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Recognizing and Managing Personal Conflicts of Interest

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Recognizing and Managing Personal Financial Conflicts of Interest

COGR

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The Council on Governmental Relations (COGR) is an association that includes among its membership 150 research-intensive universities. This document is the result of the efforts of the COGR Working Group on Conflicts of Interest. The Working Group members are:

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INTRODUCTION

Background

Research universities encourage interactions and the establishment of relationships between their faculty and federal, state, and local governments, and business and industry as important parts of their research, education, and public service activities. External corporate relationships enrich faculty teaching and research, expand career and research opportunities to students, and provide the obvious mechanism for the translation of university developed inventions and discoveries into commercial ventures that benefit the public. However, interactions with the private sector also carry with them an increased potential for financial conflicts of interest, or at least perception of the potential for conflicts. Because of the role of universities as stewards of public funds and the public trust, every university assumes the responsibility to assist its faculty in identifying activities that present the potential for conflicts and in reducing or managing these potential conflicts to assure that they do not threaten the integrity of the university's and faculty's core activities. To do otherwise could impair the credibility of the academic research enterprise.

Financial Conflicts of Interest

A potential financial conflict of interest occurs when there is the possibility, from the perspective of an independent observer, that an individual's private, financial interests, or his or her family's interests, may influence the individual's professional actions, decisions, or their judgment in pursuing research. It is not possible, nor is it necessary, to eliminate all perceived, potential, or real financial conflicts of interest. The existence of a conflict is not necessarily a problem; it is how individuals and institutions respond to conflicts that may be problematic.

Purpose and Intended Audience

The primary goal of this brochure is to inform and guide faculty, academic officers, and administrators about the potential consequences of engaging in relationships and partnerships with private business and the potential threats to academic and institutional values that may arise. The brochure is intended to assist these stakeholders in recognizing situations with potential to elicit financial conflicts of interest and to review options for managing, reducing, or eliminating these conflicts.

From the outset, it is important to recognize that the missions and cultures of academic institutions vary and, particularly for public institutions, the laws of the states in which they are established may be more or less explicit with regard to situations that give rise to potential financial conflict of interest. As a result, institutional policies and practices may be more or less permissive, and it will remain critical for faculty and administrators to be familiar with the expectations and standards of their own institution.

Organization

The commonly recognized situations in which individual financial conflicts of interest should be considered are:

- Consulting
- Licensing of University Technology
- Clinical Studies Involving Risks to Human Research Participants
- Procurement
- Mentoring

This brochure examines each of these topics through scenarios or case studies and identifies relevant issues and some management strategies.

Because all potential conflicts are situational, and because the cultures and management practices of institutions vary, our goal is to suggest issues and options for management, not to prescribe "best practices" or "preferred approaches." While this brochure is focused on financial conflicts, some of the examples include situations in which conflicts exist without influence from personal financial interests. Furthermore, while this document describes many of the most common conflicts that may arise in a research institution, it does not attempt to provide an exhaustive or complete list of every possible situation. The reader is encouraged, therefore, to look for similarities between their particular situations and the examples presented here when attempting to formulate management strategies.

Since the same transactions that present the potential for individual conflicts may also give rise to institutional conflicts, a secondary goal of this brochure is: to identify situations where institutional conflicts might arise; to suggest possible management strategies; and to conclude with a brief summary of a variety of potential institutional conflicts that have been identified.

I. CONSULTING

Introduction

Most universities encourage faculty to engage in consulting with outside organizations. These relationships can enrich and add perspective to campus-based research and teaching, and they provide a means by which faculty expertise can be applied to real world problems. Consulting by faculty is commonly considered to be part of the university's mission of outreach to the community, and universities typically have written policies that govern consulting relationships.

Some consulting relationships can result in conflicts of interest—both financial and professional. A faculty member's consulting agreement with an outside sponsor must ethically balance the researcher's responsibility to the university, to students, and to the sponsor. These responsibilities are typically detailed in an employment or sponsored research contract, but there are other considerations as well. Common pitfalls in consulting relationships include: limiting the right to publish the results of research; creating the impression that the university has sanctioned the outside activity; undermining the faculty member's responsibility to graduate students; and overextending ownership and intellectual property rights. All of these pitfalls can lead to disputes between the university and a company that may affect the ability of either to commercialize the inventions and discoveries.

The following scenario highlights these problems and suggests approaches to deal with these situations when they occur.

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 free-wheeling, 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 it a straightforward scientific exchange among peers similar to a presentation at a professional scientific meeting?
- Does the presentation 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

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.

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.

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's cooperation, RWP proposes a consulting fee that is lucrative and attractive. The agreement is structured for Dr. Oak to sign the agreement 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.

ISSUES

- The agreement requires Dr. Oak to maintain the confidentiality of RWP information. What is RWP information and what is Dr. Oak's information under this agreement?
- Is it appropriate for Dr. Oak's discoveries on adhesins to be restricted to RWP?
- What are the NSF's rights to the discoveries?
- Will the information developed by the graduate student be available for the report to NSF? For publications? Or incorporation into a dissertation?
- Does RWP have any responsibility to protect Dr. Oak's research?
- Does the use of university resources (the graduate student, the laboratories, etc.) pose any problems for the other work conducted in Dr. Oak's lab?
- Is Dr. Oak signing the agreement as an individual or a representative of the university?
- Is the consulting fee a factor in Dr. Oak's decision to enter into the agreement with RWP?

MANAGEMENT STRATEGIES

Some institutions may require disclosure of the consulting relationship. Faculty are advised to consult the faculty handbook for the policies and procedures at their institutions. Additionally, the university may wish to review the nondisclosure agreement and request renegotiation. Factors to be considered in that agreement include:

- Should the obligation to maintain confidential information be mutual, in order to protect confidential 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?
- Should the university request from RWP clarification of the disposition of inventions?
- 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?

If the modifications to the nondisclosure agreement are negotiated (as 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.

The relationship between Dr. Oak and RWP has crossed over into the sponsored research in her laboratory. An approach that may be appropriate in some institutions is for the department head or dean of the college to appoint a committee to review the results of the research conducted in Dr. Oak's lab to ensure that graduate students are working on appropriate projects, and that patentable inventions are assigned to the university.

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 grant 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 e-mails 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, where 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?

MANAGEMENT STRATEGIES

At this point, the university may wish to review Dr. Oak's time commitments and research obligations. 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 may want to have the fundraising documents reviewed for inappropriate use of the university's name.

CAUTIONS AND REMINDERS

Dr. Oak's situation raises a number of issues related to consulting relationships and to the entrepreneurial activities that may result from these relationships. Because one scenario cannot cover all of the possible variations that may occur, the checklist below is offered to help faculty members in similar situations.

- ***Avoid a consulting relationship with a company that distorts the responsibilities to the university as primary employer. Frequently this occurs in the form of the company requiring the faculty member to devote time and effort already committed to the university.***
- ***Be cautious when entering into relationships that limit publication.***
- ***Refrain from creating any impression that the university has sanctioned the outside activity, unless the university has approved this.***
- ***Do not use university resources to benefit a consulting relationship without permission.***
- ***Do not use students to support consulting activities.***
- ***Keep a contemporaneous journal or notebook that summarizes unique information or intellectual property discussed in all consultations.***
- ***Seek the advice of a dean or member of the sponsored research staff before entering agreements that may limit future sponsored activities.***

II. LICENSING UNIVERSITY TECHNOLOGY

Introduction

Licensing transactions present many potential conflicts of interest, especially those involving start-up companies with which the institution and inventors have a continuing relationship. In the following case study and discussion, the focus is primarily on those transactions that involve one or more of the following factors:

- Establishment of a company based on a license of university-owned technology;
- Distribution and management of equity in that company to the inventor and the university;
- Provision of sponsored research from the company back to the university;
- Management of research in areas closely related to the licensed technology; and
- Supervision of students and other employees in the context of the relationship between the university and the start-up.

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 the course of 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 has 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.

In order 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

- Because of his financial relationship with Purple, Inc., can Dr. Elm be expected to objectively weigh the merits of accepting the SRA? 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?

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.

CAUTIONS AND REMINDERS

Many complicating factors arise in licensing technology to a start-up, and the specific roles and terms of the licensing, equity, and research relationships have bearing on how conflicts are identified and managed. Whether perceived or real, problems will generally arise and need to be managed, reduced, or eliminated.

- ***Balance activities between the university and the company to avoid compromising commitment to research, teaching, and mentoring.***
- ***Consider ability to manage research and mentoring when a company in which one holds significant financial interests sponsors the research. Questions may be raised about the selection of research goals and the assignment of students and other personnel. (Note: see "V. Mentoring Relationships" below).***
- ***Ensure that university officials who manage institutional equity holdings do so without regard to their own financial interests. Public perception of trustees or other officials benefiting from "private" deals is damaging to the reputation of the institution and higher education in general.***
- ***Understand that 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 the investigator has a financial interest. Greater scrutiny of the use of public funds for such research, especially research involving human participants, is increasing as more attention is paid to potential conflicts of interest.***

III. CLINICAL STUDIES INVOLVING RISKS TO HUMAN RESEARCH PARTICIPANTS

Introduction

Financial conflicts of interest take on even more ethical constraints when the research involves human participants. It is paramount that humans who volunteer as participants in clinical studies are assured that no financial bias, positive or negative, is influencing the recruitment, the trial per se, the gathering and interpreting of data, or the impartiality of the reporting of the outcome of the clinical study.

Investigators and institutions should consider that even the perception of investigator or institutional financial gain may distort the value of the participant's role in the trial. Clearly, if real financial conflicts of interest exist, they must be addressed in the most conservative manner to ensure human research participants that the studies are adhering to the highest ethical standards. Ambiguities or appearances of questionable judgment by individuals or institutions are unlikely to be tolerated by the public when the research places at risk the life or health of a participant.

Both the Association of American Universities (AAU) and the Association of American Medical Colleges (AAMC) have recently developed policies and management practices for academic biomedical research involving human participants. However, the public safety consequences of research in some nonclinical research areas should also be recognized when outside financial interests could influence research design, conduct, or reporting. For example, engineering research leading to development, testing, and commercialization of new materials can involve human research volunteers and put them at some risk. There are also research projects in social and behavioral studies where financial conflicts may be sensitive. Investigators whose human participant research is considered less than minimal risk—i.e., the prospect of harm to the individual person in the course of participating in the research is low—may not be subjected to the same "zero tolerance" standard that high-risk clinical studies have warranted.

The case study which follows is designed to show a progression of increasingly complex financial conflicts that raise concerns from the simple to the most troubling.

Clinical Studies/Human Research Participants Scenario III.A.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 has an existing relationship with Blue Drug: she and her family regularly travel to conferences sponsored by the company; she speaks at the conferences while her family enjoys the luxury accommodations and other perks offered at no charge by the company; and last year, she received a $5,000 honorarium from the company.

ISSUES

- May Dr. Maple serve as the principal investigator (PI) of the clinical study?
- Do all of Dr. Maple's financial interests tied to Blue Drug pose a significant risk of conflict of interest?
- Are human research volunteers at risk because Dr. Maple participates in the company's speaker's program and is presented with an honorarium?
- Would a reasonable person conclude that the financial incentives provided to attend the conference are sufficient to impact the integrity of the trial?

MANAGEMENT STRATEGIES

Since Dr. Maple has a financial relationship with the company sponsoring the trial, it may be prudent to include a disclosure of the PI's participation in conferences sponsored by the company to ensure informed decision-making by volunteers for the trial. Publications and presentations about the study should acknowledge Dr. Maple's role as a speaker for the company supporting the trial.

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

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 to 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, she will be directly involved in the data analysis of all sites participating in the study. For her SAB/consulting work, Dr. Maple will be compensated 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, a 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. 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.

Clinical Studies/Human Research Participants Scenario III.B.

When Dr. Chestnut presents the Phase II trial sponsored by Blue Drug to UMC's institutional review board (IRB), one of the members of the IRB is openly negative about the promise of the new study drug. He informs the board the he recalls an abstract that described severe side effects in mice given high doses of this drug, with little tumor reduction. He expresses amazement that the study is progressing.

ISSUES

- Can the IRB question the scientific merit of the study drug?
- Is there any chance that the IRB member might have his own personal financial reasons to negatively influence the IRB's decision?

MANAGEMENT STRATEGIES

The IRB is responsible for assuring that Dr. Chestnut's protocol receives a thorough and impartial review. The IRB must examine Blue Drug's protocol for indications of reasonable risks. The IRB also looks independently at the literature cited and evaluates the background of the drug's promise. The IRB should thoroughly examine the protocol to weigh risks and benefits to the participants, and to ensure that a thorough informed consent is provided.

Federal Regulations [45CFR46.107(e)] require IRB members to recuse themselves from participation in the review of a protocol in which they have a conflicting interest. The member may provide information – in this case, information from the animal studies – to assist the IRB in its review. A member of the IRB could have stock interests in Teal Drugs, a competitor of Blue Drug, and be

exerting a negative bias on the testing of a promising competitive drug to the established standard treatment produced by Teal Drugs. Alternatively, he may be aware of recently presented information that needs to be considered by the investigator before the trial proceeds.

Clinical Studies/Human Research Participants Scenario III.C.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?
- Does Dr. Juniper's interest in White Drugs affect his role in the study? Since White Drugs is not publicly traded, there is no implicit financial value in his equity ownership. Where is the financial gain?
- Would there be a conflict of interest if Dr. Juniper didn't design this study?
- 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. While 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 and his personal, collegial relationship with the inventor of the technology preclude UMC from participating in the trial.

On the other hand, UMC might determine, with full disclosure of the nature of Dr. Juniper's ownership in the company, that the Phase I could proceed at UMC. This decision would be fortified by appointing a data safety monitoring board to be primarily responsible for assuring that the 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 manage 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 normal process of information provided 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 the trial.

From the eye of the public, holding stock options is likely to be perceived as actually holding equity. If UMC permits Dr. Juniper to act as PI on the trial, all the standard disclosures in written and oral presentations, publications, and abstracts would be necessary.

Clinical Studies/Human Research Participants Scenario III.C.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 the majority of 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 on its scientific advisory board, an unpaid position. 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 the IRB review the only one 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, it seems unlikely the UMC would be an appropriate choice to conduct clinical studies of this therapy. However, 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. But the protection of the participants volunteering for clinical studies is a principal concern. All steps that clarify responsible individual and institutional behavior in light of inevitable conflicts of interest must be considered. If Phase I studies at UMC were considered appropriate by the IRB, the informed consent disclosure should be explicit about 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 as well as the IRB must consider the financial conflicts of interest of the individuals with the sponsoring company.

At the point of Phase II studies, if warranted, it is likely that the investigators should confine their involvement to consulting roles with the company.

The IRB will play a critical role in the consideration of risk-benefit for children participating in the study and of the specific details that should be disclosed about investigator and institutional financial interests in the company sponsoring the study.

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. 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.

The institution's equity interest in the company should be managed in accordance with an institutional financial conflict of interest policy (see "VI. Institutional Conflict of Interest" below). Such a policy is particularly important in clinical research areas where perceptions of conflicts and the ethics of use of human research participants are pertinent.

Clinical Studies/Human Research Participants Scenario III.D.

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 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?
- If chair Spruce named another faculty member in the department to be PI, should clinical studies involving this drug be permitted?
- 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?
- Do the institutional conflicts of interest 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 study, what information should be disclosed to the research participants during the informed consent process?
- 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 are or could be perceived as relationships that could 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 and even 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 and institutional financially benefiting relationships indicate that UMC should not be involved 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 (this oversight would include reviewing the referral and consenting of participants and the roles more traditionally associated with a data safety monitoring board) would assist in ensuring the integrity of the clinical program.

The financial interests of the investigators and the institution must be fully disclosed to any human volunteers. Some IRBs might recommend an independent participant advisor or advocate be involved in the consent process to ensure that the participants understand the relationships between 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 in general and other research collaborators, including residents, staff, and study coordinators, should be aware of all the individual and institutional financial conflicts in this situation.

Federal regulations [45CFR46.107(e)] require Dr. Hickory, the IRB chair, to recuse himself from participation in the review of the protocol. Dr. Hickory should be fully disclosing to the IRB any financial interests of his family that could influence his deliberations on a protocol. A very cautious UMC might ask an independent oversight committee to ensure that past 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 inventive role in all relevant publications and presentations pertinent to the drug or the business interests of Pink Drugs.

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

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.

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.

CAUTIONS AND REMINDERS

Utmost attention must be paid to avoiding conflicts of interest in clinical studies involving human research participants. The following points summarize the precepts to be extracted from the above scenarios:

- ***Expect that personal financial interests that intersect with participation of human volunteers in research will be held to a higher***

standard of disclosure, review, and management practices, and that some relationships and activities may be deemed unmanageable.

- ***Disclose all financial relationships. Full disclosure begins the process of protecting the participants, the investigator, and the institution.***
- ***Understand that the greater the risk to the human research volunteers in the clinical study, the more likely an institution will be to limit or bar completely faculty with significant financial interests in the study from involving the institution as a clinical study site.***
- ***Recognize that the more complex and closer the activities of the faculty are to the business interests of the company, the more likely the institution will be to restrict the faculty's multiple roles.***
- ***Avoid conducting clinical trials when both the institution and the investigator have financial interests in the outcome of clinical studies.***

IV. PROCUREMENT (Purchasing)

Introduction

The acquisition of goods and services for university research represents a large portion of the expenditures of an institution and is generally subject to the oversight of the controller, the office of business and finance, and internal audit. Procedures, which are usually well-documented, vary from highly centralized systems to greater or lesser degrees of control at the department level. Institutions that have federal grants and contracts must have a federally-approved procurement system that complies with the regulations set forth in Office of Management and Budget Circular A-110. For state institutions, state laws and regulations may also apply to university purchasing. Universities may have policies and/or may be subject to state laws that preclude entering into contracts with employees or with companies in which their employees have a significant financial interest. However, materials, supplies, and services needed in research may be very specific and suppliers may be limited.

In almost all cases, investigators initiate purchases. To the extent that individuals making procurement decisions have an interest in a vendor of goods or services to the institution, conflicts of interest may arise and must be reduced, eliminated, or managed. Management strategies in procurement transactions are often built into university procurement policies and procedures for competitive bids and quotes, sole source justifications, and centralized purchasing. The policies and procedures should be clearly articulated, widely available, and updated with changes in technologies used for purchases.

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., in a nearby research park to market these services to private and not-for-profit researchers. The company 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

While there is no obvious conflict of interest at this point, many universities have restrictions. Public institutions may be subject to state law 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; but for contracts of intermediate value, departments are often permitted to submit quotes from competing vendors. Dr. Larch should disclose her majority interest in the company to the university to ensure that all state and university procedures are met when purchasing services from Aqua, Inc.

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 only where 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 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 create a compromise in 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 win 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

The conflict of interest may or may not be considered manageable. When federal funds will be used, the university's written, enforced conflict of interest policy will apply. Such a policy will reduce, eliminate, or manage conflicts of interest for research personnel with a role in the design, conduct, or reporting of research. Dr. Larch has a conflict of interest in the selection of the vendor for services to the university. Since 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, there is a clear conflict of interest. The conflict of interest would be subject to both the rules of the university and to the rules that apply to conflict of interest in federally-funded research.

If state law and university policy permit such transactions, 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. The university needs to 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 sponsor. In addressing these issues, the university (or its conflict of interest committee) will also consider appropriate disclosure to the sponsor if the conflict of interest is deemed to be manageable.

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 her spouse returns as an employee, she will be in the position of supervising a relative. Most universities have policies that prevent the existence of a subordinate-superior relationship between an individual and a relative through any line of authority.

Universities and American workplaces increasingly recognize the existence of dual-career couples. In academia, there are a number of spouses who work as a team in 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.

Where it is permissible, 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. 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. 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.

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 decides that she wishes to remain on the faculty, continue her career in research and education, and spend less time with the company and welcomes the buy-out offer. 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 lab?

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 removed from selection decisions in many universities through centralized planning for construction projects and centralized procurement for large contracts.

Procurement Scenario IV.B.

Dr. Pecan has earned tenure and, with her post-doctoral 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

Since 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 and competitive procurement process that is fair to other vendors.

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.

CAUTIONS AND REMINDERS

Conflicts of interest are often overlooked in the area of procurement, but they are equally significant. Faculty should remember that the purchasing of goods and services are governed by university policies; for a state-assisted university, by state laws; and, for all federal grantees and contractors, by federal regulations. Many purchasing situations can be managed if disclosed by the faculty member at the beginning of the transaction.

- ***Disclose personal ownership or significant financial interests in companies doing business with the university to appropriate officials for review.***
- ***Disclose ownership positions or significant financial interests of family members if related to purchases made by a faculty member for the university.***

V. MENTORING RELATIONSHIPS

Introduction

Mentoring[1] graduate students, post-doctoral fellows, and junior faculty colleagues is one of the most important roles and responsibilities assumed by faculty members and academic administrators. The tie of a mentor to the individual mentored is a close and special relationship of trust often combined with an unequal distribution of power and influence between the individuals in the relationship. Because of this relationship of trust and the imbalance in power, the person being mentored may not feel they have the freedom to refuse the mentor's request. Moreover, whenever the possibility exists that a mentor's advice or counsel might be influenced by personal financial interests, then there also exists the potential for significant damage to be inflicted on the training or career development of the person being mentored.

As a result of this potential for conflict, institutions may wish to review carefully and monitor closely situations where mentors may also become employers of the persons they mentor, or otherwise benefit financially from requests made of this vulnerable population to provide inappropriate support for the mentor's personal financial interests. Some institutions may choose to prohibit certain commercial activities that have clear potential to compromise a trainee's or junior colleague's professional or career development.

Mentoring Scenario V.A.

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 has 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 patents to a start-up company, Indigo, Inc., in which he has a substantial financial interest 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 post-doctoral 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 interest 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 trainees and post-docs be able to use aspects of the work for their theses and dissertations or continue aspects of the work after the post-doctoral tenure?
- Will the trainees continue to make progress toward their degrees?

[1] *The term "mentor" derives from Homer's Mentor, the "wise and trusted counselor" whom Odysseus left in charge of his household during his travels.*

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 post-doctoral associates. Inherent in Dr. Redwood's proposal is the potential that the efforts of trainees may be directed to pursuing high-risk research priorities that benefit Indigo, Inc.'s commercial interests rather than being directed to 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. This may severely limit the trainees' options for future employment.

Options to provide this protection for trainees and post-doctoral fellows range from prohibiting the appointment of potentially vulnerable trainees mentored by Dr. Redwood to projects sponsored by Indigo, Inc. to requiring that another senior faculty member or members, who have no financial interest in Indigo, Inc., be appointed as major advisors or co-major advisors for trainees who would work on projects funded by Indigo, Inc.

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.

Mentoring Scenario V.B.

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 implies, without any commitment, that this opportunity has the potential to allow Dr. Yew to gain rapid scholarly recognition and also 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 the application?
- 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.

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.

CAUTIONS AND REMINDERS

Potential financial conflicts of interest may occur in any relationship when there is a real or perceived imbalance in power or influence between a mentor, advisor, or supervisor and a student, trainee, or junior colleague, and the potential for significant financial benefit to the more powerful individual. To preserve the integrity of their programs of education and training and to foster optimal professional development of faculty, institutions may wish to closely monitor these relationships through assignment of responsibility to other senior individuals isolated from or immune to the specific financial conflict or, in some cases, by intervening to eliminate the potential for financial conflict of interest.

VI. INSTITUTIONAL CONFLICT OF INTEREST

Introduction

As illustrated in the case studies presented above, the insitution often becomes involved with added complexity resulting from the roles often played by trustees, executives, influential faculty, or senior academic administrators. Additionally, business decisions by the institution or public authorities that foster and facilitate the transfer of technology to benefit society may further complicate matters.

In the past decade, academic institutions have placed an increasing emphasis on bringing their innovations directly to the market place. This evolution in the role of the institution and its technology transfer office has placed increasing stress on the institution's ability to make impartial judgments regarding its faculty's financial interests, patient care, and student well being. Likewise, institutions increasingly face a greater inability to impartially judge and manage situations where the institution itself has a financial stake in the success of the technology.

Sponsored Research, Equity, and Licensing of Technology

In each of the previous illustrative cases, issues of institutional conflict of interest can be introduced simply by the institution having a license agreement with, or an equity position in, a company sponsoring a faculty member's research. When an institution has a license agreement with a company sponsoring research in the inventor's lab, or even with another faculty member, there may be a bias to accept terms and conditions more favorable to the company in order to facilitate the company's success.

Other opportunities to obtain equity abound. Equity positions are often accepted in lieu of licensing fees, reduced royalties, or sometimes in lieu of indirect costs. From a financial viewpoint, the upside potential is great with potential returns far exceeding lost income or opportunity costs. Such arrangements, however, may bring into question a university's role in subsidizing the company through lower-cost research programs or through provision of "free" laboratory space.

Endowment management and institutional initiative to create venture funds to invest in faculty start-ups are also candidates for institutional conflict of interest management. These issues will be more thoroughly addressed in a separate COGR publication.

Interested or Interlocking Directors/Trustees

Trustees and former trustees often have close connections to the local business community. As a result, they can become aware of promising technologies and can be useful conduits or even sources for capitalization of faculty start-up companies. The pressures that such trustees can bring on the institution to make special arrangements can be powerful and difficult to resist.

Additional sources of conflict can arise when university trustees or officials sit on boards of companies doing business with the institution. The nature of the relationship may be a vendor-buyer relationship or a research relationship. Judgments of such individuals can be clouded. Public institutions often are governed by laws that define the precise nature of permissible relationships. Though both public and private institutions have statutes, policies, and regulations governing permissible trustee relationships, they are often less clear on the extent of permitted activity by individuals at lower levels.

Management of Institutional Equity Holdings

When institutions hold equity in faculty start-ups, conflicts can arise with respect to opportune times to sell or even buy additional shares. Once Securities and Exchange Commission or contractual restrictions on selling stock expire, conflicts can arise based on who within the institution has the authority to recommend equity purchase or sale. When technology transfer officials' remuneration is

tied to stock values, personal biases can play a role in judgments about stock sales or even the pressure brought to bear to accept sponsored research agreements.

Separation of Technology Transfer Activities from Business Development/Start-up Initiatives

Increasingly, technology transfer offices are engaged in promoting economic development or assisting faculty inventors in writing business plans, obtaining financing, establishing management schemes, or placing start-up ventures in institutional or state-run incubator facilities. Most often these forms of assistance are directed toward companies where the institution has taken an equity position in lieu of some other consideration that it would normally receive from a third party. Inevitably, several potential conflicts might arise in such situations. The university should ask itself:

- Has it chosen the best vehicle to fulfill its Bayh-Dole mandate of bringing the invention to societal benefit as quickly as possible?
- Can it objectively monitor the diligence of the licensee company in developing the technology?
- Is it biased toward a faculty member's company as a potential licensee versus a third party licensee?
- Is the university receiving fair market terms?

Such questions can arise in public. Some institutions have addressed these issues by formally separating licensing and commercialization of intellectual property activities from business and economic development by establishing independent organizations for these purposes.

MANAGEMENT STRATEGIES

Management of institutional conflicts of interest is by its very nature more complex than that of individual conflicts of interest. External relationships to sponsors and supporters of the institution, the local community's acceptance of economic development activities, the institution's obligations as a charitable organization receiving preferential tax treatment, and the institution's perception of its teaching, research, and academic missions all impact on how potential conflicts of interest are managed. Current federal regulations for managing individual conflicts of interest can be instructive, but they suffer from the difficulty of objectively assessing the adequacy of institutional management schemes.

At this time, several management options that some institutions have already implemented include:

- Reduce or eliminate involvement by institution employees in institution-associated company activities.
- Actively manage and review conflicts using external reviewers or independent managers.
- Build organizational firewalls so that potentially conflicted parties do not interact on these matters. For example, institutional technology transfer offices should not be in the decision chain of identifying or managing conflict.

CAUTIONS AND REMINDERS

The examples and issues presented above do not necessarily constitute inappropriate conflicts of interest. Each situation must be judged on the facts and merits of the relationship with an eye to what reasonable individuals outside the affected community might consider to be appropriate. Some activities that could protect institutions as they consider their involvement in technology transfer and economic development activities would include:

- ***Develop written policies.***
- ***Strive for impartiality.***
- ***Seek alternative arrangements external to the institution.***
- ***Anticipate situations that could be perceived as compromising research and fiduciary integrity.***
- ***Publicize and open the decision-making process.***

CONCLUDING REMARKS

While virtually all research universities and organizations have written policies governing individual financial conflicts of interest in research-related areas, most institutions are still developing formal and informal education programs to assure that the policies are well understood and that compliance by affected faculty and researchers is fully in place. In addition, management practices, especially if the financial interests intersect with research involving human research participants, are becoming increasingly stringent. Recent studies by both the AAU and AAMC have concluded that faculty, academic medical centers, and research universities should expect to be held to high ethical standards if they expect to continue to benefit from federal research funds. Keeping abreast of evolving standards and assuring that the integrity of the research enterprise is responsibly protected is the duty of all faculty and institutions. Disclosure of individual financial interests and responsible management of such relationships by the institutions strengthens research, protects faculty members, and assures the public trust in the academy.

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Additional bibliographic resources, including copies of federal regulations, can be found on the web site of the US Department of Health and Human Services' Office of Research Integrity (http://ori.dhhs.gov/#); and the National Institutes of Health's Office of Extramural Research's Conflict of Interest web site (http://grants.nih.gov/grants/policy/coi/index.htm). Contact your university's compliance office or research officer for more information.

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