorney General, Memorandum to the Heads of Executive Departments and Agencies, Freedom of Information Act, Mar. 19, 2009, *available at* <http://www.justice.gov/ag/foia-memo-march2009.pdf>.
55. Pub. L. 109-282, 120 Stat. 1186 (Sept. 26, 2006).
56. Pub. L. 111-5, 123 Stat. 115, 215 (Feb. 17, 2009).
57. See Section 1512 of the Recovery Act. Also, see Office of Management and Budget, Memorandum For The Heads Of Departments And Agencies, Implementing Guidance for the Reports on Use of Funds Pursuant to the American Recovery and Reinvestment Act of 2009, June 22, 2009, *available at* http://www.whitehouse.gov/omb/assets/memoranda_fy2009/m09-21.pdf.
58. See endnote 57 for applicable references.

59. Many other papers and resources address academic-industry collaborations. For example, see the Council on Governmental Relations brochure on University-Industry Relations, available at www.cogr.edu/viewDoc.cfm?DocID=151558, and see the National Academies Government-University-Industry Research Roundtable (GUIRR), available at <http://sites.nationalacademies.org/PGA/guirr/>

LITERATURE CITED

Chronicle of Higher Education. (2010, July 18). New earmark limits make universities desired partners, but some just say no.

Federal Demonstration Partnership. (2000). <http://thefdp.org>.

Henderson, J. A., & Smith, J. J. (2002). Academia, industry, and the Bayh-Dole Act: An implied duty to commercialize. Center for Integration of Medicine and Innovative Technology. Last available at http://www.cimit.org/news/regulatory/coi_part3.pdf.
