RESEARCH MANAGEMENT REVIEW

The Journal of the
National Council of University Research Administrators

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NCURA's annual membership dues pays for the subscription to Research Management Rewiew.

One-year subscription rate is $20. Orders for single copies must be accompanied with prepayment of $10.

Subscription requests and changes of address should be sent to Research Management Rewiew, One DuPont Circle, N.W., Suite 420, Washington, D.C. 20036. Printed in the U.S.A.

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Volume 3 Number 2 Fall 1989

Editor's Preface

"Conflict of interest" is not a new topic in the academic community. The potential for faculty or staff to find themselves in situations which compete for their institutional allegiances and/or resources is a concomitant of the quasi-entrepreneurial or relatively autonomous status accorded to faculty members compared to their scientific or technical counterparts in the private sector. The broadly accepted day-a-week faculty consulting privilege is valued for its synergistic return to both research and student training. Technology transfer in agriculture, engineering, chemistry and other physical sciences based on strong linkages between academic researchers and their industrial colleagues has a long and productive history. Involvement of teaching and research hospitals with pharmaceutical firms in the conduct of clinical trials is an established and respected enterprise. So how did conflict of interest become essentially the year's contentious issue, accepting that it lags somewhat behind the related though not synonymous issue of misconduct in scientific research? Confronted with several highly publicized instances of entanglement of clinical research programs with direct financial benefit, has the public valid reason to conclude that inappropriate behavior or questionable standards are being tolerated within the research community? Has conflict of interest and more specifically financial conflict of interest become blurred with scientific misconduct in the public eye?

In its annual meeting in November, 1988, the Editorial Advisory Board for "RMR" endorsed a "Special Topic" issue for Fall, 1989, and then deliberated the questions of critical significance for research and research administration in the '90s. The emphatic consensus was conflict of interest. The elements of complexity, sensitivity, and institutional as well as individual ethics are bound into this subject; the concerns can neither be dismissed as frivolous nor eliminated by ignoring them.

Between the "Call for Manuscripts" in the spring of 1989 and the publication of this issue, the NIH / ADAMHA proposed Guidelines for Policies on "Conflict of Interest" (September, 1989), and Secretary of Health and Human Services Louis Sullivan halted their further consideration. Congressional attention peaked during the year with Congressman Weiss's hearings and public comments. Clearly, the topic is one that will be with us for some time. The papers selected for publication look at conflict of interest in a multiplicity of ways; these articles reflect depth, breadth, and insight into the underlying principles, political considerations, and the dynamics of implementing institutional conflict policies.

The lead article by Robert Killoren sets the tone for the more specific and focused papers which follow. He provides a historical perspective and summarizes many of the reasons conflict-of-interest situations are now with the academy. His identification of the potential choices that institutions will have to confront, and some possible consequences, offers provocative and thoughtful reading.

The research community is the unprepared recipient of mixed signals: first the scrutiny of various congressional "integrity watchdogs"; then the charge to action from other elected officials who hold researchers accountable for seeding the economic development and technical health and well being of American industries. The standard measure of the university is one that can examine its research practices and find them spotlessly pure with respect to "entanglements" with the private sector while simultaneously forging innovative and productive partnerships to transfer its university-developed technologies from the academic to the public sector.

Gunsalus and Rowan have approached this tension of expectations in a clear and considered manner, using their experience in dealing with conflict-of-interest issues to produce a "checklist" article that many research administrators will find helpful. They offer a good balance between presenting problems and offering solutions.

Since the early 1980s, California public universities have been required to review disclosures of potential conflicts of interest, broadly defined, in conjunction with applications for non-federal funding. Richard Seligman has described the implementation and experience at UCLA with the state law, including data on disclosures and a few case studies. Although some institutions already may accommodate California's guidelines at the department or collegiate proposal review level, many will find the process he describes a useful model for an institutional program to monitor and detect conflicts of interest.

Belle Cole again uses the California state-mandated experience to evaluate and comment upon the late NIH/ADAMHA guidelines on financial conflict of interest. Although these guidelines have been withdrawn, Cole's analysis of the issues is well articulated and her informed grasp of the subject matter will provide good counsel in consideration of future HHS regulations. The principles identified here can provide guidance in formulating a reasoned and responsible institutional position.

While some may argue with his thesis, John Mishler's manuscript proposes an activist role for the research administrator in overseeing the mechanics of conflict-of-interest policies and procedures. Many researchers say this is an academic function and should be handled through faculty governance procedures.

Finally, I have reprinted the NIH / ADAMHA Proposed Guidelines on Financial Conflict of Interest, excluding the agency commentary, and several of the responses from higher education organizations, institutions, and individuals, either in their entirety or abstracted portions. Although we will not see these particular guidelines again, HHS has indicated that regulations will be issued. The ability to evaluate future regulations should be improved if we are able to consider the principles and concerns identified in the course of review of the first agency attempts to regulate the research community's policies and procedures. In the course of reviewing one of the manuscripts for the issue, one reviewer wisely noted that regularion should be unnecessary if the emphasis is directed toward creating an institutional culture that through consensus eliminates the tarnish that conflict-of-interest problems would apply to the institution and faculty as a whole. The faculty must guide institutions in the establishment of a desirable code of conduct and support voluntary compliance within the research community. No regulations will create personal integrity where there is none.

I also wish to acknowledge the invaluable editorial assistance of Melanie Oyster and administrative assistance of Nancy Ingold in preparation of this issue.

Mary Ellen Sheridan
January, 1990

Letters

I read with interest the recent article in *Research* Management *Review* by Parker and Clark entitled "Research at Liberal Arts Colleges: Is More Really Better?" The article correctly points out the exemplary record of the liberal arts colleges in producing graduates who go on to Ph.D. degrees. Before proceeding with this note I should mention that I am one such individual, and am proud of it.

Nevertheless, I feel compelled to clarify one misleading statement in the article. In a paragraph entitled "Science Baccalaureate Programs in Liberal Arts Colleges," the authors assert that "During the same period (1910-1969) 137 undergraduate institutions graduated approximately 60% of the baccalaureates who became Ph.D.'s in science. . . ." The sentence is correct only if one deletes the word "undergraduate" or, alternatively, defines major universities such as Illinois, Minnesota, and California-Berkeley, and medium-size universities such as Miami, as "undergraduate institutions." The statistic cited is based on a 1976 study by Elizabeth Tidball and Vera Kistiakowsky of 137 selected institutions, published in *Science* (Volume 193, pgs. 646-652). The 137 institutions which were studied did indeed produce 60% of the baccalaureates who went on to Ph.D.'s, but included major and midsize universities with large undergraduate programs, as well as 4-year colleges.

Parker and Clark's main theme remains valid, however, and their article represents a nice contribution to the NCURA journal.

William H. Rauckhorst
Associate Dean for Research and Sponsored Programs
Miami University
Oxford, Ohio

Response:

In response to Dr. Rauckhorst's letter, in the original *Science* article the text on page 648 specifically describes the 137 institutions as "undergraduate institutions." Thus, the wording in our article is not ours, but that of Tidball and Kistiakowsky.

Linda E. Parker

"Erratum

Research Management *Review,* Spring 1989.

The column headings, Table I, page 48, list 4-Year Public twice. The right-hand column heading should be 4-Year *Private.*

Institutional Conflict of Interest

Robert Killoren

The university community possesses a most cherished prize - the trust of the people. If it loses this trust, it risks losing all. And universities risk it most seriously by putting the interest of the people it serves second. This is the most serious conflict of interest an institution can commit.

What does conflict of interest really mean for an institution? A dictionary of legal terms defines conflict of interest as inconsistency between the public interest and the personal *interest of a public official,* which *arises in connection* with the *performance of official* duties? A fabled lawyer once called it a division of loyalties and cited scripture, "a man cannot serve two masters:'

Can a university itself be guilty of a conflict of interest? Institutions, like individuals, can abuse their public trust for self-enrichment. No matter how worthy one might judge the enrichment of one's own institution or how many gains one might project for society as a result of that enrichment, a university cannot betray its basic principles to gain financial security. The end does not justify the means, even for universities.

To deal with the problem of conflict of interest, it is not enough to simply deal with the conflicts presented to individual faculty. It is also important to examine the conflicts in which institutions themselves may be involved. A university's major difficulty in doing this is sorting out what the true demands of society are. Conflicting messages can lead to conflicting interests.

The most basic question is: what role does society wish universities to play? If society wants to keep academic research beyond all outside influences, then it must keep universities in the "ivory tower." If it wants academe to play an important role in the real world, then society must be willing to take some chances and, to a certain extent, suffer some abuses.

This article will briefly set up the background for contemporary institutional conflicts of interest and then present a discussion of concerns.

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A Brief History of "Academic Capitalism"

In a previous era, *academic capitalism,*[2] as one university president has named the whole university-industry connection, seemed like an answer to so many problems. Universities saw the potential for commercializing some of the research being conducted in faculty labs; the federal government saw a way of dealing with increasing international competitiveness in science and technology; industry saw a less expensive way to get new product ideas in an era in which in-house R&D was getting too expensive; state and local governments saw a way of bolstering sagging local economies with the flourishing of new, high-tech small businesses; venture capitalists saw the potential for big profits with quick turn-arounds in high-tech startup companies; and faculty saw a way of promoting long term, major support for their labs.

The decade of the eighties started off with a new message for universities. . . . Federal funding for non-defense-related basic research was being reined in, and if universities wanted to keep their research programs growing they would have to turn to industry for additional support.[3] Of course, there had been those universities that had longer histories of strong relationships with industry, like MIT and Penn State, and others, like Georgia Tech and the University of Arizona, that were climbing in national ranking in large part because of their industrial liaisons.4 But many universities initially were reluctant to engage in industry-university ventures, fearing a violation of the sanctity of basic research. Some faculty felt that any interaction with industry presented a fundamental conflict of interest with the basic principles of university research.[5] However, as institutions began entering into productive relationships with industry, attitudes began to change. Perhaps it was possible to wed the profit orientation of industry to the quest for knowledge at a university. The faculty could pursue the basic research, with perhaps a *slightly* applied thrust, and then turn the results over to industry for development. The result of this reorientation was demonstrated by a tripling of industrial support of university research from 1980-86.[6]

The growing industry-university relationship brought about another twist - concern about patents and licensing.7 Very few universities conducted licensing programs prior to the eighties. Most universities did little or nothing with faculty inventions.[8] Those that did offered only a minimum service to faculty, usually in the form of assisting in the filing of patent applications. This function was usually relegated to the research office on a very part-time basis. Some universities contracted for the services of Research Corporation or University

Patents, Inc., to do the marketing of university patents, but for the most part, universities that received patents simply ended up with a file drawer full of ribboned documents.

The marriage of industry and universities in research soon led some universities to see a great potential for financial rewards from the technology coming from their labs. Some research activities did yield applications that industry could use, and some universities hit bonanzas. Soon all universities began paying more attention to intellectual property clauses in contracts, and started cutting deals with industry. Spurred by the success stories of a few universities - like the University of California, Stanford, Wisconsin, and MIT, which reported over $28 million in royalties in 1988 - universities began to become aggressive in their licensing efforts.[9]

At about this same time the government became extremely concerned about America's competitive position in technology, especially since Japan was asserting its leadership in developing and marketing new technologies. The government was particularly alarmed by the amount of U.S. technology being commercialized by the Japanese. The technology sieve had to be plugged. Thus, when universities, flush with their dreams of lucrative incomes from licensing ventures, approached Congress to have the laws affecting ownership of federally sponsored inventions changed to allow universities rights of ownership, they found a highly motivated audience. Congress hoped that by allowing universities ownership rights they could assure that these U.S. technologies would be transferred to U.S. companies and be manufactured in the U.S.[10] Public Law 96-517 resulted, which allows a university to retain rights to technologies it discovers and to license them to industry.

The Silicon Valley and Research Triangle successes in spinning off research technologies into businesses and fostering university-industry interactions in a research park setting showed universities additional ways of exploiting their resources. During the eighties, there was a mushrooming of entrepreneurial activities at universities. The University of Utah created a research park that spun off more than two dozen enterprises, Baylor College of Medicine began a for-profit development firm to start new companies, and Washington University became a partner in A/W Company to help faculty get their new products to market! [11]

A more recent development is the generation of university venture funds. Cornell, as a result of a $2.28-million deal with DuPont and a successful faculty start-up company, is starting a seed-fund to identify and market university technologies. Harvard, Johns Hopkins, and the University of Chicago all have venture funds, and many other universities are starting them as well.[12]

Faculty and research administrators started talking a new language, using words like "equity shares," "seed capital," "second tier funding," all the language of the entrepreneur. Technology hunters, looking for hot new technologies to invest in, started calling university research offices about inventions and scientific discoveries they read about in newspapers and magazines. Venture capitalists started courting university officers in search of limited partnerships and joint ventures,

Also appearing at about this time were reports that heralded small businesses, especially those based on high tech, as the solution to regional economic woes. It was said that small businesses generated more new jobs than big business[13] Cities and states stopped chasing smoke stacks and started chasing lab hoods. A whole new twist was emerging on the age-old town and gown relationship, as state and local governments started looking to universities for help in creating local economic development strategies.

In addition, university administrators discovered the power of leverage. With the National Science Foundation's push of a university-industry-government model to "big science" and their requirement for industry participation in big centers, with industry's interests in the products of university research, and with state and local governments' interest in fostering economic development through high tech, universities found they could put together all these interests to form major research programs using one source of funding to leverage another. Large multidisciplinary research centers were created, each with its own industrial affiliates program and federal and state sponsorship.

The Pressures and the Conflicts

All the above factors created pressures that diverted the university community's attention away from its historic missions of teaching, research, and public service. During the entire decade, these societal pressures grew, challenging universities to get more fully involved with the commercial sector. These pressures came from governors and state legislatures wanting universities to play the economic development ball game.14 They came from the federal government pushing industry-university interactions and technology transfer to aid our international competitiveness. They even came from entrepreneurial faculty wanting to pursue their inventions beyond the laboratory into the marketplace.

As the pressures mounted, so did the problems. As universities began to make more deals with industry and as the contracts became more complex, serious concerns emerged. It got harder to create situations that did not present the potential for conflicts of interest. Universities

were entrapped in a "Catch-22." If they did not respond to the pressures, they could lose significant funding that in part maintains their traditional programs. If they did respond they opened themselves for future criticism.

Each of the models in "academic capitalism" discussed in the above section presents its own unique portfolio of potential conflict-of-interest situations. It would be helpful to examine each briefly.

One form of the industry-university model in which a single corporation is linked with a single university research program presents universities with great opportunities and equally dangerous pitfalls. It offers a research program and a university financial security, usually in the form of major, long-term support. It is also appealing scientifically because it pairs up university and industry researchers to work on long term projects. However, this model may present a potential for an institutional conflict of interest by creating a fundamental challenge to its researchers' autonomy and bringing into question the institution's dedication to the good of the whole of society. Before embarking on such a program, an institution would have to ask some key questions.

Can an institution exclusively dedicate an entire research program to the interests of a single donor? An agreement with a company under the corporate program model would almost certainly have provisions that grant exclusive options to the sponsor on technologies developed under the program. However, even under a corporate program model, funding for the participating researchers is probably not coming exclusively from the corporate source. A good number of the investigators in such a program most likely will also have some federal support for their labs. Even with finely described scopes of work, one would have tremendous difficulties in separating what research was performed under which sponsorship.

The more fundamental the discovery, the more difficult would be the process of sorting out sponsorship. How would one truly separate what was invented under the corporate umbrella from what was invented under federal sponsorship? And if that separation were impossible, would it then be justifiable to grant options to a single company for all the technologies arising out of such a program?

Another question an institution would have to ask is, how much of an investigative team's efforts would be diverted away from research that has little commercial value to the pursuit of research which has commercial potential? Certainly there would be pressures on the investigator to keep producing research that is of commercial interest to the sponsor so that the investigator's research can continue to be funded under the industry program. The corporate sponsor, while

willing to support basic research, is going to expect to see results that will benefit the company somewhere down the line. This influence, in varying degrees, is going to pervade the program from top to bottom. This too could present an institutional conflict of interest because it might pressure individual researchers away from a program that ultimately might lead to more significant results.

The standard university-industry model can also present potential conflicts. By putting too much emphasis on bringing in industrial funding, universities could divert the attention of their researchers from suitable basic and applied projects to the provision of routine lab processing work. This kind of work can be very rewarding financially, but is usually non-productive scientifically. In addition, institutions that engage excessively in this kind of research could be charged with abusing their tax exempt position, using it in unfair business competition against private labs. This would certainly cause a major conflict of interest for an institution.

The technology transfer model also presents problems. An undue emphasis on the potential for financial rewards from licensing could seriously jeopardize a researcher's objectivity. Any institution which sets as its primary goal for technology transfer the generation of a big royalty stream is going to skew the whole process away from research toward product development. If an institution's goals are financial in nature, this will be clearly sensed by the investigator who in turn may feel pressured to produce viable products at the expense of basic research or to exaggerate research results or product potentials to heighten the interest of a potential licensee.

An institutional conflict of interest can also arise when institutions, hard pressed for resources, place all their hopes and expectations on rising technologies. An overemphasis on getting the commercial edge over the competition can sometimes outweigh the importance of allowing science to take its natural course through publication and replication.15 Exploiting the media to stir up commercial interest in discoveries is counterproductive. In addition, raising the expectations of the public and exaggerating the potential for discoveries and technologies can erode public trust in universities when promises remain unfulfilled.

This emphasis on licensing technology also spills over into federally sponsored research. While few would question the benefits that have resulted from Public Law 96-517, increasing doubts are surfacing over the manner in which some universities are exploiting their federally sponsored technologies. Again, questions of institutional conflicts of interest arise. Are some universities "pipelining" federally sponsored research to favored companies? Are technologies developed with American

taxes being syphoned off by foreign companies participating in university industrial affiliates/consortium arrangements?

As stated before, some universities may be putting undue emphasis on the financial rewards of technology transfer, even for research conducted under federal sponsorship. The technology manager who takes a national statistic (such as, one invention disclosure for every millions dollars of research funding) and turns that into a gold standard may be subtly influencing the research work of investigators. The university may begin to pressure faculty for a quota of inventions. There is also growing pressure from federal agencies upon universities for licensing. At least one federal agency has begun investigating final invention statements that report that no inventions were made. Newly appointed federal technology managers are beginning to demand increased surveillance by universities over their faculty's research in order to identify potential inventions. Through all this, PIs sense where their rewards are going to come from, and if they think that making invention disclosures will bring more rewards then they will divert time to that effort, possibly even at the expense of their research.

Economic development activities, such *as* research parks and university start-ups can present significant institutional conflicts of interest if not properly guided and motivated. When research parks, faculty spin-offs, and incubators are motivated by a need to "keep up with the Joneses," rather than emerging almost spontaneously from an extremely active research and economic development environment, then universities risk diverting valuable institutional resources away from primary missions toward quasi-commercial activities fraught with potential financial pitfalls and liabilities.

Reports of one university's subsidy of a private company show the magnitude of the risks that can be associated with major business ventures. This university's investments in a company reportedly exceeded $47 million.16 The situation this university found itself in is one that many universities are also facing now on a smaller scale or will be facing in the near future. Universities typically are not expert at making the kinds of decisions called for in these ventures. The basic question, "At what point does the pursuit of commercial ventures conflict with and endanger the basic mission of a university?" must be asked by every university considering a joint venture with a private company.

The degree to which a university allows for unregulated exploitation of faculty business operations determines an institution's culpability for ensuing conflicts. An individual faculty member cannot be held fully responsible for a personal conflict if an institution's policies and

guidelines permit questionable practices, Institutional policies should address potential conflict situations similar to those in the following list, partially based upon a list developed by Lita L. Nelsen of MIT[17]:

- Directing research toward commercial goals at the expense of scientific goals.
- Giving undue emphasis to technology development and transfer at the expense of scientific discovery and publication.
- . Giving overemphasis on getting the commercial edge over the competition at the expense of free scientific exchange.
- Pipelining federally sponsored research to favored (or university-associated, or faculty-owned) companies.
- Unduly diverting research time to the preparation of invention disclosures.
- Putting the interests of university-affiliated start-up companies ahead of the interests of the university's research program.
- Unregulated SBIR activity by faculty-owned small businesses.
- Unmonitored faculty consulting with companies in areas overlapping with university research responsibilities.
- Using of university labs to manufacture products.
- Unregulated and unmonitored transfer of university-developed technologies to faculty-owned companies.
- Concealing or suppression of research results in order to protect the interests of a university-associated or faculty-owned company.
- Changing the direction of research project toward product development for a faculty-owned company.
- Unmonitored involvement of faculty in the operations of his or her company, allowing for he or she to spend less time on teaching and other faculty responsibilities and less time to students.
- Using graduate students as "low paid development engineers" for faculty-owned companies.

Back to the Future

To begin to correct the situation, universities must examine the sources of conflicts for individual faculty and the institution itself and establish guidelines for faculty activities to assist and protect them from potential conflicts. In the absence of such guidelines, institutions are perhaps responsible for the abuses that occur. These guidelines, however, must be developed with faculty participation. This will not be an easy task,

for the issues involved are far from black and white, and the faculty at institutions are far from speaking with one voice.

It is quite likely that establishing universal principles will not be possible. What will serve as a guideline for one institution may not work for another. For example, a land grant university will have a different mission from a private institution, and thus may require a more active participation in economic development. Likewise, principles that serve one college within a university may not work for the faculty of another. How an institution adapts its tenure and promotion system to these "new" activities may be the most important and most telling guideline of all.

The "ivory tower" is a thing of the past. Universities can no longer distance themselves from the needs of society. The fact is that universities must play a crucial role in pushing the technologies developed in their labs into the commercial sector where they can be of tangible benefit to society. Universities must get involved in regional economic development not only as a service to their communities but for self-protection as well. State institutions particularly, but privates as well, benefit or suffer from the economic condition of their environs.

Meeting these obligations and balancing them against our most vital missions of instruction and research is our most difficult challenge. To do this, however, universities must first admit that there are some problems, then clearly identify them and prepare to avoid the pitfalls they present.

Notes

1 Steven H. Gifis, *Dictionary* of Legal Terms, Barron's Education Series, Inc., 1983.

[2] A term coined by Chase Peterson, President, University of Utah. It is used in this article to describe the overall university-industry framework, including collaborative research, consortium relationships, technology transfer, and economic development initiatives.

[3] This trend continues even to today. The NSF reports that Federal R&D spending, when adjusted for inflation, represents the lowest rate of growth since 1977. The study also shows that development support is increasing at the expense of research, taking more of the R&D pie (up to 68% in 1988). See Anne Wright, "Technology Transfer from University to Industry: Responsive and Responsible University Policy," Research Management Review, Spring 1989.

4 For a clearer picture of Universities' interactions with industry, see "The Academic Elite," Business Week **- Innovation** 1989. MIT and

Penn State ranked first and third, respectively. Second place belonged to Georgia Tech, which increased its research base by a factor of 13 in 15 years; 20% of their research budget is from industry.

5 It is curious to observe the National Institutes of Health struggle with the same ethical dilemmas that universities faced earlier in the decade concerning relationships with industry and which universities continue to face today particularly in the area of conflict of interest. Federal employees and labs now have similar authorities and responsibilities in technology transfer as do universities; these were gained through new legislation. NIH conducted a retreat on "Conflict of Interest in Collaborations Between NIH/ADAMHA and Industry" in December 1988 to discuss the issues. Science reported that there is confusion and anxiety: "We don't want to see NIH selling its soul to any company," says Philip Chen, associate director of intramural affairs at NIH. "NIH Scientists Agonize Over Technology Transfer," *Science*, Vol. 243, 6 January 1989.

[6] "Patent Profit," Laura Jereski, Forbes, May 2, 1988.

7 "Trends In Technology Transfer at Universities," Report of the Clearinghouse on University-Industry Relations, Association of American Universities, 1986.

[8] "The Evolving Market for Academic Research," Irwin Feller, presented to the Western Economic Association Annual Meeting, June, 1989.

[9] "Intellectual Property and the University," Lita L. Nelsen, Saratoga Conference on Intellectual Property, October, 1988.

10 "Academia's New Role in Technology Transfer and Economic Development," Donald R. Baldwin, Research Management Review, Fall 1988.

11 "Academia Goes Commercial," Peter Dworkin with Andrea Gabor, U.S. News & World Report, May 2, 1988.

12 'Cornell U. to Step Up Efforts to Market Its Research. . . ," Gilbert Fuchsberg, The Chronicle of Higher Education, June 7, 1989.

13 David Birch was the leading figure promoting this theory, and his work is summarized in his book, lob Creation *in* America, Free Press, 1987.

14 This emphasis continues in the governors' latest report on research and technology. The report calls on universities to join with industry and government to conduct research that is "more attuned to market needs" and "driven by rapid technological innovation and consumer preferences," according to Christopher Myers. The report also urges states to "provide incentives for collaborative research projects between industry and higher education." "Governors Ask Universities to Focus More Research on Commercial Needs," Christopher Myers, The Chronicle *of* Higher Education, May 24, 1989.

15 As an example of one's opinion, see, "The 'Cold Fusion' Story Has Been an Object Lesson on Why Science Flourishes Only in the Open," Robert L. Park, The Chronicle of Higher Education, June 14, 1989.
16 "At Boston University, Biotech 101 Is No Breeze," Laura Jereski, Business Week, April 10, 1989.
17 Nelsen, op. cit.

Conflict of Interest in the University Setting: I Know It When I See It

C. K. Gunsalus and Judith Rowan

Abstract. Potential conflicts of interest are a fact of life at research universities today. This paper offers guidelines for dealing with potential conflicts openly and directly, making it possible for university administrators to balance the institutional risks and benefits of relationships and interests faculty may have with outside agencies or companies. The paper offers basic definitions, flags the kinds of activities that may raise conflict-of-interest questions, and provides guidelines for assessing risks to the institution. It provides advice on developing effective conflict-of-interest policies and procedures that will minimize risk to the university and the individual.

The entrepreneurial spirit has found a home on university campuses throughout the United States. It was invited by presidents and chancellors, embraced by faculty inventors, and encouraged by state and federal governments eager to reap the social and economic benefits of technology transfer.

Innovative approaches to technology transfer have led to new kinds of partnerships between the academic and private sectors: corporate researchers can be found working side-by-side with faculty and graduate students in university laboratories; universities have licensed new technologies to corporations; corporations are establishing outposts in university-owned or -sponsored research parks in order to take advantage of the proximity of faculty scientists and campus resources; universities are building incubator facilities to provide a supportive environment for developing new technologies; universities are licensing new technologies to spin-off corporations formed by their faculty members.

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The very fact that so many segments of society welcome these developments may be a sign that private enterprise and the public good can more than coexist in academia; they can positively flourish. At the same time, however, conflict of interest has become one of the more controversial aspects of university life in the late 1980s. Administrators at all kinds of institutions - public and private, big and small - are engaging in reviews, analyses, and no small amount of hand-wringing as they wrestle with the issues presented by the flurry of entrepreneurial activity taking place on their campuses.

The well-founded fear that motivates much of this activity is that the basic missions of the university - teaching, research and service - may be jeopardized if conflict-of-interest situations are not managed properly. Mistakes in this area will draw the attention and quite possibly the intervention of outside regulators, from government agencies, from state and federal legislatures, and even from prosecutors. The bad news is that it is not possible to enter into innovative relationships and garner all the benefits without exposure to the risks. The good news is that, with a better understanding of the risks, institutions can make a balanced determination of whether it makes sense to accept them in pursuit of the benefits.

Potential conflicts of interest don't disappear simply because they go unacknowledged. On the other hand, discovering potential conflicts need not result in the termination of entrepreneurial activities. On the contrary, with appropriate protective mechanisms and safeguards, some arrangements may become possible that would otherwise be untenable. In this way, dealing openly and directly with potential conflicts can improve the flow of technology and protect both individuals and institutions. Unless the issues of potential conflict of interest are confronted and contained, they can pollute the purest waters and turn a "win-win" situation into just the opposite.

To minimize the risks, institutions must have and enforce a conflict-of-interest policy. If such a policy is to work, it must include a thorough reporting and disclosure program. While a policy is necessary, however, it is not sufficient. It would be hard to find a faculty member who fails to condemn conflict of interest in the abstract, and most also find it easy to spot someone else's conflict. But it is extremely difficult for the most honest and upright of scholars to acknowledge their own conflicts for what they are. The most important single step an institution can take is to sensitize its faculty and administrators to the possibilities of conflict, and to provide them with the tools and examples they will need if they are to recognize it and rationally weigh the risks.

THE LEANING TOWER OF IVORY

If every faculty member devoted every waking minute to his or her university work, conflicts would not arise. In the late twentieth century, however, it is a fact of life that most university staff members also engage in outside activities of one sort or another. It is also true that faculty members often control university resources. This situation - where an individual who controls university resources also engages in outside activities - creates the possibility of conflict.

What are the ways in which faculty members, who after all spend most of their time conducting research, performing service and teaching, can be said to control university resources? Often, they determine the direction that entire research, service and teaching programs will take, which may affect the distribution of a wide range of resources - dollars spent on supplies and equipment, human time of students and support staff, machine time on computers and other sophisticated equipment, and the use of rooms and laboratories belonging to the institution.

It is in the nature of a university for the role of decision-making in these matters to fall to the individual faculty researcher. In itself, that does not give rise to a conflict situation. However, when those same faculty members and companies active in their area of expertise have financial relationships of one kind or another, conflicts of interest may arise. Such financial relationships could include consulting, an advisory role, stock holdings or management responsibility, for example. Other red flags are faculty-owned spin-off companies, in which not only financial interests but questions of research agendas and scientific objectivity may arise. Special attention is called for whenever students are involved in the private business activities of a faculty member.

Careful monitoring and management of potential conflicts can help avert disturbing and destructive situations. Scientific fraud, insider trading and misappropriation of funds are just a few of the direct outcomes that are possible when conflicts are allowed to go unchecked. Objectivity - disinterest - is the key to much of the work that takes place in universities. By definition, disinterest and personal financial interest are incompatible. Objectivity is nearly invariably compromised, in appearance if not in fact, when the financial stakes of a researcher are too great.

CONFLICT OF INTEREST

“Conflict of interest” encompasses two separate concepts: conflicts of interest, which have to do with private financial gain, and conflicts of commitment, which involve time. When personal financial interests

could affect the decisions someone makes at work, conflict of interest may be a problem. Financial gain can mean not only direct profits, but use of facilities, staff, or other resources at no cost or reduced cost. Conflicts of commitment may arise when, pulled in too many different directions, an individual is unable or unwilling to meet fully the responsibilities of the primary professional position. Both types of conflict stem from an individual's having multiple interests that can be simultaneously compatible and competitive. The more complex the interactions among these interests, the more difficult it can be to protect against potential or actual conflicts of interest.

If a faculty member stands to gain financially, making a personal profit by using public resources, it is likely that a conflict exists. If a staff member's time is used in a way that benefits the private interests of the faculty member, it is again likely to be a problem. Not only the faculty member himself or herself, but friends, family and associates should be taken into account when conflicts are assessed.

It is not sufficient to know that all the individuals involved are operating in good faith - it is possible for real problems to be caused by the appearance of conflict or the potential for conflict as well as by the full-blown reality of conflict. An **unacceptable conflict of interest** exists when a faculty member in fact makes a decision that is not in the institutional interest, based on personal factors. A **potentially unacceptable conflict** exists when the situation would permit that faculty member to do so. **Apparent conflicts** can be equally problematic. The faculty member may have made a decision quite properly, but in retrospect it may appear to have been influenced - or open to influence - by personal factors. Careful documentation and disclosure mechanisms can make a critical difference in such cases. Where appropriate, safeguards must be implemented or - on occasion - activities prohibited.

Consulting is the activity most commonly thought of when considering outside activities of faculty, but university employees also own and manage real estate, play in symphonies, create art, breed dogs and horses, and do volunteer work - sometimes in their area of professional expertise. Some of these activities are strictly within the private lives of the employees. Others may complement the university's mission by making expert contributions to communities, corporations, and professional societies, for example. Universities generally try to accommodate a wide range of such activities, both because faculty should have no less freedom than professionals of any other sort when it comes to their personal financial decisions, and because the outside activities of faculty often are seen to be in the public interest. Sometimes,

however, conflicts of interest make it impossible or inadvisable for universities to give faculty a free rein.

Conflicts of commitment, because they are related to time instead of money, may arise from volunteer activities as well as those that are remunerated. A faculty member who is deeply involved in the management of a professional society, runs for local political office, or serves on the board of a charitable organization may be just as vulnerable to neglecting university duties as one who is paid for his or her efforts. In general, university contracts presume that a faculty member's primary loyalty is to the institution. Faculty members do not punch a time clock; many work long, if irregular, hours. When a faculty member has competing outside interests, it can be very difficult for anyone - even the professor in question - to know exactly how to allocate time, energy and ideas between two masters. One faculty member at the University of Illinois asked a research administrator whether an idea he had in the shower belonged to the university or his company. The administrator's advice was that the idea might well "belong" to the university, and the safest course was to presume that it did. The question never would have arisen a generation ago.

It is important to remember that the simple fact of multiple time commitments does not necessarily signal a potential conflict. It is common for faculty members to spend large amounts of time, for which they are often compensated, outside of their direct university responsibilities but well within the professional activities that are expected of them if they are to flourish in the academic environments. These sorts of activities frequently are taken into account in promotion and tenure decisions, and may include book authorship, professional society activities, lecturing at conferences, editing of journals, site visits at other institutions, and so forth. The sure sign of a troublesome conflict of commitment is that the faculty member's university obligations are not being fulfilled to the satisfaction of the institution. The flip side of this is that, if the university obligations are being met, conflict of commitment is not a problem.

Thus, whether or not financial interests are involved, institutions should measure conflicts in terms of the damage they may cause to the basic missions and goals of the institution.

RECOGNIZING CONFLICTS

In reviewing outside activities of faculty and staff to assess the risks of conflicts of interest, institutions should be alert to four possible dangers: (I) that the educational programs of the university -

particularly those involving graduate students - could be adversely affected; (2) that research agendas might be subverted; (3) that the free flow of scientific information might be unreasonably constrained; and (4) that public resources might be used for private gain, possibly to the detriment of the public good.

Each of these flows from the traditional missions of universities in teaching, research, and public service. Remembering the university's mission is a constructive way to evaluate the potential benefits and risks in a given situation. Does the activity in question advance the university's basic missions? Harm them? Advance one at the expense of another? On balance, is the benefit worth the risk?

The public policy debate at the beginning of this decade on technology transfer initiatives produced a policy of sharing royalties with researchers when technologies they invent are commercialized. In the most recent wave of concerns about conflicts of interest, questions have been raised about whether these royalties might create disqualifying conflicts. It would be possible to eliminate almost all conflicts of interest by prohibiting broad categories of activities and relationships, including royalty-sharing with inventors, but the costs of such an approach in terms of discouragement of activities with many beneficial effects are likely more than is sensible to pay.

Risks are not necessarily problems. Institutions should recognize that some risky undertakings fail, but some benefits are not possible without accepting some risk. Sometimes, if a conflict of interest is possible, it will in fact materialize and subvert the hopes of the institution. Often, it will not.

Educational programs. A university's educational programs are susceptible to a variety of ill effects from the personal conflicts of interest of staff members. It is human nature to turn to familiar people when help is needed, and in a university setting familiar people are likely to be students and colleagues. Students may benefit from involvement in a faculty member's outside activities. The experience of working in the real world with a scientist who shares their interests may give them specific educational experiences that will be valuable to them, and also may help prepare them for their future professions inside or outside the academy.

Nonetheless, students are particularly vulnerable to exploitation, and it is important for universities to be alert to the possibility that the students' best interests are not being served. For example, the selection of a dissertation topic might be skewed so that the thesis research would fit more neatly into the plans of the outside activities of the faculty member. Faculty mentors could deliberately slow the progress of graduate students if they wish to keep them around to help in the private enterprise.

Or, students' degree progress could be speeded up unreasonably in order to make them available sooner for full-time employment. It is not only students who willingly participate in a faculty member's outside activities that may be hurt. If students involved in the outside project are favored, those who are not could be adversely affected.

Research *agendas.* Outside interests may cause faculty members to make decisions about research agendas that are not in the best interests of the institution. Is the work appropriately undertaken in a university laboratory, or is it simply private business conducted in university space? Is it fundamental research, rather than product development? Might the profit motive call into question the integrity of the research results?

When a faculty member serves as a consultant to a company that is also a research sponsor, inappropriate technology transfer is a real possibility. Unless specific other arrangements are made in advance, technology developed at the university properly belongs to the university. This sometimes is not well understood by either the scientist or the sponsoring company. If the risks inherent in this situation are recognized, negotiators for the company and for the university can deal in advance with use and compensation questions, licenses and royalties, establishing procedures by which to determine how technological advances are to be allocated among the parties.

Other problems also may arise in this situation, however, and may be more difficult to control. When a faculty member is paid a large retainer as a consultant or scientific advisor, it may well be difficult for him or her to remain objective when the company's financial well-being is at stake. At best, this creates a situation where the appearance of impropriety may exist. At worst, it can lead to insider trading, withholding of research results, falsification of findings, or other illegalities. If the faculty member also has an ownership interest in the company that is sponsoring research, the situation becomes even more untenable.

Another danger is that research that properly belongs at the university may be diverted to a private company. The motive for doing this could be financial or could be competitive, but in any event it is important for the institution not to let it happen.

Dissemination of knowledge. The free exchange of scientific information or theories is one of the fundamental virtues of the academic setting. Once again, the profit motive may threaten to jeopardize this exchange. When private interests are at stake, decision-makers *may* be swayed in their determination to maintain openness. The prospect of profit, or the very success of a private venture, may outweigh the public good if those in a position to make decisions are also those who stand to gain if the release of scientific information is denied or delayed.

Publication could be affected in a number of ways. In the worst case, private interests could cause researchers to suppress or alter information that would be harmful to the outside interest. A less egregious but equally unacceptable outcome would be the simple delay in publication of data in order to gain competitive advantage.

Competition among scientific groups is a common enough phenomenon on university campuses. Adding the prospect of personal financial gain to the existing reasons faculty members may have for wanting to be first with an idea may deal a death blow to the notion of collegiality, leading researchers to become increasingly secretive and proprietary about their results.

Use of public resources for private gain. The principal concern that both legislators and journalists harbor about conflicts of interest focuses on the inappropriate or unauthorized use of public resources for private gain. Private universities are not immune from such concerns about misuse of public resources, because the vast preponderance of support for research comes from tax-supported public agencies. Legislators and journalists, who see themselves as watchdogs acting on behalf of the public, are well aware of the sources of these funds. Many go so far as to describe any funds being used by institutions of higher education, regardless of the source, as essentially public.

Resources, it should be remembered, include not only dollars and staff time, but use of the university's name, facilities and equipment. A university's name is a valuable asset, and private interests often want to enhance the market value of their products or services by putting the weight of the university behind them. Institutions should carefully guard against inadvertently implying endorsement of products or services.

Several classes of expenditures are subject to abuse - or the appearance of it. Travel and purchases that might have been perfectly acceptable university expenses if no private interests are involved may be questionable in other circumstances, in light of new profit-driven arrangements. Uncompensated use of office space, staff or specialized equipment acquired or maintained with public funds constitutes an inappropriate use of public resources unless specifically agreed to in a contract.

One situation that is becoming increasingly common at major research universities is the spin-off company, in which a researcher forms a private enterprise to develop or market a technology developed at the university, frequently with public funds. In some instances, the researcher maintains a formal affiliation with the university. Spin-offs are riddled with possible conflicts, not only for the individual but for the university itself, which may stand to gain financially from a successful company. Despite the possible difficulties, spin-offs sometimes represent

the best way to transfer a new technology from the university to the marketplace. The elements that may signal unacceptable conflicts are the same as those in the other situations we have discussed, but the added layers of complexity in spin--offs call for a particularly scrupulous review.

CONFLICT OF INTEREST POLICIES AND PROCEDURES

A university must have a conflict-of-interest policy that includes provisions for mandatory disclosure of outside activities by its faculty and professional staff. The basic elements of the policy should include early and complete disclosure and an objective process of evaluation, based on uniform standards. The policy could specify that individuals report the time they spend on outside activities, the compensation they receive, or both. The University of Illinois, like many universities, requires disclosure of outside income-producing activities but not of the income generated through those activities. In specific situations, it may be necessary to ask for further details - but that is not always the case. When such details are needed, though, the university must have clear authority to obtain them. Whichever course the university takes, a disclosure process is necessary because it is impossible to evaluate potential conflicts without the fullest possible description of them. And without evaluation, it is impossible to reach sound judgments about which risks are worth taking, and which are not.

No matter how sound the guidelines, they are always susceptible to subversion by the determined. Most people, however, are more than willing to play by the rules as long as they are rational, clear, explicit and published.

Most disclosed information is not troublesome. Our experience so far tends to show that only a relatively small percentage of the forms that are submitted require close scrutiny, and a vastly smaller percentage signal real problems. It is important to keep this in mind when designing a disclosure process. The procedure should be as "user-friendly" as possible, both to encourage compliance and to keep the burden light for the great majority of faculty for whom this represents one more hoop to jump through and an unwelcome diversion from their scholarly pursuits.

Universities, therefore, should require disclosure of the minimum information they need to make informed judgments about which situations require more careful attention. In deciding what to ask, universities always should keep in mind that conflicts are particularly risky if they jeopardize one of the basic missions of the institution. Risks in this category always require close scrutiny and seldom are worth

taking. For this reason, any policy should require disclosure of relationships with companies that specialize in the faculty member's area of expertise, sponsor research, or do business with the university, as well as any outside activities that involve students.

Once all possible conflicts have been disclosed the institution must sort through them and deal with any problem situations. Many conflicts - both actual and potential - may be relatively harmless. It is not possible to attack the contemporary research environment like a homeowner in search of the perfect lawn, weeding out every sign of crabgrass. The individuals conducting the evaluations must understand that some conflicts are acceptable and others are not, and must be adept at knowing the difference. The limits of the acceptable, therefore, must be understood both by those submitting the forms - the faculty - and by those reviewing them. Finally, when unacceptable conflicts are identified, the institution must be willing and able to act. It doesn't do much good to know that conflicts exist if the institution allows them to continue unchecked.

BEYOND DISCLOSURE

The most important result of the formal disclosure process may be the simple fact that it frequently serves as the catalyst that causes faculty and administrators alike to think carefully about these issues. Those who expect the process to yield clean, clear-cut results, revealing all possible conflict situations, will be disappointed. Of all the conflicts that have caused difficulties at the University of Illinois, none first was identified through campus review of the submitted forms. Some might ask, if that is the case, why go to all the trouble of collecting the data? For one thing, department heads may be required to sign faculty and staff conflict-of-interest disclosure forms. This provides a strong motivation for administrators to understand the true nature of the relationships described on the forms submitted by their faculty. In addition, if an individual knowingly omits or falsifies data on these forms, and a problem subsequently is discovered, it may be easier to impose sanctions.

The first line of defense against problems is not the forms; it is the departments. They are closest to the action and in the best position to identify, avert, or flag conflict-of-interest problems. Administrators at the departmental level must be given assistance in understanding the issues, and back-up when problems arise. Colleagues at the departmental level often are the most knowledgeable about the scholarly work of the staff member, and may be in the best position to assess

the effect of outside activities on the ability to carry out university obligations. On the other hand, they are also the most likely to be swayed by personal affinities and feelings.

For these reasons, while the review must begin at the departmental level, it cannot end there. It is important to have guidelines that will direct an impartial central review of certain departmental findings. For example, if the preliminary review turns up a financial relationship between a faculty member and a sponsor of research, this should automatically be forwarded to the central administration for review.

Some individual, or group, should be designated to serve as the central reviewing point for possible conflicts requiring additional attention. The issues and individual cases are seldom black and white; far more often, they fall along a continuum of shades of gray. It requires a good deal of exposure to the variations on the conflict theme before people begin to learn to sort them out with consistency, rationality and equity.

PROTECTIVE MECHANISMS

Protective Mechanisms Once information about a potential conflict has come to the attention of the administration, either through the routine disclosure process or through any other route, it should be analyzed in view of the institution's basic missions as outlined above.

For each possible conflict, consider whether some aspect of the university's mission is in danger. If the answer is yes, try to identify possible ways of protecting against that danger. Brainstorm with those who can provide the best expert advice available, inside or outside of the institution. These are the people who will best be able to suggest specific safeguards in specific situations. This may mean consulting with staff from:

- **Research Administration.** Is the institution's research agenda or credibility likely to be affected adversely? What steps could be taken to protect against that?
- **Department Heads.** Would the proposed situation be likely to jeopardize the free flow of information within the department or within the discipline? If so, is it possible to devise a means to minimize the problem?
- **Graduate Dean.** Are the educational interests of student laboratory assistants adequately protected? How could that be accomplished?
- **Legal Affairs.** Are the university's legal interests adequately protected? Would special contractual arrangements circumvent problems?

- **Public Relations.** How would reporters be likely to respond if they knew about the possible conflict? What steps could be taken to make the situation more acceptable in their eyes?
- **Government Relations.** Do local legislators - state or federal - have particular concerns in this area? Should they be kept informed?

It is absolutely essential to involve the faculty members themselves in these discussions. Their initial reaction to scrutiny may be a defensive one, and they may believe that the university is only attempting to protect itself. In fact, however, though it may not be evident on the face of it, it- is in the best interest of individual faculty as well as the institution to avoid these conflicts. In any event, the cooperation of the faculty and departmental administration will be the key to a successful resolution of any problem.

Specific safeguards can be put in place to deal with particular situations. In cases where students' interests are involved, a disinterested party should be asked to take responsibility for monitoring academic progress and maintaining open channels of communication. Another faculty member in the department, the department's graduate advisor, or the head of the department could play this role.

Where private use of university facilities or resources is requested, decisions must be made about whether to allow the use, under what circumstances, and for what compensation. Contracts can be written to spell out these decisions for the protection of both the institution and the individual.

In the event that an individual discloses a financial interest in a company that supplies the university with equipment, purchase decisions can be transferred to or approved by others. If a faculty member who owns or manages a company wants to support research at the university, a disinterested faculty member should be found to supervise the research.

If a faculty member travels to demonstrate a university-developed technology, but might benefit personally in some way from the demonstration, someone with no personal financial interest in the situation can be required to approve travel expenditures. Similar approaches can be taken for other types of travel.

Sometimes, outside professional consultants offer a good mechanism for reviewing projects and progress. Knowledgeable but disinterested outsiders may be the best people to spot subversion of research agendas and improper technology transfer.

The list of possible mechanisms is endless, and at first it may appear that each solution has to be tailored to fit a specific conflict situation. Eventually, however, those working with these issues will begin to build a base of knowledge that will enable them to make all but the least routine decisions without specific consultation. They also will develop working relationships with the professional staff in all of the other relevant areas that will make advice relatively quick and easy to obtain because everyone will be operating from the same set of experiences.

CONCLUSION

Those who spend time thinking about conflict of interest tend to fall into two camps - those who believe the problem is so serious that it will cause the entire research enterprise to grind to a halt, and those who believe it is so trivial that it should be ignored and eventually it will go away. Members of both camps agree that conflict of interest is a bad thing, and they generally believe that they recognize it when they see it. (The one obvious exception to this is that individuals usually can find ways of rationalizing and justifying their own conflict situations.)

The truth lies somewhere in-between. The situations that typically give rise to conflicts of interest in university settings are so much a part of today's culture that hopes that the problem will disappear are quite vain. At the same time, Congress, state legislatures and journalists are more interested than ever in monitoring the integrity, productivity and accountability of universities. On the other hand, fears over conflict need not cause universities to retreat from the important contributions they are making in the areas of technology transfer and economic development.

The best approach is a balanced one that keeps in mind the basic goals and missions of the university; the welfare of its employees; and its broadening social responsibility in the area of technology transfer. The dangers are real and present, but if they are carefully thought through, some of them will be judged to be negligible, and others will be worth the risk. By applying a rational system of guidelines, institutions can do everything possible to keep conflicts within acceptable limits. This will allow them to be participants in the world of affairs without sacrificing their institutional identity and integrity.

Implementing California's Regulations on Conflict of Interest in Research

Richard P. Seligman

Editor's Note: *This article* is based upon a presentation made *by the* author as part of a panel discussion at the June 8, 1989 meeting of *the* Council *on Governmental* Relations.

Since May, 1982, the University of California, Los Angeles (UCLA) has had procedures in place for the systematic review of principal investigators' financial disclosures prior to the acceptance of grants, contracts, and gifts for research under their direction. This article examines the origins of these procedures and the manner in which they are presently working. The disclosure requirements themselves are presented, along with a description of the structure and function of the faculty committee that has been created to review them. The criteria used by the committee are also discussed. Data on the disclosures made during calendar year 1988 are included. Finally, the article concludes with two case studies that illustrate potential conflict-of-interest situations.

BACKGROUND

The Political Reform Act of 1974 was enacted by the people of the State of California as a ballot initiative measure. In the post-Watergate atmosphere that prevailed at the time, there was strong public support for measures to "reform" the activities of government officials. The Political Reform Act brought about the creation of the California Fair Political Practices Commission (FPPC), a government agency whose five members are appointed by the governor and other state officials. One of the first activities of the FPPC was to develop regulations concerning annual disclosures of financial interests by public officials throughout the state. The disclosure requirements were applicable to elected and appointed officials, to civil servants at the state and local

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level, and to administrative officials at the University of California, including faculty serving in administrative positions, e.g., deans and department chairs. In 1982, the FPPC established regulations that would require faculty members at public universities, i.e., the University of California, to disclose their financial interests in non-government sponsors of their research. The initial response of the University of California was to challenge the FPPC, arguing that the imposition of financial disclosure requirements on faculty members went far beyond the intent of the Political Reform Act, which was directed primarily at elected officials. The disagreement was resolved in the state court system, which sustained the FPPC's position.

The University was thus forced to acquiesce and acknowledge the right of the FPPC to promulgate rules that would affect the conduct of research by faculty members at the University of California. The FPPC regulations governing sponsored research require principal investigators to disclose certain types of financial interests and mandate that a grant, gift, or contract involving a principal investigator with a financial interest in the sponsoring agency could be accepted by the University only following a review and recommendation by an "independent substantive review committee" consisting of members of the faculty. The FPPC thus fell short of setting itself up as the final arbiter of what would be an acceptable or unacceptable financial relationship between a principal investigator and a sponsor of his or her research. Instead, the FPPC delegated that authority to the University and, in so doing, forced the University to take an active role in the consideration of potential conflict-of-interest situations involving members of its faculty.

DISCLOSURE REQUIREMENTS

Figure 1 shows the actual form mandated by the FPPC for use by principal investigators at the University of California to disclose their financial interests in non-governmental sponsors of their research. Investigators must indicate whether they serve as a director, officer, partner, trustee, or employee of the entity that is proposing to fund their research. In addition, they must report on investments in the sponsoring agency as well as income, gifts, and loans received from the sponsor. These disclosures are to be made on behalf of the principal investigator, as well as his or her spouse and dependent children. The disclosure form also includes a declaration by the principal investigator that ". . .under penalty of perjury [I declare] that I have used all reasonable diligence in preparing this statement and to the best of my knowledge, it is true and complete."

Figure I

Form 730-U

Principal Investigator's Statement of Economic Interests

To be completed for all research projects which have been or will be funded, in whole, or in part: (1) through a contract or grant of $250 or more with a non-governmental entity; or (2) by a gift from a non-governmental entity which is earmarked by the donor for a specific research project or a specific principal investigator, provided the amount of the gift, or the aggregate over a 12-month period, from the same donor is $250 or more.

Title of Research Project: _____

_____

Name of Principal Investigator: _____

Department: _____

University of California at: _____

A. Provide the following information about each non-governmental entity which will fund (or has funded) this project, in whole or in part:*

Name of entity: _____

Address of entity: _____

Principal business of entity: _____

Amount of funding: $_____ Estimated Actual

B. This statement is:

__ APPLICATION STATEMENT: This is an application for initial funding, or for renewal of funding for the research project.

PROJECT COMPLETION STATEMENT: The research project expired on _____

C. Are you a director, officer, partner, trustee, or employee of, or do you hold any position of management in, any entity listed in A?

__ No __ Yes Title: _____

D. Do you, or does your spouse or dependent child, have:

1. An investment of $1,000 or more in any entity listed in A above?

__ No __ Yes - value does not exceed $10,000

__ Yes - value exceeds $10,000, but does not exceed $100,000

__ Yes - value exceeds $100,000

* *If more space is needed for listing* multiple entities, *add* these on a separate *piece of paper labeled* "Section A, continued" and attach to this form.

2. Income (including any payment, such as salary or consulting fees) of $250 or more received from any entity listed in A within the last 12 months? (Do not include any salary or summer salary paid by the University with funds provided by an entity listed in A.)

___ No __ Yes - value does not exceed $1,000

__ Yes - value exceeds $1,000, but does not exceed $10,000

__ Yes - value exceeds $10,000

3. Gifts from any entity listed in A of $50 or more?

__ No __ Yes - describe gift and state value _____

_____

4. Outstanding loans.

a. Loans** received from any entity listed in A for which the outstanding balance has exceeded $250 in the past 12 months?

__ No __ Yes - amount owed did not exceed $1,000

__ Yes - amount owed exceeded $1,000, but did not exceed $10,000

__ Yes - amount owed exceeded $10,000

b. If you answered yes (any yes box checked) to 4a:

was the loan __ secured or __ unsecured?

What was the interest rate of the loan? _____ %

Was the loan entirely repaid within the past 12 months? _ No _ Yes

E. If you listed more than one entity in A, and have answered yes to D or to any question in E, indicate in which entity you, your spouse or dependent child has each financial interest disclosed.

_____

_____

_____

_____

_____

_____

_____

_____

**Do not include a loan from *commercial* lending institution made in *the* ordinary course of business on term *available to* the *public* without regard to the official status if the loan: (1) was used to purchase your principal place of residence, or (2) is less than $10,000, including indebtedness *from an installment* sale or contract.

Verification

I declare under penalty of perjury that I have used all reasonable diligence in preparing this Statement and to the best of my knowledge it is true and complete.

Executed on _____ (date), 19____, at _____ (location)

_____

Signature: _____

All of the information on this form is mandatory, is required by the provisions of the Political Reform Act, Government Code Sections 81000, *et* seq., and will be available to any member of the public upon request. This information is to be used to reveal public scrutiny certain financial interests of public officials and employees in order to disclose potential conflicts of interest and to aid in the prevention of actual conflicts of interest.

1 / 83 Fair Political Practices Commission

Disposition Schedule: Original - 7 years
Copies - 4 years

STRUCTURE AND FUNCTION OF THE INDEPENDENT SUBSTANTIVE REVIEW COMMITTEE

When UCLA was required to create a formal mechanism for reviewing financial disclosures, the Chancellor established the Independent Substantive Review Committee (ISRC). The ISRC consists of five faculty members appointed by the Chancellor in consultation with the Academic Senate. Members are appointed for a three-year term and currently represent the schools of Law, Medicine, Engineering, and Management. Although representation from particular professional schools or departments on the ISRC is not required by the FPPC, the Chancellor sought to form a committee that would have sufficient breadth to provide substantive reviews of the projects that come before it. Staff support for the ISRC is provided by the Office of the Campus Counsel as well as the Office of Contract and Grant Administration and the Gifts Policy Administration office.

The ISRC meets monthly throughout the year to review positive disclosures of financial interests that have been submitted in connection with a proposed research gift, grant, or contract. Prior to the meeting, ISRC members receive information on each case that is to be considered. This includes the principal investigator's disclosure form, correspondence between the University and the sponsor, the proposal describing the

work to be done, award documents, and, in some instances, written statements from the principal investigator elaborating upon the financial interests that have been disclosed. In rare instances, the ISRC invites the principal investigator to meet with the Committee. Following the presentation of each case, the ISRC forwards its recommendation to the Vice Chancellor-Research Programs. The recommendation can range from acceptance of the award to rejection of the award. Recommendations can also be made for a "conditional" acceptance of the award, i.e., the award can be accepted if the principal investigator changes some aspect of his or her relationship with the sponsoring agency.

The Vice Chancellor-Research Programs receives the recommendations of the ISRC and then determines the final disposition of each case. It is notable that in nearly eight years of operation, all the recommendations of the ISRC have been implemented by the University.

REVIEW CRITERIA

When the University first implemented the procedures for the review of financial disclosures, the Office of the President established a set of criteria to be used by the ISRC at each campus. Six criteria form the basis of the review that is conducted by the ISRC. The criteria include the following:

1. Traditional conflict-of-interest situations should *be* avoided.

Principal investigators, along with all University employees, are required to separate their University interests from their private interests. Thus, University employees are required to remove themselves from any decision-making process at the University that involves an outside organization in which they have a financial interest.

2. The proposed research *is* appropriate for the University.

This criterion represents the "substantive" aspect of the ISRC's review. The assumption is that judgments regarding the substantive nature of the work to be carried out by the principal investigator can only be made by academic colleagues who can thoughtfully review the proposed work to determine its appropriateness at the University. The intent of this criterion is to ensure that work done is of an appropriate academic or scientific nature and not simply work that will serve primarily to enhance the principal investigator's personal financial interests.

3. The teaching and research environment is open.

Part of the Committee review process is to determine that there are no conditions in the proposed arrangement between the sponsor and

the University that will inhibit or restrict the teaching or research environments.

4. There is no restriction on the freedom to publish and disseminate research results.

This criterion is a restatement of a fundamental University policy applicable to all research activity. Regardless of the presence or absence of a financial interest in the sponsor on the part of the principal investigator, the University is unwilling to accept funding that imposes unreasonable restrictions on the publication and dissemination of research results.

5. Licensing agreements are appropriate.

This criterion is directed at those instances in which the relationship between the sponsoring organization and the University contemplates the licensing of patentable inventions or other intellectual property. The ISRC is to assure that "the best interests of the public and the University are served." Since the University has an elaborate set of policies regarding the licensing of intellectual property, and since this activity is performed by individuals other than principal investigators, there have been virtually no difficulties with respect to intellectual property issues reviewed by ISRC.

4. University facilities *and resources* are *used appropriately.*

This final criterion is related to the second one listed above. The ISRC is required to determine that the facilities and resources of the University are being used appropriately, i.e., in accordance with all applicable University policies and, if for the benefit of either the sponsor or the principal investigator, only with proper compensation to the University.

By considering each case in terms of the six criteria enumerated above, the ISRC is then able to come to a decision concerning whether or not an unacceptable conflict-of-interest situation would occur if the award were accepted.

Upon first consideration, the criteria other than the first (traditional conflict-of-interest situations should be avoided), may not seem particularly relevant to the topic of conflict of interest. In fact, the remaining five criteria (appropriateness of research, openness of teaching and research environment, freedom to publish results, appropriateness of licensing arrangements, appropriateness of use of university facilities) sound like the sort of criteria that should be considered in the review

of any and all sponsored research arrangements. The existence of these particular criteria caused some initial frustration for the University's contract and grant administrators. How could they in good conscience accept an award that did not meet these criteria? Why was it necessary for a faculty committee to look over their shoulders to make sure that they were doing what they ought to be doing? Over time, the wisdom and relevance of these criteria began to emerge. Issues such as the appropriateness of a particular research activity, publication restrictions, and the appropriateness of the use of the University's facilities can become the tangible evidence of the existence of an unacceptable conflict of interest in the research enterprise. The confirmation of the absence of these problems - as well as those identified earlier as "traditional conflicts" - permits the ISRC to determine that a proposed arrangement would not constitute a conflict of interest.

ISRC DATA FOR **1988**

During 1988, UCLA faculty members submitted a total of 850 Disclosures of Financial Interest. Of these, 791 were "negative," i.e., the person making the disclosure indicated no financial interests in the sponsoring organization, and 59 cases were "positive," i.e., the principal investigator made a positive response to one or more of the items included in the financial disclosure form.

Disposition of the 59 positive disclosures was as follows:

56 recommended for approval
1 recommended for disapproval
1 recommended for conditional approval
1 withdrawn by principal investigator
(would have been disapproved)

Distribution of the positive disclosures in terms of academic areas is as follows:

School of Medicine	**63%**
School of Engineering	**24%**
College of Letters and Science	**12%**
School of Dentistry	1%

Three-quarters of the sponsoring agencies involved in the positive disclosures during 1988 were profit-making organizations and one-quarter of the agencies were non-profit.

Table 1 shows the types of financial interest that were disclosed by the 59 principal investigators who made positive disclosures during 1988.

The table indicates that most of the financial interests involved the receipt of income from the sponsoring agency. There were 17 cases in which the income received was more than $1,000 but less than $10,000. Of those cases, seven represented honoraria received (one from a computer company, one from a manufacturing company, and five from pharmaceutical companies). Ten cases represented consulting fees received (two from pharmaceutical companies, seven from engineering or aerospace companies, and one from a hospital).

Table 1

Financial Interests Disclosed: 1988

Category	No.	%
1. Employee/Officer	15	25
2. Investment	7	12
3. Income	37	63
Total	**59**	**100%**

There were ten instances in which principal investigators reported receiving income in excess of $10,000 during the 12-month period immediately prior to the disclosure. Three cases involved salary payments to the investigator. One was from a non-profit "think tank" in which the professor had a joint appointment; one was from an aerospace firm where the principal investigator serves as a "part-time" employee, and one was from a non-profit organization that provides medical services.

The remaining instances of income in excess of $10,000 involved consulting fees paid to principal investigators. The organizations for whom the principal investigators consulted included three pharmaceutical or biotechnology firms, three engineering or aerospace firms, and one health organization.

Table 1 also shows that one-quarter of the positive disclosures involved instances where the principal investigator was an employee of, or officer in, the sponsoring agency. In most cases, these principal investigators were unpaid officers or board members of non-profit organizations. Table 1 also shows that there were seven instances where the nature of the financial interest was stock ownership. In each of these cases, the ISRC asked the investigator to provide supplementary information regarding

the stock acquisition, e.g., does the investigator have an option to acquire additional stock, what is the proportion of stock now owned - or to be owned as a result of the exercise of options - relative to the total assets of the sponsor? With this information at its disposal, the ISRC has been able to review each case on its own merits and make the judgment that the investigator's equity interest in the sponsor did, or did not, constitute an unacceptable conflict of interest.

CASE STUDIES

To illustrate some of the issues that confront the ISRC, two case studies are presented. In each of these instances, the names of the investigators, their departments, and the sponsoring agencies have been changed. All of the other essential facts of each case, however, remain unchanged.

The Case of Dr. Melville

Dr. David Melville, a professor of biological science, has submitted a Statement of Economic Interests in connection with a gift to the University from the Foundation for Better Health. The Foundation is the non-profit arm of Better Health Centers, Inc. The case before the ISRC involved the review of a $105,000 gift to the University to support Dr. Melville's research. The financial disclosures made by Dr. Melville indicate that he is the Chair of the Scientific Advisory Board of the Foundation for Better Health, a member of its Board of Trustees, its Director of Research, and he is also a consultant to the Foundation. The disclosure further indicates that in the past 12 months, Dr. Melville has received income from the Foundation in excess of $10,000.

In its review of this case, the ISRC applied the criteria that were described earlier.

1. Traditional conflicts of interest should be avoided.

The case of Dr. Melville presents a classic illustration of a "traditional" conflict of interest. That is, his activities as an official of the Foundation for Better Health make it extremely difficult for him to separate his University interests from his private interests. In this situation, Dr. Melville functions as both the "donor" and the "recipient" of the research funds. To what extent, therefore, is Dr. Melville using the University to support and enhance his private, outside activities?

2. Is the research appropriate to the University?

Since the funding under consideration by the ISRC was in the form of a gift "to support the research of Dr. Melville," it was virtually impossible

for the ISRC to address this criterion at the time of its initial review of the case. Since gifts normally are not accepted for the support of a specific research project and Dr. Melville had not provided the ISRC with a proposal describing his research project, it was not possible for the ISRC to determine if the research activities to be conducted by Dr. Melville under this funding would be appropriate or inappropriate.

3. Are the teaching and research environments *open?*

4. Is there freedom *to* publish and disseminate research results?

Once again, since the proposed project was to be supported by a gift, rather than a grant or contract with a particular scope of work and other terms and conditions, it was extremely difficult for the ISRC to determine whether or not there were limitations on the teaching and research environments or upon the freedom to publish.

5. Does this project constitute an appropriate use *of* university facilities and resources?

Since the ISRC had many questions about the relationship between Dr. Melville and the Better Health Foundation, Dr. Melville was invited to meet with the Committee. During his appearance before the Committee, Dr. Melville indicated that this project really was not meant to be a "gift" in the usual sense. Rather, it was an award made in response to a specific research proposal that he submitted to the Foundation directly, not through the University. Dr. Melville went on to say that the only reason that the Foundation described the award as a gift (at his suggestion) was to avoid the need to include University indirect costs in the award. The ISRC pointed out, however, that notwithstanding the issues of indirect costs, by treating the award as a gift rather than as a grant or contract, Dr. Melville had circumvented the campus review processes in place for sponsored research programs.

Having determined that the proposed activity did, in fact, constitute a sponsored project, the ISRC was then able to address the issues relating to the appropriateness of the research and the use of university facilities.

The ISRC's recommendation to the Vice Chancellor-Research Programs was that the award be accepted, but only if two conditions were met. First, that the award be received by the University as a grant, following successful completion of all of the normal institutional review and approval procedures for sponsored projects. The second condition was that prior to the University's acceptance of the award, Dr. Melville must disassociate himself from the decision-making processes of the

Better Health Foundation and that he not in any way attempt to perform the roles of both "donor" and "recipient." Dr. Melville and the Foundation agreed to accept these conditions.

Why should it have been necessary for Dr. Melville to remove himself from the decision-making processes of the Better Health Foundation? Why is this a conflict of interest? If Dr. Melville does not remove himself from the Foundation's management and its funding decisions, then he has an unequivocal conflict of interest, i.e., he must simultaneously serve two masters (the Foundation and the University) whose interests do not always coincide. The arrangement contemplated by Dr. Melville would cast a long shadow of doubt over the objectivity and scientific dispassion of his work and over the relationship between the Foundation and the University. This situation would be particularly troublesome because the Foundation is the non-profit arm of Better Health Centers, Inc., a profit-making health services organization.

The Case of Dr. Albert

Dr. Philip Albert is a professor in the Health Professions School. He is the principal investigator on a proposed agreement between the University and Over The Counter Pharmaceuticals (OTC). The case before the ISRC was a proposed Clinical Trial Agreement to be funded at the level of $100,000 for a six-month study comparing OTC's brand of medicated bandages with those of two other companies. Dr. Albert's financial disclosure form indicated that he is a consultant to OTC in the areas of new product development and the clinical evaluation of first aid products. During the past 12 months, Dr. Albert received income from OTC in excess of $10,000.

The ISRC applied the standard criteria to its review of this case as follows:

1. Traditional conflicts of *interest should be avoided.*

On the face of it, there appears to be a conflict for Dr. Albert between his role as a consultant to OTC in the evaluation of their first aid products and his role as the director of a clinical trial designed to test one of OTC's products. The objectivity, impartiality, and scientific integrity of Dr. Albert's work could certainly be questioned. Further, Dr. Albert is in a situation in which his University activities and private business activities are being intermingled.

2. Is the research appropriate to the University?

In its application of this criterion, the ISRC demonstrated the necessity of its work being performed by faculty members and fellow scientists.

The Committee that reviewed this project included two biomedical scientists, one physical scientist, a behavioral scientist, and a legal scholar. It was the view of this Committee that the proposed study *was* not a particularly appropriate one for the University as it was lacking in scientific rigor. It did not appear to be a "research project," but rather was described by one Committee member as a "consumer preference study," hardly appropriate for the Health Professions School. However, had this been the only problem in this case, it is highly unlikely that the ISRC would have recommended against acceptance of the award.

3. Is this *an* appropriate use *of* University facilities *and resources?*

In attempting to answer this question, the ISRC turned to the longstanding University policy prohibiting the use of its facilities for "routine testing." The Committee could find little academic, scientific, or scholarly justification for using the facilities of the University for the proposed study.

In summary, the ISRC found that Dr. Albert's role as a consultant to OTC substantially overlapped with his proposed role as principal investigator on a clinical trial of one of their products. In addition, the ISRC found that Dr. Albert could be viewed as having a financial interest in the outcome of the study. That is, as a consultant to OTC, having received more than $10,000 in the past year, Dr. Albert may be influenced in the conduct and outcome of the study that would take place. For these reasons, the ISRC recommended that the University not enter into the agreement with OTC for the proposed clinical trial. The Committee's recommendation was upheld.

SUMMARY AND CONCLUSION

Although beginning in a somewhat reluctant manner, the University has nonetheless become an active participant in the examination of the financial interests of faculty members who receive research support from organizations in which they may have a financial interest. Evidence suggests that the ISRC process is working. One of the keystones of its success is that disclosure leads to review and follow-up action. It is certainly true that the University is better off with the ability to administer the ISRC and the conflict-of-interest policies and procedures and engage in self-governance and regulation, rather than having these activities imposed and conducted externally. The faculty committee has taken its role seriously and has acted with fairness and concern for the rights and interests of their colleagues, the University, and the public.

Although this will certainly not endear them to their colleagues, leaders of American research universities will soon have to come face-to-face with the issues of conflict of interest in research, and will have to take deliberate action to bring this activity under control before that function is taken over for them by someone else.

Conflict of Interest and Research

Belle Cole

Abstract. The proposed NIH / ADAMHA guidelines for policies on conflict of interest have been withdrawn following a strong negative response from the scientific community. Some features of the proposed guidelines could survive the next round of formal rule making. This article explains how universities safeguard their mission from potential financial influences through their research policies and peer review practices. The article focuses on the experience of the University of California in regulating potential conflict-of-interest situations in research as a way of assessing the proposed NIH / ADAMHA guidelines, drawing lessons from this experience that may be useful for those attempting to develop effective guidance.

Introduction

On September 15, 1989, the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) proposed new guidelines in the NIH Guide for Grants and Contracts which were intended to address potential conflicts of interest in research supported by NIH and ADAMHA grants. NIH reports receiving about 700 comments during the three-month comment period. On December 29, 1989, the Secretary of Health and Human Services virtually withdrew the proposed guidelines and asked NIH to submit to him ". . .options for addressing potential conflicts of interest that properly treat potential abuse while keeping the research process free of unnecessary burdens and disincentives," The Secretary plans to implement changes through a formal regulatory procedure ". . . involving at the minimum the publication of a Notice of Proposed Rule Making, a specific comment period, and publication of Final Rules with additional opportunity for comment before the rules become effective!"

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This article was written before the "Proposed Guidelines for Policies on Conflict of Interest" were rescinded. The article reviews the experience of the University of California (UC) in regulating potential conflict-of-interest situations in research as a way of assessing the proposed NIH/ADAMHA Guideline. The article provides background on the relevant features of UC policy and extracts from that experience specific lessons that are essential ingredients of effective guidance. Discussion of this experience is still pertinent because elements of the rescinded guidelines may reappear in the next NIH proposed rule.

NIH/ADAMHA Proposed Guidelines

Current Public Health Service (PHS) policy requires institutions receiving PHS financial support to have written guidelines on conflict of interest. PHS policy also expects that participating investigators and consultants will not have financial interests in organizations that produce drugs or devices studied in a controlled clinical trial. The intent of the Proposed Guidelines was to build on existing policy by providing a framework to assist institutions funded by NIH /ADAMHA to establish acceptable criteria for their own conflict-of-interest policies. They specified responsibilities of NIH, ADAMHA, awardee institutions, and individuals; disclosure requirements of all individuals; prohibited situations (standards governing individual equity holdings, consulting and honoraria, and information exchange); criteria for waivers and exceptions; and remedies (sanctions).

Universities share the intent of NIH/ADAMHA to prevent unsuitable research and use of public resources for private enrichment. University institutional policies generally provide this assurance, and the university community has gained considerable experience in self regulation. Specifically on conflict of interest, experience shows that, to be effective, guidelines must be adapted to the research environment and must:

- specify the problems to be addressed
- develop advice specifically about the problems
- avoid sweeping prohibitions that could prevent significant research
- have support of the faculty and the administration.

The proposed NIH/ADAMHA G uidelines did not meet these tests. d 1 They lacked context and focus, were too broad, and contained many arbitrary prohibitions. They imposed heavy administrative and financial costs, created serious obstacles to the conduct of important research, and interfered with the transfer of knowledge and technology to industry. They assured few compensating benefits. Also, as a matter

of principle, university employees, including researchers, should not be prohibited from having private financial interests if such interests do not interfere with their obligations to the university or the integrity of their research activity.

Traditional Safeguards

A distinction needs to be made between the usual conflict-of-interest obligations of all university employees related to financial decisions of the institution and the potential conflict of interest of research investigators. It is characteristic of state universities that all employees, including researchers, who exercise authority to spend money are obliged to avoid conflict of interest and are subject to sanctions for violating state law. For example, in California, state law prohibits all UC employees from making or influencing a broad range of purchasing, contractual and administrative decisions in which they have a financial interest and imposes legal and financial sanctions.

Universities deal with the potential effects of conflict of interest in research through policies bearing on the conduct and funding of research. These intend to:

Prevent the use of public *funds* and *other resources* for *private* gain. The university protects public resources and is accountable for their use through a number of policies including those pertaining to the full recovery of research costs, the assignment of patents, and the use of university facilities. For example, as a condition for accepting a contract or grant from extramural sources (public and private) a university usually insists on full recovery of direct and indirect costs. An institution's patent policy typically requires mandatory disclosure to the university of potentially patentable inventions by employees and may require assignment to the university of patent rights to inventions developed in the course of university employment. University staff time, facilities, and other resources must be used for activities appropriate to the university's mission and not for routine tasks of a commercial nature.

Assure *that no time due to the university is devoted to private purposes.* Adherence to this principle is fundamental to an institution's consulting and outside professional activities policies. Faculty members who engage in such activities do so with the understanding that their consulting does not interfere with the performance of their university duties - their obligations in teaching, research, and public service. Some universities specifically limit the time devoted to outside activity.

Assert *primacy of an open academic environment and freedom to publish.* Freedom to publish and disseminate results is a major criterion of the appropriateness of any research project. Publication policy precludes

assigning to extramural sources the right to keep or make final decisions about what may be published and excessively delaying publication.

Establish *rules that prevent exploitation* of *students.* Faculty responsibility to students, often set forth in codes of conduct, is to assure students protection from potential exploitation, harassment, or discriminatory treatment. For example, students must be able to choose research topics for educational reasons, without being overly influenced by the need to advance investigations of direct interest to a particular firm.

Certain assumptions underlie all policies. One is that the only truly effective safeguard against abuse is the integrity of the faculty and staff. Secondly, research behavior is assumed to be guided by standards, rules of thumb, clear-cut ways to obtain advice, and independent review in all matters. Another assumption is that the principal type of research carried on in the university is fundamental research, which has unpredictable outcomes. It is research that advances scholarship and explores frontiers of knowledge.

No rules work in the absence of these fundamental conditions. To assume otherwise is to invite loss of enthusiasm, excessive caution, and avoidance of risk - with little compensating benefit.

University of California Experience

Over the past seven years the University of California has struggled with the issues raised by university-industry relations and touched on by the proposed NIH/ADAMHA Guidelines. In what follows I provide some background on this process and then lay out the principal elements of what we at the University of California have found to be a workable approach to conflict of interest in the conduct of research.

In the early 1980s the University of California undertook extensive review of policies relevant to university-industry relations. It concluded that one situation may require extra insurance that normal safeguards to university research continue to operate with privately funded research, *viz.*, when an investigator has clearly defined financial interests in a private sponsor of his or her research. The reasoning is that the investigator's judgment about the appropriateness of the research activity might be influenced by a substantial financial stake in a private sponsor. Secondly, such a situation is vulnerable because even though the research is subject to the traditional peer review within the institution, the consistently rigorous peer review of federally funded projects is absent.

Consequently, the University of California designed a policy for this kind of situation. The policy entitled "The University Policy and Guidelines for Disclosure and Review of Financial Interests in Private

Sponsors of Research" was instituted in 1981 and subsequently revised in 1982 and 1984. The policy requires all principal investigators whose research is privately funded to specify whether they have a financial interest in the sponsor of the research. The University agreed to use definitions of financial interest already established by the state for administrative and legislative officials. Financial interest in the sponsor is defined by state law to be:

- a direct or indirect investment of $1,000 or more
- a position as director, officer, partner, or any position of management
- income (consulting, salary) of $250 or more within the last 12 months
- gifts of $50 or more
- loans for which the outstanding balance has exceeded $250 in the last 12 months.

When a financial interest in a sponsor is disclosed, an independent substantive review of the disclosure statement and research project is carried out by a university committee before the funding of the contract, grant, or gift can be accepted. The areas of expertise on individual campus committees reflect the kinds of research and issues presented in disclosures for a particular campus.

The main purpose of an independent substantive review is to assure that privately sponsored research meets established and normal standards. Most importantly, the review committees must be assured that the research is appropriate to the mission of the University, i.e., promising significant contributions to scholarship and knowledge and, when possible, providing suitable opportunities for students. Other principles used by the review committees focus on specific University policies bearing on openness of the teaching and research environment, freedom to publish, appropriate use of university facilities, and suitable conditions for licensing agreements, especially when an exclusive license is contemplated.

Each UC campus's independent substantive review committee reviews positive disclosures in light of all the criteria as well as other University policies. The review attempts to assure that there is an arm's length relationship between the investigator and the company and that there is a clear separation of proposed research and consulting activity. Committees, to the extent possible, consider the potential financial effects of the research on the sponsor.

UC policy requires careful scrutiny but does not prohibit any specific kind of relationship. University of California independent substantive review committees are instructed to give special attention to conditions of research that involve: a) the testing of a sponsor's products or inventions; b) research conducted in the sponsor's facilities; c) research performed jointly with someone from the sponsor; and d) research involving the provision of proprietary information from the sponsor.

Very special attention is paid to situations involving an investigator who has a significant ownership interest in the sponsor or otherwise has the opportunity to receive substantial financial benefits from the sponsor and has a long-term continuing consulting relationship with the sponsor. Changes, including modifications of research agreements or funding and refusal to accept the proposed project, can be recommended as appropriate to the situation.

Over the past seven years the University has processed over 28,000 disclosures from principal investigators who have indicated that they do not have a financial interest in the private sponsors and over 1,700 disclosures which define financial interests in relation to specific research projects. On the average then, of the annual 4,000 disclosures, about six percent (approximately 250) reveal a financial interest in the sponsor and are reviewed. Most proposals ultimately satisfy the university's criteria, sometimes after changes. Some proposals are withdrawn; a very few are rejected outright. In a few cases committees have established an ad hoc review panel to monitor a project according to clearly stated criteria. The University reports its results on a monthly basis to the state agency responsible for implementing state law in this area.

Lessons We Can Draw from Our Experience

1. Define the problem carefully and as narrowly as possible.

The proposed NIH/ADAMHA Guidelines were vague about the problems. They suggested that expanded relations of investigators with private industry threatened the integrity and objectivity of investigators and others. They stated that private financial interests were likely to affect adversely the quality and integrity of publicly funded research. They expressed the need for objectivity and for research results that are not influenced by financial gain. They did not identify specific problems, except by inference.

As was previously stated, the University of California designed a policy applicable to one group, principal investigators with a financial interest in a firm funding their research. At that time the University considered whether to require disclosure by researchers who are federally

funded and have financial interests in private companies. The decision not to require such disclosure was based on the known effectiveness of the competitive and rigorous system of Federal peer *review*. The likelihood of flawed research emerging from this process was considered negligible.

2. Limit disclosure requirements to *people* responsible *for* the *conduct of the research and* to information that is pertinent to the identified problem.

The proposed NIH/ADAMHA Guidelines called for full disclosure of financial interests and outside professional activities by all who are in a position to make any decisions concerning any NIH/ADAMHA-supported projects or are currently applying for grants at the time a research proposal is submitted. "All investigators, key employees, consultants, and persons with primary management, advisory, or supervisory responsibilities. . .and all persons who are in a position to have a critical influence on, or substantive control over, that research" must disclose their own financial interests and those of their spouses, dependent children, and other dependents as well as their outside professional activities.

The problems here are the extensive list of people who may have to disclose, a vague standard for determining who is affected, lack of a rationale for what has to be disclosed, and the monumental administrative and financial costs. It has to be understood that it is the investigator who has substantive control over the initiation and conduct of the research. Therefore disclosure of financial interests and activities by anyone other than the investigator is irrelevant.

Though disclosure may seem to be the most assured way of surfacing potential conflict-of-interest situations, there is a downside to disclosure, namely, exposure of a person's private financial situation to possibly hostile groups or individuals. This risk is worth taking only if disclosed information will contribute to the solution of a clearly identified problem. Otherwise such disclosures may be used for fishing expeditions on the grounds that something important might turn up.

3. *Develop* a process for review of disclosures that *uses* criteria or principles *that are* clear *and* derived from *accepted* research criteria to *be* carried out *by people* who are qualified through their experience to promote *respect for their advice.*

The proposed NIH/ADAMHA Guidelines had broad objectives and were too prescriptive, flatly prohibiting certain situations. Appropriate guidance is lacking. Furthermore they suggested that " . . . in order to assure timely and objective evaluations. . ." institutions appoint a panel

of at least three members, one of whom has no institutional affiliation and one of whom is the institutional official responsible for signing the grant application or contract proposal.

The institution should be left to decide on the best mix of people for the task at hand, including whether to appoint an outside member. What is more important is that the people appointed have the necessary academic, professional, and administrative competence and expertise. (See previous discussion of committee criteria and approaches.)

4. Assess each research *situation on its own merits,* weighing *any* potential *conflict* against *the importance* of *the* research *in* question.

The proposed NIH/ADAMHA Guidelines flatly prohibited certain types of relationships. They barred investigators (and all others to whom the Guidelines apply) from holding personal equity or options in any company that would be affected by the outcome of the research or that produces a product or equipment being evaluated in the research project.

This was a most troublesome proposal. First, how can one foresee what companies will be affected? Second, we at the University of California have learned that all research projects are unique. They often require difficult judgments by reviewers. For example, sometimes important exploratory research sponsored by a closely held venture capital firm in which an investigator has a $10,000 investment warrants ad hoc review while an unrestricted gift from a large corporation in which a PI has a $100,000 interest is acceptable because the gift poses insignificant potential for influencing the research. Most often, financial interests in private sponsors of research have little relation to the research sponsored. Finally, it is clear that absolute disqualification will certainly prevent extremely important research in some cases.

The proposed NIH/ADAMHA Guidelines permitted granting of waivers by the institution if the institution determined that such holdings did not have the potential for influencing research results, the reporting of research results, direction of research, or putting the individual in a situation of being able to derive special advantage because of information obtained during research. All waivers and exceptions would have been reported to NIH/ADAMHA before an award could be accepted.

Our experience at the University of California suggests that by far the largest number of disclosures will fall in the waiver category. In fact the University of California recently instituted expedited review and a streamlining of the disclosure process because about one-third of all disclosures present minimal to no potential for financial conflict of interest.

Even though it may be reasonable to question the objectivity of researchers with economic interests in companies whose drug or device is under study, the most effective approach is to require that these conditions be disclosed and reviewed and modified or restricted as appropriate to the case.

5. Recognize that there will *be* substantial institutional *costs associated with even a* limited *disclosure and review policy.*

There are substantial costs associated with implementing current University policy in the form of staffing, faculty time, record keeping, and information dissemination. The University estimates, based on the requirements of the proposed NIH/ADAMHA Guidelines and its experience, that the Guidelines would apply to approximately 52,000 individuals, would require about 156,000 hours a year for review, and would generate almost three million pages of paper a year. The annual cost for this one institution would be $9.4 million.

6. *Protect and advance other institutional goals such as openness,* dissemination, *expanded relations with industry, and technology transfer.*

The NIH/ADAMHA Guidelines prohibited sharing of information generated by NIH/ADAMHA-funded research with any company "with which a conflict exists" until the information or research products are made publicly available. This together with the prohibitions on financial relationships will chill interaction with industry.

The transfer of advanced technologies from research laboratories to private companies is a long-term process. It involves consulting relationships and exchange of information between university scientists and industry about the work in progress. Given the uncertainty created by these proposed Guidelines, an investigator who depends mostly on federal funding might very well have decided it isn't worth sharing information or pursuing collaborative arrangements with industry.

Restricting exchange of information before publication would adversely affect federally funded studies as well. In connection with FDA approval in carrying out the review of human subjects, development of new drugs and treatment may require sharing of information before publication.

Conclusion

The whole system of university science - competition for leadership, for support, for honors, with external peer reviews and internal critical evaluation - is designed to minimize any concern about bias in results. The system has produced unexcelled science and increasingly effective

university relations with the private sector. Although it certainly is not a perfect system, an occasional bad actor or confused investigator does not demonstrate that the system of science needs a major overhaul. Is there any need for additional federal guidance in this area? What is required by related federal laws and regulations? What has been NIH /ADAMHA experience with particular conflict-of-interest problems? How are institutions managing them? These are questions that need to be addressed before proceeding with federal rule making on conflict of interest in research.

Addressing Conflict-of-Interest Issues: The Crucial and Multiple Roles Played by Research Administrators

John M. Mishler

Abstract. When conflict-of-interest issues affect research programs and sponsored activities, those individuals who are engaged in research administration may undertake several crucial roles: (1) Participant and/or Advisor (in conjunction with appropriate faculty members, students, and other senior administrative personnel) in the formulation, implementation, and subsequent oversight of institutional policies and guidelines that specifically address such concerns; (2) Counselor to develop ways of avoiding conflict-of-interest situations (e.g., creation of fee-for-service agreements, a confidential "hotline" for advice or consultation, and reporting/disclosure methods); and (3) Mediator-Expeditor between different parties (i.e., institution, faculty, students, and external constituencies), insuring that campus-wide policies are upheld while safeguarding the rights and privileges of the individual.

Introduction

Conflict-of-Interest Issues: General Overview

By its most elementary definition, "A conflict of interest may. . . arise whenever a. . . person's duty to the University is improperly diluted by or adverse to that individual's interest in or responsibility toward another entity or person."[1] "A person's duty" includes obligations undertaken by faculty members, administrative staff, and students. In a more extensive sense, conflict of interest is not limited to the individual; newer definitions include those associated with private and public institutions.

Issues of conflict of interest, as well as those pertaining to ethics in academia.[2,3] and scientific fraud / misconduct,[4-6] are undergoing renewed evaluation within the field of higher education. In particular, this renewed attention to conflict-of-interest issues has been fostered

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by the complex set of cooperative vehicles established by universities, the industrial sector, and project directors to encourage joint research endeavors.[1,7] These innovative devices have taken the form of direct support of research (vis-a-vis gifts, grants, or contracts), faculty consulting, personnel exchanges, continuing education programs, membership on advisory boards, use of fee-for-service arrangements, tripartite agreements involving university, industry, and government, etc.[1,7-11] As these cooperative vehicles multiply in number and subsequent complexity, it could be argued that there will also occur a direct and parallel growth in conflict-of-interest issues.

Within the present academic setting, the majority of conflict-of-interest cases involve: (1) institutional interactions with external and, at times, internal entities, [1,7,8,12,13] or (2) misunderstandings between faculty and/or staff members and their respective institutions (Note: This category may be expanded to include instances of conflict of commitment),[7,12-15] or (3) problem situations that involve faculty members and their colleagues or students.[9,16] Not all conflict-of-interest cases involve sponsored activities or financial gain; e.g., conflict of commitment and improper utilization of one's institutional position would fall under this category.17

Appropriate institutional Responses to Resolving Conflict-of-Interest issues

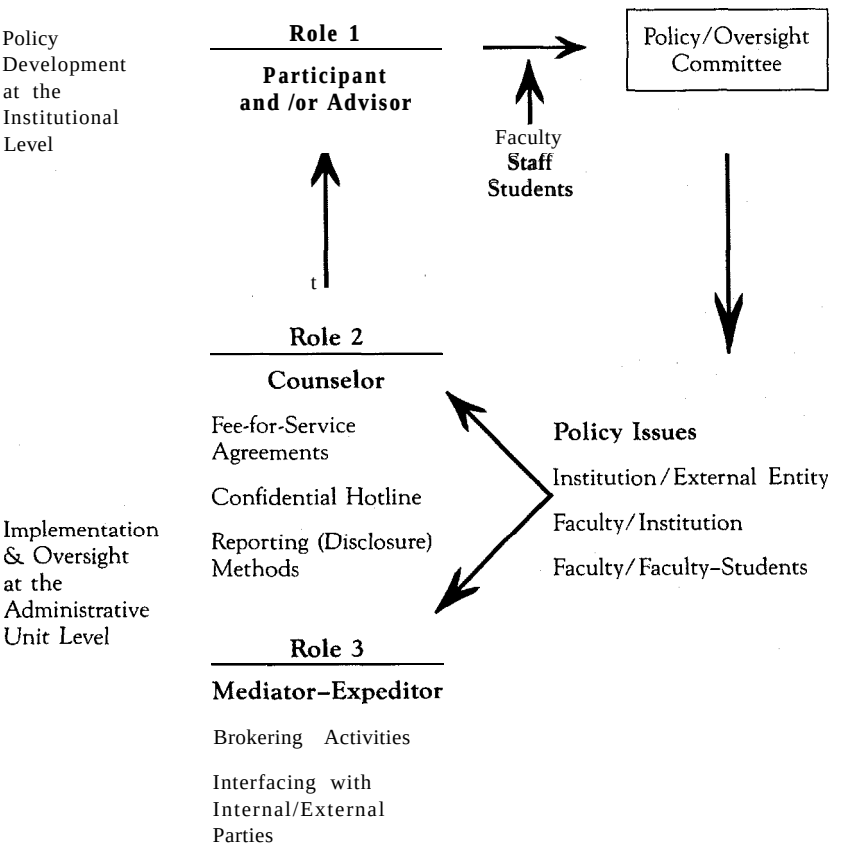
Given the complex nature of cooperative research ventures, an institution of higher education may be well-served by establishing a Policy/Oversight Committee (Committee) composed of administrative staff, humanities and scientific faculty members, and students.[16] Membership on the Committee must be broad-based in order to represent the general concerns of the campus-at-large as well as the specific concerns of diverse disciplines. The Committee's wide representation will thus enable it to better discern the situations that foster inappropriate institutional and personal behaviors.

The Committee's overall responsibility must be to create uniform, defined, comprehensive, and specific policies as a means to adequately measure and judge the appropriateness of institutional and personal interactions with a variety of internal and external entities.[1,12,17] Within this charge, the operative word is *appropriateness,* for the Committee must determine how new arrangements could affect an institution's mission, philosophy, and overall purpose. [1,12,18] In creating these policies on the appropriateness of interactions, the Committee should address an extensive list of issues and situations where the institution, faculty, staff, and students are involved with commercial enterprisess[8,10,13] (especially in circumstances where either a faculty

member or institution involved in a joint research venture may have stock, stock options, or some controlling influence in the commercial company involved in the ventureg), publication rights,', l[6] copyright or patent rights,1,7,8,10 trade secrets,1 indirect cost recovery rates,1 etc. (see Figure 1).

Figure 1

Multiple Roles Performed by Research Administrators



Once these in-depth policies have been debated and subsequently formalized they must be implemented. The implementation and oversight stages, however, are not static; the various policies should be assessed on a regular basis to ascertain if they still remain viable and appropriate in addressing new and ongoing relationships and arrangements.[12,17]

Role of Senior Academic Officers

Senior academic officers participate in the formulation, implementation, and subsequent oversight of campus-wide policies on conflict-of-interest issues at several key junctures, e.g., establishment of and charge to the Policy / Oversight Committee, appointment of Committee members, and review (and initial approval) of proposed policies, guidelines, regulations, etc. In preparing for these critical tasks, senior academic administrators,[19-21] deans,[19] and department chairpersons,[19,22] will find that handbooks describing their duties and responsibilities offer little or no pertinent counsel on methods or mechanisms to resolve conflict of interest. An exception to this general observation can be discovered in advice offered to deans. In conflict-of-interest cases involving misunderstandings between faculty members and their respective institutions, Tucker and Bryan[15] suggest that prior to meeting with the faculty member in question, the dean should confer with the appropriate chairperson. These two authors also state that a dean should never render a decision until he or she fully understands the situation and the campus-wide policies that govern its circumstances. At no time in their discussion of handling conflict of interest do Tucker and Bryan suggest that a dean consult the Policy / Oversight Committee, senior academic officers, or research administrators.

The absence of timely methods to assist senior academic officers in managing conflict-of-interest issues has left a void in the communication and decision-making processes utilized by these officials. Yet, as the following discussion will show, research administrators can play crucial roles in mitigating such voids. For example, by virtue of their institutional duties and training, research administrators interact with a variety of internal and external parties; thus, they are in a suitable position to more fully appreciate the requirements of each party, and, therefore, anticipate the circumstances in which conflict of interest may occur.

Roles Played by Research Administrators

General Background

Several comprehensive studies in research administration have documented who research administrators are as managers,[23] what duties they presently perform,[24] and, in some instances, how research administrators should execute their obligations.[25-29] With respect to issues of conflict of interest, scant information is available to guide research administrators. One solution to this dilemma may entail the identification of new, more focused roles for research administrators

at two separate but interchangeable levels within the institution, e.g., at the campus-wide and the local administrative unit levels (see Figure 1). As a Participant and/or Advisor to the Policy/Oversight Committee, research administrators may assist in the formulation of campus-wide conflict-of-interest policies (Role 1). During subsequent implementation and oversight stages, research administrators undertake additional roles within their own respective administrative units (Roles 2 and 3). The experience gained from dealing with front-line issues can be further utilized to reinforce their campus-wide advisory function (Role 1). Thus, this closed-loop scheme allows research administrators to be involved with policy development at an institutional level, and implementation and oversight responsibilities at the administrative unit level.

Role I

As Participants on and/or Advisors to the Policy/Oversight Committee, research administrators are valuable sources of much-needed practical information and experience, qualities that are all the more relevant because they are influenced by contact with both internal and external constituencies. In regard to outside constituencies, Alvin C. Eurich[25] stated, "The administration of sponsored research in the university is one of the crucial areas in [higher education]. For here the university and the surrounding [business sector, public and private agencies, etc.] work out the terms of their symbiotic relationship." These external relationships may provide the milieu for conflict of interest, and so the terms and conditions under which these interactions occur are important aspects which research administrators can offer to the Policy/Oversight Committee membership, vis-a-vis in Role 1, as tempered by experience gained in Roles 2 and 3 (see the following).

In regard to internal constituencies, research administrators should have routine access to the sound counsel advanced by two important groups: faculty research advisory bodies (e.g., University Research Board, Faculty Research Council, etc.) and fellow administrators and staff members, especially in circumstances where the total spectrum of pre-award, award, and post-award sponsored activities are not located within a single administrative unit. Concerning faculty research advisory bodies, direct participation by research administrators is recommended; if this is not possible, collection of written documents (e.g., meeting minutes, policies, guidelines, etc.) may be useful. Such faculty research bodies are reliable, campus-wide barometers of the climate for research, and they offer quite valuable perspectives. Fellow administrators and staff members can add much-needed support to the advisory duties housed within Role 1 in addition to coordinating the implementation

and oversight strategies associated with Roles 2 and 3. In organizational settings where sponsored program activities cross jurisdictional lines of authority, it may be both prudent and efficient to establish an interdepartmental advisory committee as a means to process the flow of relevant information concerning external relationships and the potential for conflict of interest.[30]

Role 2

One of the more crucial roles performed by research administrators is that of a Counselor to faculty, staff, and students in developing ways of avoiding conflict-of-interest situations. In fulfilling this Counselor function, Mooney[28] proposed a set of relevant management strategies including planning effectively, being creative, and adopting high standards of excellence. Another important strategy which must also become part of an effective research administrator's approach to management (especially in the context of handling potential conflict-of-interest cases), is anticipating a myriad of troublesome circumstances. [1,19,31] In an effort to both anticipate and avoid conflict of interest, it has been suggested that research administrators create "checklists" in advance of formulating new university-external party relationships; such a checklist would identify areas of concern and recommend appropriate means of protection.[7,12]

In this proactive role as Counselor, research administrators should introduce methods to encourage compliance with institutional conflict-of-interest policies. Examples of such initiatives might include:

- Fee-for-Service Agreements

  In the performance of outside consulting activities, a faculty or staff member may be required to use university-owned property, facilities, or equipment. In an effort to mitigate against the unauthorized use of such items, research administrators should create suitable instruments to allow faculty and staff use of these items under agreed-upon terms and conditions.' In cooperation with senior administrative officers, deans, and department chairpersons, fee-for-service agreements could be developed to address such issues as: (1) full recovery, if possible, of both direct and indirect costs; (2) liability concerns; (3) ownership and utilization of generated data, materials, and software; (4) publication, copyright, and patent rights; (5) methods of payment; etc.

  In some instances it may be beneficial for research administrators to issue regular newsletters, bulletins, or special mailings in which fee-for-service agreements are discussed in detail for faculty and

staff members. In such mailings research administrators might urge interested parties to contact them directly about these forms of university-external party agreements.

- Reporting (Disclosure) Methods

  In association with the appropriate administrative office (e.g., Office of Academic Affairs, Office of the Provost, etc.), research administrators should adopt relevant disclosure policies to reduce the impact of conflict of interest.[13] Ideally, reporting methods should be of two types: (1) Annual Consulting Questionnaire. Faculty and staff members would be asked to complete annual standardized consulting questionnaires providing information pertaining to: whether or not a consulting service or activity was rendered; the type of external entity for whom the service or activity was rendered; the type of service or activity performed (e.g., execution of research project, membership on advisory board, telephone consultation, or review of company reports, manuals, or brochures, etc.); use, if any, of university-owned property, facilities, or equipment (and, if any of these said items were utilized, was a fee-for-service agreement implemented?); and employment, if applicable, of other staff, students, or faculty members; and (2) Principal Investigator(s) Disclosure Statement. Under this category, the principal investigator(s) must complete a standardized form indicating any direct or indirect monetary dealings with the supporter(s) of the intended research endeavor. If there are monetary dealings, a review will be conducted to ascertain the nature and degree of interest; a real or potential conflict of interest may disallow the acceptance of the sponsor's support.[9]

  The routine review of both Consulting Questionnaires and Disclosure Statements will allow research administrators to aid faculty and staff members in anticipating and avoiding potential conflict-of-interest situations. For example, the annual inspection of Consulting Questionnaires may reveal some personal circumstance that could be perceived as violating institutional policy. By working directly with the faculty or staff member in question, research administrators may be able to suggest viable alternatives, thus avoiding the appearance of a conflict of interest.[16]

- Confidential "Hotline"

  As previously noted, efficient research administrators anticipate untoward circumstances.[1,19,31] Establishing an informal, confidential "hotline" (i.e., any system, including mail, individual or group meetings, or telephone service, that allows the transmission

of confidential information) is a simple, cost-effective device that would help research administrators anticipate and apply early-avoidance strategies to conflict-of-interest situations. Faculty, staff, and students could use this hotline to contact research administrators regarding institutional conflict-of-interest policies.

Role 3

Quoting again from Alvin C. Eurich,[25] "The [person] who administers research is at the interface between the university and [the business sector, public and private agencies, etc.]. And interfaces mean friction, constant change, wear and tear." When dealing with traditional institutional matters (e.g., grants and contracts administration) as well as conflict-of-interest issues, research administrators should assume a Mediator-Expeditor[26] or Liaison[27] role at the interface between the various bodies (i.e., institution, external entities, and project directors) striving to achieve a common objective.

As a Mediator-Expeditor, research administrators are in a unique position to significantly reduce the occasional difficulties and misunderstandings between principal investigators and sponsors. Nowhere is this more the case than research under the sponsorship of private organizations such as biotechnology companies and pharmaceutical firms. Here a multitude of circumstances (e.g., consulting arrangements, fee-for-services, use of facilities and/or equipment, elimination of indirect costs, employment of personnel, etc.) may be present to provide an environment for conflict of interest. In efforts to reduce conflict-of-interest situations concomitantly with promoting enhanced research opportunities, several universities have initiated a novel system to "broker" projects between their faculty members and private biotechnologys[32] or pharmaceutical[33] sponsors. In these cases the research administrator is both a Mediator-Expeditor and a Broker. This dual role is advantageous in helping to eliminate most conflict-of-interest situations as all correspondence, telephone inquiries, financial transactions, coordination of IRB activities, etc., are funneled directly through the Mediator-Expediter/ Broker.[33] In most situations, then, principal investigators and sponsors never interact regarding institutional procedures or financial matters; their discussions are somewhat restricted to the research protocol/project itself.

Partnerships between industry and institutions of higher education must be formed with care; differences in management and decision-making styles, for example, must be considered.[34] The exact nature of the relationship, whether it be teaming agreement, subcontract, or contract, is essentially defined by considering a "common checklist"

of operational elements, i.e., budget, schedule, scope of work, personnel, patent rights, etc.[7, 17, 35-37] As a Mediator-Expediter/ Broker, research administrators reduce the friction at the interface between principal investigator and sponsor by directly negotiating these operational elements with respect to institutional regulations, especially conflict-of-interest policy. In this context, as well as in a myriad of other circumstances, the Mediator-Expediter/Broker is: (1) the agent of interface between the institution and the external entity; (2) an expert on contractual matters, thus saving faculty and staff time and effort in formulating agreements; and, as a Broker facilitating the placement of clinical trials,[33] the research administrator is (3) a funnel for directing the procedural and financial relationships between faculty and staff and interested private organizations.

Conclusions

Conflict-of-interest situations will increase in number and complexity as institutions of higher education and private sector organizations accelerate their use of cooperative agreements. One solution to combating conflict of interest is to recognize its possibility and establish appropriate steps to mitigate against its occurrence. Steps may include creating a Policy/Oversight Committee to develop institutional policy, involving senior academic and administrative officers in the process and, when possible, allowing research administrators to perform crucial roles as Participant and/or Advisor, Counselor, and Mediator-Expeditor (see Figure 1). Placement of all three roles within an institution creates a closed loop of information gathering and sharing, an essential element in understanding and dealing with conflict of interest. Research administrators also can be authors of useful strategies to eliminate conflict-of-interest situations, providing fee-for-service agreements, reporting (disclosure) methods, confidential "hotlines," and brokering functions.

An opinion often expressed by other academic administrators regarding the duties and responsibilities of research administrators is that such functions are support or service activities, which are somewhat passive in nature.38 The present report, however, has indicated that at the interface between the university and external parties research administrators can play crucial and proactive roles with respect to conflict-of-interest issues: providing sound counsel on the promulgation and oversight of campus-wide policy (Participant and/or Advisor); serving as a Mediator-Expeditor between different internal /external constituencies; and, as a Counselor, creating new strategies to avoid conflict of interest. As university-industry relationships expand in complexity, research

administrators will be expected to assume even greater and more crucial roles in safeguarding institutional rules and regulations.

Finally, it could be argued that these crucial roles played by research administrators in dealing with issues at the interface between the university and external parties can also be applied against the management of internal research-promoting endeavors. In support of this observation, recent studies [39-42] have clearly indicated that research administrators are vital components within any system that creates, organizes, and promotes an institution's program of sponsored research.

Acknowledgment

I should like to express my appreciation to Sigrid R. E. Fischer-Mishler for her invaluable assistance in the preparation of this report.

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Reports/Observations

Proposed Guidelines for Policies on Conflict of Interest

developed by

The National Institutes of Health
and
The Alcohol, Drug Abuse, and Mental Health Administration

PROPOSED POLICY

Research activities supported by NIH or ADAMHA must be conducted in an objective manner, free of any potential for undue influence arising from the private financial interests of those responsible for the conduct of the research. Public funds must be expended to advance public purposes, in this case, the conduct of biomedical and behavioral research. Private financial interests can adversely affect the accomplishment of this public purpose by directly affecting the manner in which the research is conducted, by creating the appearance that the research has been influenced by those financial interests, or by inhibiting the dissemination of research results.

Recipients of research funds are responsible for ensuring that the funds are expended for the public purposes for which they were awarded. As part of this responsibility, recipients must adopt procedures that will prevent the research from being influenced or potentially influenced by the private financial interests of those responsible for the conduct of research. The following proposed guidelines establish minimum standards for the procedures to be adopted by recipients, including identification of those financial interests which are incompatible with the need to ensure that publicly funded research is conducted objectively.

Abstracted from "NIH Guide for Grants and Contracts:' Vol. 18, No. 32, September 15, 1989.

I. Proposed Responsibilities of NIH and ADAMHA, Awardee Institutions, and Individuals:

A. NlH AND ADAMHA:

The NIH and ADAMHA are responsible for formulating and disseminating conflict-of-interest guidelines to assist institutions to develop their own conflict-of-interest policies. The NIH and ADAMHA also are responsible for:

- In specific instances, reviewing institutions' conflict-of-interest policies.
- Routinely reviewing actions that the institutions have taken with respect to waivers and exceptions.
- Assuring that the necessary terms and conditions are discharged satisfactorily prior to making an award. In the absence of fulfillment of the necessary terms and conditions, funding may be affected.

B. AWARDEE INSTITUTIONS:

Institutions that receive NIH or ADAMHA funds are responsible for establishing and implementing policies and procedures in accord with this draft issuance. Upon request, institutions shall provide copies of their policies and procedures and information regarding their implementation to the appropriate NIH or ADAMHA officials. The institutions also are responsible for:

- Maintaining records of disclosures made and actions taken regarding persons associated with any NIH or ADAMHA award for a period of at least three years beyond the termination of that award.
- Promptly notifying the funding agency if they identify any practice or situation involving a conflict of interest which could potentially affect one or more NIH or ADAMHA-supported projects.
- Resolving any failure to comply with these proposed guidelines prior to accepting an award.

Policies

Each institution that applies for assistance to the NIH or ADAMHA for any project or program that involves the conduct of biomedical or behavioral research shall certify by the institutional signature on its application or proposal that it has institutional policies in place that are in accord with this draft issuance or will have such policies in place no later than the date that any award would be accepted.

Institutions are encouraged to adopt policies that build upon this framework and reflect their specific needs and situations.

Education

Institutions are expected to establish a means of informing all investigators applying for or receiving funding from the NIH or ADAMHA, as well as all relevant research employees, consultants, and administrative staff at that institution who are in a position to make decisions about or to affect the outcome of the research, of the institutional policies covering conflicts of interest. This information should include, at a minimum, identification of prohibited financial interests, disclosure procedures, and sanctions for non-compliance.

C. INDIVIDUALS:

These proposed guidelines apply to all investigators, key employees, consultants, and persons with primary management, advisory, or supervisory responsibilities for NIH- or ADAMHA-funded research, and all persons who are in a position to have a critical influence on, or substantive control over, that research. Those persons are responsible for avoiding circumstances that would put them in a conflict-of-interest situation with that research. These provisions also apply to the spouses, dependent children, and other dependents of the individuals mentioned above.

Full disclosure of all financial interests and outside professional activities, by all who are in a position to make decisions concerning one or more NIH- or ADAMHA-supported projects, shall be made to the institution at the time a research application or proposal is submitted to the NIH or ADAMHA. This shall include the financial interests of their spouses, dependent children, and other dependents. These disclosures shall be updated to the institution annually.

All individuals for whom these proposed guidelines apply shall comply with the conflict-of-interest policies of the institutions through which the NIH or ADAMHA funding is provided and shall report immediately any conflicts of interest to the appropriate institutional officials.

II. Disclosures:

Full disclosure of all funding other than that from the applicant institution is required of all personnel of awardee institutions as described above who are currently involved in, or currently applying for, research funds from NIH or ADAMHA. This disclosure includes support for laboratory activities, special instrumentation or other products, services, consultancies, honoraria, and other benefits.

All disclosures and waivers shall be reviewed at the institution in a timely manner by knowledgeable and objective individuals appointed by institutional officials. In order to assure timely and objective evaluations, institutions may wish to appoint a panel of at least three members, one of whom has no institutional affiliation and one of whom is the institutional official responsible for signing the grant application or contract proposal.

Confidentiality shall be maintained at all times unless that confidentiality would interfere with the interests of the institution or the federal government.

Institutions may grant waivers in unusual situations when it can be demonstrated that the financial interest is so insignificant that it would not compromise the objectivity of the research results or the interests of the federal government or the public. The NIH or ADAMHA shall be informed within thirty days of any such waiver granted to an individual involved in any way with a NIH- or ADAMHA-funded project related to the waiver.

If a conflict-of-interest situation is identified that involves one or more NIH- or ADAMHA-supported project(s), the NIH or ADAMHA and appropriate institutional official(s) shall be notified immediately, and the institution shall take immediate steps to safeguard Federal funds until such time that the conflict-of-interest situation is eliminated.

Disclosure information shall be updated to the institution at least once per year. Changes that could reflect possible conflicts of interest should be reported immediately to the responsible institutional official(s).

The institution shall maintain records of disclosures, waivers, and of all actions in response to review of disclosures for personnel associated with NIH- or ADAMHA-supported projects for a period of three years after the termination of that project.

III. Prohibited Situations:

Institutions may establish their own policies on prohibited situations. However, the following are basic standards for all institutions.

1. No investigator, key employee, consultant, or other persons with primary research, management, advisory, supervisory, or purchase authorization responsibilities, or their spouses, dependent children, or other dependents, shall be allowed to have personal equity holdings or options in any company that would be affected by the outcome of the research or that produces a product or equipment being evaluated in the research project. This does not apply to equipment or products that are commonly found in

research laboratories, such as commercially available centrifuges, pH meters, and common reagents. This prohibition does not include blind trusts, diversified mutual funds, or other financial interests over which the individual investor has no discretionary control. The institution may grant a waiver to this requirement if it determines that such holdings are so insignificant they do not have the potential of influencing research results or the direction of the research.

2. Information and/or research products derived from NIH- or ADAMHA-funded studies shall not be shared with any company with which a conflict exists unless or until the information or research products are made publicly available.

3. Specific requirements shall apply if an investigator, key employee, consultant, or other involved person receives funds from NIH or ADAMHA as well as commercial funding, for any of their research, as follows:

   All research funding for all research projects must be disclosed as required in the appropriate sections of applications and proposals to the NIH or ADAMHA (under the "Other Support" section), as well as to the institutional official(s) responsible for conflict-of-interest review.

   Institutional conflict-of-interest reviews need to be particularly careful to ensure that private companies are not in a position to influence the research plan, results, or the reporting or interpretation of results of NIH- or ADAMHA-supported research.

   An investigator, key employee, consultant, or other involved person may not receive honoraria, fees for service, or a management position from a private source if that individual is involved in an NIH- or ADAMHA-supported project that is evaluating or testing a product of the source. Honoraria, fees for service, or management positions from other sources are allowed provided that their acceptance does not jeopardize the recipient's objectivity with respect to the NIH- or ADAMHA-supported project or result in special access to information that is not publicly available, and that full disclosure is made to designated institutional officials. For example, care must be taken to ensure that the private company has no role in any decisions that would impede the standard practices for the publication or other dissemination of research results related to NIH- or ADAMHA-supported research.

IV. Criteria for Waivers and Exceptions:

The institution may grant waivers in certain circumstances if it determines that such holdings do not have the potential for influencing research results, the reporting of research results, the direction of the research, or putting the individual in a situation of being able to derive special advantage because of information he/she has available through the NIH/ADAMHA research results.

All waivers and exceptions shall be reported to the Deputy Director for 'Extramural Research, NIH, if they relate to NIH-supported projects, or to the Associate Administrator for Extramural Programs, ADAMHA, if they relate to ADAMHA-supported projects, prior to accepting an award or, if disclosure is made after the award, within thirty days of granting the waiver or exception.

The NIH or ADAMHA may allow a conflict-of-interest situation to exist if it has been reported to NIH or ADAMHA and the agency determines that this is in the best interests of the public and of NIH or ADAMHA.

V. Remedies:

If situations involving a conflict of interest related to NIH- or ADAMHA-supported research are discovered, the awardee institution has the first responsibility to resolve the problem. If the institution does not resolve the problem in a timely manner, then the NIH or ADAMHA will take action.

Awards will be made without prejudice if prohibited conflict-of-interest situations are rectified prior to the award date.

Institutions are required to notify the funding agency immediately if prohibited conflict-of-interest situations are detected or develop after awards have been made and the conflict is not resolved promptly.

NIH or ADAMHA may include special terms and conditions in an award if (1) an institution is not complying with these proposed guidelines or (2) to resolve a conflict-of-interest situation that has not been resolved by the institution. Failure on the part of the institution to meet these special terms and conditions could affect funding.

Comment on NIH/ADAMHA Proposed Guidelines on Financial Conflict of Interest

(Note: The Editor requested members of the Editorial Advisory Board to share *their institution's response and /or their personal* views *about the NIH/* ADAMHA *proposed regulations.)*

COGR RESPONSE TO PROPOSED GUIDELINES:

COGR welcomes the opportunity to comment on the proposed guidelines for policies on conflict of interest published in the NIH *Guide* for Grants and Contracts on September 15, 1989. We share with NIH/ADAMHA the commitment to assure that research is conducted in an objective manner, free of undue influence which might arise from inappropriate personal financial interest. However, we express our serious concern about the proposed policy, on behalf of our membership which includes one hundred and thirty-five of the leading research universities in the United States.

While we support efforts which encourage institutions to develop appropriate policies to deal with potential conflicts of interest, we believe that the NIH/ADAMHA proposed guidelines are too broadly framed. They attempt to establish an unnecessarily complex system of disclosures and review for most instances of multiple research support; rather they should focus on the far fewer instances where there is potential for abuse. The NIH/ADAMHA proposal is too prescriptive regarding what activities are unallowable. We believe that the guidelines should provide a framework within which individual institutions can review possible conflict situations and make determinations on the merits of each case. The goal here is to manage potential conflicts through review and disclosure, not to eliminate them. The only way to eliminate conflicts would be to prohibit university-industry cooperative arrangements.

We believe that review and disclosure are essential but that they should be narrowed to research having a commercial relationship, i.e., testing of products, processes or improvements thereto, having potential commercial value. Further, such disclosure and review should

focus on related personal financial interests which a person receives from a private company which has a direct and immediate interest in that person's research.

Our institutions have in place policies and procedures that address the overall integrity of the research enterprise. Many of them are assessing the impact of new arrangements between faculty and industry sponsors with the intent of upgrading those policies and procedures. These NIH/ADAMHA guidelines require careful reassessment. As proposed they cannot be supported by the academic community. NIH/ADAMHA has overreached in defining the types of projects to which the guidelines apply, the specific individuals to be subjected to disclosure requirements and the financial arrangements which should be categorically not allowed.

The proposed policy appears contradictory to P.L. 96-517 which encourages technology transfer and licensing of publicly funded research. It thereby occupies the same track as a multitude of significant relationships which have evolved between the federal government, private industry, universities, venture capital companies and state and local governments. The NIH /ADAMHA policy is moving on the same track, but it is running in the opposite direction to economic development and international competitiveness. These mixed signals are not only confusing, but also severely undermine cooperative university-industry research relationships.

In summary, although we share the same goals as NIH/ADAMHA with respect to safeguarding the integrity of the research process, we object to the extensive coverage of the proposed conflict-of-interest policy. The NIH/ADAMHA proposal lacks definition, converts normally accepted university-industry collaborations into exceptions or waivers, is contrary to existing governmental economic development policy (both within states and among federal agencies) and negatively affects the transfer and commercialization of technology. Unless fundamentally reconsidered, the proposed policy could have a negative effect on federal programs which have been launched to encourage and explore cooperative research between universities and industry. Significant relationships could be disturbed that arise from these cooperative ventures, which contribute to this country's competitive position in world markets. In the attachment to this letter, we expand on the individual points of concern listed above and present alternatives for consideration. We would be pleased to work with you on these issues.

COGR Attachment - Issues for Consideration

1. Research Covered by the Policy

All research activities must be conducted in an objective manner. However, we believe that it is reasonable to agree that only certain types of activities have the potential for inappropriate influence arising from the personal financial interests of those who have influence or control over the research. This is notably research having a commercial relationship. We would characterize it as NIH or ADAMHA funded research which involves the development, evaluation or testing of products, processes or improvements thereto, having potential commercial value to or which may reasonably have a substantial effect on products or processes of a commercial organization.

2. Related Personal *Financial Interests*

Blanket disclosures will not be instrumental in achieving our common goal; rather, they will frustrate it. An NIH/ADAMHA policy should be applicable only to investigators. These are in fact the individuals who have a critical influence on or substantial control over the research. We propose, therefore, that NIH /ADAMHA focus only on the financial interest which an investigator responsible for NIH/ADAMHA supported research acquires or receives from a commercial relationship which has a direct and immediate interest in that person's research.

3. Scope of Financial Interests

The NIH/ADAMHA guidelines "prohibit personal equity holdings or options in any company that would be affected by the outcome of the research or that produces a product or equipment being evaluated in the research project!' This prohibition is overreaching and should be narrowed to individuals who are "directly and substantially" affected. The scope of financial interest should be further narrowed in accordance with the points made here and our point 5. below, which deals with "Reviewing and Resolving Related Personal Financial Interests." Decisions regarding personal financial interests are dependent on the nature and degree of that interest; therefore, such decisions should be made by the institution according to the individual circumstances and not by general fiat.

With regard to dependents, such financial interests should only include those of spouses, dependent children and other dependents to the extent these interests are reasonably known to the investigators, over which he/she exercises shared or sole discretionary control or

influence, and from which the investigator can reasonably expect to substantially benefit, directly or indirectly.

Financial interests should not include sharing by the person in licensing income received and distributed by the employing institution or its technology transfer agent, or in equity interest in an institution's licensee when that equity is acquired in lieu of sharing in licensing income.

4. *Disclosures*

Disclosure is a most important tool for preventing bias. However, disclosure requirements should cover only the related personal financial interests which an investigator for NIH/ADAMHA supported research acquires or receives from a commercial relationship where there is a direct and immediate interest in that person's research. These disclosures should be reviewed, but the institution should have the right to resolve situations involving financial interests. (See point 5.)

5. Reviewing and Resolving Related Personal Financial Interests

The institutions are capable of and should be relied on to review and resolve situations involving related personal financial interest. This review might result in the following types of decisions.

1. No Conflict - The financial interest is supportive of or otherwise not in conflict with objectives of the NIH or ADAMHA supported project, or contributes materially to the transfer of technology produced in performance of the project.
2. Insignificant *Conflict* - It can be demonstrated that the personal financial interest is so insignificant that it would not compromise the objectivity of the research results or the interests of the federal government or the public.
3. *Resolved Conflict* - The potential conflict has been eliminated, reduced to insignificance or effectively controlled in a timely manner, pursuant to the institution's policy and consistent with the definitions in l., 2., and 3. above, and federal funds have been adequately safeguarded.
4. Unacceptable *Conflict* - The university determines that an unacceptable conflict of interest exists, which might be resolved only by an individual's divestiture of respective interests or by declining federal funds. We believe that the institution should have full responsibility for making such determinations and for implementing these decisions.

Conflict situations thus resolved may be permitted to proceed. Conflict-of-interest situations not resolved pursuant to the four options above should be reported to NIH/ADAMHA for a determination.

6. Information and Research *Products*

Industry's wisdom and perspective quite apart from its financial support are essential ingredients for the research environment. The free flow of communication between faculty and industrial colleagues must be reasonably protected. Attempts to restrict information flow would have a chilling effect on any real cooperation between the parties. Information and/or research results derived from an NIH/ADAMHA funded study may be shared with a company with which a conflict has been resolved, as in 5 above, and such information or research results will be made publicly available in accordance with accepted academic practice.

Milton Goldberg
Council on Governmental Relations (COGR)
(letter to Dr. Katherine Bick, December 11, 1989)

UNIVERSITY RESPONSES:

The University differs strongly, however, with NIH on certain of the proposed procedures for implementing the policy. In general, the University feels that educating and sensitizing staff about conflict-of-interest concerns can be accomplished by statements of policy in the NIH application kit as well as through many internal mechanisms in the University. Our University publicizes these matters in manuals, campus publications and public discussions, and convenes special oversight committees to review potential conflict when necessity so dictates. The conflict-of-interest policy is referred to on all internal routing forms before a funding proposal leaves the University.

An acknowledgment by the investigator that assures understanding of and compliance with our conflict-of-interest policy should be sufficient. Such a statement is as valid as a disclosure of financial interests. Both documents require the institutional reviewer to accept the statements given. Indeed, universities operate, and have always operated, on the basis of acceptance in good faith of assurances by their faculty members, staff members, and students of compliance with applicable regulations. Unless a credit check similar to that which some financial institutions require before issuing mortgage loans is made, if a person were to choose deliberately to circumvent the policy, the disclosure could be incomplete, and as invalid as if an investigator signed

a dishonest assurance of compliance with policy standards. Ultimately, the reviewer must rely on the honesty of the person providing the information or assurance. Disclosures cannot assure integrity.

Rex Montgomery
The University of Iowa

We suggest the following modifications:

1. Limit their applicability only to those research projects that are product testing in nature, that is, clinical trials as supported by NIH and ADAMHA.
2. Eliminate the specific prohibitions as delineated in the guidelines and allow universities to avoid and/or manage possible conflict based on requiring them to be knowledgeable of such situations and to have policies and procedures in place to address them so as to avoid any possible biasing of research results.

The first modification would certainly allow NIH and ADAMHA to address the type of situations they have encountered in the past and can be expected to encounter in the future, while still permitting the active collaboration of the nation's best faculty with the commercial enterprises (and their scientific staffs) that are striving to make this country competitive again in the world marketplace. If this narrowing of applicability is not made, most of the states' economic development programs, similar to Ohio's Thomas Alva Edison Program, will find it almost impossible to accomplish their goals, at least in the biomedical areas that are funded by NIH/ADAMHA. No company will want to participate in funding a project with the state if they believe they will be subject to restrictions as now proposed by the subject guidelines. Specifically, the prohibition on sharing of research results with the supporting industry only after publication will negate any opportunity that the industry will have to obtain foreign patents and greatly diminish any incentive the company has to file domestic patents. This, in turn, would have a significant negative impact on a company's ability to obtain a fair rate of return on any investment it might make in the research effort. Since NIH is a large provider of basic research funds to the laboratories who are also participating in these state-funded programs, it would be difficult, if not impossible (and certainly not the best way for the university to operate), to attempt to segregate all of the NIH supported research from those efforts being supported by industry, the state, or with university funds. Likewise, by doing this

the entire research effort would be greatly diminished in its output, since results obtained under one funded project could not be used to build a basis for the next project.

The concept that any type of financial involvement must be prohibited in all cases of research is also incorrect. In our capitalistic system the greatest advances are many times made by the biggest risk takers, and they need incentives, more specifically, financial incentives, in order to encourage them to take these risks. To expressly prohibit our best faculty to receive any financial incentives for their efforts would in all probability ensure that they would not participate in these programs. This loss of human resources to our companies, especially to our small companies, would be devastating. Universities need to be able to objectively evaluate possible conflict situations to ensure that no situations are permitted to exist that could improperly influence the research effort. The strict prohibitions as delineated in these guidelines would not give the universities this opportunity.

Frank R. Tepe, Jr.
University of Cincinnati

The peer review processes used by scientists in reporting their work, by universities in making academic personnel decisions and by federal agencies in making funding decisions remain the primary mechanisms for enhancing the integrity of the research environment and detecting bias in conducting and reporting research. The proposed guidelines will not add significantly to these existing procedures. In addition, I assume that researchers committed to ignoring existing policies and procedures could avoid the proposed NIH guidelines now being considered.

If the aim of the proposed guidelines is to avoid bias in conducting and reporting research, I submit that financial interest in the findings of research may not be the major contributor to bias. There are many factors that contribute bias to conducting and reporting research, including, for example, peer recognition, professional rewards, and inadvertent weaknesses in experimental design. Detecting and correcting unintentional bias is part of what we expect from our peer review process. I doubt that disclosure of financial interests in entities who “might profit” from the research will reduce bias any more than disclosure of professional interest in attaining membership in the National Academy of Science. The proposed guidelines fail to acknowledge the role of incentives in the process of science. They could destroy appropriate incentives without altering what some would classify as inappropriate incentives.

We in the university research community have a deep interest in proposals for maintaining and strengthening the integrity of the research environment. We seriously assume our responsibility for the appropriate use of public funds. We are committed to processes that refine and improve our present system for assuring you that we use your resources appropriately and for public benefit. We do not believe, however, that the proposed guidelines, as presently written, contribute significantly to our ability to meet those responsibilities.

Albert A. Barber
University of California at Los Angeles

We urge that the following comments on the specific rules be considered:

1. Disclosure requirements should cover only those personal financial relationships with commercial sources that are directly and immediately related to the research supported by NIH/ADAMHA. The university is the appropriate and responsible party to review any required disclosures and to monitor and resolve potential conflicts of interest.
2. The proposed guidelines require scrutiny of personal financial details of individuals who are only peripherally related to the research. The required disclosures would exceed all reasonable bounds and in the overwhelming majority of cases would be an unwarranted invasion of privacy. The guidelines should be narrowed to cover only those individuals who are "directly or substantially" related to the project work.
3. The rule that would prohibit NIH-funded investigators, their consultants, and the spouses and children of any of those involved from owning stock in any company that might be affected by the outcome of the research is troubling. Beyond our objection to the breadth of this rule, we are opposed generally to a catalog of prohibited situations. Institutions should be permitted to use their own policies and applicable laws to tailor safeguards to the specifics of each situation. The goal should be to find an acceptable way to do the research without compromising the objectivity of the researchers, not to find a way to stop the research if there is even an infinitesimal chance of inappropriate personal gain.

   The spirit of the proposed guidelines seems to violate the commonly accepted dictum that individuals are innocent until proven guilty.

4. The proposed policy may be contradictory to P.L. 96-517 which encourages technology transfer and licensing of publicly funded research. The sharing by the inventor in licensing income received and distributed by the employing institution or its technology transfer agent and the sharing in equity interest in an institution's licensee when that equity is acquired in lieu of sharing in licensing income should be explicitly recognized in the guidelines as acceptable and desirable.
5. The proposed guidelines inhibit the sharing of information and research projects resulting from NIH/ADAMHA funded studies. The normal and highly desirable transfer of information between faculty and industrial research colleagues would be greatly impeded. The rule would probably prevent and would certainly inhibit academic consulting and it also would limit the ability of university researchers to participate in strengthening the nation's economy through technology transfer. These are highly desirable and beneficial activities and we must find a way to encourage them to continue.

   The guidelines would increase bureaucratic obstructions to the transfer of information and could preclude university researchers from the pursuit of research of great potential to the public good.
6. Of particular concern to faculty researchers is the requirement that disclosures be updated once per year and that changes reflecting possible conflict of interest be reported immediately to institutional officials. On its face, this would require that every decision by stockbrokers with regard to portfolios of university faculty and their families be reported.

The reality is that the vast majority of biomedical researchers have neither real nor potential conflicts of interest with respect to their research. The proposed guidelines would require administrative procedures that are dramatically out of proportion to any existing problem, thereby diverting countless hours from the work of some of the nation's most talented citizens into bureaucratic minutia.

Thomas L. Sweeney
The Ohio State University

In letters to the "RMR" Editor several individuals *commented on the proposed guidelines as follows:*

> . . . A workable policy would require principal investigators to self-police and report any possible conflict of interest. This policy should be clearly promulgated on campus. All faculty should be aware that the campus will not tolerate conflicts on research projects.
>
> Then, when a proposal is routed for signature, the principal investigator will file a negative declaration on his or her behalf and on behalf of all those involved in the project, or include disclosure of any holdings that could appear to compromise the research integrity of the principal investigators or any of those who work on the project. This disclosure would be reviewed by the committee proposed by the NIH guidelines, and a decision about whether a waiver of conflict appearance should be issued.
>
> This system won't be perfect. But it will function just as well as the one that is proposed, and with a whole lot less paperwork.
>
> Robert A. Lucas
> California Polytechnic State University, San Luis Obispo

The NIH / ADAMHA proposed Guidelines for Policies on Conflict of Interest has a number of major flaws. Principally, it focuses on the minutiae of exceptions rather than potentials for major conflicts and abuse. Its overall message appears to be to discourage cooperative research with industry, even if that is not the intent.

Further, it represents an overkill approach to the situation, is costly to implement, and is confusing and self-contradictory as written. In the case of specific issues in biomedical research [product testing and evaluation], there should be some correlation with FDA restrictions in this area. In addition it doesn't adequately address remedies for non-compliance nor address the potential conflicts that patents and royalties could create.

True guidelines in this area should focus on accountability, the nature of prohibited relationships or ones that need specific disclosure, and sanctions, rather than micromanagement of local implementation.

This package is billed as guidance but is actually very specific procedural requirements. The implication is that they are voluntary, but the certification requirement appears to mandate that they be followed as written.

Issues not addressed:

. If equity positions represent a potential for conflict, one could argue that potential for royalty income from patents derived under publicly supported work offers the same and perhaps more direct temptation. Where is the line drawn between incentive and conflict? If federal policy is to support technology transfer and increased cooperation with industry, what effects could these policies have on discouraging progress in this area?

- Because so much of the conflict issues are based on product evaluation and testing, there should be some correlation with FDA restrictions in this area and elimination of overlaps, if any.
- Clearly, biomedical product testing and evaluation introduce issues that are unique to NIH/ADAMHA. It should be made clear that whatever the outcome of these conflict requirements they do not necessarily represent a model for other agencies.
- The exception for small businesses leaves other issues unaddressed. On what basis should they be excluded? How are the temptations/conflicts different when the PI is an employee of a profitmaker or has equity ownership? Wouldn't a PI be just as affected by his/ her own firm's profit potential? What about awards to other profitmakers, where employees are likely to have an equity interest as part of their compensation plan? [Or does NIH policy preclude awards to profitmakers other than small businesses?]

William A. Cole
(personal comment)

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