

AAU

TASK FORCE ON
RESEARCH
ACCOUNTABILITY

REPORT AND
RECOMMENDATIONS

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**Report on
Individual and Institutional Financial
Conflict of Interest**

ASSOCIATION OF AMERICAN UNIVERSITIES

TASK FORCE MEMBERS

Steven B. Sample, *Co-chairman*
President
University of Southern California

L. Dennis Smith, *Co-chairman*
President
University of Nebraska-Lincoln

Susan Berry
Professor of Pediatrics
University of Minnesota, Twin Cities

Mark Brenner
Vice Chancellor, Research and Graduate Education
Indiana University

Gary Chadwick
Executive Director, Research Subjects Review Board
University of Rochester

Mary Sue Coleman
President
University of Iowa

Robert C. Dynes
Chancellor
University of California, San Diego

Geoff Grant
Associate Vice President for Research Administration
Stanford University

David Korn
Senior Vice President for Biomedical and Health Sciences Research
Association of American Medical Colleges

Kate Phillips
President
Council on Governmental Relations

Dorothy Robinson
Vice President and General Counsel
Yale University

George Rupp
President
Columbia University

Carol Scheman
Vice President, Office of Government, Community and Public Affairs
University of Pennsylvania

Harold T. Shapiro (*through June 2001*)
President
Princeton University

David Skorton
Vice President for Research
University of Iowa

EX OFFICIO

Nils Hasselmo
President
Association of American Universities

TASK FORCE STAFF

Mollie R. Benz
Legislative Assistant
Association of American Universities

Richard J. Turman
Director of Federal Relations
Association of American Universities

ASSOCIATION OF AMERICAN UNIVERSITIES

Task Force on Research Accountability EXECUTIVE SUMMARY

Research universities are concerned about financial conflict of interest because it strikes to the heart of the integrity of the institution and the public's confidence in that integrity. The Task Force identified several key values which universities want to protect from such conflicts:

- ◆ their commitment to educating students;
- ◆ their commitment to academic freedom;
- ◆ their commitment to advancing the range and depth of knowledge and understanding of the natural world and our human condition;
- ◆ their commitment to the safety of patients under their care and participants in research;
- ◆ their commitment to open and timely communication and dissemination of knowledge; and
- ◆ their commitment to protect both the appearance and the actual integrity and objectivity of research, instruction, and public service.

Transferring university-developed knowledge to the private sector fulfills one of the goals of federally funded research, by bringing the fruits of research to the benefit of society. With this important technology transfer comes increasingly close relationships between industry and universities, which provide benefits but also increases the risk of academic research being compromised in two ways, through:

1) *individual* financial conflict of interest in science, which refers to situations in which financial considerations may compromise, or have the appearance of compromising, an investigator's professional judgement in conducting or reporting research. The

bias such conflicts may conceivably impart not only affects collection, analysis, and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants, and the use of statistical methods; and

2) *institutional* financial conflict of interest, which may occur when the institution, any of its senior management or trustees, or a department, school, or other sub-unit, or an affiliated foundation or organization, has an external relationship or financial interest in a company that itself has a financial interest in a faculty research project.¹ Senior managers or trustees may also have conflicts when they serve on the boards of (or otherwise have an official relationship with) organizations that have significant commercial transactions with the university. The existence (or appearance) of such conflicts can lead to actual bias, or suspicion about possible bias, in the review or conduct of research at the university. If they are not evaluated or managed, they may result in choices or actions that are incongruent with the missions, obligations, or the values of the university.

The Task Force concluded that the problem is rarely a particular conflict itself – rather it is the question about what is *done* with the conflict. In most cases, problems arise when the conflict is not made apparent, or when it is not assessed or managed. Other than in the particular case of research involving human participants, much of the challenge is for universities to develop robust systems so that both types of conflicts are disclosed, assessed, and managed. While with *individual* conflict of interest, the focus is on improving existing management

¹This sentence does not apply to affiliated foundations if the structure of the relationship between the university and the foundation effectively eliminates any potential conflict of interest on the part of the foundation (e.g., if the foundation simply provides financial support for a particular project through the university and does not retain any direct financial interest in the project).

systems and regulatory compliance, with *institutional* conflict, the focus is on developing policies and principles, since no regulations guide this area.

The Task Force developed guidelines for managing *individual* conflict of interest, focusing on common approaches to disclosure and review processes, generally not allowing related financial interests in research involving humans except in compelling circumstances, and on interactions with human participant protection systems. Beyond the guidelines, it assembled some promising management practices and a checklist of questions that senior campus officials can use to assess how well their systems are designed and operating.

The Task Force concluded that a university's *institutional* financial conflict of interest processes – for both financial holding-related conflicts and those involving senior officers – should follow a three-fold approach:

- 1) *disclose* always;
- 2) *manage* the conflict in most cases;
- 3) *prohibit* the activity when necessary to protect the public interest or the interest of the university.

A key goal is to segregate the decision making about the financial activities and the research activities, so that they are separately and independently managed.

Given the dearth of previous policy making in institutional conflict of interest, the Task Force is cognizant that its efforts are but a first step in developing and institutionalizing processes in this field. It hopes that

through future assessments within the university community and through dialogue with our partners in the nation's research enterprise – federal agencies – the principles and practices enunciated here will continue to be refined and strengthened.

By providing appropriate institutional policies, procedures, and incentives, universities should sustain a climate in which research, teaching, and public service are carried out responsibly, and in so doing foster an atmosphere of openness and integrity.

The partnership between research universities and their principal research sponsors – including the federal government – must be based on the conviction that universities are accountable for the research they perform. If research universities do not demonstrate their ability to maintain accountability for individual and institutional conflict of interest, more prescriptive approaches may well be pursued by either the executive or legislative branches of government, or both.

The Task Force therefore urges universities to give prompt attention to reviewing and, where necessary, strengthening their conflict of interest policies and management using the individual conflict of interest Operating Guidelines in Section II, and the three-fold approach for managing institutional conflict of interest described in Section III. This will help ensure that the integrity of research universities can be maintained, and that the confidence of the public they serve can continue to be deserved.

I. INTRODUCTION AND TASK FORCE APPROACHES

The Association of American Universities believes it is vital for leaders of the academic community to ensure that research conducted on our campuses meets the highest standards of ethics and integrity, and promotes the public health. AAU therefore established the Task Force on Research Accountability in March, 2000.

The Task Force's first assignment was to assess university research management challenges related to the protection of human subjects in research, which resulted in the *Report on University Protections of Human Beings Who Are the Subjects of Research*, released in June, 2000. The Task Force's second assignment has been to examine issues that arise from the increasing collaboration between industry and research universities, specifically individual and institutional financial conflict of interest. In both assignment areas, the Task Force was charged with developing recommendations for providing appropriate accountability and oversight of university research and regulatory compliance.

After developing working definitions of individual and institutional conflict of interest, which are included in the succeeding sections, the Task Force found that it had two very different tasks. Helping universities meet their obligations to achieve objectivity in research in cases of potential individual conflict of interest meant *improving* existing management systems and regulatory compliance, while achieving objectivity in research in cases of potential institutional conflict of interest meant *developing* policies and principles, since there are no common approaches or regulations governing the latter.

Early in its deliberations on individual conflict of interest, the Task Force concluded that developing a list of promising management practices could help campuses

ensure objectivity in research, and reduce the variability in approaches within academia. The Task Force, therefore, sponsored a workshop on individual conflict of interest practices in January, 2001, to examine what operating principles campuses had developed and see if a consensus could be reached on common operating approaches. The workshop materials formed the basis for the list of Operating Guidelines and promising practices discussed in *Section II*.

The Task Force concluded that a separate workshop would be needed to develop principles addressing institutional conflict of interest, and in June, 2001, convened a session of current and former AAU presidents and chancellors for this purpose. The workshop materials formed the basis for the material in *Section III*.

Early in its deliberations, the Task Force recognized that presidents and chancellors can often benefit from lists of questions that they can ask on their own campuses to assess the adequacy of various management systems, and developed a list of questions for campus leaders on managing individual conflict of interest, which is included in the *Appendix*.

One summary conclusion the Task Force reached is that the problem is rarely a particular conflict itself - rather it is the question about what is *done* with the conflict. In most cases, problems arise when the conflict is not made apparent, or when it is not assessed or managed. Other than in the particular case of research involving human participants, much of the challenge is for universities to develop robust systems so that conflicts are disclosed, assessed, and managed.

II. INDIVIDUAL CONFLICT OF INTEREST

A. Defining Individual Conflict of Interest

For the purposes of this report, the Task Force adopted a definition of individual conflict of interest which was based on one developed by the Association of American Medical Colleges in 1990:

The term individual financial conflict of interest in science refers to situations in which financial considerations may compromise, or have the appearance of compromising, an investigator's professional judgement in conducting or reporting research. The bias such conflicts may conceivably impart not only affects collection, analysis, and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants, and the use of statistical methods.

Based on this general definition, the Task Force further defined the scope of its analysis as follows:

- ◆ Conflict of interest will be considered across all academic fields, not just biomedical ones (though biomedical conflicts have some unique aspects and invoke a special intensity and interest);
- ◆ The analysis will center on financial conflicts of interest in research, and exclude conflicts of commitment and non-research and non-financial conflicts, which bear separate scrutiny;
- ◆ Conflict of interest for individuals primarily concerns faculty, but also addresses other officials and staff involved in research administration; and
- ◆ Financial conflicts of interest involving individuals in senior positions (such as presidents and chancellors,

departmental chairs, deans, provosts, and trustees) have a somewhat different character, and will be addressed in the section on institutional conflict of interest.

B. How Big is the Problem? Why is Action Needed?

In recent years, numerous journal and news articles and statements and reports by government officials have raised questions about how well universities are managing their responsibilities regarding individual conflict of interest, as defined in regulations promulgated by two major federal agencies in 1995. The Task Force examined the available information, and concluded that although definitive data about the prevalence of conflicts of interest is lacking, academic-industry relationships are clearly increasing, and with them, the risk of conflicts of interest compromising the integrity of research conducted in academia continues to rise. Journal articles make clear that the stringency of financial conflict of interest policies varies substantially among institutions, as does the diligence of enforcement.

The Task Force concluded that since the risk to the integrity of the academic enterprise from individual conflicts of interest is substantial, research universities should re-double their efforts to ensure objectivity in research. Such increased conflict of interest management efforts will also improve universities' compliance with the federal regulations governing individual financial conflicts of interest.

By increasing university efforts to manage conflicts of interest, and increasing the visibility and transparency of such processes, universities can help assure the public of the integrity of the striking research results they read about on a weekly or even daily basis. The Task Force

concluded that developing management guidelines and promising practices would help universities as they strive to improve their conflict of interest management processes.

C. Developing Management Guidelines and Promising Practices Concerning Individual Financial Conflict of Interest

The process of knowledge discovery and technology transfer has been and continues to be enormously successful. It is important not only to the individual investigator and institution, but to patients and their families in the case of clinical research, to industry, and to society at large. It fulfills one of the goals of federally funded research by bringing the fruits of research to the benefit of society. With this important technology transfer come increasingly close relationships between industry and universities, which in turn increasingly require robust conflict of interest processes to protect research integrity and human participants, in the case of research involving human beings. For research universities to retain their standing as independent arbiters of knowledge, research must continue to be conducted according to the highest ethical standards. Changes in our approaches to identifying and managing real or perceived conflicts should take care not to unduly inhibit the ongoing progress in scientific discovery and technology transfer while trying to ensure that the integrity of research – and the interests of human participants – are fully protected.

The 1995 requirements established by the National Science Foundation (NSF) and the Public Health Service (PHS) require federally supported investigators to *disclose* to their institution significant financial interests that would reasonably appear to affect research funded by PHS or NSF. Institutions are then required to determine if a conflict of interest exists, and if so, how the conflict of interest can be managed, reduced, or eliminated. In 1998, the Food and Drug Administration

(FDA) established regulations requiring companies filing a New Drug Application to certify that no financial arrangements with an investigator have been made where study outcomes could affect compensation, and requiring disclosure to FDA of any pertinent investigator financial arrangements and steps taken to minimize the potential for bias.

After six years of experience with these new requirements, during which the volume of investigator interactions with industry has continued to increase, sizeable variation in practices and policies has developed as institutions created their own operating principles and processes. These years of campus experiences give rise to several questions:

1. *is disclosure and case-by-case management sufficient? Put another way, can all arrangements that give rise to individual financial conflicts of interest be managed, or should some be prohibited?*
2. *how should the important interests of human participants in research be integrated into conflict of interest policies (e.g., managing conflicts vs. prohibiting them?) and processes (e.g., which regulations govern in the case of human participant research – the PHS/NSF conflict of interest regulations and policies or the “Common Rule” regulations governing human participants in research)?*

The Task Force sponsored a workshop on individual financial conflict of interest practices in January, 2001, to examine what operating principles campuses had developed, and to see how similar and different they had become over time. The group of campus experts analyzed seven case studies, and found that in some cases, nearly all campuses would treat the case the same way, while in others, they would not. The participants also found that case-by-case reviews played a vital role in conflict of interest determination processes, since cases can be quite complex and nuanced.

The group worked to identify common operating approaches on which consensus could be reached, as well as to identify promising practices which a particular school had found useful for managing individual financial conflicts of interest. In many cases, the consensus went beyond current regulatory requirements. These lists formed the basis for the *Operating Guidelines* below, and the list of *promising practices* that follow them.

The Operating Guidelines are written as normative statements, and indicate that there should be some limits to campus management of conflict of interest. This is consistent with the view expressed by many at the AAU workshop that the research community should identify common management approaches/techniques and adopt some as a whole community. The Guidelines are also an attempt to indicate that not all conflicts can be managed through regular case-by-case reviews; in some cases either special scrutiny is required, or prohibition is appropriate.

By contrast, the promising practices are offered in the spirit of information-sharing within the university community. The goal is to offer conflict of interest management methods that campuses might find helpful as they work to improve their own management systems.

D. Operating Guidelines

1. Financial conflicts of interest in research require robust campus management systems -

Institutions should have adequate procedures for identifying potential conflicts through annual disclosure, and ensure rigorous and consistent review of such disclosures. The procedures should indicate how relevant officials (and in the case of clinical research, human participants) are to be informed of conflicts, and how those conflicts are to be managed. Institutions should sufficiently document conflict of interest decisions, and monitor their implementation. Institutions should also ensure that policies,

procedures, definitions, and sanctions for non-compliance are well-understood by all persons involved with research, including students and research participants. Finally, institutions should ensure intra-university coordination on matters of conflict of interest management among the various offices involved, including research/grants administration, institutional review boards, technology transfer offices, research policy offices, and cognizant deans/department chairs.

2. Many financial interests are not conflicts, and many conflicts can be managed - Given the complexity of financial relationships within universities, the best way to handle many conflict of interest situations is on a case-by-case basis - to determine whether a researcher's financial interests are related to university research and constitute a conflict of interest, and if so, how the conflict should be managed. Many individual financial interests are not conflicts of interest in research, and many that *are* can be managed to avoid a conflict of interest that might affect research results or care of human participants. However, universities and researchers sometimes determine that certain research should not be performed as originally proposed if the integrity of the research is to be maintained, or research participants protected. The institutions or investigators may then decide to alter the protocol, divest a financial interest, or not undertake the research.

3. Research involving human participants requires special scrutiny - Since research involving humans creates risks that non-human research does not, any related financial interest in research involving humans should generally not be allowable. If compelling circumstances justify an exception to this general rule, the research should be subject to more stringent management measures (including disclosure to research participants and students) to ensure the integrity of the research and

the safety of the human participants. In addition, it is important to be mindful of the physician/human participant relationship and the special demands it involves -- to do no harm and to safeguard the human participant's welfare above all things.

4. **Treat research consistently, regardless of funding source** - All research projects at an institution, whether federally funded, funded by a non-federal entity, or funded by the institution itself, should be managed by the same conflict of interest process and treated the same.
5. **Disclose financial information to the institution** - Individuals engaged in research should disclose on an annual basis all financial interests related to university research, and provide updated information when new financial circumstances may pose a conflict of interest and when grant applications are submitted. Disclosure should be to the campus's designated official, consistent with PHS and NSF regulations.
 - *For these purposes, individuals include faculty, staff, and administrators who are involved in the design, conduct, management, or reporting of research, and financial interests include equity, consulting fees, and other payments. Financial interests should also include royalty interests, which are not all currently required to be disclosed under federal regulations.*
 - *Disclosure of financial interests related to non-federally sponsored research (which is not subject to regulation) ensures that all potential conflicts of interest are identified and handled similarly, instead of having an extensive process for some potential conflicts but not for others.*
6. **Disclose financial information to publications** - When individuals engaged in research (see above definition of individuals) submit manuscripts for publication, they should disclose any financial

interests they have which are related to the research. Consistent with the policy on disclosing conflict of interest adopted by the International Committee of Medical Journal Editors, publications should print this information so that it can become available to the public.

7. **Disclose financial information in oral presentations** - Individuals engaged in research should disclose to their audiences when presenting research results any financial interests that are related to the research on which they are reporting.
8. **Disclose financial information to federal agencies** - Federal regulations and policies announced in the *Federal Register* on July 11, 1995, require institutions using PHS funds to report to the Department of Health and Human Services (HHS) the existence of conflicting interests found by the institution and to assure HHS that the institution has managed, reduced, or eliminated the conflicts prior to the expenditure of funding. By contrast, institutions using NSF funds must report only if the institution finds that it is unable to satisfactorily manage a conflict. Campuses must comply with these requirements. Increased cross-agency consistency in disclosure requirements could help increase such compliance.
9. **Disclose financial information in the human participant review process** - Both conflict of interest processes and human participant protection systems have a role regarding conflict of interest:
 - A campus Institutional Review Board (IRB) has jurisdiction over determining whether a relevant financial interest (and how it is being managed, if applicable) should be disclosed to human participants in research, and if so, in what form and detail. The campus's human research protection system is responsible for ensuring that the human participants are so informed.

— The PHS and NSF conflict of interest regulations and policies vest authority to determine if an individual has a conflicting interest that needs to be managed, reduced, or eliminated in *institutional officials* responsible for the campus's conflict of interest processes. However, the Common Rule, which governs human research protections in 17 Federal agencies, vests authority to approve research involving humans in *IRBs* – and is silent with respect to conflicts of interest (except for those of IRB members). Both campus processes have an important and legitimate role to play in determining if a financial conflict of interest in research exists regarding clinical research, and in determining if a proposed remedy is sufficient to protect research integrity and human participants.

One effective way to integrate these processes is for conflict of interest committees or officials to try to review financial interest disclosures regarding human subject protocols before protocols are submitted to the IRB (however the timing works out, the idea is for the conflict of interest review to take place in time to affect any informed consent). The conflict of interest committee or official can then determine whether a conflict exists, and if so, how it should best be managed, if it should be (see guideline above indicating that such conflicts should generally not be allowable), or can be. This determination, and summary information about the financial interests, can then accompany a protocol when it is presented to the IRB. The IRB could then take this information into account when determining whether and under what circumstances to approve a given protocol.

Universities should consider designing systems so that an IRB also may determine if there is a financial conflict of interest that needs to be managed, or if a

management plan implemented by the conflict of interest committee or official should be made more stringent. In such a system, neither the IRB nor the conflict of interest committee would be able to override the other's management requirements if the result would be to lessen the stringency of the management requirements. Either one could prohibit the research from proceeding, unless the financial conflict was removed or mitigated. Such a double-protection system would be consistent with the two sets of federal regulations governing clinical research, and provide the additional safeguards that research involving human participants demands. In whatever way a campus's conflict of interest and human participant protection systems are designed, the focus should be on coordination and communication of the two systems.

10. **Increase resource availability** - Universities should provide the resources necessary to carry out the requirements of applicable conflict of interest laws and regulations, and to meet the highest ethical and professional standards. Research sponsors also should pay a fair share of the costs of conflict of interest systems. Caps on recovery of administrative costs can limit the reimbursement of actual costs in some cases. Accordingly, alternative methods of direct or indirect cost recovery should be developed.

E. Management Practices that are Reported to Work at Some Institutions

Beyond the Operating Guidelines listed above, the Task Force has identified successful individual financial conflict of interest practices. Since conflict of interest and IRB processes often vary across institutions, it is not the intent of the Task Force to recommend that this partial list of practices be adopted by all universities, but rather that this list of practices should be shared and discussed in the research community.

General -

1. Emphasize principles of protecting research from bias rather than paperwork processes.
2. Develop all processes collaboratively with researchers and administrators, to promote broad understanding of the policies and the need for adherence to them.

Committees -

3. Utilize committees comprised of a mix of faculty, research staff, and administrators which best fits a campus's governance traditions to: a) review disclosures; b) design management plans; c) review the progress of cases being managed; and d) provide advice to the campus's designated official on particular cases and on conflict of interest policies. Some campuses use their committees solely for developing policies; others assign them the main operational role in the conflict of interest process.
4. Consider using a single conflict of interest committee to administer this process across an entire campus, which helps ensure that similar cases are treated similarly. It is vital for campuses that operate with two systems simultaneously (such as one in a medical school and one outside) to closely coordinate all criteria used to determine if a disclosure contains a relevant and significant financial interest, and other processes and management plan elements.
5. Include at least one member of the outside community on conflict of interest committees, since community trust is so important.
6. Strive to have the members of the conflict of interest committee reflect the distribution of conflict of interest cases that occur in different colleges within a campus.

Education -

7. Provide regular education to individuals engaged in research on the purpose of conflict of interest policies, and on the procedures to be followed.
8. Create a simple handbook of the campus's policies and procedures to serve as an adjunct to regulations, to help researchers and administrators more clearly understand what is required of them.
9. Conduct campus seminars on conflict of interest issues.

Disclosure -

10. Develop clear policies and procedures for disclosure and for management plans.
11. Use as simple a set of disclosure forms as possible. Some institutions have found IRB protocol-specific disclosure forms to be helpful.
12. Have in place methods for supporting faculty who are performing research in accordance with the law and with agency and university guidelines, both in general and as it relates to conflict of interest. Investigators should be made aware of these safeguards and the rules under which they function.
13. Share disclosure and conflict management information, as needed, with sponsored project offices, technology transfer offices, IRBs, conflict of interest management staff, and department chairs/deans, using appropriate safeguards to maintain the privacy of the information. Some campuses use an electronic disclosure form that facilitates an integrated management system between these offices. Some campuses will not allow or process licensing, sponsored projects, gifts, or IRB applications that have disclosed any conflicts of