

interest until the conflict of interest review is completed; an electronic system increases the efficiency of such integration.

14. Use regular system audits to determine whether disclosure forms are completed and processed appropriately, and shared with other offices as necessary (as discussed in item #13).
15. Include questions on disclosure forms submitted with grant applications about whether or not students are working on a research project to help identify situations which may compromise the independence of a student's thesis or research project.
16. Consider requiring researchers, especially those working with human participants, to disclose all equity interests (any stock or options in a company) instead of using the higher threshold of 5% or \$10,000 in equity, as specified in the PHS and NSF regulations and policies.
17. Have journal article authors send to the conflict of interest committee or official a copy of any financial disclosure statements that they submit to journal editors.

Management -

18. List points for consideration that a campus takes into account when deciding how to manage those conflicts of interest which can be managed, including: phase of clinical trial, whether stock is privately held or publicly traded, size of company, kind of intervention (diagnostic vs. therapeutic), if faculty have any influence in the company, and whether a financial relationship is fixed (e.g. fixed payment) or variable (e.g. equity, stock options).

19. Be explicit about possible sanctions for non-compliance, which can range from listing possible sanctions to citing professional misconduct procedures and associated sanctions.
20. Allocate resources available for conflict of interest management in a way that best fulfills scientific integrity obligations, including conflict of interest education, outreach, developing a culture of compliance, administering the system, monitoring, and auditing.
21. Require sufficient documentation so that conflict of interest files are clear on how a particular individual's disclosures have been reviewed, had determinations made about them, had a conflict managed, and been reported to federal officials, if necessary.

Monitoring -

22. Focus monitoring attention on critical control points during the conflict of interest management process, including such actions as: disclosure, grant application, IRB review, any necessary reporting to agencies (such as NIH, NSF, FDA), publication, and technology transfer activities. When managing an individual with a conflict of interest, a campus could require that the individual be precluded from involvement in such critical activities as enrollment of human participants, obtaining informed consent, and analyzing data - at whatever critical points the particular research could be influenced by a conflict of interest. Some campuses use their internal auditing office to help map out conflict of interest/disclosure processes and identify control points to be used to measure the effectiveness of these processes.

F. Will Following these Guidelines and Adopting Some of the Practices Improve Management of Individual Financial Conflicts of Interest?

Hopefully, through the sharing and adoption of guidelines such as these and by identifying promising practices, better conflict of interest management can increase the commonality of campus approaches, and the transparency of campus conflict of interest processes (which leads to public trust) can also be increased. Most importantly, the Task Force hopes that through these actions, the community can reduce real and perceived conflicts of interest, with their attendant threats to the integrity of our research institutions and to the well-being of human participants in research.

In the case of human participants, the Operating Guidelines stipulate that financial relationships in research involving humans deserves to be held to a higher standard, since human lives are at stake, and that the conflict of interest and human protection systems need to be harmonized. Since the Task Force is aware that the Association of American Medical Colleges has

convened a committee on this topic, the Task Force's guidelines have remained general in this domain with the understanding that the AAMC committee will add some of the necessary operational details to make this higher standard a reality.

It is worth noting that several of the guidelines and practices listed above go beyond current federal regulations. These include disclosure information about all royalties, generally not allowing related financial interests in research involving human participants, disclosure regarding non-Federal research, and the practice of disclosing all equity interests, regardless of the current regulatory thresholds of 5% equity ownership or \$10,000, among others. The Task Force encourages universities to carefully review and consider the Operating Guidelines and promising practices, and encourages the adoption of as many as possible. Whether federal regulations need to be changed will depend on how aggressively and consistently universities voluntarily take action to increase the robustness of their individual conflict of interest management policies and implementation.

III. INSTITUTIONAL FINANCIAL CONFLICT OF INTEREST

Research universities are also concerned about institutional financial conflict of interest, because it strikes to the heart of the integrity of the institution and the public's confidence in that integrity. This section defines institutional financial conflict of interest, examines particularly troublesome types of such conflicts, reviews the core values universities want to protect from erosion by such conflicts, and then proposes some ways to assess and manage institutional conflicts of interest.

A. Defining Institutional Financial Conflict of Interest

Several possible definitions are available, but the approach used here is as follows:

An institutional financial conflict of interest 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.² 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.

B. Categorizing Institutional Conflicts

Institutional financial conflicts of interest arise in different contexts across campuses, but in general they concern universities (and the public) if they have a

significant potential to compromise the university's mission, no matter the field or context. Two major categories of such conflicts are:

- ♦ potential conflicts involving university *equity* holdings or *royalty* arrangements and research programs; and
- ♦ potential conflicts involving university *officials* who make decisions with institution-wide implications, which can include department heads and leaders of laboratories.

Equity - In the first category, the greatest concern about potential bias arises in the case of decisions about research where the university holds relevant equity positions or has royalty arrangements, *and* the equity or royalties are derived from university inventions, start-ups, or other university technology transfer.

Can research agendas be affected by the university's direct financial interest in a company with which it collaborates in research? Universities are transferring technology to the private sector with increasing rapidity, consistent with the Bayh/Dole Act of 1980. Particularly when transferring the technology to small start-up firms, universities often end up holding equity positions in companies where the stock is not yet traded on the open market. Universities are required to use equity and licensing income for education and research activities (as well as for licensing expenses) according to the Bayh/Dole Act, so the control of these types of equity is often separate from the university's endowment holdings, sometimes being managed by offices with research responsibilities. Since both equity holdings and royalties derived from tech transfer *and* industry involvement in university research have increased in recent years, the potential for conflicts has increased markedly. Research parks, incubator programs, venture

²This 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).

capital funds, and the like are helping universities realize their missions, but they can also give rise to financial conflicts of interest, which in turn raise the issue of the credibility of the university's oversight of research processes.

The more familiar type of university equity positions – those held in university endowments or gift funds – are another potential source of institutional financial conflict of interest within this category. However, most universities have long-standing “firewall” arrangements governing the management of these funds and their separation from the campus's research enterprise. Such firewalls are provided when the equity is part of an institution's general endowment or investment portfolio, is managed in accordance with standard institutional investment policies, with no special restrictions or considerations, and is overseen by an appropriate oversight or board of trustee finance and investment committee that exercises no control over university programs and operations. Such firewalls are vital, and need to be carefully designed, but they are of less immediate concern here than the policies and procedures that must be developed to address the newer sort of equity holdings and royalty income derived from technology transfer.

Officials – The second main category of institutional financial conflict concerns individuals in a position to make decisions with institution-wide implications. These include presidents, chancellors, other senior officers, deans, research center leaders, and members of governing boards. The first and most obvious potential source of conflict is between an individual's personal financial holdings and their institutional responsibilities. While similar to a potential conflict between an individual researcher's financial holdings and their research activities, these potential conflicts are distinguished by the type of decision the senior officer is making – in the latter case, they are institution-wide, and taken on behalf of the institution. Universities have many different types of governing bodies, but whether

they are boards of trustees or boards of governors, their members can all have potential conflicts of interest (many of which are currently governed by state laws).

A less obvious potential source of institutional conflict of interest involving individuals (and one not related to research) occurs when, for example, a university officer is a member of the board of a corporation that is a major supplier of some goods or services (such as electricity) to the university. In this case, it is not the individual's own financial interests that are at stake; rather it is a potential clash of the interests of the university and those of the corporation which the university official must navigate. Trustees who are executives of firms that do considerable business with the university must similarly navigate these issues.

A related situation involves senior university officers who serve on government-appointed boards. Where these boards involve federal or state agencies which provide research funds to the university, the university official must navigate between the potential clash of interests between the university and the government agency involved.

In the case of public institutions, state ethics laws usually govern potential conflicts concerning personal financial holdings of senior university officials and trustees, though with varying degrees of stringency.

Multiple Potential Conflicts – It is also worth noting that some situations may have several layers of potential conflicts. For example, both a university and a principal investigator could hold equity that was derived from a university's successful transfer of technology, and both the university's and the individual's financial interests could be affected by a proposed research activity involving the company. The levels of concern are different, however, because of the university's roles in oversight and accountability. Both sets of conflicts should be addressed by institutions, and the decisions about the potential individual and institutional financial

conflicts should be consistent. Since in some multi-level conflict cases the assessment of the individual conflict of interest case results in the proposed research not being undertaken, some potential institutional conflict cases become moot before the institutional process is undertaken.

C. What is at Stake? Why Do Universities Want to Address Institutional Financial Conflicts of Interest?

Research universities have an interest in addressing financial conflicts of interest because it is substantively the right thing to do relative to the mission of universities, but also because public confidence can be eroded if such conflicts are not addressed. Institutional conflicts can reduce a university's role as an objective arbiter of knowledge on behalf of the public. In addition, federal agencies and legislators have expressed interest in regulating this arena, and the research university community recognizes that, if it does not act to address growing concerns, others will.

What are the key values that universities want to protect from being harmed by institutional conflicts of interest? They include at least the following:

- ◆ a commitment to educating students;
- ◆ a commitment to academic freedom;
- ◆ a commitment to advancing the range and depth of knowledge and understanding of the natural world and our human condition;
- ◆ a commitment to the safety of patients under its care and participants in research;
- ◆ a commitment to open and timely communication and dissemination of knowledge;
- ◆ a commitment to protect both the appearance and the actual integrity and objectivity of research, instruction, and public service.³

Why does this issue need to be addressed today? As discussed in the section on individual conflict of interest, universities are collaborating with industry more frequently as they seek to fulfill their research, teaching, and community service missions, and are increasingly seen as regional "economic engines." Because of this increasing collaboration, universities must develop systems to address the two main categories of institutional financial conflict of interest.

D. Addressing Potential Institutional Conflicts of Interest

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:

- a. *disclose* always;
- b. *manage* the conflict in most cases;
- c. *prohibit* the activity when necessary to protect the public interest or the interest of the university.

In terms of the portion of institutional conflict of interest involving institutional financial holdings, 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. Much of the challenge involves achieving a high degree of such segregation.

To implement these approaches, universities should review their current institutional conflict of interest policies and administrative structures, and strongly consider the following steps:

1. **Develop and publicize clear policies** – Universities should have clear, publicly available *policies* addressing institutional conflict of interest,

³Based on a document from the Council on Governmental Relations entitled *Institutional Conflicts of Interest: Points for Consideration*, November 21, 2000, and modified to include a reference to clinical care and research.

including standards and guidelines. These policies should ensure that the answers to the myriad questions raised by the three-fold approach can be answered (such as Who discloses what to whom? Who manages what? Who can prohibit which actions? How are trustees covered? What is the relationship between these policies and existing endowment policies?). Part of this policy development would involve deciding what sort of arrangements are to be avoided rather than managed, such as a situation where a university takes equity in a company when there is some intention of a continuing research relationship between the parties. Governing boards should periodically review these policies to ensure they remain adequate to the task.

2. **Establish administrative processes** – Universities should have explicit *processes* for assessment and management of institutional financial conflicts of interest, to implement the policies established in (1). Processes should include checkpoints and system audits to ensure compliance, and reporting to senior management.
3. **Establish a review group on institutional conflict of interest** – Such a group could include some mix of senior officers, including the general counsel, faculty, and possibly citizen participants, to perform triage on the potential conflicts of interest brought before it, and to make recommendations concerning how the potential conflicts should be addressed. Alternatively, such a group could be comprised of members of the university's governing board, and report to some committee of the governing board. This could be structured similarly to the way many universities' audit functions operate. Another option would be to have a review group comprised of senior officers reporting to the president or chancellor. Another option would include officials from peer institutions in the review group. A review group could address both types of

institutional conflict of interest, or sub-groups could be created to address the institution's financial holdings situations separately from those involving university officials and trustees.

4. **Disclose potential conflicts to such a review group** – The administrative process should specify the types of individuals who would need to provide conflict of interest disclosures, for example, on an annual basis, to the review group, and the type of university equity/royalty arrangements and related research activities that would need to be disclosed to and reviewed by the group.
5. **Use the review group to assess potential conflicts, weigh risks and benefits** – The key in the decision making is to analyze when it would be appropriate and in the public interest to accept and manage a conflict, rather than require that it be eliminated. In some cases, the benefits of conducting a proposed research activity at a particular institution will be potentially high, and the risks low, while eliminating the conflict (by not conducting the research, for example) could eliminate the possibility of benefiting the public. In other cases, the scientific advantages of conducting the research at a particular institution may be so speculative, and the risks so great, that the conflict should be avoided by refusing a research interaction with industry. The review group should make such assessments, and then recommend actions to the president/chancellor or governing board, depending on how the administrative processes are structured.
6. **Take action regarding institutional conflicts** – There are myriad types of actions available to universities, in those cases where a potential conflict requires action. In cases of institutional investments conflicting with research activities, options available for a review group to recommend include:

- a. not conducting proposed research at that institution, or halting it if it has commenced;
- b. reducing or otherwise modifying the financial (equity or royalty) stake involved;
- c. increasing the segregation between the decision-making regarding the financial and the research activities; and
- d. establishing a research monitoring process, so that the research can be closely scrutinized to ensure that potential conflicts do not undermine the integrity of the work (and of the university).

In cases of institutional conflict involving university officials or trustees, actions available for the review group to recommend include isolating/recusing the official from knowledge of, or decision making regarding research, or less frequently, the review group could recommend reducing equity holdings or royalty interests.

7. **Strictly scrutinize institutional conflicts involving humans** – Universities have special responsibilities when dealing with human beings as patients, and as participants in research. Special responsibility for research participants is lodged in IRBs. However, when institutional conflict of interest review groups confront potential conflicts that involve human volunteers, special scrutiny of the potential conflict is required (the same as that described above concerning individual conflict of interest), since the university has even greater responsibility to the patients or human participants in research than to the research itself. Moreover, IRBs are not set up to deal extensively with conflict of interest issues. The review group should provide this special scrutiny and interact with a campus IRB in the same way as that described above regarding individual conflict of interest (see Section II).

8. **Strictly scrutinize equity that is not liquid, or is less liquid** – In general, the less liquid are the equity interests of the university in a company, the more a review group should be wary of potential institutional conflicts. The value of a university's non-liquid assets in a company can be much more affected by research or other actions taken by the university than if the assets are liquid.

E. Will Pursuing These Principles and Approaches Help?

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. Universities have a responsibility for making sure that they have active institutional conflict of interest processes, if they are to continue to protect what they value most – their integrity as institutions. The credibility of the institutions depends in part on the credibility of the management systems universities establish to identify and manage institutional conflicts of interest.

To the extent that institutions establish explicit administrative policies and processes to disclose always, manage in most cases, and prohibit when necessary, using review groups, the public will have greater confidence in the integrity of research universities, a very important matter to universities individually and collectively. 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.

IV. CONCLUSION AND CALL TO ACTION

The Task Force was animated by its concern that individual conflict of interest processes were not always achieving the highest standards, and that institutional conflict of interest policies had rarely been developed. The group concluded that the risks to the objectivity of research are large enough to require prompt action. It urges AAU members to assess promptly the adequacy of their systems if they have not already done so.

The Task Force believes that this report's recommendations offer useful guidance for improving these tremendously important integrity protection systems, and urges campuses to strongly consider adopting these proposals, from which both individual campuses and the academic community can benefit. As the Task Force noted in its report on humans who are participants in research, today's ever-changing research environment requires continued vigilance to ensure that universities administer research as carefully as they conduct it. This is true for conflicts of interest as well.

Finally, 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 ensure that the integrity of research universities can be maintained and that the confidence of the public they serve can continue to be deserved.

APPENDIX

Checklist of Questions for Campus Leaders on
Managing Individual Conflict of Interest

1. Who makes the decisions on individual conflict of interest cases on campus, at what level in the institution are they situated, and who is responsible for the oversight of this process? Through what channels does information about the cases and about the adequacy of the process go to reach the president/chancellor? What does this process look like in a flowchart?
2. How are faculty conflict of interest policies developed? Who holds ultimate authority over the policies: faculty senate, provost, president, trustees, state government? Are there separate policies, or separate implementation, in the medical center?
3. When a faculty member discloses a financial interest to an institutional official, as required, what happens next?
4. Are faculty members clear on what financial interests they need to disclose, to whom, and when?
5. Are there any sanctions for individuals who are required to report financial interests but do not? Have such individuals ever been discovered, and have sanctions ever been applied?
6. When financial disclosure identifies a potential conflict of interest, most such cases are handled on a case-by-case basis. What are the *tools* the campus uses to manage conflict of interest cases: disclosure to the research participants and possibly to the funding agency, divestment, monitoring, other means? What are the *criteria* that the campus uses to determine which of these tools should be employed? Which tools are most effective at measuring different types of conflict of interest? How have the last 10 cases where a conflict was identified been managed? Do federal regulations require an agency to be notified about any of these particular cases? If so, were they notified?
7. Is the IRB informed by the campus conflict of interest committee or official when conflicts of interest have been identified in an investigator's protocol review, and told how the conflicts are being managed? Do the IRBs require that prospective research participants be informed of investigators' related financial interests, if any? Are they informed of related institutional financial interests, if any. Are research participants informed in all cases, or only in some?
8. Are there campus policies in place regarding conflict of interest of members of any campus committees that review the research proposals (such as for IRBs, conflict of interest committees, and animal care committees)?
9. Are there rules governing whether companies in which the university has an equity stake—acquired through the university's technology transfer activities—can sponsor research at the university? Are there rules if the equity stake is acquired through investments from the university's endowment? If the company can sponsor research, can the principal investigator have an equity stake in the company? Can that individual be an officer of the company?
10. Are there any rules governing a group of faculty, such as those in a private practice plan, using their resources to purchase large equity positions in companies that directly relate to their area of research or clinical practice?

11. How is conflict of interest defined in the university's policies? Do the rules apply equally to faculty, administrators, and governing or university-controlled foundation boards?
12. Who oversees what the campus Office of Technology Licensing (OTL) does and how it interacts with research management and conflict of interest management? To whom does OTL management report? Who reviews the details of decisions made by the OTL on behalf of the university? How variable are its practices? Are there published guidelines that inform and bind the OTL's degrees of freedom?
13. Are there rules about trustee involvement (such as venture capitalists) in the commercialization of university/faculty intellectual property?
14. Are there coordinated data systems to track data and alert management where problems are developing and require follow-up?

AAU

ASSOCIATION OF AMERICAN UNIVERSITIES
1200 New York Avenue, NW, Suite 550 • Washington, D.C. 20005
tel 202.408.7500 • *fax* 202.408.8184 • *web* www.aau.edu