

COGR

An Association of Research Institutions

**Analyzing Personal Financial and
Institutional Conflicts of Interest in
Academic Research Contexts**

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COGR is an association of over 200 research-intensive universities and their affiliated research institutes and academic medical centers. This document is the result of the efforts of a working group assembled by COGR’s Research Ethics and Compliance Committee. The Working Group members are listed below:

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Introduction

Research institutions and their faculty have numerous interactions and relationships with government, business, and commercial entities that form an important component of their research, education, and public service activities. For example, a faculty member’s consulting work with an outside company may enrich their teaching and provide an opportunity for the translation of university discoveries into commercialization opportunities that can eventually advance society. Yet, despite these and other benefits, such interactions with the private sector also create the potential for financial conflicts of interest (COI). Similarly, institutions may have financial interests such as ownership in a start-up company or revenue from the licensing of technology that pose institutional COIs with respect to the institution’s mission and activities. Unmanaged personal and institutional financial conflicts, at their worst, can result in biased research, loss of public trust in the research enterprise, and reputational harm for the researcher and institution. For this reason, institutions, and funding agencies, have long had policies and regulations intended to protect the objectivity of research from financial COIs.

Although regulators and institutions have typically been neutral regarding the source of financial interests, recent changes in global economic and geopolitical circumstances have raised concerns regarding conflicts of interest that pose the opportunity for “malign” or “inappropriate” foreign influence by allowing certain countries to receive unfair, non-reciprocal, access to intellectual capital generated by federally funded research. Over the past few years, federal research funding agencies have begun to focus on conflicts of commitment (COCs), which may arise when a

researcher has competing or conflicting obligations to multiple institutions or entities. Historically, institutions have addressed COCs separately from COIs. At times, however, the federal government has referred to COCs as “non-financial COIs,”¹ generating a potentially confusing overlap of terms and concepts.

As this paper makes clear, research institutions of all types are responsible for ensuring that their organizations have appropriate policies and processes for identifying, reducing, managing, and/or eliminating COIs to maintain the integrity of the institution’s research activities. Additionally, institutions must educate and provide assistance to faculty on recognizing and reporting conflicts and understanding their obligations under applicable regulations, funding agency guidelines, and institutional policies.

Purpose and Organization

The paper is designed to assist research administrators, academic officers, and faculty members in identifying, analyzing, and developing strategies for addressing different types of COIs in the context of federally grant-funded research. Section I provides a general overview of the various types of COIs (i.e., personal financial, institutional) and applicable regulations. Section II addresses COIs in the context of malign foreign influence, including a discussion of recent agency efforts to recast COCs as “non-financial conflicts of interest,” and the impact of this effort on institutions. Section III addresses the following common situations where personal financial and/or institutional conflicts often arise, and it describes key issues and questions to consider in evaluating scenarios and developing management strategies:

- Consulting
- Licensing of university technology
- Start-up entities
- Clinical studies and other research involving human subjects
- Mentoring
- Procurement
- Institutional COIs

Finally, the Appendix contains case studies based on real-world scenarios, with context-specific management strategies.

¹ See, GAO, *Federal Research: Agencies Need to Enhance Policies to Address Foreign Influence* ([GAO-21-130](#), Dec. 17, 2020, “GAO Report”) and subsequent testimony of the same name by Candice Wright, Director Science Technology Assessment and Analytics before the House of Representatives Subcommittee on Investigations and Oversight and Research and Technology Committee on Science, Space and Technology ([GAO-22-105434](#), Oct. 5, 2021).

In applying the information contained in this paper, it is important for readers to keep in mind that research institutions may approach COIs in different ways, based on their mission, culture, risk tolerance, structure (i.e., public or private entity), as well as applicable state and local laws. As a result, it is critical for faculty and administrators to be familiar with their institutions' standards, policies, and expectations and how they apply to specific circumstances. Accordingly, it is impossible to address every type of situation in research settings that may result in a COI, and readers are encouraged to look for similarities between the scenarios discussed here and their particular situations.

Section I: Overview of Types of COIs and Applicable Regulations

This section provides an overview of personal financial COIs and institutional financial COIs, including major applicable federal regulatory requirements.

PERSONAL FINANCIAL CONFLICTS OF INTEREST

A potential, personal financial COI occurs when there is a possibility, from the perspective of an independent observer, that an individual's private financial interests, or their family's interests, may influence the individual's professional actions, decisions, or judgment in pursuing, conducting, or reporting research. It is not always possible, nor is it necessary, to eliminate all perceived, potential, or real personal financial COIs. Rather institutions should focus on promoting transparency in disclosing interests that give rise to COIs, identifying and managing COIs, and responding appropriately to conflicts of concern.

The Office of Management and Budget (OMB) Uniform Guidance (UG) states that federal awarding agencies "must establish conflict of interest policies for Federal Awards,"² and both the Public Health Service (PHS) and the National Science Foundation (NSF) have long had regulations and/or other policies/guidance that govern the disclosure and review of personal financial interests to determine if they constitute a conflict.³ Investigators' personal financial conflicts of interest in the context of healthcare and clinical research⁴ are a particular focus for regulators, and the Centers for Medicare and Medicaid's (CMMS) implementation of the OpenPayments⁵ procedures require

² [2 CFR §200.112](#).

³ See, Public Health Service, regulations on "Promoting Objectivity in Research," [42 CFR Part 50, Subpart F](#) ("PHS COI Policy"), which apply to NIH funded research. See, also, [NSF, Proposals and Awards Policies and Procedures Guide \(PAPPG\), NSF 23-1](#) ("PAPPG 23-1"), Part II, Chapt. IX.A ("NSF COI Policy").

⁴ See, AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research, [Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research](#) (Feb. 2008); [AAMC Conflicts of Interest and Transparency Initiatives webpage](#).

⁵ CMMS, [Open Payments webpage](#).

the reporting of certain payments and financial support (including research support) from drug and device manufacturers to physicians, teaching hospitals, and other specified health care providers.

Funding agency COI policies have focused on protecting research from potential bias that could result from an individual researcher's opportunity for financial gain. As the National Institutes of Health's (NIH) regulation states:

This subpart promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.⁶

Although agency policies for the disclosure and review of investigators' personal financial COIs differ as to specifics, they have certain common core requirements:

- Institutional written and enforced COI policy.
- Investigators' disclosure of their, and their spouse and dependent children's, "Significant Financial Interests" (SFIs) at the time of funding a proposal (or earlier) and with updates provided periodically thereafter.
- Inclusion in SFI definitions of monetary thresholds (which may be as low as zero dollars) for different types of financial interests (e.g., equity interests, remuneration) and a nexus between the interest and an investigator's research or institutional responsibilities.
- Designation of person(s) to review disclosed SFIs and determine if there is a financial COI that impacts the funded research.
- Management of any COI and reporting of the COI and any management plan to the funding agency.
- Maintenance of records regarding the disclosure, review, and management of COIs.

Table 1 on the following pages summarizes key points of NIH, NSF, and Department of Energy (DOE) requirements for the disclosure/review of investigators' personal, financial COIs. Additionally, COGR has published a [Word document that directly compares the text of the PHS and interim DOE conflict of interest policies](#).

⁶ [42 CFR §50.601](#).

Table1 Chart: Comparison of PHS, NSF, and DOE Personal Financial COI Requirements for Funded Investigators

	PHS (applies to NIH)	NSF	Dept. of Energy
Source of Requirements	<p>42 CFR Part 50, Subpart F NIH Grants Policy Statement, §4.1.10 NIH Financial Conflict of Interest webpage NIH Guide Notices Related to Financial Conflict of Interest</p>	<p>NSF’s annually issued PAPPG. PAPPG current as of the date of this publication: PAPPG 23-1. NSF’s Grant Terms and Conditions. Terms and conditions current as of the date of this publication: Terms and Conditions NSF, Research Security webpage NSF, Policy Office webpage with links to COI and current and pending support materials</p>	<p>Dept. of Energy, FAL 2022-92 - Interim Conflict of Interest Policy for Financial Assistance Interim Conflict of Interest Policy Frequently Asked Questions (“DOE Interim COI Policy FAQs”)</p>
Policy & Documentation	<ul style="list-style-type: none"> ◆Recipient organization must have up to date, written, enforced policy that is publicly available on website. ◆Subrecipients must follow the prime recipient’s policy or have their own policy. ◆Organization must maintain records relating to investigator disclosures and review of and response to disclosures for three years after the date the final expenditure report is submitted to PHS (or per 45 CFR §75.361). ◆Information on financial conflicts of interest (FCOIs) must also be made available via a publicly accessible web site or provided in response to a written request. 	<ul style="list-style-type: none"> ◆Recipient organizations with >50 employees must have written and enforced COI policy. ◆Subrecipients must follow the prime recipient’s policy or have their own policy. ◆Organization must maintain records of investigator disclosures and actions taken to resolve COIs for at least three years after end of award to which they relate or resolution of any NSF action involving the records. 	<ul style="list-style-type: none"> ◆Recipient organization must have an up to date, written, enforced policy that is publicly available on its website, or if an entity has no presence on a public website, it must provide a copy of the policy to a requestor within five business days of request. ◆Subrecipients must follow the prime recipient’s policy or have their own policy. ◆Organization must maintain records relating to investigator disclosures and review of and response to disclosures for the period specified in 2 CFR §200.334 (or other applicable dates in award conditions). ◆Information on FCOIs must also be made available via a publicly accessible web site or provided in response to a written request.

<p>Scope/ Applicability</p>	<ul style="list-style-type: none"> ◆ Policy requirements apply to each entity that applies for or receives PHS research funding. ◆ Disclosure obligations apply to “Investigators,” i.e., project director (PD), principal investigator (PI), or other person “responsible for the design, conduct or reporting of” proposed or active Public Health Service (PHS) funded research.” ◆ Investigators must disclose “Significant Financial Interests” (SFIs) of themselves, their spouse, and dependent children. 	<ul style="list-style-type: none"> ◆ Policy requirements apply to NSF funding recipient organization with >50 employees. ◆ Disclosure obligations apply to “Investigators,” i.e., PI, co-PI, and any other person on the proposed project who is responsible for “design, conduct or reporting” of research or educational activities funded/proposed for funding by NSF. ◆ Investigators must disclose SFIs of themselves, their spouse, and dependent children that would reasonably appear to be affected by the funded/proposed research activities or are in entities whose financial interests would reasonably appear to be affected by such activities. 	<ul style="list-style-type: none"> ◆ Policy requirements apply to each non-federal entity that applies for or receives DOE financial assistance. ◆ Disclosure obligations apply to “Investigators,” i.e., PI and any other person who is “responsible for the purpose, design, conduct, or reporting of a project funded/proposed for funding by DOE. ◆ Investigators must disclose SFIs of themselves, their spouse, and dependent children. ◆ DOE program offices may expand the definition to include any person who participates in the purpose, design, conduct or reporting of the DOE funded/proposed project.
<p>Investigator Interests to be Disclosed to Institution</p>	<p>◆ “Significant Financial Interests” are financial interests that meet certain dollar thresholds and “reasonably appear to be related to the investigator’s institutional responsibilities.” They include remuneration, equity, and IP rights. Certain interests are excluded.</p>	<p>◆ “Significant Financial Interests” are anything of monetary value, equity interests, venture or other capital financing and IP rights that meet certain dollar thresholds. They include salary, payments for services, consulting fees, honoraria, stock or other ownership interests, venture or capital financing, and IP rights. Certain interests are excluded.</p>	<p>◆ “Significant Financial Interests” are financial interests that “reasonably appear to be related to the Investigator’s “non-Federal entity responsibilities.” They include remuneration, equity, and IP rights. Certain interests are excluded.</p>
<p>Thresholds for Conflicts of Interest based on Dollar Values</p>	<ul style="list-style-type: none"> ◆ Publicly Traded Entities: >\$5,000 Value of any remuneration received from the entity “in the twelve months preceding the disclosure” and value of any equity interest >\$5,000. ◆ Non-Publicly Traded Entities: Remuneration >\$5,000/\$0 equity 	<ul style="list-style-type: none"> ◆ Equity: >\$10,000 and >5% Value >\$10,000 as determined by reference to public prices or other reasonable measure of market value and does not represent >5% ownership interest in a single entity. ◆ Any Payments: >\$10,000 for prior 12-month period. 	<ul style="list-style-type: none"> ◆ Publicly Traded Entities: >\$5,000 Value of any remuneration received from the entity “in the twelve months preceding the disclosure” and value of any equity interest >\$5,000. ◆ Non-Publicly Traded Entities: Remuneration >\$5,000/\$0 equity

	<p>Value of remuneration from the entity “in the twelve months preceding the disclosure” >\$5,000. \$0 threshold for equity in the entity.</p> <p>♦Intellectual Property Rights/Interests: Reportable upon receipt of <u>any</u> income related to the rights/interests.</p>		<p>Value of remuneration from the entity “in the twelve months preceding the disclosure” >\$5,000. \$0 threshold for equity in the entity.</p> <p>♦Intellectual Property Rights/Interests: Reportable upon receipt of <u>any</u> income related to the rights/interests.</p>
<p>Timing of Investigator Disclosures to Institution</p>	<p>♦No later than the time of an application for PHS funding, with updates provided within 30 days of discovering/acquiring a new SFI, and at least annually during the term of the award.</p>	<p>♦At the time a proposal is submitted to NSF with updates provided during the award period either annually or as new, reportable SFIs are obtained.</p>	<p>♦No later than the time of an application for funding, with updates provided within 30 days of discovering/acquiring a new SFI, and at least annually during the term of the award.</p> <p>♦Disclosures must include a certification statement signed by the investigator.</p>
<p>Review/ Determination of Financial Conflict of Interest</p>	<p>♦Institutions must designate one or more officials to review SFI disclosures and decide if they are related to the PHS-funded research and constitute an FCOI by determining if an SFI could “directly and significantly affect the design, conduct, or reporting of PHS-funded research.” If so, the institution must develop/implement a management plan for the FCOI, which may require reducing or eliminating the FCOI or ending the relationship that created the FCOI.</p> <p>♦The FCOI and the management plan must be reported to NIH (unless the FCOI is eliminated).</p> <p>♦Reporting and retrospective review is also required if an FCOI was not reported in a timely fashion.</p>	<p>♦Institutions must designate one or more persons to review SFI disclosures to determine if they constitute an FCOI, i.e., the SFI could “directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.” If so, institutions must develop/implement conditions/restrictions to “manage, reduce or eliminate” the FCOI.</p> <p>♦NSF must be notified if an organization determines it is unable to satisfactorily manage a FCOI and that the research will proceed without conditions/restrictions if FCOI exists.</p>	<p>♦Institutions must designate one or more officials to determine if reported SFIs are related to a project funded under a DOE award, and if so, whether the SFI is a FCOI, i.e., SFI could “directly and significantly affect the design, conduct, or reporting of DOE-funded research.” If so, the institution must take action necessary to manage the FCOI.</p> <p>♦DOE program offices may require reports on (a) only unmanaged or unmanageable FCOIs; or (b) all FCOIs - managed, unmanaged, or unmanageable.</p> <p>♦Reporting and retrospective review is also required if an FCOI was not reported in a timely fashion.</p> <p>♦DOE may require institutions to routinely submit all or some Investigator disclosures of financial interests.</p>

Other Required Investigator Disclosures	♦Reimbursed or sponsored travel related to institutional responsibilities (except when reimbursed/sponsored by certain government entities or higher education/medical centers/research entities).		♦Reimbursed or sponsored travel related to institutional responsibilities (except when reimbursed/sponsored by certain government entities or higher education/medical centers/research entities) or when otherwise disclosed in current/pending support disclosures.
Communication & Training	♦Train investigators on policies and requirements before engaging in PHS-funded research and at least every four years thereafter, and immediately when there is a change in the policy or the investigator does not comply with policy, or an investigator is new to the entity.	♦Institutions must take “reasonable steps” to ensure that investigators follow the COI policy.	♦Train investigators on policies and requirements before engaging in DOE-funded research and at least every four years thereafter, and immediately when there is a change in the policy or the investigator does not comply with policy, or an investigator is new to the entity.
Organizational COIs			♦Institutions that have a parent, affiliate, or subsidiary organization that is not a “state, local government, or Indian tribe” must maintain written standards of conduct covering organizational conflicts of interest.

Note: At the time of this paper’s publication, the National Aeronautics and Space Administration (NASA) has published a notice seeking public comment on a new COI and COC policy for awardees,⁷ and this policy is further discussed in Section II. The Department of Energy has stated it will develop a final COI/COC policy to replace the interim COI Policy summarized in the above chart.⁸

⁷ [New Conflict of Interest and Conflict of Commitment Policy for Recipients of NASA Financial Assistance Awards \(88 FR 5930\) \(Jan. 30, 2023\).](#)

⁸ [DOE, Interim COI Policy FAQs, FAQ #2.](#)

INSTITUTIONAL CONFLICTS OF INTEREST

An institutional COI occurs in the research context when an institution, or institutional leader who has the authority to act on behalf of the institution (typically a high-ranking individual who has the authority to commit the institution and its resources) has a financial interest that may impact (or appear to impact) the institution’s research activities. Although institutions and institutional leaders may not have a direct role in the conduct of research, their decisions concerning funding, personnel, procurement, licensing, and investment can directly influence the type of research that is conducted and its conduct.

Legal and policy requirements to address the handling of institutional conflicts of interest are primarily addressed in the areas in which these conflicts most frequently arise: contracting and procurement, gifts, and research involving human participants. For example, an institutional conflict may arise if a university is awarded a grant to conduct research and grant funds are used to purchase services from a testing laboratory owned by the institution’s vice president for research. Further, if an institution licenses a chemical compound that it developed to a pharmaceutical company for development as a new drug, an institutional conflict of interest may arise if the institution were to conduct the clinical trials necessary to establish the drug’s safety and efficacy. This is the case even when this research is sponsored by an entity other than the institution. Additionally, institutional COIs may arise when an institution invests in companies that licensed technology from the institution for commercial development. Accordingly, institutions need to be aware of situations in which institutional COIs may arise and ensure that they have appropriate policies and processes for identifying, reviewing, and managing these COIs.

In the procurement and contracting area, the U.S. Internal Revenue Service (IRS) suggests that non-profit organizations adopt a conflict of interest policy⁹ to govern transactions between the organization and its directors or officers, and states frequently have laws to this effect.¹⁰ Similarly, §200.318 of the UG¹¹ requires awardee entities to “have and use documented procurement procedures” that conform with UG standards, as well as “written standards of conduct covering conflicts of interest” and governing employee actions concerning award and administration of contracts. Further, in the case of private entities not affiliated with a state or local government or Indian tribe, the entity must “maintain written standards of conduct covering organizational

⁹ See, IRS, [Instructions for Form 1023, Application for Recognition of Exemption Under Section 501\(c\)\(3\) of the Internal Revenue Code](#) (rev. Jan. 2020) at Appendix A.

¹⁰ See, e.g., O.C.G.A. § 14-3-862; Va. Code Ann. § 13.1-871; N.C. Gen. Stat. 55A-8-31.

¹¹ [2 CFR § 200.318](#).

conflicts of interest,” and the DOE has included this requirement for an institutional COI policy into its COI requirements for grant recipients.¹²

Concern about the possible impact of institutional COIs on the conduct of research involving human subjects came to the forefront after the tragic death of gene therapy clinical trial participant Jesse Gelsinger in 1999. In this case, both personal financial and institutional COIs were identified as contributing factors.¹³ Since that time many institutions have adopted institutional COI policies applicable to research,¹⁴ and the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), a major accreditation body for institutional review boards (IRBs), requires such policies for human subjects research.¹⁵ At the federal level, however, there are no current requirements for an institutional COI policy other than the previously noted UG requirements applicable to procurement.¹⁶

Section II: Conflicts in the Context of Malign Foreign Influence

Over the past several years, the federal government has become increasingly concerned about research security, particularly mechanisms for “malign foreign influence” by which foreign governments that do not share U.S. values on research transparency and integrity take unfair advantage of America’s scientific openness.¹⁷ Agencies have examined ways by which both researchers’ personal financial COIs and “non-financial COIs” (i.e., COCs) may present opportunities for such inappropriate influences.

PERSONAL FINANCIAL COIs

The Guidance for Implementing the [National Security Presidential Memorandum 33 \(NSPM-33\) on National Security Strategy for United States Government-Supported Research and](#)

¹² DOE, [Financial Assistance Letter 2022-02, Interim Conflict of Interest Policy Requirements for Financial Assistance](#) (Dec. 20, 2021); *see, also*, [DOE, Interim Conflict of Interest Policy for Financial Assistance Frequently Asked Questions](#) (Sept. 2022).

¹³ [Shields, B., Addressing Institutional Conflict of Interest to Promote Patient Safety, Patient Safety & Quality Healthcare](#) (Nov. 18, 2010).

¹⁴ *See, e.g.*, [Duke University, Institutional Conflict of Interest in Research Policy](#) (Jan. 2010); [Emory University, Institutional Financial Interests Involving Human Subject Research](#) (Feb. 23, 2016).

¹⁵ AAHRPP, [Evaluation Instrument for Accreditation, Standard I-6.A.](#) (May 15, 2022).

¹⁶ *See*, [Dept. of Health & Human Services, Office of the Inspector General, Institutional Conflicts of Interest at NIH Grantees](#) (Jan. 2011).

¹⁷ *See, generally*, [COGR Science and Security webpage](#); *see, also*, [COGR Laws, Policies, and Agency Guidance Concerning Research Security](#) for links to agency disclosure requirements; [COGR Table of Pre-Award & Post-Award Disclosures Relating to the Biographical Sketch and Other Support](#); and [COGR Matrix of Science & Security Laws, Regulations, & Policies](#).

[Development](#) (“NSPM-33 Implementation Guidance”) makes the following statement about personal financial COIs:

Research agencies should require that recipient organizations instruct covered individuals on how to disclose information related to potential financial conflicts of interest, including but not limited to: private equity, venture, or other capital financing. If required by law or policy, covered individuals must provide these disclosures to both the research agency and to the organization applying for or receiving the Federal funding. Policies at some other research agencies require that covered individuals provide conflict of interest disclosures only to the organization applying for or receiving the Federal funding.¹⁸

This statement includes a significant change to types of personal financial interests researchers must disclose with its addition of “venture, or other capital financing.” NSF has incorporated this wording into its definition of “significant financial interest,”¹⁹ and other agencies may follow suit. However, it is unclear how this new definition dovetails with the NSF FCOI regulations’ focus on individual researchers, given that venture and other capital funding is typically given to separate corporate entities, not individuals. Even when a researcher’s start-up company receives venture capital funding, the researcher may not be privy to the identity of individual investors (e.g., investment is made via a venture capital fund), and it is unclear what level of detail NSF expects in such disclosures. NSF has indicated that it expects to publish frequently asked questions on this change, and COGR will update this publication as additional information becomes available.

In addition to NSPM-33’s requirements, the Government Accountability Office (GAO) published a report²⁰ recommending that federal research funding agencies adopt requirements for both financial COIs and COCs, which the report characterizes as “non-financial COIs.” Agencies have responded by implementing personal financial COI requirements if they did not already have them²¹ and adopting/modifying other disclosure mechanisms to capture information about all sources of support for an investigator’s research and all researcher affiliations and appointments.²² For example, the National Aeronautics and Space Administration (NASA) recently published a notice seeking public comments on a policy requiring disclosures for COIs and COCs,²³ and the DOE has indicated that it will do so as well.²⁴

¹⁸ Subcommittee on Research Security, Joint Committee on the Research Environment (JCORE) (Jan. 2022) at p. 5.

¹⁹ PAPPG 23-1, *supra* n. 3, at Section IX.A.2.

²⁰ GAO Report, *supra* n.1 (report recommended that the Department of Defense and DOE develop agency-wide policies on financial and non-financial COIs and that the DHHS, NSF, and NASA adopt agency-wide policies addressing non-financial COIs).

²¹ See, e.g., [DOE, Interim Conflict of Interest Policy](#), *supra*, n. 12.

²² See, COGR resources, *supra*, n. 17.

²³ [New Conflict of Interest and Conflict of Commitment Policy for Recipients of NASA Financial Assistance Awards \(88 FR 5930\) \(Jan. 30, 2023\)](#).

²⁴ [Interim Conflict of Interest Policy for Financial Assistance Frequently Asked Questions](#) at Question 2.

CONFLICTS OF COMMITMENT

As noted, the GAO Report²⁵ recommended that federal research funding agencies adopt disclosure requirements for both financial COIs and COCs, which GAO categorizes as “non-financial COIs.”²⁶ Both the [NSPM-33 Implementation Guidance](#) and the GAO Report define COC as follows:

Conflict of Commitment – Situation in which an individual accepts or incurs conflicting obligations between or among multiple employers or other entities. Many organizational policies define conflicts of commitment as conflicting commitments of time and effort, including obligations to dedicate time in excess of organizational or research agency policies or commitments. Other types of conflicting obligations, including obligations to improperly share information with, or to withhold information from, an employer or research agency, can also threaten research security and integrity, and are an element of a broader concept of conflicts of commitment used in this document.²⁷

Financial COIs and COCs impact research in very distinct ways. Financial COIs may bias the conduct of the research. They have long been subject to agency regulations, and they are the subject of robust institutional disclosure and review processes to identify and manage any potential for bias. COCs, on the other hand, impact a researcher’s capacity to conduct the research. Agencies require disclosure of research support and biographical information to assist in identifying COCs, and institutions have long-standing processes for evaluating and managing researchers’ efforts across multiple projects/responsibilities. Both financial COIs and COCs may present the potential for research security concerns (e.g., improper disclosure of information) if they involve certain foreign entities, and institutions and agencies address these concerns through the review of researchers’ disclosures.

The NSPM-33/GAO definition of COC, however, intertwines concerns about capacity issues arising from conflicts of time and effort with “other types of conflicting obligations” such as an obligation to “improperly share information with, or to withhold information from, an employer or research agency.” The breadth of this definition encompasses not only actions that may pose research security concerns if foreign entities are involved, but also activities that *serve to promote* research integrity. For example, to protect data integrity, a faculty member may be required to sign a non-disclosure agreement to serve as a paid consultant on a data safety monitoring board (DSMB) for a federally supported clinical trial to test the safety and effectiveness of a U.S.

²⁵ *Supra*, n. 1.

²⁶ *Id.* at p. 5-6.

²⁷ NSPM-33 Implementation Guidance at p. 22; GAO Report at p. 5-6.

pharmaceutical company’s investigational new drug. Accordingly, as agencies work to develop requirements to implement NSPM-33 and institutions design associated compliance processes, it is critical to ensure that both are tailored to the threat posed by the activities they seek to regulate.

COGR’s publication “[Principles for Evaluating Conflict of Commitment Concerns in Academic Research](#)”²⁸ more fully describes the important distinctions between financial COIs and COCs. It also provides a framework for institutions to use in evaluating their COC policies, recognizing that inappropriate foreign influence is just one of many issues that must be considered in this undertaking. Finally, this report discusses common situations in which COC concerns arise and provides several illustrative case studies.

Section III: Common Situations in Which Various Types of Conflicts of Interest Arise

This section discusses common areas in the academic research landscape in which personal financial and institutional conflicts frequently arise. For each area pertinent regulations/guidance, key analysis points, and issues to consider in developing management strategies are discussed.

CONSULTING

Pertinent Regulations/Guidance/Resources:

- [PHS, Promoting Objectivity in Research, 42 CFR §50.603 & §50.605\(b\)\(3\)\(v\)](#)
- [NSF Conflict of Interest Policies, PAPPG 23-1, Ch. 9 sec. A.](#)
- [DOE, Interim Conflict of Interest Policy, §III & V.b.3.](#)
- NIH, [Other Support webpage](#) and [FAQs on Other Support and Foreign Components](#)
- [NIH Pre-Award and Post-Award Disclosure Table webpage](#)
- [NSPM-33 Implementation Guidance](#)
- [NSF Pre-Award and Post-Award Disclosures Table webpage](#)

Most universities have institutional policies that permit faculty to engage in consulting with outside organizations concurrently with their institutional appointment. Faculty are permitted to consult because these relationships often enrich campus-based research and teaching activities, facilitate community outreach, and provide an avenue for applying research theories to real world issues. Nonetheless, these policies typically limit the amount of consulting that can be done (e.g., one day per week), and they also may include other limits as well (e.g., require approval of certain types

²⁸ Ver. 2.0 (Sept. 2021).

of activities, prohibit use of university resources in connection with consulting activities, and prohibit certain provisions such as assignment of intellectual property, etc.).²⁹

Despite their benefits, consulting activities also may pose both COI and COC concerns. Furthermore, consulting activities with non-U.S. entities have come under scrutiny as possible avenues for malign foreign influence in research, and the NSPM-33 Implementation Guidance requires disclosure of “[p]aid consulting that falls outside of an individual’s appointment, separate from institution’s agreement” as current and pending/other research support. The NSPM-33 Implementation Guidance also makes clear that consulting is a distinct activity:

Agencies and research organizations should ensure that scientists do not inappropriately characterize research activities or involvement in foreign government-sponsored talent recruitment programs as consulting. Authorship or co-authorship on a scientific or technical published paper or posted pre-print would be one manifestation of an activity that involves research.³⁰

Additionally, where a researcher is retained as a consultant or in another capacity to provide services to a non-U.S. institution, NIH requires submission of the consulting agreement or other documentation describing the engagement.³¹ These connections between consulting activities, conflicts of commitment, and foreign influence are more fully detailed in COGR’s [Principles for Evaluating Conflict of Commitment Concerns in Academic Research](#).

Key Points to Consider in Evaluating Consulting Scenarios

Broad Areas for Consideration	Specific Points for Consideration & Questions to Ask
<p>Nature of the Consulting Relationship</p>	<p>◆ Is the activity appropriately conducted as an outside activity, or should it be structured as an institutional activity pursuant to an institutional agreement? This distinction will affect the negotiation, signing, and terms and conditions of the contract. In the case of a personal agreement between the outside entity and the faculty member, there should be no impression that the university is a party to the arrangement, or has any involvement in carrying it out. As noted below, however, institutions must consider to what extent, if any, they will be involved in the review of any consulting agreement.</p> <p>◆ Is the relationship one in which the faculty member consultant will provide independent consulting services/advice, or is the external entity seeking the performance of research</p>

²⁹ See, e.g., [Brown University, Policy on Outside Professional Activities for Faculty](#) (eff. Oct. 5, 2022); [University of California System, Conflict of Commitment and Outside Activities of Faculty Members](#) (Jan. 15, 2020).

³⁰ At p. 5

³¹ NIH, FAQs, Other Support and Foreign Components [webpage](#).

	<p>services? The subject matter of the consulting relationship must conform to any university policies that limit the types of consulting activities faculty may undertake. If the outside entity is seeking performance of research services, whether or not they are related to any current research projects, institutional policies may require that the agreement be handled through its sponsored program processes. Consulting activities that involve research should address who will own IP resulting from the research. Further, the activity should not limit publication or future research pursuits.</p>
<p>Nature of the Outside Entity</p>	<p>◆Does the nature of the outside entity for whom the consulting is provided trigger any specific review requirements? If the consulting relationship involves a federally funded researcher and a non-U.S. entity, the institution may require review or prior approval to determine if there are any malign foreign influence concerns (e.g., participation in foreign government sponsored talent programs, requirement to establish a laboratory in the foreign country, etc.). The review should also consider whether the relationship triggers other requirements specific to non-U.S. entities such as export control considerations. Consideration should be given to whether the entity may pose any conflicts for the institution (e.g., consulting for an entity that may be adverse to the home institution in litigation).</p>
<p>Details of the Commitment</p>	<p>◆How much time will be needed to complete the assignment? When will it need to be completed? Does it interfere with the faculty member’s ability to carry out their university responsibilities? Consulting obligations must not conflict, interfere, or compete with a faculty member’s ability to carry out their primary responsibilities to their home institution, including any obligations to undertake or work on sponsored research. The amount of time that it will take to complete the consulting work and project deadlines must be considered in the context of university-required work and timelines.</p> <p>◆What resources are required to complete the consulting commitment, and who will provide these resources? The type and source of resources necessary to complete a consulting assignment must be clear. Many research institutions prohibit the use of university resources (e.g., computers, labs, supplies, equipment) and the use of university students or personnel to perform private consulting activities without express permission. Further, institutions typically prohibit any use of their name (including use on stationary), logos, or any other items or marks that would give the impression that the institution was part of the faculty member’s consulting arrangement.</p> <p>◆What is the subject matter of the consulting? If the subject matter of the consulting is very similar to related research being conducted at the institution, the risk of associated conflicts may be higher. For instance, if the scope of both research projects are close in nature or overlapping, this similarity may give rise to intellectual property disputes or may affect students’ ability to publish.</p>
<p>Disclosures and Review of the Relationship</p>	<p>◆Has the institution educated faculty on applicable disclosure requirements? Consulting is one of the most common external activities for faculty members, and institutions have an obligation to make faculty members aware of points they need to consider before entering into a consulting agreement, including institutional policies on consulting, problematic clauses in consulting agreements, and the need to assess whether the faculty member has the capacity to</p>

perform the consulting work and all university duties. Faculty must be apprised of all institutional and federal research sponsors' disclosure requirements relating to conflicts of interest/commitment, research support, and appointments/affiliations, including when/how disclosures must be updated, and when/how errors in prior disclosures must be corrected.

◆**Has the institution educated faculty on the disclosure review process, outcomes, and post-review responsibilities?** Institutions must educate faculty on potential outcomes from review of their disclosures, and what plans may be put in place for management of any conflicts identified (including the reduction or elimination of the conflict). Care must be taken to ensure that faculty also are aware of their specific post-review obligations and any ways in which those obligations must be memorialized or documented (e.g., documentation that relationship was disclosed in publications).

Issues to Consider in Developing Policies/Processes/Management Strategies

- Subject matter: Can the consulting activity be scoped so that it is separate and distinct from the related research taking place at the institution?
- Disclosure Process: What units are involved in receiving consulting disclosures and is any departmental, school or other approval required? Are all units involved in the review process privy to all of the information that is disclosed so that it can be compared?
- Review of Consulting Agreements: Institutions must consider whether they will review all consulting agreements, specific agreements (e.g., agreements with foreign entities), or no agreements. They must also consider the scope of the review (e.g., limited review to identify problematic clauses or full review, review not meant to serve as legal advice to the faculty member). In all cases, the institution must make the faculty member aware of the nature and purpose of its review.
 - If the institution does not review consulting agreements, has it educated faculty on provisions that violate university or sponsor policies and other items that they must consider in their review? Will the institution require the faculty member to certify that the consulting agreement does not contain any provisions that violate institutional or sponsor requirements?

LICENSING OF UNIVERSITY TECHNOLOGY AND START-UP COMPANIES

Pertinent Guidance/Regulations/Resources:

- [35 U.S.C. Chapt. 18, Bayh-Dole Act](#)
- [37 CFR Part 401](#), *Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements*
- U.S. Small Business Administration, [Small Business Innovation Research \(SBIR\) and Small Business Technology Transfer \(STTR\) Programs webpage](#)

- [COGR Intellectual Property and Innovation webpage](#)

Since the passage of the Bayh-Dole Act in 1980, universities have become more involved in commercializing inventions developed under federally supported research programs. Frequently, these commercialization efforts involve licensing of university-developed technology to other companies that are better equipped to develop the technology for marketing. These licensing efforts are a crucial component of translational research, but they also may present the potential for COIs, particularly if they concern start-up companies (i.e., a company that is established based on a license of university-owned technology) with which the institution and/or inventors have a continuing relationship.

Licensing of inventions have also become a concern in the foreign influence arena, as federal agencies have become concerned with the potential for technology developed using federal research dollars to be licensed to foreign entities that are economic competitors and do not share U.S. values.³² To address this concern, the NSPM-33 Implementation Guidance states:

Research agencies should require that recipient organizations instruct covered individuals on how to disclose information related to potential financial conflicts of interest, including but not limited to: private equity, venture, or other capital. If required by law or policy, covered individuals must provide these disclosures to both the research agency and to the organization applying for or receiving the Federal funding.³³

In response to this directive, NSF has amended its definition of “significant financial interest,” and other institutions may follow suit:

The term “significant financial interest” means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options, private equity, or other ownership interests); ***venture or other capital financing***, and intellectual property rights (e.g., patents, copyrights, and royalties from such rights. (Emphasis added.)

Yet, institutions may struggle to address this requirement because conflicts of interest disclosure requirements are typically directed to the individual researcher, as opposed to a separate corporate entity that is investing in intellectual property in which the researcher has rights. Further, the identities of investors in venture capital entities may be protected by non-disclosure agreements.

³² See, [Congressional Research Service \(CRS\), U.S. Technology Made in China: The Role of Federal Technology Licensing Policies \(Sept. 20, 2022\)](#).

³³ [NSPM-33 Implementation Guidance](#) at p. 5.

Key Points to Consider in Evaluating Licensing Scenarios

Broad Areas for Consideration	Specific Points for Consideration & Questions to Ask
Establishment of a Start-Up Company	<p>♦What is the institution’s process for determining when and how a start-up company will be established? Institutions must be clear that the institution owns intellectual property (IP) created by faculty unless there is an express agreement to the contrary and what interests inventing faculty members have in the IP.</p> <p>♦Roles & Responsibilities: Who will make decisions regarding the licensing of the IP, and how will those decisions be made? Care must be taken to ensure that potential COIs are avoided/managed during the negotiation of the license and afterward.</p> <p>♦How will equity in the start-up be distributed to the researcher and the institution? What role will the researcher play in the start-up company? There must be full transparency regarding the researcher’s equity and role in the company. Conflicts may arise when the researcher has a management role in the start-up, has a role in negotiating the license to the IP, or is providing consulting services to the start-up.</p>
Relationship Between Company to Which Technology is Licensed and University	<p>♦The nature, ownership, and activities of the company to which the IP is licensed may affect the potential for personal financial and institutional COIs. Start-ups can set the stage for multiple types of COIs, but licensing other companies may also pose potential COIs, such as when the company is a major donor to the university. Institutions must ensure that disclosure processes cover all persons with relationships concerning the transaction (e.g., inventor, other university researchers, officers/trustees who have equity in the company) and transparency regarding the company’s relationship with the institution (e.g., donor, research sponsor). This information is necessary to develop guardrails to prevent these relationships from impacting IP-related decisions.</p> <p>♦The nature, ownership, and activities of the company also may raise foreign influence concerns. Licensing to non-U.S. companies can raise foreign influence concerns, and institutions need to consider federal agency requirements for disclosing venture capital and other funding, as well as processes for how the company will be screened for specially designated nationals or other export control concerns.</p>
Boundaries Between the Start-Up Company and University Activity	<p>♦How will the institution ensure that university resources are not diverted to the start-up company? Clear boundaries must be established to prevent the use of university space, equipment, materials, personnel, students to benefit the start-up.</p>
Management of Research in Areas Closely Related to the Licensed IP	<p>♦How will the institution ensure that all research is conducted objectively? COI concerns arise when the research involving the licensed IP or related to the IP is conducted at the inventing institution. Steps that the institution may take to ensure that any research related to the licensed IP is conducted independently and objectively include having an independent PI, requiring review of data by an independent review board, and/or conducting the research at a separate institution.</p>

Issues to Consider in Developing Policies/Processes/Management Strategies

- **Clearly Delineated Boundaries**: Conflicts of interest and commitment are more likely to arise when boundaries between the start-up company and university activities are blurred. Ensuring clear demarcation of activities lowers the risk of conflicts and makes management easier.
- **Striking an Appropriate Balance**: Institutions and researchers have legitimate interests in seeing the successful translation of IP into products that help the broader community, but pursuit of these opportunities via separate companies must be carefully balanced with university commitment to research, teaching, and mentoring. Research results may be viewed as having less integrity if they are seen as having a real or perceived impact on a company in which a researcher and/or the institution have a financial interest.
- **Policies to Promote Transparency**: Institutional policies must ensure that university officials who manage institutional equity holdings do so without regard to their own financial interests, as the perception of officials benefitting from “private deals.” Institutions must also ensure that officials are aware of and comply with these policies.

CLINICAL STUDIES AND OTHER RESEARCH INVOLVING HUMAN SUBJECTS

Pertinent Guidance/Regulations/Resources:

- PHS, Promoting Objectivity in Research, [42 CFR Part 50, Subpart F](#)
- [Common Rule, 45 CFR Part 46](#)
- FDA Protection of Human Subjects and Institutional Review Boards (IRBs), [21 CFR Parts 50 & 56](#) and Financial Disclosure by Clinical Investigators, [21 CFR Part 54](#)
- [CMS, Open Payments Program](#)
- [DHHS, Financial Conflict of Interest Guidance \(2004\)](#)
- [COGR, COI/COC webpage](#)
- [Association of American Medical Colleges \(AAMC\) - Association of American Universities \(AAU\) Advisory Committee on Financial Conflicts of Interest in Human Subjects Research, *Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research*](#)

Heightened ethical considerations in human subjects research call for intense scrutiny of financial COIs that arise in this area. It is paramount that persons who volunteer to participate in clinical studies are assured that no financial bias, positive or negative, influences trial recruitment, planning or conduct of the research, data collection or analysis, and reporting of the study’s outcome. Even the perception that an investigator or institution may financially benefit from a study’s outcome may distort the value of a participant’s role in the trial, and actual financial COIs

must be addressed in the most conservative manner. Institutions and their researchers must pay particular attention to avoiding ambiguities or appearances of questionable judgment when the research poses risk to the life or health of participants.

Although the Common Rule and comparable FDA regulations do not explicitly mention individual researchers' FCOIs, they address them through the provisions requiring that:

- Risks to participants be minimized and be reasonable in relation to any anticipated benefits;
- Selection of participants be equitable;
- Informed consent be obtained; and
- The possibility of coercion or undue influence over the participant be minimized.³⁴

These requirements are not limited to the consideration of the FCOIs of individual researchers, but also encompass institutional COIs (e.g., conduct at an institution on technology licensed by the institution).

The FDA also requires sponsors to collect the following disclosures from investigators conducting clinical trials in support of marketing applications: compensation to the investigator affected by the outcome of the trial, significant equity interests in the trial's sponsor, proprietary interests in the article being tested, or significant payments of other sorts from the sponsor to the investigator (excluding costs for conducting clinical trials).³⁵ Along these lines, the aforementioned joint AAMC-AAU report concerning practices for academic biomedical research involving human participants recommends a rebuttable presumption against participation in the research by a conflicted investigator, that may be overcome only in "compelling circumstances."

Finally, FCOIs also must be considered in non-clinical research involving human participants, when financial interests may influence research design, conduct, or reporting. Although the same "zero tolerance" standard that is applied to high-risk clinical investigations may not be adopted for research that poses less than minimal risk (i.e., prospect of harm to the individual in the course or participating in the research is low), the impact of FCOIs on participant safety must still be considered. For example, engineering research leading to development, testing, and commercialization of new materials can involve human volunteers and put them at some risk. Similarly, social and behavioral research in sensitive areas warrants close scrutiny of potential FCOIs.

³⁴ 45 CFR §§46.111(a)(1)-(4) & 45 CFR §46.116; 21 CFR §§56.111(a)(1)-(4) & 21 CFR §50.20.

³⁵ 21 CFR Part 54.

Key Points to Consider in Evaluating FCOIs in Clinical Research and Other Research Involving Human Participants

Broad Areas for Consideration	Specific Points for Consideration & Questions to Ask
<p align="center">Relationship between Investigator & Research Sponsor</p>	<p>◆Does the investigator conducting the clinical trial have a relationship with the research sponsor, apart from the trial? Investigators may have relationships with sponsors apart from the conduct of the clinical trial that can pose actual or potential FCOIs. For example, the investigator or a family member may have an ownership interest in the sponsor or may serve as a consultant or speaker for a drug or device company that is sponsoring the trial and receive direct compensation or payment for travel from the company. Many institutions have placed bans/strict limits on physician receipt of compensation, gifts, travel, etc. from pharmaceutical and device companies,³⁶ and the CMS Open Payments process requires that such activities be publicly reported by the payers although the payment attributions in CMS Open Payments may not align with institutional COI policies. If relationships are permitted, disclosure to members of the research team and/or trial participants may be necessary.</p>
<p align="center">Relationship between Investigator and/or Institution and Test Article</p>	<p>◆Licensing/Ownership of Equity: As noted in the section on Licensing, FCOI issues are presented when the investigator and/or institution have ownership/intellectual property interests in the product/technology that is being tested and/or in the company to which the product/technology is licensed. When such relationships arise in the context of clinical and other human subjects research, consideration must be given to whether the conduct of the research should involve the investigator and/or institution, and if so, the guardrails (e.g., disclosures, additional reviews) that must be put in place to manage the conflict.</p>
<p align="center">Involvement of a Conflicted Investigator in the Conduct of the Trial</p>	<p>◆Is there justification to support a conflicted investigator being permitted to participate in the clinical trial? The AAMC-AAU Report states that a conflicted investigator should participate in clinical research only if there are “compelling circumstances.” Institutions should consider in advance what such circumstances would be (e.g., need to know a complex surgical procedure in which only a few physicians are trained) and ensure that they are communicated to researchers and reviewers (e.g., IRB, COI Committee).</p> <p>◆What protections should be implemented to protect human subjects and preserve research integrity, if a conflicted investigator is permitted to</p>

³⁶ See, e.g., [Conflict of Interest Policy on Education, Clinical Care, and Administration for Faculty and Researchers at Columbia University Irving Medical Center](#) (last rev. Sept. 8, 2022); [University of Central Florida, Industry Relations Policy and Guidelines webpage](#); [Emory University School of Medicine, House Staff Policies & Procedures Manual, Conflict of Interest/Industry Relations](#); see, also, AAMC, [In the Interest of Patients: Recommendations for Physician Financial Relationships and Clinical Decision Making](#) (June 2010); [PhRMA, Code on Interactions with Health Professionals](#).

	<p>participate in the conduct of the trial? Institutions must be prepared to incorporate measures that mitigate the impact of the conflict and protect human subjects. Measures may include limiting the role of the conflicted person, such as no involvement in recruitment or consent process, independent study data analysis, independent data safety monitoring, additional IRB review (e.g., review after a specified number of patients are enrolled), and disclosure of the conflict to subjects in the informed consent. In some cases, conflicted investigators may be involved in early stage trials, but stop involvement in later stages when additional investigators have been trained in the conduct of the trial. If no compelling circumstances exist for the conflicted investigator’s participation, institutions must consider how the trial will be appropriately administered, such as using independent PIs who are trained in study procedures or providing a subaward to an independent site to conduct the trial.</p> <p>◆When should institutional conflicts prevent the conduct of a clinical trial at institutional facilities? If the institution owns substantial equity in the test article or start-up company, it may be necessary to ensure that clinical trials involving the item are conducted at independent facilities to minimize risk to participants and support the research’s integrity.</p>
<p>Review of the Research by the IRB and Others</p>	<p>◆What is the IRB’s role in addressing FCOIs in human subjects research? Institutions must consider how the institution’s various units that are involved in the review of conflicts of interest work with each other. Institutional units that review significant financial interest disclosures and analyze them for FCOIs must have open communication channels with the IRB about findings and recommended management plans. IRBs, in turn, must have the discretion to review these plans and determine if they require additional protections for subjects.³⁷</p> <p>◆Review Considerations: First, the IRB members must ensure that members’ own conflicts do not influence their reviews by recusing themselves from the review of protocols in which they have a conflicting interest. Next, the IRB must consider the structure of the study, its logistics, study site, and study personnel, in conjunction with any institutional conflict of interest review/management plan to determine if it adequately minimizes risks to human subjects or if additional safeguards are required. Further, the IRB must carefully consider how to disclose any conflicts in the informed consent form to ensure that participants are aware and to promote transparency regarding the research.</p>

Issues to Consider in Addressing Policies/Processes/Management Strategies

- **The Strictest Review Standards Must Always Apply to Clinical Research:** The intersection of personal/institutional financial interests with the participation of human

³⁷ See, e.g., [AAHRPP Evaluation Instrument for Accreditation, Standard I-6](#).

volunteers in clinical research calls for the application of the highest standards of disclosure, review, and management practices and a low bar for deeming relationships and activities unmanageable. In particular, institutions should avoid conducting clinical trials when both the institution and the investigator have financial interests in the outcome of the studies.

- **Addressing Individual and Institutional FCOIs:** Actual or potential institutional and individual FCOIs concerning clinical research can harm participants and dramatically undercut participant and public confidence in the research, the institution, and the scientific enterprise as a whole. Accordingly, the institution must ensure that both institutional and IRB policies address the handling of these matters, and the IRB, as the independent entity charged with oversight of human subjects research, must have ultimate authority over addressing FCOIs in this type of research.

MENTORING

Pertinent Guidance/Regulations/Resources:

- [Office of Research Integrity, Mentorship Resources webpage](#)
- NSF, Postdoctoral Researcher Mentoring Plan and Responsible and Ethical Conduct of Research Requirements, [PAPPG 23-1](#), pp. II-31 & IX-3

Mentoring trainees and junior faculty is one of faculty members’ most important roles and responsibilities. Mentors and mentees may have close and long-lasting relationships, but these relationships also involve power differentials, seniority, and influence that often make mentees feel beholden to their mentors. If mentors are biased because of FCOIs, their actions and advice may not be in their mentees’ best interest. Examples of situations in which FCOIs may impact mentor-mentee relations include mentees feeling pressure to work for a mentor’s start-up company or on other external activities, or mentees feeling compelled to work on research projects that will financially benefit their mentors. Further, any souring of the mentor and mentee’s relationship may potentially impact students and trainees in a negative manner, as they work to fulfill academic research requirements or obtain recommendations for their first professional positions.

Key Points to Consider in Evaluating the Impact of FCOIs in Mentor/Mentee Relationships in Research Settings

Broad Areas for Consideration	Specific Points for Consideration & Questions to Ask
Mentees Participation in Mentor’s Start-Up Company or Other External Activities	◆Should the institution permit trainees to participate in their mentor’s start-up company? Start-up companies often lack access to financial support and other resources, and the faculty member who has equity in the company may view having

	<p>trainees’ participation in the start-up’s research activities as a “win-win” situation. Yet, the commercial interests of the start-up company may make it difficult for the trainee to publish research results, use results in a thesis or dissertation, or continue aspects of the research outside of the start-up. Institutions may want to ensure that prior to permitting the trainee to begin research work at a faculty member’s start-up, there is full disclosure of the faculty member’s relationship with the start-up, an independent advisor or co-advisor for the trainee, and clear specifications permitting research to be used for the trainee’s publications, dissertation, or other academic activities. COI issues and problems associated with “power inequalities” also may arise if a faculty member becomes an investor/equity holder in their student’s start-up company.</p> <p>◆Should the institution be similarly concerned about a junior faculty member participating in a senior faculty member’s start-up? The power differential between a senior and junior faculty member (especially when the senior member has managerial authority) may cause the junior member to feel compelled to work for the start-up and sacrifice their own research and career interests. At a minimum, faculty members should be required to fully disclose their FCOIs, and additional measures should be considered to ensure that the junior faculty member experiences no real or perceived pressure to pursue the start-up’s interests over their institutional responsibilities.</p>
<p>Identifying Potential Mentor/Mentee Conflicts During Review of External Activities</p>	<p>◆Institutions should ensure that review of faculty external activities include questions to identify potential mentor/mentee conflicts. When institutions review outside activities they should seek information on any plans for involvement of trainees, staff or other faculty and be clear on institutional expectations and restrictions in this regard.</p>

Issues to Consider in Addressing Policies/Processes/Management Strategies

Protecting the Integrity of the Training Experience: The institution’s primary goal must always be to ensure that each trainee can undergo their training process free of bias or negative influence from FCOIs held by mentors or senior faculty members in positions of power. Processes and procedures should be developed based on this end goal and potential mechanisms for achieving this end may include: independent review of relationships; appointment of a co-advisor or advocate who has no relationship to the external activity; modifying reporting lines or research programs; and ensuring that trainees receive full disclosures relevant to the relationships that they are contemplating.

PROCUREMENT

Pertinent Guidance/Regulations/Resources:

OMB Uniform Guidance, [2 CFR §§200.317 - .327](#)

DOE, Interim Conflict of Interest Requirements for Financial Assistance ([FAL 2022-02](#)) & associated [FAQs](#)

Acquisition of goods and services for research projects comprises a large portion of institutional expenditures and is typically subject to well-established internal controls that vary from highly controlled centralized systems to lesser degrees of control at the department level depending on the type and amount of the purchase. Institutions must have and use documented procurement procedures that comply with the Uniform Guidance procurement standard for the acquisition of property or services under a federal award or subaward. They must also comply with any other procurement-related COI requirements from the awarding agency, as well as applicable state laws and regulations, which often apply to public institutions. Universities generally may be precluded from entering into contracts with employees or companies in which their employees have a significant financial interest. However, in cases in which very specific materials/supplies/services are required to conduct the research, institutions may find that there is a very small universe of potential suppliers, and thus they may be faced with providing required justifications to proceed with these purchases.

Key Points to Consider in Evaluating FCOIs in Procurement

Broad Areas for Consideration	Specific Points for Consideration & Questions to Ask
<p>Authority for Procurement Decisions</p>	<p>◆How should an institution identify and manage potential vendor conflicts? PIs or their designees in the lab frequently initiate the purchase of supplies/equipment/services, but selection may be biased if the PI/designee has a personal financial interest in the vendor or is otherwise inappropriately influenced by the vendor (e.g., gifts, entertainment, meals). Many institutions require purchases at a certain price threshold and/or continuing supply contracts to be handled via a central procurement process that obtains competitive bids or quotes. Institutions may also require the use of university approved vendors, even for smaller acquisitions that can be made through university issued credit cards (i.e., purchasing or “p-cards”). Institutional policies may also expressly prohibit purchases from an entity in which the purchaser has a financial interest, require all purchases to be made through an independent committee, and/or ban gifts, meals, or other inducements from vendors.</p> <p>◆Uniform Guidance Requirements: Under 2 CFR §200.318, “no employee, officer or agent” of a grantee institution “may participate in the selection, award, or administration of a contract supported by a Federal award if he or she has a real or</p>

	<p>apparent conflict of interest,” and the grantee’s written standards must include these requirement. A “conflict of interest” is defined as occurring when an employee of the institution or their agency, partner, immediate family member or organization that employs or is about to employ any of these parties “has a financial or other interest in or tangible personal benefit from” a vendor under consideration. State laws may have similar prohibitions/requirements.</p>
<p>Sole Source Purchases</p>	<p>◆When are sole source purchases appropriate? Many institutions have requirements for competitive bidding of purchases over a certain monetary threshold and require a sole source justification where other bidders are not available or cannot meet project specifications.</p> <p>◆Uniform Guidance Requirements: 2 CFR §200.320(c) permits non-competitive procurement for (i) purchases that meet specific minimum dollar threshold; (ii) items available only from a single source; (iii) situations in which public emergency/exigency does not permit any delay; (iv) the federal awarding agency authorizes the purchase pursuant to a written require; or (v) competition is found to be inadequate after solicitation of a number of sources. State procurement laws may contain similar requirements.</p>
<p>Purchases from Entities in which Researcher or Institution has an Interest</p>	<p>◆Is a purchase from an entity in which a researcher or the institution has a financial interest ever appropriate? As noted, the Uniform Guidance prohibits institutional employees, officers, or agents from participating in the award of a contract funded by a federal award if they have a real or apparent conflict of interest. Nonetheless, situations may arise in which the materials or services necessary for the conduct of the research are so specific that the only source for their supply is the entity in which the researcher or institution has an interest. If permissible under applicable laws/policies, it may be possible to effect the purchase if it is awarded and overseen in a manner that provides sufficient justification for the purchase and ensures its independence.</p> <p>◆Services Provided by Family Members of the Researcher: Many workplaces recognize dual-career couples who work in the same area of research, but conflicts arise when one spouse/family member is paid under another’s grant and/or works under the other’s supervision. If the spouse/family is to be paid under a contract funded by a federal award, then the forgoing Uniform Guidance requirements apply. Additionally, institutional policies and/or state laws may prohibit or restrict the employment of family members, particularly where one family member has a supervisory role over the other. If the family member’s work involves tasks that impact the conduct of the research, (e.g., consultant to perform study data analysis), then there must be justification as to why another independent person/entity cannot perform the work, and if not, how independence and integrity will be maintained.</p>
<p>Gifts</p>	<p>◆Do gifts pose similar conflicts of interest? The control of the use of gift funds may pose conflicts if the funds can be leveraged to the benefit of the donor. (Gifts that benefit the donor also may implement tax laws concerning the deductibility of the donation, and</p>

	<p>legal counsel should be consulted.) The entity that manages gifts and endowments for the institution may establish criteria for distinguishing true gifts from sponsored research, as well as guidance for awarding funds for specific projects and establishing accounts for use by departments for research programs. These procedures may remove COIs by removing beneficiaries of gifts from the decision-making process and independently identifying how expenditure decisions will be made.</p>
<p>Organizational Conflicts</p>	<p>◆How should institutions address organizational conflicts that arise in the procurement context? Organizational COIs may arise when the institution, or one of its officers, has an interest (e.g., full ownership, equity) in a potential vendor that sells products the institution requires. In such situations, institutions often take actions to separate the institution from direct involvement with the vendor or decisions concerning the company.</p> <p>◆Uniform Guidance Requirements: Section 200.318(c)(2) of the Uniform Guidance states that an “organizational conflict of interest” arises when “because of relationships with a parent company, affiliate, or subsidiary organization” the organization is/or appears unable to be impartial in handling procurement from the related entity. Under this provision, any non-federal entity that is not a “State, local government, or Indian tribe” must maintain “written standards of conduct covering organizational conflicts of interest.” Federal agencies may incorporate these requirements for organizational COIs into overall COI requirements (<i>see, e.g., DOE links noted above</i>), and call for organizational COIs to be disclosed to the funding agency, along with a management/mitigation plan.</p>

Issues to Consider in Addressing Policies/Processes/Management Strategies

Procurement Processes at All Levels: Institutional purchases take place via various channels, and institutions must consider the processes they will employ to mitigate conflicts that may occur in each procurement path. Larger dollar purchases are typically handled via procurement units or purchasing committees with processes (e.g., competitive bidding, approved vendor lists) in place to mitigate improper influence. Smaller purchases, however, are often handled via lab purchasing cards, and institutions must consider processes for researchers to disclose any interests they (or their family members) have in potential vendors. Finally, institutional processes must be developed to address COIs posed by institutional officers, directors, and trustees, as well the organization itself, also must be mitigated. All processes that are developed must comport with any applicable federal, state, and local laws.

INSTITUTIONAL CONFLICTS OF INTEREST

Institutional COIs have been addressed in many of the common situations discussed above. These types of conflicts have added complexity because they often involve high level faculty and

University leaders (e.g., trustees, executives, senior academic administrators), also referred to as “institutional officials” within this context, as well as important business transactions (e.g., licensing of technology, ownership in start-up companies, large dollar purchases). In addition to complexity, these situations can be extremely high profile and pose the potential for institutional reputational risk, especially when they involve human subjects research and/or the potential of large financial returns.

The following chart provides additional detail on areas in which institutional COIs frequently arise, along with points to consider in their management.

Areas/Circumstances that May Lead to Institutional COIs	Points to Consider in Developing Management Strategies
Sponsored Research, Equity, and Licensing of Technology	
<ul style="list-style-type: none"> ◆Licensing agreement with or equity position in a company sponsoring faculty research may bias institutions to accept terms or conduct research that only facilitates the company’s success. ◆Endowment management or other institutional initiatives to develop venture funds to invest in faculty start-ups. ◆Institutional “incubator” sites that offer lab space, equipment to faculty start-up companies in exchange for equity. 	<ul style="list-style-type: none"> ◆Reduce or eliminate involvement by institutional officers, trustees, and employees in institution-associated company activities. ◆Develop processes for employee/ officer/trustee disclosure of significant financial interests in entities with which institution does business. ◆Actively manage and review conflicts using external reviewers or independent managers. ◆Carefully scrutinize human research contexts in which institutional conflicts exists and consider the use of external reviewers to approve and monitor such research.
Interests of Interlocking Directors/Trustees	
<ul style="list-style-type: none"> ◆Close connections between institutional directors/trustees and start-up companies (e.g., facilitation of capitalization, access to promising technology that they may want university to develop). ◆Close connections between institutional directors/trustees and vendors of products/services purchased by the research institution. ◆Institutional trustees sitting on the boards of companies with which the institution does business. 	<ul style="list-style-type: none"> ◆Ensure that all directors/trustees are trained on institutional policies and applicable legal requirements governing relationships between non-profit corporations and the boards. ◆Creation of “firewalls” to ensure that trustees are not involved in decisions concerning entities/areas in which they have conflicts.
Institutional Equity Holdings	
<ul style="list-style-type: none"> ◆Influence over those within the institution who have authority to recommend purchase or sale of 	<ul style="list-style-type: none"> ◆Establish clear roles and responsibilities regarding the purchase and sale of equity to protect

equity.	independence of decision-making (e.g., decisions made by an independent endowment and investment committee).
Connections between Tech Transfer and Business Development/Start-Up Initiatives and Personnel	
♦Close connections between institutional tech transfer offices/officials and faculty members with start-up companies in which institution has equity (e.g., providing assistance to develop business plans, attracting capital, recommending for inclusion in institutional incubator facilities)	♦Ensure the independence of decision-making lines concerning start-ups. ♦Consider conflicts that arise if compensation plans for tech transfer personnel are tied to financial goals and/or the success of licenses, start-ups. ♦Consider formally separating activities regarding licensing and commercialization of institutional IP from business and economic development activities.
Competing Non-Profit Corporations	
♦Faculty may want to establish their own non-profit corporations that directly compete with institutions for grants, sponsors, etc.	♦Include the development and management of, and participation in, non-profit corporations, under the same disclosure and conflict management rules that govern other faculty external activities.
Politically Sensitive Research	
♦Institutional officials, trustees, alumni, governing boards, and others may try to influence whether and how an institution conducts research activities in politically sensitive areas (e.g., climate change, genetically modified organisms, fetal tissue, cloning).	♦Ensure that decisions regarding research to be conducted are made via academic channels and free from influence that jeopardizes academic freedom.

Section IV. Concluding Remarks

Disclosure of individual and institutional financial interests and responsible management of such relationships by the institutions strengthens research, protects faculty members, and assures the public trust in the academy. While virtually all research universities and organizations have long had written policies governing individual financial COIs in research-related areas, recent activity by federal research funding agencies in the area of malign foreign influence raise concerns about COI compliance, and the related, but distinct issues of COCs and investigators’ disclosures of research support and affiliation information. As a result, institutions are reexamining efforts, and developing/implementing new policies and processes, to address these new concerns and to continue to promote transparency and protect the integrity of the research enterprise.

Appendix: Case Studies

I. CONSULTING SCENARIOS

Consulting Scenario I.A.1.

Dr. Jane Oak is an assistant professor in the biology department at a well-known research university. She has a promising research program funded by NSF to study adhesins, the molecules that help mollusks attach to surfaces. Red Water and Power (RWP) is a major electricity supplier to the five-state area that includes Dr. Oak's university. RWP has a research program that is trying to identify practical approaches to eliminate infestations of zebra mussels that are threatening to clog inlet pipes to several of its power generating plants. William Birch, a RWP engineer, is leading a team working on this problem. He reads an article in a local newspaper about Dr. Oak's research and calls Dr. Oak to discuss RWP's problem.

Following their productive telephone conversation, Mr. Birch confers with his colleagues and managers at RWP and concludes that it would be of value to invite Dr. Oak to RWP for a seminar. RWP offers to pay Dr. Oak's travel expenses and provide her with a modest honorarium.

Dr. Oak agrees to visit RWP. In a seminar, she gives the engineering staff and managers an overview of the research that she and others have done in adhesins. She also presents the group with some of her most recent unpublished results that suggest approaches to block the activity of these molecules.

After the seminar, Dr. Oak meets with the research team at RWP in what becomes a brainstorming session on how to apply the basic research in adhesins to RWP's problem. These discussions are very productive, suggesting to Dr. Oak additional experiments based on RWP's experience with zebra mussels at its plants.

ISSUES

- Is the seminar presentation and the discussion that followed a straightforward scientific exchange among peers similar to a presentation at a professional scientific meeting?
- Is it clear whether Dr. Oak is engaging with RWP in her university role or in a personal capacity?
- Does the presentation of unpublished university research constitute a “disclosure” of information to RWP?
- Are there reasons for Dr. Oak to consider what information is disclosed at this type of meeting?

Management Strategies

An investigator like Dr. Oak with external research support, whether federal or private, should discuss her consulting relationships with the university before presenting seminars or workshops for private industry. Dr. Oak should be clear about whether she is meeting with RWP in her capacity as a university researcher or in her individual capacity. If RWP is interested in Dr. Oak’s line of university research, she should consider whether RWP may be interested in sponsoring research at the university. If not, then Dr. Oak should be clear about the university’s policies and expectations related to consulting and conflicts of interest prior to her seminar and meeting with RWP.

Because of the innovation and potential for commercialization of Dr. Oak’s work, the university may want to initiate a nondisclosure agreement between the university and the company to protect any patentable inventions that might have been disclosed during the initial visit to the company.

Consulting Scenario I.A.2.

Dr. Oak's visit inspires the research staff at RWP and generates significant internal discussion of the problem that they are trying to solve. Mr. Birch proposes to his management that the research project would be greatly advanced if they could collaborate with Dr. Oak. After gaining approval for his plan, Mr. Birch proposes a consulting relationship to Dr. Oak.

The consulting agreement that is provided by RWP includes provisions that Dr. Oak not disclose any information that she learns during her discussions with RWP, and it further provides that any patentable inventions made in her field of expertise will be owned by RWP. To compensate Dr. Oak, RWP proposes a consulting fee that is lucrative and attractive. The agreement is structured for execution by Dr. Oak in her capacity as an assistant professor at the university, and the signature block of the agreement lists the name of the university with Dr. Oak as the signatory. Dr. Oak scans the agreement, sees nothing wrong with its terms, and signs it.

Dr. Oak, enthused about the consulting and collaboration, volunteers one of her graduate students to conduct experiments that complement the studies at RWP.

Management Strategies

Some institutions may require prior approval and/or disclosure of the consulting relationship. Faculty are advised to consult the policies and procedures at their institutions. Additionally, some universities may require review of the consulting agreement prior to Dr. Oak entering into the agreement. Factors for Dr. Oak to considered *prior* to entering into the in the agreement include:

- The consulting agreement as structured appears to be an agreement between the university and RWP. It should be clarified prior to signing whether this is an agreement for sponsored research with the university or a private, consulting agreement with Dr. Oak.
- If this is a private, consulting agreement, then Dr. Oak must sign the agreement in her personal capacity and any reference to the university in the agreement should be removed. All contact information in the agreement, such as addresses and phone numbers, should include Dr. Oak's personal information. Additionally, Dr. Oak should understand what her university's policies dictate regarding use of university resources, such as student and personnel time and commitment, facilities, and equipment, for personal consulting activities.
- If this is an agreement between the university and RWP, then Dr. Oak needs to follow university policies for negotiation, approval, and execution of such agreements. Issues such as allocations of costs, personnel, and resources must be considered and agreed upon by

the university. At most universities, Dr. Oak would not have signature authority for agreements that bind the university.

- Should the obligation to maintain confidential information be mutual, in order to protect confidential university information disclosed by Dr. Oak to the company?
- Should there be reasonable limits on the length of time that Dr. Oak will keep company information confidential?
- Should both parties confirm in writing which disclosed information is to be considered confidential?
- Dr. Oak should refer to the university's intellectual property policies and the university's IP agreement she has already signed to ensure that the provision in the consulting agreement which assigns all patentable inventions made in her field of expertise to RWP does not conflict with either the policies or the IP agreement. This provision seems overly broad and may conflict with the pre-existing university IP agreement.
- Should the university request from RWP clarification of the disposition of inventions? The university may want to negotiate a separate intellectual property agreement that outlines what IP is university owned.
- Should the university require that RWP acknowledge that: a) the university is Dr. Oak's primary employer; b) the university has dominant rights in inventions made by Dr. Oak; and (c) the federal support of Dr. Oak's research and the ownership of inventions resulting from that research?
- Should the university request that RWP acknowledge that Dr. Oak can publish the results of her research?
- Should the university direct Dr. Oak to enter into this agreement as an individual, and advise her of her individual liability in doing so?

The relationship between Dr. Oak and RWP appears to have crossed over into sponsored research in her laboratory. If RWP and Dr. Oak wish for this to be a private consulting agreement between Dr. Oak and the company, then all references to the university and use of university resources and information should be removed. Some universities require that outside consulting agreements be reviewed by the university prior to being entered into by faculty. During this review, the university may require or recommend that certain provisions be modified to protect university information and resources and ensure Dr. Oak is abiding by university policies pertaining to consulting, conflicts of interest and intellectual property. Further, in cases where a consulting agreement involves non-U.S. entities, the university may review the agreement for indication of malign foreign influence and/or educate the faculty member about provisions of concern, such as a requirement to establish a laboratory in a foreign country.

Most universities do not allow faculty to use university resources, which include time and effort of students and other university personnel, for personal consulting. Instructing graduate students to "volunteer" their time and research for outside companies can be detrimental for the students

and should be carefully managed by Dr. Oak and the university so as to not impede the students' scholarly progression towards graduation.

Dr. Oak also will need to update her financial disclosure to the university if her compensation rises above the thresholds defined in university policy. The university will need to review Dr. Oak's disclosure and any related university research to determine if there is a conflict of interest as defined in its policy. If the university determines there is a conflict or potential conflict between Dr. Oak's financial interest in RWP and her university research, then a conflict of interest management plan will be developed. Depending on Dr. Oak's source of funding, the university may need to report the conflict and its management to her federal sponsors.

If the modifications to the consulting agreement are negotiated (as identified above), Dr. Oak should provide written confirmation to RWP of the information that was disclosed during the discussions with the company that she considers to be confidential.

Consulting Scenario I.A.3.

The collaboration of the two research groups is highly productive, and RWP soon recognizes that Dr. Oak has developed a completely new approach to solve the problem of zebra mussel infestation. RWP's vice president for business development also realizes that the solutions now emerging from the research have applications extending beyond the business scope of RWP, into areas that might present a profitable new business opportunity. He retains a business development consultant who reviews the research, conducts a market survey, and proposes that RWP spin out the research project into a separate company (Green Company).

The consultant proposes that RWP assign both its consulting agreement with Dr. Oak and RWP's intellectual property in this area to Green Company. Under the business plan, RWP will also provide the initial working capital, and Green Company will seek additional investors to fund the further research and development. Finally, the company consultant recommends that, for scientific credibility and the prestige that comes with the name of her university, Dr. Oak be named co-founder and the head of Green Company's scientific advisory board. For her participation, Dr. Oak will receive a significant research contract for her laboratory from Green Company, along with founder's shares in the company and stock options.

Dr. Oak is delighted with this opportunity and signs the agreements that implement these recommendations.

As the new enterprise develops, it becomes clear that significant effort is required to focus the research and participate in fundraising. Dr. Oak begins spending most of her time at Green

Company. She manages her university research staff by late evening emails and weekend meetings. When confronted by her department head regarding her activities, Dr. Oak argues that Green Company represents a significant opportunity for her, and that she should be allowed to remain a faculty member while she pursues what may be a breakthrough opportunity for an effective solution to an enormous economic and environmental problem.

ISSUES

- Does the sponsored research agreement from Green Company, per which Dr. Oak serves as the head of the scientific advisory board and holds shares of stocks, create a potential for a financial conflict of interest?
- Have Dr. Oak's commitments to the company begun to make it difficult for Dr. Oak to meet her responsibilities to the university?
- Should the university know that a private company is using its name in fundraising efforts?
- Should the university review the research and resulting IP to ensure no university IP was used in its development?
- Does the university consulting policy require prior review and approval for Dr. Oak's role with Green Company?

Management Strategies

Dr. Oak will need to ensure that she is following all university policies related to consulting and conflict of interest in her new relationship with Green Company. Most university conflict of interest policies require disclosure within 30 days of acquiring any new significant financial interests and, in alignment with federal regulations, many universities define any equity interest in a non-publicly traded company as a significant financial interest requiring disclosure. Many university COI policies will also require a conflict review, and management if appropriate, of the research award from Green Company prior to entering into the agreement. Some common

management strategies used by universities include assignment of someone other than Dr. Oak to conduct the research, assignment of a COI monitor to help ensure Dr. Oak's financial interest in Green Company does not bias university research or allow Dr. Oak to appear to influence other university researchers, etc.

At this point, the university may wish to review Dr. Oak's time commitments and research obligations. Many institutional consulting or conflict of commitment policies limit the amount of time faculty can spend on outside, personal activities during their appointment time. These policies also usually make clear that outside activities should not interfere with the faculty's commitments to the university's teaching, research and service. One option for overcoming a conflict in this area could be to suggest that Dr. Oak consider a leave of absence while she engages in this entrepreneurial activity.

Rather than accept the research grant from Green Company, the university may want to review other options for the research, such as not accepting the research contract, or having the research conducted by another investigator. The university also may want to have the fundraising documents reviewed for inappropriate use of the university's name.

II. LICENSING SCENARIOS

Licensing Scenario II.A.1.

Dr. Elm is the chair of a major department in the school of medicine. As such, he has considerable influence over all activities of the department, including budgetary matters and research relationships. Dr. Elm is also the inventor of an innovative technology that, if aggressively commercialized, will change how the markers for certain diseases can be detected. The invention was made during a federally funded research program, and Dr. Elm has assigned ownership of the invention to his university. The university views this invention to be a "platform technology" and has filed a patent application on it. As a novel platform technology, the invention will have broad applicability, and the university's technology transfer office (UTTO) believes that, with the right capitalization, a start-up company will be the best commercialization vehicle.

Unbeknownst to the UTTO, Dr. Elm has held discussions with several investors associated with the Orange Investment Group. Dr. Elm told Orange Group that if they can secure sufficient funding for a start-up company, he will deliver the new technology to them. Robert Willow, who owns 50% of Orange Group and is a long-time supporter of the university and a member of its board of trustees, ardently supports Dr. Elm's proposal.

ISSUES

- Can Dr. Elm pledge the technology to the Orange Group?
- With the assignment of the invention to the university, what is Dr. Elm's role in the licensing of the invention?
- Does Mr. Willow's position as a university trustee place him in a unique position in relation to the development and licensing of the invention?
- Should Mr. Willow disclose his role in Orange Group? To whom?

Management Strategies

While policies vary among institutions, most require disclosure by trustees of financial interests that might influence their trusteeship. Some elect to limit trustee involvement in university start-ups. Some state statutes governing the roles and responsibilities of university trustees require that the trustees approve the licensing of technologies to companies in which faculty members have significant interests. Thus, Mr. Willow's role in Orange Group might compromise the exercise of his responsibilities.

If Mr. Willow is allowed to participate in a university-spawned start-up, however, there should be restrictions on his use of his trusteeship to access information from university sources that would provide an unfair advantage to Orange Group. Moreover, he may be required to refrain from voting during board decisions that would potentially impact Orange Group.

The university, not Dr. Elm, owns the intellectual property and retains the right to license it. The UTTO should maintain a close relationship with the inventor and should be prepared to disqualify the inventor from any decisions regarding the licensing of the invention.

Licensing Scenario II.A.2.

Dr. Elm and Mr. Willow approach the UTTO with a proposal for the university to license the invention to a start-up company, Purple, Inc. The UTTO is unaware of Mr. Willow's investment holdings, but believes that with Orange Group's backing, Purple, Inc. has the wherewithal to commercialize the invention. The UTTO is further encouraged to look favorably on Purple, Inc. once it learns that Purple, Inc. is willing to fund further development of the invention in Dr. Elm's laboratory. This funding may lead to improvements to the technology that would also be licensable, income-generating properties for the university. A licensing relationship is finalized, with the assistance of Dr. Elm and Mr. Willow, providing royalties and an equity position for the university. Dr. Elm also will receive equity in the company as founder and is promised the position of CEO.

ISSUES

- While investigators are often the primary source for information to “market” their inventions and to establish industry contacts, should Dr. Elm negotiate on behalf of the university with the company?
- Should Dr. Elm's equity in the company and proposed role as CEO be disclosed to the university before the negotiation of the license?
- Should Dr. Elm participate in the negotiations?
- Does Mr. Willow's relationship with the Orange Group and as a university trustee have the potential for conflict?

Management Strategies

Some universities have policies that would require the disclosure and review of Dr. Elm's consulting agreement and disclosure of his seat on the board of Purple, Inc. Some universities require special oversight and approval of consulting agreement language when faculty consult with companies in which they also hold equity. Special language may stipulate that the university owns all intellectual property developed and grants the company an option to license the technology once disclosed.

Dr. Elm and Mr. Willow should not represent the company or the university in the negotiations of the license. Their financial interests give the appearance of compromising their roles as members of the university community.

The university may find Dr. Elm's desire to become Purple, Inc.'s CEO to be a conflict of commitment and suggest that a seat on the board of directors and a long-term consulting contract might be a preferred alternative that would satisfactorily ensure successful implementation of the technology.

Licensing Scenario II.A.3.

As required under the license, Purple, Inc. and the university enter into a sponsored research agreement (SRA), under which Purple, Inc. agrees to fund research in Dr. Elm's laboratory for three years at \$200,000 per year. Under the terms of the SRA, Purple, Inc. will receive an option to negotiate for a license to new inventions resulting from the research and to any improvements dominated by the patent (if and when it issues) for a period of five years.

To increase the likelihood of the success of the important and innovative technology, Dr. Elm submits a proposal to NIH for a multi-year grant to investigate new diseases that might be responsive to the new marker-detecting technology. Dr. Elm agrees to keep his colleague, Mr. Willow, informed of the progress of the NIH research program, if it is funded.

The UTTO pays an outside patent attorney to review Dr. Elm's progress reports for patentable inventions.

ISSUES

- Can Dr. Elm be expected to objectively weigh the merits of accepting the SRA in view of his financial relationship with Purple, Inc.? As an individual researcher? As chair of the department?
- Will Dr. Elm's responsibilities as chair to allocate department resources – graduate students, teaching assignments, etc. – be perceived by others in the department as conflicted as well?
- Should the NIH-supported research results be “pipelined” to Purple, Inc.?
- Will Dr. Elm's financial interest and role in Purple, Inc. be viewed as influencing the objectivity of his NIH research?
- Does Mr. Willow's relationship with the Orange Group and as a university trustee have the potential for conflict?

Management Strategies

Research projects should be consistent with the academic standards and goals of university research, and the appropriateness of the proposed work scope should be determined through an independent review process by the chair or, in this case, by the dean or a designee.

It may be appropriate in this circumstance to have another faculty member (if possible, one *not* under Dr. Elm's administrative umbrella) serve as the principal investigator for the research sponsored by Purple, Inc.

If the grant is awarded by NIH, the agency should be notified of the existence of Dr. Elm's financial relationship with Purple, Inc. and that the university has implemented a conflict management plan.

Dr. Elm's financial relationship with Purple, Inc. should be disclosed to all research staff and students in the laboratory. If there is ever an issue or conflict related to this relationship, the

laboratory members, including graduate students, should be instructed to freely discuss these issues with an appropriate university official who has a sufficiently powerful relationship with Dr. Elm, such as the dean or an associate vice president for research.

Dr. Elm's relationship with Purple, Inc. should be disclosed in publications and oral presentations reporting on company-supported research or other research whose results are related to the commercial interests of the company.

III. CLINICAL STUDIES/HUMAN RESEARCH PARTICIPANT SCENARIOS

Clinical Studies/Human Research Participants Scenario III.A.1.

Dr. Juniper, a professor of cardiac medicine, holds equity in White Drugs, a company that wishes to sponsor a Phase I clinical trial at UMC testing the safety of a novel gene therapy treatment for heart disease. Dr. Juniper, who founded White Drugs, owns approximately 10% of the stock, which is not publicly traded. Dr. Juniper does not participate in the operations of the company.

A colleague of Dr. Juniper, Dr. Alder, who is employed at a neighboring university, is the inventor of the gene therapy treatment to be studied, and he designed the clinical trial. Dr. Juniper and Dr. Alder are collaborators on several NIH-funded research grants, none of which are directly related to this treatment.

ISSUES

- May Dr. Juniper serve as PI on the Phase I trial at UMC? May he play a different role if he is not PI?
- If Dr. Juniper does participate in the trial, are there reputational risks to UMC? Is there a perception of conflict? Given that White Drugs is not publicly traded, there is no implicit financial value in his equity ownership. Where is the financial gain?
- Does the fact that Dr. Juniper did not design this study mitigate his conflict?
- Would the issues be any different if Dr. Juniper held stock options instead of actual stock?

Management Strategies

Dr. Juniper clearly has a financial interest in the outcome of the clinical trial. Although the company is not publicly traded, there is the potential for significant future financial gain. UMC may determine that Dr. Juniper's equity ownership of the company precludes him, and possibly UMC, from participating in the trial.

On the other hand, UMC might determine that the Phase I trial could proceed at UMC if there is full disclosure of the nature of Dr. Juniper's ownership in the company. This decision would be fortified by appointing a data safety monitoring board to be primarily responsible for assuring that participant recruitment, conduct of the trial, and reporting of the data are independent of Dr. Juniper.

Generally, because of his equity ownership in White Drugs, Dr. Juniper would not be permitted to lead the trial. Investigators assuming responsibility for the design, conduct, or reporting of clinical trials have a special obligation to avoid bias or the appearance of bias in all aspects of these studies. Any possible conflict of interest relating to human research participants by any investigator must be routinely disclosed to the IRB as part of the standard information submitted for review and approval. However, because Dr. Juniper has some knowledge of the specifics of the trial and the benefit to the participants, it may be that the IRB would permit him to play some role in the trial.

In the eye of the public, holding stock options is likely to be perceived as actually holding equity, and these options provide the potential for future financial gain. If UMC permits Dr. Juniper to play a role in the conduct of the trial, all the standard disclosures in written and oral presentations, publications, and abstracts would be necessary.

Clinical Studies/Human Research Participants Scenario III.A.2.

Dr. Juniper assists with the recruitment of Dr. Alder to UMC, so they can continue their collaboration and expand their areas of mutual interest and expertise. Dr. Juniper has developed a gene therapy approach to correct a serious congenital heart problem in newborns. Currently this defect causes most affected newborns to die within days of birth. He and Dr. Alder, whose lab did the underlying animal studies indicating the likelihood of success of this therapy, are certain this approach will correct the defect and will eliminate the need for the far more ineffective treatments on the market.

Dr. Juniper is a founder of a second biotech company, Beige Drugs, which wants to sponsor a Phase I clinical trial to test the safety of this new therapy. Dr. Juniper owns 12% equity in Beige Drugs and serves in an unpaid position on its scientific advisory board. Dr. Alder also owns 12%

equity but serves in no consulting or advisory capacity to the company. In addition, UMC licensed the therapy to Beige Drugs and, instead of future royalty payments, has taken a 10% equity stake in the company, half of which is distributable to Juniper and Alder as inventors under the university's patent policy.

ISSUES

- May either Dr. Juniper or Dr. Alder serve as the PI for the clinical study? If Dr. Juniper serves as an officer or member of the board of directors of Beige Drugs, does it make a difference? If this was a multicenter, Phase III trial, would it affect their participation?
- Does UMC's equity ownership make a difference in conducting the clinical trial at the medical college?
- Is IRB review the only review necessary?
- Can the conflicts be managed sufficiently if the participants are fully informed of the individual and institutional conflicts in the informed consent process?
- Should the institution's conflict of interest review and management process take special steps because the research subjects are children?
- In the early-phase studies of the therapy, is it permissible to have the inventor clinicians be solely responsible for the design, conduct, and reporting of the trial to Beige Drugs?

Management Strategies

Given the significant equity positions in Beige Drugs of both the inventor/investigators and the university, careful consideration should be given as to whether UMC would be an appropriate choice to conduct clinical studies of this therapy. At the early stage of identification of a new treatment, drug, or device there may be compelling reasons why the unique skills and experience

of the inventors are critical to achieving the promise of the therapy. However, the protection of the participants volunteering for clinical studies must always be the principal concern, and the institution must take action to ensure responsible individual and institutional behavior in light of inevitable conflicts of interest. If Phase I studies at UMC were considered appropriate by the IRB, the informed consent disclosure should be explicit in disclosing existing financial relationships.

A data safety monitoring board would likely benefit the study by providing additional oversight to avoid individual and institutional conflicts.

UMC's conflict of interest committee(s) as well as the IRB must consider the financial conflicts of interest of the individuals with the sponsoring company, as well as the institutional conflicts. The IRB will play a critical role in assessing the risks and benefits for children participating in the study, and therefore, it must be informed of the specific details of the investigator and institutional financial interests in the company sponsoring the study.

At the point of Phase II studies (if not Phase I), it is likely that the investigators should no longer be involved with the research, unless they divest their interests in the company. Given the financial conflicts of interest of both the investigators and the institution, it seems unlikely that a management strategy could be developed to adequately protect the interests of the participants from the perceived biases of the investigators and the institution.

Overall, in this case, it appears the long-term interests of the public for a promising therapy to be independently and impartially tested are best served when UMC and its faculty inventors avoid any clinical testing at UMC.

Clinical Studies/Human Research Participants Scenario III.B.1.

UMC has long fostered translational “bench to bedside” research. After a long process of pre-clinical investigation, Dr. Teak is greatly encouraged with his new drug that seems to offset the negative side effects of some opiates used in anesthesia and pain treatment. A patent is issued for the drug. The University Tech Transfer Office (UTTO) licenses the development of the drug to Gray Pharmaceuticals, which promises to support further product development. But Gray Pharmaceuticals consistently misses the development milestones that are part of the licensing agreement.

In the meantime, Dr. Spruce, chair of the department, allocates significant resources of her department to support Phase II studies in-house. The department is committed to the promise of the drug and energetically proceeds with entrepreneurial efforts to commercialize their work.

Eventually the UTTO assists with the creation of a new start-up company, Pink Drugs, to sublicense the drug from Gray Pharmaceuticals. Dr. Spruce solicits start-up funds to support drug

development and testing from a personal friend, the wife of one of her colleagues, Dr. Hickory. Dr. Hickory, whose own research interests are completely unrelated to this area of research, is the chair of the UMC IRB. Dr. Hickory's wife invests \$500,000 in Pink Drugs in exchange for 5% equity and future stock options.

Dr. Spruce persuades the president of UMC that her faculty will only assist in these efforts if the department can recover "off the top" of any potential revenues, all of the money which it invested over the last ten years. With the hopes of recovering sunk costs, UMC's president agrees to this special arrangement.

Dr. Teak is engaged by Pink Drugs as a consultant to develop clinical studies for the new formulation of the drug and to guide the company in the design of Phase III studies leading to FDA approval of the drug as well as identification of new uses of the drug. The company is compensating him with generous cash and stock options. Dr. Teak insists that clinical studies should be conducted at the university, claiming he has the only knowledge base that can move this drug forward and, as creator of a new formulation, he is in the best position to ensure its commercial success. He is convinced that he is the person best suited to protect the interests of the research participants, since he knows the risks of the drug.

ISSUES

- Should UMC permit Dr. Teak to be PI on clinical studies on campus? What if UMC is only one site of a multi-site trial? If NIH were funding the study and not a company, would this make a difference?
- What disclosure responsibilities does Dr. Hickory have to the institution? Should Dr. Hickory inform the IRB of his wife's financial interest in Pink Drugs? Should he recuse himself from the IRB's review of the protocol?
- Is there a risk that the institutional conflicts of interest could influence, or appear to influence, the management of the individual faculty conflicts of interest?
- If the conflict of interest oversight group and the IRB approve the UMC site for clinical studies, what information should be disclosed to the research participants during the informed consent process?

ISSUES, CONT'D.

- Can the investigator simultaneously serve the interests of the company (where he will be designing the trial, soliciting trial sites, examining all the study data, and assisting the company through the FDA approval process) and avoid the appearance of conflicts that could influence or appear to influence the conduct of the study under his direction at the UMC site?
- Can the department chair maintain a neutral position if questions arise about the conduct of the trial at the UMC site when the department stands to benefit financially if the commercialization proves successful?
- What relationships might be determined to be unmanageable conflicts?

Management Strategies

The overall issue is whether, even with full disclosure of the individual and institutional financial relationships to the participants in the trial, all aspects of the multiple proposed relationships with Pink Drugs can or should be managed. Assessing whether individual financial conflicts of interests can be managed becomes increasingly complex when the institution also has a financial stake in the outcome of the clinical studies. Since the inventor plans to work closely with the company on designing the trial, analyzing trial data, and seeking FDA approval, many campuses would conclude that the combination of the individual/institutional financially beneficial relationships dictate against UMC serving as a performance site for any clinical studies.

Dr. Teak may be encouraged by UMC to assist Pink Drugs in developing the drug through his consulting relationships, thereby avoiding any UMC role in the clinical studies. Or, if Dr. Teak is determined to serve as PI on UMC studies, he should consider divesting himself of his stock options provided in the consulting agreement and modify the scope of his consulting activities to focus on his participation after the study is completed at all the sites. UMC may want to examine the consulting agreement to ensure that the terms are in accordance with UMC policies.

If UMC determines that a neutral clinical investigator could be identified to manage a study on campus, an external oversight mechanism would assist in ensuring the integrity of the clinical program and managing the institutional conflict. Such oversight would include reviewing the

referral and consenting of participants and roles traditionally associated with a data safety monitoring board.

The financial interests of the investigators and the institution must be fully disclosed to any study participants. Some IRBs might recommend that an independent participant advisor or advocate be involved in the consent process to ensure that participants understand the relationships among the university, investigators, and drug company.

While the colleagues of Drs. Teak and Spruce are probably already aware of their considerable commitment to the promise of this drug, the department and other research collaborators, including residents, staff, and study coordinators, also should be made aware of the individual and institutional financial conflicts presented by this situation.

Federal regulations [45 CFR §46.107(e)] require Dr. Hickory, the IRB chair, to recuse himself from participation in the review of the protocol. The institution's conflict of interest policy should include special disclosure responsibilities of an IRB chair if his or his family's financial interests intersect with any protocol presented to the IRB for consideration. Dr. Hickory should fully disclose to the IRB any financial interests of his family that could influence his deliberations on a protocol. A very cautious UMC might require review by an independent oversight committee to ensure that internally funded studies meet a "best-practice" standard for protocol design, IRB reviews, consent forms, patient safety, and data records.

Dr. Teak should disclose his financial relationships with the company and his role as an inventor in all relevant publications and presentations pertinent to the drug or the business interests of Pink Drugs.

An institutional conflict of interest policy and review should address the special management issues raised by the chair's special arrangement to set aside the usual institutional revenue sharing policies.

If NIH funded the study, the institution must report to NIH that there are financial conflicts of interest associated with the NIH grant, and that these interests have been reduced, managed, or eliminated in accordance with NIH regulations.

Clinical Studies/Human Research Participants Scenario III.C.1.

Dr. Maple is a highly regarded oncologist at University Medical College (UMC). A major pharmaceutical company, Blue Drug Company, wants to sponsor a clinical study testing whether its existing soft-tumor drug is effective in treating certain atypical forms of solid tumors. Dr. Maple's career is progressing, and she is becoming a recognized leader in this area. Blue Drug asks Dr. Maple to chair a new scientific advisory board (SAB) that is considering another promising drug. Blue Drug also asks Dr. Maple to act as a consultant and assist in the design of the clinical studies for this new drug, beginning with Phase II, but likely continuing through at least Phase III, if all works out as expected. Finally, Dr. Maple will be directly involved in analyzing the data collected from all sites participating in the study. For her SAB/consulting work, Dr. Maple will be paid approximately \$30,000/year.

ISSUES

- Should Dr. Maple serve as the PI for the Phase II study at UMC?
- Does Dr. Maple's expanding relationship with Blue Drug raise additional concerns for protecting the rights of participants volunteering for the clinical studies?
- Can a fully informed consent process be assured?
- How can the integrity of the scientific process (data gathering, analysis, and reporting) be assured?

Management Strategies

Dr. Maple is involved in a significant consulting role in the commercial development of the study drug. She will be evaluating data and making recommendations about the future of the drug, during which time she is well-compensated by Blue Drug. UMC may recognize how valuable her role is in the company's planning and decision-making processes but require that Dr. Maple be precluded from serving as PI on the UMC study site. Dr. Chestnut, an independent colleague of Dr. Maple

who does not have such financial ties, may be a suitable PI, bringing the benefit of access to the study drug to UMC while shielding Dr. Maple from a conflict of interest.

UMC might also permit Dr. Maple to serve as PI, particularly since the study is a multisite study, but establish an oversight committee to review participant recruitment and enrollment including the consent process, study data, and reporting to Blue Drug. UMC could also determine that Dr. Maple's role handling data analysis for all the study sites is a UMC research activity that should be the subject of an institutional agreement between UMC and Blue Drug and should not be separately compensated as an outside activity. Finally, any publication or presentation of the study results should disclose Dr. Maple's consulting role with Blue Drug, whether Dr. Maple is PI or even just a co-investigator permitted to enroll participants in the study.

IV. PROCUREMENT SCENARIOS

Procurement Scenario IV.A.1.

Dr. Ruth Larch, distinguished professor of molecular genetics at Mountainside University, has developed extremely efficient techniques and refinements for gene sequencing and screening programs. Dr. Larch and several of her senior staff recently formed a company, Aqua, Inc., to market these services to private and not-for-profit researchers. The company is located in a research park close to the university, and it includes among its customers a number of leading biomedical research universities and pharmaceutical companies. Dr. Larch is president and owns a majority interest in the company but remains a full-time employee of the university.

Dr. Ronald Pine, a faculty member in virology, needs to procure some gene sequencing services for his work funded by the American Disease Society. Dr. Pine turns in a purchase order along with quotes from two companies who nominally compete with Aqua, Inc. One vendor's quote is higher than Aqua, Inc.'s price, and the other is not able to deliver the services without a prolonged delay.

ISSUES

- Should Dr. Pine be allowed to purchase the services from Aqua, Inc.?

Management Strategies

Dr. Larch should disclose her majority interest in the company to the university to ensure that all state and university procedures are met when the university purchases services from Aqua, Inc.

Although there is no obvious conflict of interest at this point, many universities have restrictions that may prohibit this purchase. For example, public institutions may be subject to state law prohibitions if the business transaction involves companies in which employees have a significant financial interest.

University procurement procedures require competitive bidding for contracts of a certain size. For contracts of intermediate value, however, departments are often permitted to submit quotes from competing vendors.

Procurement Scenario IV.A.2.

Dr. Larch serves on the departmental promotion and tenure committee and is a mentor and colleague of Asst. Professor Pecan, who recently arrived on campus and is continuing work she started during her post-doctoral research. Dr. Pecan has worked with Aqua, Inc. in the past and wants to continue to use their services. She does not feel it would be appropriate to obtain quotes from other vendors because they could not provide continuity with the methods used in her previous work and would require her to duplicate experiments already performed. She has turned in a purchase order and a sole source justification to buy services from Aqua, Inc. using her institutional start-up funds.

ISSUES

- Does Dr. Larch's position on the promotion and tenure committee affect the purchase from Aqua, Inc.?
- Should Dr. Pecan be allowed to avoid the competitive bidding process?

Management Strategies

University procurement procedures generally require competition but often have a provision for a sole source justification when other bidders are not available or cannot meet the project specifications.

This relationship would generally be viewed as having a potential for conflict of interest since Dr. Larch would be in a position to benefit from Dr. Pecan's selection of a vendor and would also be in a position as a member of a significant department committee to influence that selection.

Dr. Pecan may feel she does not have a real option to choose another vendor without offending Dr. Larch. Universities should be mindful of relationships that may create or appear to compromise the objectivity of decision-making. Individuals may need to disclose relationships or be recused from certain decisions.

Procurement Scenario IV.A.3.

Dr. Larch assembles a team to write a proposal for an NIH Program Project. With Dr. Larch as principal investigator, they receive a \$4 million award. Dr. Larch wants the university to permit her, under a sole source justification, to procure the gene sequencing work for her project from Aqua, Inc.



ISSUES

- How can Dr. Larch purchase services for the university from her own company on a federal grant?

Management Strategies

Dr. Larch has a conflict of interest in the selection of the vendor for services to the university because she has a majority ownership in the company and, as principal investigator, is in a position to select a vendor to provide services to the university. The conflict of interest would be subject to both the rules of the university (including those that specifically apply to procurement) and to the rules that apply to conflict of interest in, and procurement of items and services for, federally-funded research.

Under 2 CFR §200.318, “no employee, officer or agent” of the grantee institution “may participate in the selection, award, or administration of a contract supported by a Federal award if he or she has a real or apparent conflict of interest,” and the grantee’s written standards must include these

requirements. Section 200.318 goes on to state that a conflict of interest arises when an employee of the grantee institution (or their agent, partner, member of their immediate family, or an organization that employs, or is about to employ, any of these parties) has “a financial or other interest in or a tangible personal benefit from” an entity being considered for the contract. Mountainside University must have written, enforced standards that include these requirements. Given that federal funds will be used, these standards will apply, and Dr. Larch would be unable to participate in the selection of the vendor.

If state law and university policy permit this transaction, the university may choose to manage the conflict by establishing an independent body to make decisions with respect to the purchase of goods or services from the company. Additionally, university standards governing this transaction must comply with the 2 CFR §200.320(c)’s requirements for non-competitive procurement. Section 200.320(c) only permits non-competitive procurement for:

- Purchases that meet specific minimal dollar thresholds;
- Items available only from a single source;
- Situations in which public emergency/exigency does not permit any delay;
- Situations in which the federal awarding agency authorizes the purchase pursuant to a written request; or
- Circumstances in which competition is found to be inadequate after solicitation of a number of sources.

In determining whether one or more of these requirements are met, the university also must also be mindful of other relationships, including tenure and promotion decisions, the progress of students, consulting, and other activities that might also involve the company.

A sole source contract may require review by the federal sponsor. The university (or its conflict of interest committee) will want to consider appropriate disclosure to the federal sponsor, as well as obtaining authorization from the sponsor, even if authorization is not specifically required per the Uniform Guidance.

Procurement Scenario IV.A.4.

Mountainside University directs the department of molecular genetics to establish a procurement oversight and review committee to review the proposed services contract and select an appropriate vendor, and Dr. Larch proceeds with her research with some exciting results. Now in the fourth year of the program project, she and her colleagues determine that they need to find a new biostatistician to help analyze some of the results. Dr. Larch’s spouse retired from Mountainside’s department of applied statistics the previous year and is eligible to do consulting work for the

university. He has agreed to serve as a consultant for the program project, and Dr. Larch has turned in a request to purchase consulting services. However, given her previous experience with the potential for conflicts of interest in university contracting, she has asked if it would be better to have her spouse return as a temporary employee.

ISSUES

- Can Dr. Larch hire her spouse? Does federal funding affect the decision?
- Can Dr. Larch supervise her spouse?

Management Strategies

As defined in the policies of most universities, Dr. Larch is in a position to direct a university contract (the consulting agreement) in a manner that would benefit a family member. Therefore, she would appear to have a conflict of interest. If the consultant position is to be funded via a federal award, the Uniform Guidance procurement requirements noted above will apply. If Dr. Larch's spouse returns as an employee, she will be in the position of supervising a relative. Universities and other U.S. workplaces increasingly recognize the existence of dual-career couples, and there are a number of spouses who work as a team in academic research. However, in the situation described above, the institution may be prohibited by institutional policy or state law from allowing an individual to work on a grant or contract awarded to a family member. Further, most universities have policies that prevent the existence of a subordinate-superior relationship between an individual and a relative through any line of authority.

Where it is permissible under applicable laws, regulations, and policies, the institution may choose to have the contract (consulting agreement) awarded and overseen in a manner similar to a contract to procure goods or services from a company in which a faculty member has a significant interest and/or a sole source procurement. Given that Dr. Larch's spouse will be analyzing her data, the university must be able to ensure that review independence and integrity can be maintained and be prepared to justify why other consultants cannot perform this role. In this respect, the institution may choose to appoint Dr. Larch's spouse under the supervision of a chair or a dean to eliminate nepotism or the appearance of such. Further, the contract could have explicit milestones or "deliverables," e.g., reports, tables, etc. that can be used to measure performance and authorize payments. Alternatively, the institution may choose to appoint Dr. Larch's spouse under the supervision of a chair or a dean to eliminate nepotism or the appearance of such.

Procurement Scenario IV.A.5.

Dr. Larch has several students who hold university procurement cards. These P-Cards, as they are sometimes called, work like credit cards and permit purchases up to \$2,500 per month. They simplify purchasing, speed delivery by allowing internet and telephone orders, and save the university money in processing small dollar value purchase orders. The charges are posted directly to Dr. Larch's NIH grant account. The students have used their P-Cards to order reagents from Aqua, Inc.'s new e-commerce site.

ISSUES

- Should Dr. Larch have told the students not to purchase from Aqua, Inc.?
- Who is responsible for monitoring these types of streamlined procedures?

Management Strategies

Streamlined procurement procedures might eliminate reviews that would prevent purchases that might pose conflicts of interest or other issues. Such streamlined procedures may be permitted for purchases that do not exceed a certain threshold amount under applicable federal or state law or university policy. In the case of purchases made using federal grant funds, 2 CFR §200.320 addresses the use of streamlined procurement methods for purchases under certain dollar thresholds. In all events, Dr. Larch should disclose her relationship with Aqua, Inc. to anyone involved in the project and refer project staff to the procurement oversight and review committee chair to manage or approve purchases from Aqua, Inc.

Implementation of new systems may be accompanied by training and written documentation to ensure that those who make procurement decisions understand the procedures. Further, some institutions block certain vendors or categories of expenditures from purchases using procurement cards.

Procurement Scenario IV.A.6.

Ruby, Inc., a publicly traded company that wants to acquire Aqua, Inc, approaches Dr. Larch. Dr. Larch welcomes the buy-out offer because she wants to remain on the faculty, continue her career in research and education, and spend less time with the company. As part of the deal, she receives shares of Ruby, Inc. but less than 1% of the outstanding shares. She sells part of the stock and donates \$500,000 to “Reach for the Summit,” Mountainside University’s recent capital campaign. The gift is designated for use in “research programs in molecular genetics,” in part to provide matching funds for the expansion of its laboratories. As a member of the building committee, Dr. Larch has developed plans for the expansion of her lab and has asked that funds from her gift be used for upgrades in the renovation of her space.

ISSUES

- Can Dr. Larch designate her gift to her home department?
- Should the university take the gift with the restrictions that it be used in Dr. Spruce’s

Management Strategies

The control of the use of gift funds may pose issues of conflict if the funds can be leveraged to the benefit of the donor. The entity that manages gifts and endowments for the university may establish procedures for awarding funds for specific projects and for establishing accounts for use by departments for research programs. Such procedures may remove conflicts of interest by identifying how expenditure decisions will be made and by establishing accountability for such decisions.

Direct beneficiaries of gifts, like Dr. Larch, are often removed from selection decisions in many universities through centralized planning for construction projects and centralized procurement for large contracts. Finally, legal counsel’s advice should be sought in cases in which a donor’s gift may benefit the donor, as such an arrangement may implicate tax laws concerning the deductibility of the donation.

Procurement Scenario IV.B.1.

Dr. Pecan has earned tenure and, with her postdoctoral fellow, has been remarkably successful in designing software used in analyzing blood samples to diagnose genetic disorders. Their algorithms, software systems, and subsequent improvements are patented by Mountainside University and licensed to a medical device corporation, Sapphire Co. All of the inventors receive stock in Sapphire, and Mountainside University holds an equity interest in Sapphire Co. as well.

Recently, the FDA approved a diagnostic scanner based on the work of these researchers. Two clinical departments at Mountainside University, including Dr. Pecan's department, want to buy this new instrument. No other vendor has such an advanced tool for scanning samples and diagnosing genetic disorders.

ISSUES

- Do the equity interests of Mountainside and the inventors prohibit them from purchasing the scanner for use in the clinics?

Management Strategies

Given that the institution owns equity in the vendor, the university should consider whether there is a conflict between its institutional interest in the company and an open, fair, competitive procurement process. Because of the diagnostic value of the scanner to the clinic patients, Mountainside may consider how its equity interests are managed. Some universities transfer the equity to a foundation that manages the equity for the benefit of the university, but which removes the institution from decision-making about the stock and isolates those making other decisions for the university from direct involvement with the company.

V. MENTORING SCENARIOS

Mentoring Scenario V.A.1.

The laboratory of Dr. Redwood, a professor at Major Biotechnological Institute (MBI), has been successful in developing a new method to introduce foreign genes into the commercial varieties of wheat that had previously been recalcitrant to transformation. The lab also succeeded in developing promoters that control high-level expression of introduced genes in specific wheat tissues. These novel technologies have been disclosed to MBI and are the subject of several pending patents.

Being intensely interested in seeing the technology benefit food production, Dr. Redwood persuades MBI to license the technology to a start-up company, Indigo, Inc., in which he has a substantial financial interest through founders shares and for which he serves as chair of the scientific advisory board. Like many start-up companies, Indigo, Inc. does not have sufficient resources to establish its own research laboratories and wishes to sponsor research in Dr. Redwood's laboratory. Graduate students and postdoctoral trainees for whom Dr. Redwood serves as major professor and mentor would conduct this research. Following his institution's policy requiring disclosure of significant financial interests in a sponsored project, Dr. Redwood discloses that trainees would perform the sponsored research funded by Indigo, Inc.



ISSUES

- Should MBI's conflict of interest committee approve this relationship?
- Will the graduate students/trainees and postdoctoral trainees be able to use aspects of the work for their theses and dissertations and/or continue aspects of the work after the postdoctoral tenure?
- Will the trainees continue to make progress toward their degrees?
- Should Dr. Redwood serve as a member of any graduate student's thesis committee if any part of the thesis research is sponsored by Indigo, Inc.?

Management Strategies

Clearly, it is important for MBI to protect the integrity of the training experience, as well as the professional and career opportunities it provides to students and postdoctoral trainees/associates. Inherent in Dr. Redwood's proposal is the potential for efforts of trainees to be directed to pursuing high-risk research priorities that benefit Indigo, Inc.'s commercial interests (with attendant financial benefit to Dr. Redwood), rather than other worthwhile basic academic projects with more conservative goals. The ability of the trainees to publish or otherwise communicate their results to the broader scientific community may also be curbed by the conflicting business needs of Indigo, Inc., thus limiting the trainees' options for future research and employment.

Options to provide protection for student trainees and postdoctoral trainees/fellows range from prohibiting the appointment of trainees mentored by Dr. Redwood from conducting research on projects sponsored by Indigo, Inc., to requiring that another senior faculty member or members, who have no financial interest in Indigo, Inc., be appointed advisors or co-advisors for trainees working on Indigo, Inc. funded projects. In the event that the latter strategy is adopted, MBI may also consider instituting a formal, regular, review and reporting mechanism to monitor the trainees' progress and publication activity.

Other normative measures for conflict of interest management also must be put in place, such as regular disclosures of Dr. Redwood's interests in Indigo, Inc. to students, trainees, and staff, as well as appropriate disclosure in publications and presentations.

Mentoring Scenario V.B.1.

Dr. Walnut is professor and chair of a department of electrical and computer engineering (ECE department) at Major Engineering University (MEU). She is also a prolific researcher in the application of nanotechnology in the development of new technology producing greater Internet bandwidth. Her research has generated several breakthroughs that have been patented by MEU and licensed to a start-up company, Rose Co., in which Dr. Walnut and the institution hold equity interests. Dr. Walnut also chairs Rose Co.'s scientific advisory board.

Dr. Walnut's department is recruiting to fill a vacant faculty position in a field with potential to produce future advances in the application of related nanotechnology. Dr. Yew, who is a young investigator having recently completed a productive post-doctoral experience, is identified as a strong candidate and ultimately hired. Shortly after Dr. Yew arrives, Dr. Walnut contacts him, offers him an attractive consulting relationship with Rose Co., and implies that if the consulting relationship is productive for the company, there is an opportunity for substantial research support and perhaps even potential stock options in the future. Dr. Walnut also implies, without any commitment, that this opportunity has the potential to allow Dr. Yew to gain rapid scholarly

recognition and a fast track in promotion and tenure review. After considering the opportunity, Dr. Yew follows MEU policy and requests permission to engage in consulting activity with Rose Co.

ISSUES

- Should MEU approve Dr. Yew's request to engage in consulting?
- As chair of the ECE department, does Dr. Walnut have a special responsibility to young faculty? Is this role compromised by her role with Rose Co.?
- Will Dr. Yew be able to establish an independent research program?
- Will Dr. Yew be able to publish results of the work done under a Rose Co. agreement?

Management Strategies

MEU has a clear responsibility and interest in protecting the professional and career interests of new faculty members. MEU has reason to look closely at the proposed consulting relationship. As a young, potentially vulnerable new faculty member, Dr. Yew may feel compelled to put aside all his prior research priorities and divert disproportionate effort to advance the goals of Rose Co. to please Dr. Walnut, and to enhance the institution's value in the start-up. While one might perceive the offer of a lucrative consulting relationship as an opportunity to jumpstart Dr. Yew's career, there is also reason for concern because of the potential conflict inherent in the imbalance in power between Dr. Walnut, a department chair, and Dr. Yew, a new assistant professor.

Potential responses may range from prohibiting the proposed relationship to establishing a strong oversight plan by an individual or panel of senior faculty who have no financial interest in Rose Co. Such oversight would include additional review of Dr. Yew's research productivity and close monitoring of his teaching assignments, performance reviews, and salary recommendations. The opportunity for Dr. Yew to establish an independent research and publication track record that will hold up under tenure review is critical. Any real or perceived pressure to delay publishing or neglect teaching and service activities has to be recognized and managed. Another option would be to have Dr. Yew report to another faculty member, rather than to the chair of the department.

Because the consulting work is closely related to the academic program, any intellectual property must be disclosed through the university's technology transfer office and evaluated as to whether it belongs to the university or the company.

Mentoring Scenario V.C.1.

Dr. Ortega is an extremely successful cancer biologist with many external consulting relationships with large pharmaceutical companies. As such, she is aware of new research topics and projects pursued by these companies. She is also a highly sought after mentor due to her multiple high-profile NIH grants and large laboratory. Therefore, she has over a dozen graduate students working for her at any given time.

Sarah, a graduate student looking to graduate in the next few months with a Ph.D., asks Dr. Ortega for career advice. Dr. Ortega pulls up the job boards from two large pharmaceutical companies, both of whom she consults for, and strongly encourages Sarah to apply to these industry positions. When Sarah inquires about the possibility of recommendations for post-doctoral training programs at leading universities, Dr. Ortega responds that she does not have the time to devote in helping Sarah secure a post-doctoral position, and that she should really look at an industry position because Dr. Ortega can “open doors” for her at the companies.

ISSUES

- Is Dr. Ortega purposefully giving her graduate students biased career advice to further her own outside interests?
- Does Dr. Ortega believe that by sending newly minted Ph.D. scientists from her lab to the companies she consults for will bolster her relationship with those companies?
- Will Dr. Ortega then feel that she can influence Sarah if she were to work for one of those companies after graduation?
- How will this impact the ability of Dr. Ortega's future graduate students to obtain post-doctoral training positions if there is a lackluster track record of them obtaining such positions because they opted for industry positions based on Dr. Ortega's advice?

Management Strategies

At a minimum, Dr. Ortega should regularly disclose to everyone in her laboratory (students, postdoctoral trainees, staff, and junior faculty) her relevant financial interests. If she is providing career advice, she needs to fully disclose her relationships. The COI Office may elect to periodically query members of Dr. Ortega's laboratory as to Dr. Ortega's disclosure.

Students, postdoctoral trainees, and others in her laboratory should be provided with a mechanism to seek advice from other experienced faculty in the department. The department should work to ensure that new graduates have equal access to career opportunities.

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