



Association of American Universities Framework Document on Managing Financial Conflicts of Interest

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Introduction

Universities have long recognized the importance of maintaining policies that address conflicts of interest. In 1964, the Council of the American Association of University Professors (AAUP) and the American Council on Education (ACE) issued a joint statement *On Preventing Conflicts of Interest in Government-Sponsored Research at Universities*. This statement, which continues to serve as the basis for many university policies today, underscores the importance of the transfer of knowledge and skill from the university to industry, as well as careful attention to institutional standards and procedures that protect the integrity of the institution and the research conducted there.

As support for government-sponsored research increased, and as policies and laws were developed to encourage relationships among universities, government, and industry, additional statements and reports were issued to assist universities in developing and refining their conflict-of-interest policies. In 1978, the Association of American Universities (AAU), the ACE, and the National Association of State Universities and Land-Grant Colleges (NASULGC) published *Principles to Govern College and University Compensation: Policies for Faculty Engaged in Sponsored Research*. In 1985, the AAU issued a report of the Clearinghouse of University-Industry Relations entitled *University Policies on Conflict of Interest and Delay of Publication*. Both the Association of American Medical Colleges (AAMC) and the Association of Academic Health Centers (AHC) have also recently published reports about conflicts of commitment and conflicts of interest.

The 1990s bring a renewed emphasis on technology transfer and economic competitiveness has emerged as a national priority. It is, therefore, particularly timely that universities review their conflict-of-interest policies to ensure that these policies continue to protect the integrity of the institution and the research process, encourage the free flow of knowledge and ideas, and ensure that public and institutional resources are used appropriately. This document is designed to provide a framework within which institutions can review their conflict-of-interest policies, with specific attention to managing financial conflicts. While there are clearly other aspects of an institutional policy that should be carefully reviewed and considered (for example, conflicts involving the use of students in research sponsored by industry and other outside activities), this document focuses solely on managing financial conflicts of interest. The policies discussed are intended to cover all university employees, although particular attention is paid to faculty and their research activities. The document does not address the development of policies for institutional conflicts of interest, which develop out of links between institutional financial interests and the commercial application of faculty research results. However, universities are strongly encouraged to establish such policies, as well.

Managing Financial Conflicts of Interest Faculty and staff owe a primary loyalty to their institution. Within this responsibility are several activities that often compete for

attention. Faculty teach undergraduates, mentor graduate students, perform and report research, and participate in the management of the institution. While fulfilling these responsibilities to their institutions, faculty also advise and consult with private and public entities and provide service to professional societies. Balancing these external and internal responsibilities is difficult; conflicts over the allocation of time and resources are inevitable. Institutional policies governing conflicts of commitment (which most often involve the amount of time permitted in outside activities) have been developed to address, among other things, conflicts over the allocation of time. Conflicts involving the use of university resources for personal gain are addressed by conflict-of-interest policies. Virtually all universities have policies and procedures for managing conflicts of interest; however, demonstrating accountability requires that these policies and procedures be clearly expressed and implemented.

The transfer of knowledge and information from academia to industry gives rise to a range of activities and relationships outside the university that can be extremely beneficial to the public. Faculty involvement in private industry and national laboratories can be a powerful mechanism of technology transfer, now a national priority. However, a degree of conflict may be inevitable whenever academic research addresses problems of the real world. What is important is that such conflicts be managed so that the purpose and mission of academic institutions are not compromised, so that the investment of the public and students is protected, and so that public confidence in the integrity of scholarly activities is maintained. Coherent conflict-of-interest policies can not only help guide relationships between industry and academia, but also help ensure the protection of the mission of the university.

Accordingly, the challenge to the university is to develop a mechanism for faculty and other employees to report outside activities so that the relationship between the faculty member's institutional responsibilities and his/her outside activities can be reviewed and managed appropriately by the institution. This is essential to ensure that research conducted at the institution is free from bias or perceived bias when a faculty member stands to benefit from a particular research outcome. In some cases, appropriate management of a disclosed conflict will mean eliminating the conflict (e.g., outside relationship or activity) altogether. In other cases, appropriate management may involve careful monitoring and reporting of research activities and data, allowing important research to go forward with assurances that the integrity of the science and the institution will be protected. These situations will require careful review, monitoring, and documentation throughout the life of the project. If government funds are involved, the institution is also accountable to the government and the public for ensuring that financial conflicts are disclosed and appropriately managed by the institution.

The development and implementation of conflict-of-interest policies and procedures is the responsibility of each institution. However, there are certain key elements that should be included in every university policy for managing financial conflicts of

interest. These elements include the following: definitions, disclosure, review processes, recommendations and decisions, opportunity for appeal, and utilization of appropriate university procedure for noncompliance with the policy. The administrative responsibility for each element must be clearly specified and a system of communication must be in place to assure that each individual affected by the policy is made aware of his or her responsibility under the policy. Each of these elements is discussed in this document, with suggestions for how these elements may be organized and implemented in a conflict-of-interest policy.

Institutional Policies and Responsibilities The development and implementation of conflict-of-interest policies and procedures must remain the responsibility of the individual institution. The way in which institutions develop and implement their policies and procedures will vary since they will reflect the different culture and management styles of each university. Compliance with the laws and regulations of different states also necessitate that each institution develop its own conflict-of-interest policy. In addition, institutions also need to assure congruence of any new policy with the compendium of already existing institutional policies related to responsibility and conduct of faculty and university employees.

Institutions have codes of conduct that are derived from ethical principles related to faculty behavior toward students, colleagues, the institution, and the community. They address issues of unacceptable conduct related to instruction, scholarship, and public service. Among the types of unacceptable conduct are exploitation of students for private advantage, violations of the canons of intellectual honesty, and unauthorized use of university resources for personal purposes. Accompanying such codes are the policies and procedures applicable to enforcement and sanctions. Faculty are also bound to observe the codes of their professional societies regarding issues of integrity in exercising their professional responsibilities.

In addition, the procedures used by academic institutions for the advancement of faculty provide for peer evaluation of professional activities. These procedures are appropriate for the management of conflicts other than financial conflicts of interest. The faculty promotion process reviews critically the creativity and excellence of teaching, research performance, and service to the institution. Faculty are rewarded for professional achievements as evaluated by peers through publications, teaching evaluations, service to the profession, service to agencies, and contributions to the advancement of knowledge. Honesty, openness, objectivity, and critical judgment in performing these duties, including the conduct of research, are significant elements in the academic reward structure.

Institutions also have other mechanisms for addressing conflicts of interest in research practices, usually through policies and procedures related to contract and grant terms. Such policies address issues about the openness of the research environment, the right to

publish, the right to intellectual property, the use of the university name, and the appropriate use of university facilities.

Moreover, conflicts of interest are not limited to research performed by faculty. Academic institutions also manage conflicts of interest on the part of employees responsible for business decisions which occur in administering the institution. For example, employees involved in purchasing decisions are restrained from relationships with vendors that might impair the objective fulfillment of their duties.

Finally, the implementation of policies and procedures to review and manage financial conflicts of interest must recognize the existing codes, norms, policies, procedures, practices, and guidelines related to the issues and concerns raised. The development of new policies should be distinguished from better implementation of existing policies. Of greater importance will be the organizational structure adopted and the administrative responsibility exercised by the institution in implementing the policies and procedures. It is not enough simply to have good policies in place. They must be used, and it must be made clear who is responsible for what.

Elements of a Conflict-of-Interest-Policy

Definition Defining conflict of interest is a complex task. If not focused on the specific problem being addressed, the development of definitions will involve discussions of individual motivations, the nature of research, the nature of academic institutions, and other topics that, although very important, are not essential to defining conflict of interest. Rather, definitions need to focus on conflicts that may arise when an individual's activities inside the institution can be directed toward serving his or her outside activities.

A conflict-of-interest definition must be broad enough to include a spectrum of activities ranging from outside employment, consulting, ownership of stock, etc. The definition needs to focus disclosure categories on those activities needed to conduct a careful review and assessment of whether a particular activity or relationship is acceptable, unacceptable, or requires further review and careful monitoring.

Some university policies include specific disclosure categories, thresholds, and affected individuals as part of the definition. Others include a broader definition and identify thresholds and categories on the disclosure form. Most university policies cover certain family members, and it is important to indicate clearly who is included under the term "family."

The following are offered as examples of definitions that have been adopted by some institutions:

Institution A

A conflict of interest may take various forms, but arises when an academic staff member is or may be in a position to influence the university business, research, or other decisions in ways that could lead to any form of personal gain for the academic staff member or the staff member's family, or give improper advantage to others to the university's detriment.

Institution B

A potential or actual conflict of interest exists when commitments and obligations to the university or to widely recognized professional norms are likely to be compromised by a person's other interests or commitments, especially economic, particularly if those interests or commitments are not disclosed.

Institution C

A conflict of interest occurs when an employee has a financial interest in a university decision. A financial interest is described as:

- A direct or indirect investment in the sponsor worth more than \$1,000;
- A position as director, officer, partner, trustee, employee of any or any other position of management in the sponsor;
- Income from the sponsor, including consulting income and gifts aggregating \$250 or more in value, received by or promised to the principal investigator within 12 months prior to the time the award is made. (For the purposes of this policy, "income" is further defined as in Gov. Code, Section 82030).

A principal investigator has an "indirect investment" or "indirect financial interest" in a sponsor if:

- His or her spouse or dependent child has a financial interest in the sponsor;
- The principal investigator, his or her spouse, or dependent child own directly, indirectly, or beneficially a 10 percent interest or greater in any business entity or trust which has a financial interest in the sponsor of the research.

Disclosure In addition to a definition, a conflict-of-interest policy must specify the information to be disclosed and to whom the disclosure is to be made. Disclosure forms should be limited in scope, yet sufficiently encompassing to allow an independent reviewer of the disclosure to determine if the outside activity interferes with the researcher's primary responsibility and duty of loyalty to the institution and the integrity of the research process. The assumption that drives the development of conflict-of-interest policies and procedures is that the financial potential of outside activity might bias the academic activity of the faculty.

Disclosure forms should be designed to capture as efficiently as possible only information pertinent to university conflict-of-interest concerns. The forms need to recognize that most faculty and staff will report no conflicts and their disclosed information will not require any review past the initial stage. Disclosure forms should capture the kind of information that is necessary to identify a financial conflict of interest and provide an opportunity for discussion, review, and appropriate management. Sample disclosure forms used at institutions across the country are included as Appendix A through C of this document.

Review Process Initial Review

Disclosure forms should be submitted to and reviewed by an appropriate institutional officer, often an individual with first-line supervisory responsibility for the faculty member submitting the disclosure form. The institutional role of the officer will vary among institutions. In some cases it may be the dean, in others, the department chair. Each disclosure form should be reviewed according to criteria established to distinguish between negative disclosure (disclosures that reveal no financial conflict) and positive disclosures (disclosures that require additional review). In most cases, the criteria will suggest the questions and categories to be included on the disclosure form. A recordkeeping system should be established and maintained for all disclosures, negative and positive.

The review process should be clearly stated and consistently practiced. The goal for all reviews of positive disclosures must be to gain a better understanding of the nature and extent of the conflict and explore options for managing it. In the vast majority of cases, a discussion between the reviewer and faculty member can result in steps taken by the investigator to eliminate or mitigate the conflict of interest. These steps should be carefully documented and filed with the initial disclosure form, unless the conflict has been eliminated.

In the AAMC's *Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research*, a series of questions has been included that can assist the initial reviewer in evaluating positive disclosures. Some of these questions include:

- Has all relevant information concerning the faculty member's activities been acquired (i.e., has there been full disclosure)?
- Do the faculty member's relevant financial interests exceed predetermined thresholds of acceptability, where specified?
- Do the faculty member's reported external commitments exceed permissible levels?
- Is there any indication that research results have not been faithfully and accurately reported?
- Is there any indication that the faculty member in his or her professional role has improperly favored any outside entity or appears to have incentive to do so?
- Has the faculty member inappropriately represented the institution to outside entities?
- Does the faculty member appear to be subject to incentives that might lead to inappropriate bias?
- Is there any indication that obligations to the university are not being met?
- Could the faculty member's circumstances represent any possible violation of federal, state, or local laws and requirements?
- Do the current engagements of the faculty member present any conflicts between **outside** interests (e.g., working on projects simultaneously for competing business entities)?

Some universities may elect to institute an annual disclosure for all. Others may ask that disclosures be submitted (or renewed) whenever the institution contemplates the acceptance of an external research agreement or the execution of a technology transfer arrangement, or at the time a faculty member enters into such activities. In the latter case, the institution may wish to couple the initial conflict-of-interest review with the existing administrative review process.

Second Level of Review

In those instances where the financial conflict has not been resolved at the initial review stage, the disclosure should be referred to a second level of review. This review may

involve other individual reviewers or a committee. At this point, consideration must be given to the organizational structure and responsibility for reviewing cases and making decisions about how conflicts will be managed. The degree to which the process is centralized must be established. Centralization will strengthen the possibility for gaining the experience required for consistency and continued policy development.

Decentralization, on the other hand, can deal more effectively with issues that are specific to a given discipline at a given time. Whatever the organizational structure, the goals of second-level review should be an evaluation of the disclosure and a recommendation for how the financial conflict will be managed. The development of criteria for deciding what is unallowable and what can be conditionally allowed is crucial and should be undertaken in accordance with university policy and experience. Criteria should include, but should not be limited to, such elements as the extent and nature of the involvement, the openness of the activity, the freedom of communication about the activity, the control of the intellectual property arising from the activity, and the use of university resources, including the involvement of students. Among those at the university who may be involved in a second-level review process are department academic administrators, faculty, contracts and grants officers, technology transfer personnel, and central academic administration personnel. Some institutions have found that by including faculty members in a fair and impartial review process, the credibility of the process and the recommended outcome are significantly enhanced.

In some cases, the nature of the outside relationship or activity will be such that it will not be possible to ensure the integrity of the science or the institution if the outside relationship or activity is maintained. In these cases, the conflicts should be deemed unacceptable and the outside relationship or activity should be eliminated before the research can proceed. In other cases, elimination of the outside relationship or activity may not be necessary or prudent. In these cases, careful monitoring and reporting are crucial to ensuring that the objectivity of the science and integrity of the institution are protected.

Again, the AAMC has outlined example questions that can be used at a second-level review to help decide which financial conflicts can be managed in a way that can ensure the protection of the integrity of the science and the institution and which cannot. These questions include:

- Will the negotiation of relevant research affiliations or other contracts be handled by truly disinterested representatives of the institution?
- Will the research workplan receive independent peer review prior to its initiation?
- Are there mechanisms in place to prevent the introduction of bias into research projects (i.e., Is the protocol double-blinded? Are research subjects randomly

selected?)?)?

- Will the project be supervised by someone with authority and no conflicting interests?
- Are there means to verify research results (e.g., independent corroboration in another lab, FDA review)?
- Will data and materials be shared openly with independent researchers? If not, who determines accessibility to such resources?
- Will the product of the collaborative effort with an outside party be published in the peer-reviewed scientific literature?
- Will the sponsorship and relevant interests receive acknowledgment in public presentations of the research results?

Appeal Process A process for appealing a formal decision about approval or disapproval of a disclosed financial conflict of interest should be included in a university conflict-of-interest policy. This appeal process should include a description of the circumstances under which a decision may be appealed and to whom.

Noncompliance To the extent possible, existing institutional procedures for investigating and sanctioning violations of faculty codes of conduct should be used for any violations of the university conflict-of-interest policy. This may require institutions to include a specific designation that conflicts of interest will be addressed under university policies and codes.

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Appendix A

Unavailable at this time.

Appendix B

Unavailable at this time.

Appendix C

Unavailable at this time.