Conflict of Interest and Conflict of Commitment Management in Technology Transfer

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ABSTRACT

The potential for personal interests to influence institutional decisions in universities and public sector research institutions continues to grow. This is because of the increasing activity in intellectual property (IP) management and technology transfer undertaken by these institutions. The activities have the potential to generate both personal and institutional financial gain, making conflict of interest and conflict of commitment issues unavoidable. This chapter explains the nature of these conflicts and discusses the policies, regarding conflict of interest, of several universities, offering them as potential models for crafting these indispensable policies.

1. INTRODUCTION

Universities and public research institutions have been characterized historically by their selfless efforts to expand knowledge for the public good rather than for private gain. This has contributed to a high level of public trust in the integrity of these institutions, and they are seen as providers of unbiased information. This institutional integrity rests on the personal integrity of the people employed by or associated with that institution, which collectively represent the greatest asset of the institution. Indeed, any erosion of institutional integrity or of the public's trust can have devastating consequences in terms of public support for the institution.

One significant danger with regard to compromising the integrity of a university or public research institution is the potential for personal interests (often financial) to adversely affect an employee's professional judgment when exercising a university duty or responsibility, for example, the direction and conduct of research. The potential for a divergence between an individual's institutional obligations and his or her private or personal interests can become a conflict of interest: and a perceived conflict of interest can be as damaging as a real one.

The potential for personal interests to influence institutional decisions is greater today because every institution is doing more in the area of IP management and technology transfer, and because these activities have the potential to generate both personal and institutional financial gains, conflict of interest issues are a constant concern. Indeed, in today's modern research universities, the missions of which explicitly include the transfer of research to commercial partners, conflicts of interest are practically unavoidable. These conflicts need to be managed in ways that allow institutions to meet their technology transfer mission without compromising their integrity and the public's trust.

Another closely related pitfall is the pressure that technology transfer and commercialization activities place on employees' primary allegiance to their institution. In an era when researchers are encouraged to actively participate in technology

Bennett AB. 2007. Conflict of Interest and Conflict of Commitment Management in Technology Transfer. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

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transfer—and even in the development of new companies—it is necessary to ensure that the employee's primary professional loyalty is to the institution rather than to a private, extramural activity. When outside activities cross boundaries in ways that compromise, or appear to compromise, the employee's primary allegiance to the institution, a conflict of commitment exists. Because both conflicts of interest and conflicts of commitment are potential pitfalls in the technology transfer process, both are addressed in this chapter. Some universities address both conflicts in a single combined policy (for example, Stanford University), while most treat conflicts of interest and conflicts of commitment in separate policies.

2. CONFLICT OF INTEREST RELATED TO IP MANAGEMENT

Fundamentally, a conflict of interest is any situation in which there is a conflict between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are affected by his or her private interest.[1] It is important to note, a conflict of interest exists whether or not decisions are made that are influenced by personal interests. The conflict only indicates the potential for making biased decisions—not any likelihood of doing so or any a priori misconduct. One should also note that the precise definitions of conflict of interest are guided by national and local laws, research sponsor policies, and institutional policies; thus the definitions may vary widely depending on the geographic and institutional context.

The potential for financial conflicts of interest for individual researchers increases dramatically when an institution begins to actively support and promote the transfer of research results for commercial applications.[2] In many cases, the commercial development of early-stage research results can be carried out best by a start-up company. Typically, the university researcher is either a founder of or a consultant to the company and has substantial financial interests in the company. This gives rise to a personal conflict of interest, and any future decisions on research directions, assignment of research topics to students, the supervision of clinical trials, or any influence over institutional IP licensing decisions by the researcher/entrepreneur should be viewed through the lens of the institution's conflict of interest policies. Again, it is important to note that the existence of the personal financial interests should not, in themselves, but in general the conflict should be openly disclosed and any future activities and decisions by the conflicted individual reviewed and managed by the institution.

The potential for a researcher to have a significant financial interest in an outside potential licensee can be quite high, particularly if the licensee is a start-up company founded by the researcher/inventor. When the researcher participates in the licensing negotiations or even in discussions with the institutional licensing officer, the researcher is in a conflict of interest position: the researcher has the potential to influence an institutional licensing decision in which he or she has a direct financial interest. In California, such a position constitutes a criminal conflict of interest under the Political Reform Act of 1974. As a consequence of the Act, the University of California developed detailed guidelines and guidance on the disclosure and management of conflicts of interest in licensing. These guidelines permit participation in licensing negotiations by an inventor, even when he or she has a disqualifying personal financial interest. As the guidelines observe, such participation "*is appropriate and represents a useful contribution, because the transfer of University technology to industry is in the public interest and is consistent with the University's mission*."[3] Such participation, however, requires an appropriate intervening substantive review, called a Licensing Decision Review, which determines whether licensing decisions are inappropriately influenced (see Box 1). Although these guidelines for managing conflicts of interest in licensing are very specific to the laws of the State of California, they raise and consider a number of important issues that are both generic and specific to technology transfer.

An additional level of conflict of interest has also emerged as a result of universities taking an

Box 1: University of California Guidelines for a Licensing Decision Review

What is Licensing Decision Review?

Licensing Decision Review means there is a review by a noninterested person or persons before a proposed licensing decision goes to the final decision maker for approval. The review must be based on an independent consideration and assessment of the facts of the case. The Licensing Decision Review body, composed of qualified staff with appropriate expertise, knowledge, and professional judgment, must independently check the original data and analysis upon which the selection of licensees proposed by the licensing professional and other licensing decisions were made and make its independent recommendations concerning the decisions.

Who conducts the Licensing Decision Review?

Each University of California campus and laboratory was directed in a June 18, 2001, letter to chancellors and laboratory directors from Provost King and Senior Vice President Mullinix to establish a plan for conducting intervening substantive review of licensing decisions (in this case, called Licensing Decision Reviews), whether those licensing decisions are made in the systemwide Office of Technology Transfer (OTT) or at a campus or Laboratory Authorized Licensing Office. Each local Licensing Decision Review plan, including the processes, mechanisms, and bodies (individuals or committees) established to carry out Licensing Decision Reviews may accommodate local needs and circumstances, but must be responsive to the direction provided in that letter and, consistent with these Guidelines, must be filed with the OTT.

Source: University of California.[4]

active role in IP licensing, particularly to start-up companies. Typically, the university will accept equity in a company in lieu of upfront license issue fees, which gives the university itself a financial interest in the company. This leads to an institutional conflict of interest. Such institutional conflicts of interest have been particularly problematic in research involving human subjects, so institutional policies are being developed to ensure that the financial interests of the researcher and the institution do not create a conflict of interest in enrolling and ensuring the safety of human research subjects. Stanford University's Institutional Conflict of Interest Policy provides a concise approach to ensuring that all human-subject institutional reviews include a review of whether the university has any financial interests in drugs or devices under study or financial interests in the company that is sponsoring the research (See Box 2).[5]

3. CONFLICT OF COMMITMENT RELATED TO IP MANAGEMENT

Faculty and researchers working in educational and research institutions are expected to give primary allegiance and professional commitment to the institutions that employ them and devote primary energy to teaching and research. Even so, most institutions value their staff's contributions to professional and public service, including pro bono work and paid consulting. In addition, public institutions increasingly value the role of employees in technology transfer and its contribution to economic development. Effective technology transfer inevitably requires faculty and researchers to actively participate in the commercialization process, which often includes taking an active role in starting up new companies that are capable of developing and exploiting university inventions. These multiple institutional goals create the potential for a conflict of commitment between the institution's primary educational and research mission and the institution's interest in effectively supporting economic development and technology transfer through the external activities of its faculty and researchers.

Conflicts of commitment typically require determining the appropriate balance of time allocation between institutional and external activities—the critical test is that external activities

Box 2: Highlights of Stanford University's Institutional Conflict-of-Interest Policy

The goal of this policy is to preclude situations in which human-subjects research is carried out at Stanford or by Stanford researchers involving organizations in which the University holds ownership equity or rights to equity that is not publicly traded. The fundamental assumption underlying the policy is that such situations present a significant risk to the perceived objectivity of the research. The policy requires that the Office of the Dean of Research be informed of all such situations and provides that, after a review of the facts and circumstances, the Associate Dean of Research may either arrange the divestment of the University's holdings through the Office of Technology Licensing or, if that cannot be done, refuse to allow the research to proceed.

DISCUSSION AND DETAIL

1. **Review by the Office of Technology Licensing (OTL) of all human-subjects research protocols proposed by University Principal Investigators:**

   At the request of the Office of the Dean of Research, the Stanford Research Compliance Office has established a procedure that requires all new human subjects research protocols submitted for regular or expedited review to the IRBs to indicate (1) the nature and source(s) of all drugs, devices, or biologics (e.g., vaccine products, gene therapeutics) which will be used in the proposed research and (2) the source(s) of all funding to be used in supporting the research. Per this procedure, the information provided is then reviewed by the Director of OTL to identify situations in which the proposed research involves (1) the use of drugs, devices, or biologics that make use of Stanford-owned intellectual property or (2) funding from nonpublicly traded organizations in which Stanford owns equity or the right to acquire equity through a licensing agreement.

2. **Review by the Office of the Dean of Research of all protocols that might be subject to this policy:**

   Per the procedure described above, the Director of OTL flags for further review by the Office of the Dean of Research all proposed new human subjects research proposals involving the use of drugs, devices, or biologics that make use of Stanford-owned intellectual property or are funded in whole or in part by nonpublicly traded organizations in which Stanford holds equity or the right to acquire equity through a licensing agreement. Based on the facts and circumstances identified in this review, the Associate Dean of Research will (1) require OTL to divest that equity on behalf of the University or (2) prohibit or require modifications to the proposed human-subjects research which would remove any possibility for the University as an institution, or any University department, to benefit as a result of the conduct or outcomes of the proposed research. In the event the University's financial interest is in the form of royalties payable as a result of exclusive technology licensing rights, OTL will inform the Associate Dean of Research, who will determine on a case-by-case basis the significance and management, if appropriate, of the potential institutional conflict of interest.

3. **Monitoring compliance:**

   The University's Internal Audit Department will periodically review a sample of human subjects research protocols to ensure that all situations in which a potential exists for institutional conflict of interest have been properly identified and all risks to human subjects have been properly mitigated.

4. **Responsibilities of the Dean of Research:**

   The Vice Provost and Dean of Research is the University officer responsible for interpreting and overseeing implementation of and compliance with this Policy. Questions may be addressed to the Assistant Dean of Research.

Source: Stanford University.[6]

should not detract from their primary institutional responsibilities. Institutions vary widely regarding permissible external activities, which may reflect differing institutional priorities as well as whether the institution is public or private. Stanford University, for example, integrates both conflict of interest and conflict of commitment into a single policy that specifies the appropriate balance of time commitment to external activities to be approximately one day per week (see Box 3).

4. STRUCTURE OF A CONFLICT OF INTEREST/COMMITMENT POLICY

The development of institutional conflict of interest and conflict of commitment policies is a critical step in developing technology transfer capabilities and programs. Developing the policy will require identifying and articulating institutional priorities and determining the appropriate balance between institutional interests and the interests—both internal and external—of its researchers. In addition, the effort will require an in-depth analysis of the requirements placed on the institution by national or local laws and by the policies of agencies that sponsor research in the institution. The elements of a conflict of interest/commitment policy are outlined below; actual policies take many forms.

4.1 *The purpose of the policy and applicability*

The preamble of the policy should reiterate the primary mission of the institution and indicate in general terms how the institution views the balance between internal and external activities and the potential for developing conflicts. For example, the Washington University in St. Louis Conflict of Interest Policy is presented, in part, in Box 4.

The preamble should identify to whom the policy applies. In some cases, the policy may be broadly applicable to all institutional staff, while in other cases different policies may be required for teaching faculty, for clinical faculty, and for nonfaculty staff. Whatever the case, the applicability of the policy needs to be clearly stated early in the policy document.

4.2 *Definitions*

Definitions of key terms are typically provided to ensure the policy's clarity. For example, the definition of "significant financial interests" should be explicit with regard to applicable instruments of monetary value such as stocks and stock options. It should also explicitly state the extent to which such interests extend to the researcher's spouse, children, or domestic partner. Examples of terms that have been useful to define at our the University of California include:

- business entity
- clinical research
- compensation
- conflict of interest
- gift
- intellectual property
- investigator
- management plan
- research
- select officials
- significant financial or other interest

4.3 *Policy*

The policy statement should clearly describe acceptable and prohibited activities, requirements for reporting and disclosure, and processes for evaluating and managing specific situations that are not directly addressed by the policy.

4.4 *Process, roles, and responsibilities*

The policy should clearly describe the institutional processes for disclosing external activities, if there is a requirement to do so, as well as describing the processes for seeking a review and evaluation of conflict of interest disclosures. Most institutions have one authorized official with this responsibility and a committee that participates in evaluations. The policy should describe the processes for appointing the relevant committees and identify the institutional officials with responsibility for conflict of interest evaluations and management.

4.5 *References and links to source documents*

Finally, a conflict of interest/commitment policy does not exist in isolation but typically relies on the synthesis of a number of source documents,

Box 3: Summary of Stanford University's Faculty Policy on Conflict of Commitment and Interest

1. Faculty must maintain a significant physical presence on campus (main or overseas) throughout each quarter they are on active duty.
2. Faculty must not allow other professional activities to detract from their primary allegiance to Stanford. For example, a faculty member on full-time active duty must not have significant outside managerial responsibilities nor act as a principal investigator on sponsored projects that could be conducted at Stanford University but instead are submitted and managed through another institution.
3. Faculty must foster an atmosphere of academic freedom by promoting the open and timely exchange of results of scholarly activities, ensuring that their advising of students and postdoctoral scholars is independent of personal commercial interests, and informing students and colleagues about outside obligations that might influence the free exchange of scholarly information between them and the faculty member.
4. Faculty may not use University resources, including facilities, personnel, equipment, or confidential information, except in a purely incidental way, as part of their outside consulting activities or for any other purposes that are unrelated to the education, research, scholarship, and public service missions of the University.
5. Faculty must disclose on a timely basis the creation or discovery of all potentially patentable inventions created or discovered in the course of their University activities or with more than incidental use of University resources. Ownership of such inventions must be assigned to the University regardless of source of funding. The inventor will share in royalties earned.
6. Faculty must disclose to the University whether they (or members of the immediate family, as defined below) have consulting or employment relationships with, and/or significant financial interests (also defined below) in, an outside entity before the University will approve the following proposed arrangements involving them between such entities and Stanford: a) gifts; b) sponsored projects; c) technology licensing arrangements; and d) certain procurements. In such cases, approval by the school dean will be required prior to entering into each proposed arrangement.
7. In situations in which the objectivity of a faculty member could reasonably be questioned, the dean of a school may establish an independent oversight committee to take steps including (but not limited to) the following: to review the appropriateness of the proposed research to be conducted at Stanford, to oversee the conduct of the research, and to ensure open and timely dissemination of the research results. Such oversight committees will be required for all clinical trials raising questions of conflict of interest.
8. On an annual basis all faculty members must certify to their school deans their compliance with Stanford's policies related to conflict of interest and commitment. They must also disclose information about their (and their immediate family members', as described below) financial relationships with outside organizations that are sponsors of their teaching or research programs or are otherwise involved in current, proposed, or pending financial relationships with the University that involve the faculty member. In addition, faculty must disclose to their school dean on an ad hoc basis current, proposed or pending situations that may raise questions of conflict of commitment or interest, as soon as such situations become known to the faculty member.
9. School deans shall establish procedures to ensure timely review of their faculty's annual and ad hoc disclosures of potential or apparent conflicts, and to ensure (in consultation with the Dean of Research office) the appropriate management of such conflicts. Such procedures may involve representatives from the school's faculty as part of a reviewing body. School deans will file their own annual disclosures and certifications of compliance with the Dean of Research.
10. The Dean of Research shall approve each school dean's plans for implementing this policy, interpret policy provisions in consultation with school deans, respond to faculty wishing to appeal school deans' decisions, and report to the Committee on Research annually on the status of this policy and its implementation.
11. Should a faculty member wish to appeal a decision made by the Dean of Research, he or she may present the appeal to the Provost, who will consider the case in consultation with the Advisory Board.

Source: Stanford University.[7]

Box 4: Excerpt of Washington University's Conflict of Interest Policy

The faculty and administrators at Washington University recognize a shared responsibility to ensure that they conduct themselves in an unbiased manner and serve the goals of the University. It is thus the responsibility of the University and its employees to guard against conflicts of interest that might compromise the integrity and objectivity of the University community.

It is understood that the faculty, as developers of knowledge, have a unique opportunity and responsibility to disseminate that knowledge to the public. By adopting this Conflict of Interest Policy, the University reaffirms the value of collaboration with industry as a means of fostering public access to the practical benefits of University research. By adopting this Conflict of Interest Policy, the University also (i) demonstrates its commitment to the ethical principles that guide University research and (ii) establishes a mechanism to safeguard University and faculty integrity and objectivity so that University/industry interactions can optimally benefit society.

Source: Washington University. [8]

policies, and laws. These sources should be listed and hyperlinked from the policy.

5. CONCLUSIONS

In addition to the legal reasons to develop and enforce rigorous conflict of interest and conflict of commitment policies, the fundamental reputation of the institution rests on setting and maintaining high ethical standards. As Johns Hopkins University's policy states: "*public confidence in the University's integrity undoubtedly ranks among its greatest assets*."[9] Although technology transfer activities are only one of many areas in which the potential for conflict of interest exists, the interface between the mission of the university and the demands of industry and of private sector collaboration is a rich breeding ground for such potential conflicts. As an institution becomes engaged with the private sector and with technology transfer, the adoption of a thoughtful conflict of interest and conflict of commitment policy is essential. Not only is the policy itself an essential administrative tool, but the analytical process of developing the policy will reveal the institution's priorities. The process will also clarify what the university considers the appropriate balance of allowed and prohibited activities for achieving the university's mission(s). In the United States, there has been a convergence of norms in conflict of interest/commitment policies that is driven by our legal framework and by the policies of national research sponsors. It is likely, however, that other countries facing very different demands for research-based economic development may find that the U.S. approach does not conform to their regional and institutional needs. ■

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1 Chinn J and EC Kulakowski. 2006. Conflict of Interest in Research. In *Research Administration and Management* (eds. EC Kulakowski and LU Chronister). Jones and Bartlett Publishers: Sudbury, Mass. pp 511–21.

2 Garton JD. 2002. Conflicts of Interest and Technology Transfer. *AUTM Technology Transfer Practice Manual*, Part XIII, Chapter 2. AUTM: Northbrook, Ill.

3 University of California. 2001. Guidelines on Managing Potential Conflicts of Interest in Licensing. www.ucop.edu/ott/staff/ott00-05b.pdf. This and other conflict of interest and conflict of commitment policies are also available via the online edition of this *Handbook*.

4 Slightly edited and based on *supra* note 3.

5 An online tutorial on conflict of interest from Columbia University can be found at ccnmtl.columbia.edu/projects/rcr/rcr_conflicts/foundation/index.

6 www.stanford.edu/dept/DoR//rph/4-7.html.

7 Ibid.

8 www.wustl.edu/policies/conflict.html.

9 jhuresearch.jhu.edu/Policy_onConflict_of_Interest.pdf