Approaches to Developing an Institutional Conflict of Interest Policy - Section Four

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Published Date: 10/15/2001
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SECTION FOUR: Policy Considerations (What Should We Be Including in the Policy)

The AAU in its Report on Conflicts of Interest (2001) offers a number of procedural questions to be considered in the development of a policy. It presents a simple, three-fold approach that can serve as an outline for a university policy: 1) disclose always; 2) manage in most cases; and 3) prohibit the activity when necessary to protect the public interest or the interest of the university. The broad framework of a policy will emerge by answering the classic “who, what, when, where, and how” under each heading.

There are additional issues that warrant some consideration during the development of an institutional financial conflict of interest policy. We have listed a few below. The list is not exhaustive and is intended to supplement the “disclose-manage-prohibit if necessary” framework suggested above.

1. How will existing financial relationships and financial interests be managed after the creation of the policy? Universities will want to consider the need for transition or “grandfathering” provisions that describe what will be done with ongoing activities. Transitional provisions are typical in many new federal regulations. For example, the federal HIPAA Privacy Rule contains provisions that permit the use of private health information collected before the compliance date under a specific set of criteria. In the case of a university policy on conflicts of interest it will be important to remember that each existing situation will be unique. The university might consider describing a mechanism for the review of ongoing situations at the soonest reasonable time to ensure consistent application of the new policy.

2. What will be the effect of the new policy on existing policies, standard operating procedures, the university by-laws, etc.? Current policies may conflict with the new policies and, more often, the accompanying procedures can disrupt current procedures. A broad consultation with the various offices and administrative units that manage aspects of the research enterprise will bring any possible problems to light. This consultation can also identify opportunities to streamline the procedures. For example, information collected in a current industry-sponsors database might be easily modified to include additional questions relevant to disclosing and managing potential conflicts and procedures established to allow broader access to help in the review of disclosures.

3. How, when and what information on institutional conflicts will be distributed to other regulatory committees or offices on campus? Because of possible effects on the decisions of other committees or offices on campuses, will different categories
of research activities or different types of financial relationships require differences in the frequency of disclosures? Will annual disclosures be sufficient? Are some financial relationships and/or university activities better served by event-driven disclosures? Institutional conflicts of interest in research with human subjects should get special consideration by the university. Clear, standard mechanisms for communicating that information to the university’s Institutional Review Board (IRB) should be established to ensure the IRB has the information it needs to conduct and conclude its review of the research protocol.

4. Will the policy be administered by a committee or an individual university officer? If a committee is to be established, will it have final authority or is it advisory to a university officer? Is the process of selecting committee members described in sufficient detail to allow for regular changes in membership? How will the university ensure that the committee has access to the expertise needed to make informed decisions? In a manner similar to the creation of the policy development committee described in Section Two (Building a Consensus), the establishment of a committee to administer the policy should be carefully considered. The university may choose an approach consistent with that used for other review and/or recommendation processes like the Institutional Review Board that require technical expertise and, yet, a broad understanding of the conduct and management of the research. Because of the impact of the recommendations likely to result from committee deliberations and/or to whom the committee reports, the appointments to the committee might be made by a senior university officer on recommendations by various constituent groups, e.g., faculty, staff, etc.

5. How will the new policy and an individual’s related responsibilities be communicated to the community? How often will this communication occur and what related educational efforts will be undertaken? Should it be documented in any way? Communications and education can be key elements in ensuring compliance with any new policy or set of procedures. The research staff of the university changes each year with the arrival of new faculty, students, technical and administrative staff. The responsibilities of committees like the IRB need to be clearly stated and clearly communicated and the members of the IRB may be the focus of special educational efforts to ensure their role in the process. Formal letters, forms to be signed and returned, interlocking memberships on committees all offer communication and education pathways.

6. Who is in charge of follow-through on each aspect of the procedures? Do the designated individuals have the necessary authority and access to meet their obligations? There are structural implications to the management of any policy and these may be of particular concern in the area of institutional financial conflicts of interest. The AAU and AAMC identify as a goal the separation or segregation of the decision-making about financial activities and research activities to allow for separate and independent management. Reaching that goal may have a considerable impact on the administrative structures of the university.
One approach to the segregation of decision-making is the creation of firewalls that prevent conflicts of interest. In this situation, communications about research activities or financial activities between some members of the community will be counterproductive to the conflict management goal and thus require a thoughtful consideration of who needs to know what, when? But that communication may be critical to other aspects of the university’s business activities. These structural impacts need consideration as the policy is developed.

7. Are there relationships or interests that inherently raise the potential for institutional conflicts of interest? Once established, the new policy may affect the way the university enters into relationships and, if it is the intent of the policy to include prohibitions, the prohibitions should be clearly described. Short of absolute prohibitions, the university may choose to describe situations that need special consideration before they are finalized.

8. How will the university’s economic development activities, beyond patenting and licensing its technologies, be affected by the new policy? Many universities participate in community or university based business incubators. University participation can include a variety of incentives – shared space, reduced rents, etc., that are “returned” through equity or ownership positions. As with the question of structural impacts, the impact of the policy on other university goals or missions should be considered.

9. How do state and local statutes affect the development and implementation of the new policy? Most states have laws that govern the conduct of state employees. For state-assisted or public universities, these statutes and laws may need to be integrated into the university policy.

10. How will individuals unrelated to a managed conflict but adversely affected by the management plan seek relief? For example, a provost or senior academic officer has an interest in a private entity. To avoid potential conflicts, the university through its conflict of interest official or committee decides to prohibit the university from accepting sponsored agreements from that company. But a new faculty member’s research is focused in a unique and narrow area that is of significant interest to the company and, without knowing about the conflict management plan, she submits a proposal for research support. Will the university require her to withdraw the proposal? Will the university accept the research funding?

11. How will the institutional conflict of interest records – disclosures, management plans, committee deliberations, etc. – be managed? Depending on the approach chosen by the university, some personal financial information of senior university officers may be included with institutional financial information as part of the files and records. You may want to treat personal and institutional information differently.