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**Approaches to Developing an Institutional Conflict of Interest Policy - Section Five**

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# **Approaches to Developing an Institutional Conflict of Interest Policy**

## **SECTION FIVE: Implementation and Administration of a Policy (Now What?)**

Careful consideration of policy implications will serve an institution well as it implements its policy, and manages potential institutional conflicts of interest. In the process of developing an institutional conflict of interest policy, some of the mechanics of implementation will emerge. For instance:

1. Key players in the policy development may ultimately be responsible for the identification of institutional conflicts, and bringing them to the attention of the managing body;
2. The institution may identify and use those management strategies that are already in place in the institution, such as established firewalls between institutional investment function and technology transfer, or provisions incorporated into individual conflicts of interest policies e.g., prohibition of conducting a clinical trial if the individual held equity in a University start up company;
3. If policies incorporate a risk assessment approach, then focusing on “what to tackle first” will be made easier. Institutions can become overwhelmed at the outset creating management strategies for existing conflicts. Identifying those areas or situations that are of greatest concern will provide the institution with a risk based approach to selecting the cases that it deems priorities;
4. As noted in the previous section, communication of the policy is critical. Institutions should not be surprised that the culture of institutional decision making, especially in a much decentralized University environment, will not change overnight. Thus management plans should be crafted in a way that the local “institutional” decision makers are held accountable for management decisions impacting research.

The policy considerations in the preceding section offer excellent considerations that the university will want to carefully address in either its written policy or implementing procedures.

### **KEY FUNCTIONS for IMPLEMENTATION**

With the establishment of the policy for institutional financial conflicts of interest, the development of procedures and effective practices to implement the policy will be the next and a continuing step. The initial focus of procedures and practices can be assigned to one of five general areas: Identification of potential financial conflicts; setting priorities through risk assessment; developing a management plan, if appropriate; the

approval and execution of the plan; and on-going monitoring of the plan. Each individual case will shift the focus from identification to management; from risk assessment to monitoring. In the initial implementation phase, identification of current potential conflicts and setting priorities based on a risk analysis will take more time. The following considerations provide some additional practical solutions for conflict of interest identification and management.

#### Identification of Potential Financial Conflicts:

It is entirely possible that given the two general types of institutional conflicts of interest -- the University itself, and those institutional officials whose financial interests may conflict with their University role -- that two processes for identification may emerge.

Institutional officials, just as individuals engaged in research, should have a responsibility to report on an annual and ad hoc basis when a financial interest could, or could be perceived, to have an impact on his/her University responsibilities. Provided that institutional officials know to whom they should report, these types of institutional conflicts may be the easiest to identify and assess.

Depending upon the breadth of the institution's policy, the University's conflicts may be more difficult to identify collectively in a single list. At the outset, one or several persons could be delegated the responsibility to canvas the university's financial interests and relationships to identify real and perceived institutional conflicts to bring forward for assessment and consideration. If the institution's policy is limited to research, existing financial interests could be identified by taking an inventory of the University's equity interests in start up companies, existing royalty streams, or other financial interests and "cross-walking" these to research activities, lease arrangements, etc. Individuals from the offices of technology transfer, sponsored programs, research and counsel may be in the best position to do this. Going forward, responsibility must be vested in specific individuals to ensure identification of potential and real conflicts occurs. Whether the institution chooses to rely on a database, periodic reporting, or constant communication between offices and individuals, periodic consultations with various individuals and offices can help. For universities engaged in research involving human research participants, additional reporting of institutional financial interests during the IRB approval process may provide an additional opportunity for identification.

#### Risk Assessment

Institutions may find it helpful to define criteria that increase the potential conflict for the institutions and rank or order those criteria by risk and thus, in greater need for careful management. These criteria may include:

- Research involving the use of human research participants including clinical trials conducted at the university sponsored by or benefiting a startup/licensee
- Sponsored research conducted at the university by startup/licensee
- Purchase of supplies/services from a startup/licensee or visa versa

- Use of student employees at a startup/licensee
- Shared employees with a startup/licensee
- Existent enforcement issues with a startup/licensee
- Potential advancement/gift giving opportunities from or among startup/licensee/financial backer/University-affiliated donor
- University representation on company Boards of Directors
- Lease of University space to startup/licensee
- University as a shareholder with decision rights in a startup/licensee
- Sale of the University's equity interest in the startup or exercise of options in startup
- Incubator relationship with startup
- Significant royalty position in license based on institutional drug/device when the institution is considering participation in a clinical trial

### Research Involving Human Research Participants as a Separate Case

The first criteria, research involving human research participants (particularly clinical trials), may warrant its own set of criteria to provide considerations of issues like whether the institution would even entertain a management plan, or seek to eliminate the conflict. The Association of American Medical Colleges (AAMC) has offered advice on addressing institutional conflicts of interest in biomedical research activities that can help guide the development of criteria for clinical research. From an institutional conflict perspective, the risk assessment should take into consideration whether to conduct a clinical trial if the proposed study investigator has no individual conflicts related to the trial.

Provided the individual or committee overseeing conflict management is in agreement with these criteria, the institution may wish to delegate an individual or a subcommittee to prioritize those cases that the institution deems to be most important for management or conflict elimination.

### Development of a Plan

If the university has chosen to administer its institutional conflict of interest policy via a committee, it is usually impractical to have a committee draft a conflict of interest management plan. A designated individual with sufficient knowledge regarding the potential conflict could draft a plan and present it to the committee for its review, deliberation and approval. While each case will present unique circumstances, there may be certain management components that can be adapted to each case, and it will be important to maintain an appropriate degree of consistency in each plan. Written plans may consist of a description of the potential conflict, the delineation of criteria that may lead to risk, the justification for proceeding with management (vs. elimination of the conflict), and the management strategies addressing each of these criteria and the requirements for modification and updating the plan.

Deliberation on a specific case and plan may not always lead to a consensus. Universities will want to determine who ultimately has the authority to recommend the management strategy and/or elimination of the conflict. At this point in the process, the institution will also wish to determine whether the recommending body should include a member that is from outside the institution, or if there are specific situations when the institution because of the nature of the conflict would require an outside member.

### Approval and Execution of the Plan

A written plan may be the most appropriate vehicle for ensuring that everyone who is involved in management of an institutional financial conflict of interest has been apprised of his or her role. For instance, an institution may decide that given its financial interest, it will not enter into sponsored research with an entity, or perhaps purchase goods from that entity. In these cases, the chairs of the affected departments should be copied on the plan, or formally acknowledge the plan as he/she may have decision making that could impact the plan's instruction. The institution may decide that it will disclose the potential conflict to collaborating researcher or in press releases. In this case, the plan could be copied to these collaborators, or the head of Public Relations. If there are any questions related to the plan and ongoing conflict management, one person should be designated to answer any questions.

Final approval of the plan may be designated to the Provost, Vice President/Provost for Research, President/Chancellor, System-level or shared. Other institutions may deem that it is more appropriate to obtain written Board approval for institutional conflict of interest plans.

### Monitoring

As with individual conflict of interest cases, ongoing review and monitoring of the management plan is equally if not more critical. In the extreme, institutions may require a monitoring committee (perhaps including members from outside the University community) for the purposes of overseeing compliance with the institutional conflict of interest plan. While the general consensus is that monitoring committees may not be the most effective means of oversight, there may be situations (e.g. clinical trials) when the institution asserts that a monitoring committee may be necessary. Whether the institution chooses an individual or a committee to ensure ongoing monitoring, the responsibilities of monitoring may include: 1) reviewing publications and presentations for accurate disclosure and/or data integrity; 2) meeting with the PI of the research project and the scientific collaborators, and the responsible Chair on an as needed basis; 3) reporting to the Provost or President at least annually with respect to the management of the conflicts; and 4) reporting any significant concerns it identifies to the Provost/President immediately. The Provost or the President may, given the recommendations of the individual or monitoring committee require revisions to the management plan or terminate ongoing research studies to address concerns relating to research objectivity or subject safety.

## CASE STUDIES

Management of institutional financial conflicts of interest is by its very nature more complex than that of individual financial conflicts of interest. Current federal regulations for managing individual conflicts of interest can be instructive.

The primary goal of the case studies presented here is to help illustrate the types of situations defined and discussed in the *Approaches to Developing an Institutional Conflict of Interest Policy*. The definitions in Section One frame these studies. The policy considerations described in Section Four and implementation questions described here in Section Five can be informed by looking at the case situations and considering how the institution would address the situation. From the outset, it is important to recognize that the missions and cultures of research institutions vary and, particularly for public institutions, the laws of the states in which they are established may be more or less explicit with regard to situations that give rise to potential financial conflicts of interest. As a result, institutional policies and practices will be different, and it will remain critical for faculty and administrators to be familiar with the expectations and standards of their own institution.

These studies explore potential institutional financial conflict of interest and identify some relevant issues and possible management strategies. The examples and issues presented do not necessarily constitute inappropriate financial interests and relationships. Each situation must be judged on the facts and merits of the relationship with an eye to what reasonable individuals outside the affected community might consider to be appropriate. Because all potential conflicts are situational, and because the cultures and management practices of institutions vary, our goal is to suggest issues and options for management, not to prescribe “best practices” or “preferred approaches.” While the studies represent some of the most common conflicts that may arise in a research institution, we do not attempt to provide an exhaustive or complete list of every possible situation.