

## **Policy Statement Regarding Application of Harvard University's Conflict of Interest Policies to the Granting of Licenses**

Approved by the University Committee on Patents and Copyrights on March 19, 1993 and by the President and Fellows of Harvard College on September 20, 1993. Revisions approved by the University Committee on Patents and Copyrights, acting under prior consent of the President and Fellows of Harvard College, at its April 22, 1995, February 16, 1996, and March 16, 2001 meetings. Amended by authority of the President and Fellows of Harvard College, as granted February 4, 2008.

### **Introduction**

The University is increasingly licensing inventions or other technology to for-profit companies. The growth of such licensing activities has given rise to questions about whether and under what circumstances the University should license its technology to a company in which University faculty members, students or employees have some type of financial interest.<sup>1</sup>

Existing University policies addressing conflict of interest take two forms. First, the Governing Boards and certain Faculties have adopted policy statements that address the subject of conflict of interest in general terms.<sup>2</sup> Second, the Faculties of Medicine and Public Health have adopted policies and procedures that deal specifically with issues arising in the context of academic research (particularly biomedical research).

The present statement is intended to establish University conflict of interest policies to apply specifically to licensing transactions. Periodically, the University Provost will review the policy and the University's experience with it. Based on that review, the Provost will propose to the Corporation for its approval modifications of the policy and its procedures to the extent the Provost deems appropriate.

### **Principles**

Since the University is increasingly licensing inventions and other technology to for-profit companies and is receiving income from this activity, it must pay careful attention to and resolve potential conflicts of interest that may arise. The University has established policies and procedures for identifying, protecting and licensing innovations resulting from University activities.<sup>3</sup> The University Office of Technology Development (OTD) has been charged with responsibility for carrying out these policies under the oversight of the University Provost.

The development and application of the policies and procedures described below are based on the following considerations:

1. Individuals serving the University are expected to accord the University their primary professional loyalty, and to arrange outside obligations, financial interests, and activities so as not to conflict with this overriding commitment. In

particular, members of the University should not seek to influence the University's technology transfer decisions in ways that could lead to personal gain<sup>4</sup> or give improper advantage to their associates.

2. When granting licenses, Harvard seeks to identify licensee companies which have the capability and commitment to develop the technology and bring it to market as efficiently as is feasible. In most instances the University does not survey all potential licensees but rather targets its marketing efforts to those companies OTD identifies as suitable potential licensees based on the professional judgment of OTD staff members, who evaluate each technology partnering opportunity in light of information from a number of sources. When at least one such company expresses interest in a license, OTD may elect to negotiate and enter into one or more license agreements (which may be exclusive in one or more fields of use, or non-exclusive, depending on the technology). However, when there are potential conflicts of interest because a University faculty member, student or employee (whether or not an Inventor or Author, each as defined in the University's "Statement of Policy in Regard to Intellectual Property", dated February 4, 2008) has a Close Financial Interest (*see* Paragraph 3 of "Procedures", below, and footnote 5) in a potential licensee company, further consideration as indicated in Paragraphs (3) and (4), below, may be needed to assess the validity of an initial decision to grant a license to the company in question.
3. The University recognizes that emerging companies play an important role in the national and local economies. Since the passage of the Bayh-Dole Act in 1980, numerous new companies have been established to commercialize technology licensed from academic institutions. In order to grow, these emerging companies must focus their efforts and resources on rapid development of the technologies they have licensed to a greater extent than must established companies that have much larger technology portfolios. Inventors and Authors and other Harvard faculty members, students or employees often play a key role in these emerging or start-up companies, and the opportunity to participate in a new venture without having to leave the University can be attractive to them and advantageous to Harvard. For these reasons, an emerging company may offer the best opportunity for the rapid commercial development of at least some Harvard inventions. Therefore, when an emerging company is deemed to have the potential to obtain sufficient financial and management resources to be capable of vigorous development of a University technology, licensing to that company should be given serious consideration.
4. It is recognized that faculty members, students and employees of the University often have a Close Financial Interest in these emerging companies and that the resulting potential for conflicts of interest requires careful management. The appropriate course of action in a particular case is determined through fair and thoughtful consideration of a variety of factors, including the reason for the proposed transaction, the nature of the invention, the market for the technology being licensed, the nature of a given individual's interest in and involvement with

the licensee company, and the relation of that individual's future University research to the interests of the licensee company. For example, the highly conceptual or early-stage nature of university technologies often necessitates the ongoing involvement of Inventors or Authors in a licensee company's development efforts, and thus such individuals often become consultants to and have a financial relationship with the licensee by receiving consulting fees from or equity in the company. While the University recognizes that thorough review of these relationships is essential, it also supports the commercial development of University inventions and the involvement of its faculty, students and employees in that process.

## **Procedures**

The following steps will be taken by the staff of the OTD to minimize the potential for creating an unacceptable conflict of interest in the granting of licenses:

1. The staff of OTD will use their professional judgment and information from a range of sources to evaluate potential licensees for a given technology; this process may include suggestions provided by the Inventors or Authors, or by other faculty members, students or employees of the University.
2. The staff of OTD will disclose to the University on an annual basis any financial interests they have in companies which are or may become potential licensees and may not participate in licensing discussions or negotiations which would benefit those companies.
3. When a primary candidate for an exclusive license is identified, and before any license or option agreement is negotiated, OTD staff will ask each Author or Inventor, and any other University faculty member, student or employee whose involvement with the licensee or optionee is known to OTD, whether they or any members of their immediate family or household have, or plan to have, a personal financial relationship with the potential licensee or optionee. When options are to be granted to as-yet-undisclosed inventions (e.g., as in industrially-sponsored research or material transfer agreements) only holdings of equity (as defined in footnote 5 below) or consulting agreements which tie compensation to the value of the company, its stock, or its profits will be considered to be Close Financial Interests.<sup>5</sup>
4. If no Close Financial Interest exists or is planned between any Inventor or Author, or any other faculty member, employee or student of the University, or any member of the family or household of any such person, and the potential licensee, OTD will proceed to negotiate a license.
5. If any such individual has a Close Financial Interest, and the potential licensee company is an emerging company (i.e., a company not yet formed or a company which does not yet have initial financing), OTD shall be delegated responsibility

for determining whether the company has the potential to obtain sufficient financial, management and technological resources to enable vigorous development of the technology to be licensed. If the determination is made in favor of the proposed licensee, then OTD, at its discretion, using its best professional judgment may:

1. enter into a license agreement with the emerging company, which agreement contains provisions for license termination in the event that the company fails to meet objective, time-limited business development milestones that may include, e.g., achieving capitalization to a threshold level deemed sufficient by OTD staff to enable vigorous development of products based on the licensed technology or meeting specific technology-based milestones;

or

2. grant the emerging company a short-term 'stand-still' or option period, during which the company may seek to assemble resources identified by OTD staff as critical and/or negotiate an exclusive license for the relevant technology, the granting of which will be contingent upon the company having met pre-agreed criteria.
6. Once it appears that an exclusive license may be granted to a company in which an Inventor, Author or other Harvard faculty member, employee or student has a Close Financial Interest, each such individual will inform the Faculty committee which deals with conflict of interest issues<sup>6</sup> for the School with which they are affiliated (or, if an individual having a Close Financial Interest is not a faculty member, the appropriate University committee, office or administrator) of that possibility and will initiate discussions with the committee to resolve any conflict of interest concerns the committee might have. Before or soon after a license is signed with a company in which any such individual has a Close Financial Interest:
1. Each individual who has a Close Financial Interest will provide the appropriate committee, office or administrator with written notice of each such license, which notice will identify the licensed technology and licensee company.
  2. Each such individual will notify the relevant committee, office or administrator if the license is expected to include rights to future technology (other than that which would be contained in continuation-in-part patent applications, to the extent also contained in patent applications in existence as of the effective date of the license) such as rights to separately patentable "improvements" and whether such improvements are limited to technology dominated by the originally licensed technology.

3. In addition, each Author, Inventor or other Harvard faculty member, employee or student with a Close Financial Interest is required to provide the appropriate committee, office or administrator with the following:
  1. the details of that individual's relationship to the prospective licensee company;
  2. the relationship, if any, of such individual's ongoing University research to the activities of the licensee company; and
  3. a completed "Conflict Avoidance" statement in a form similar to that of the blank form attached. Through this statement, the individual acknowledges the potential for conflict and commits himself or herself to certain actions to minimize and manage that potential. In the case of a faculty member, the statement will be signed by the individual and countersigned by his/her department chairperson. In the case of research staff, students, or post-doctoral fellows, it will also be signed by the faculty supervisor of the individual's research activities. If the department chairperson or faculty supervisor also has a Close Financial Interest in the company, the chairperson of the appropriate Faculty committee will countersign. (It is recognized that individual Faculty policies regarding conflict of interest and commitment may require other forms of disclosure and/or action in addition to this statement.) If an employee or student not involved in research activities has a Close Financial Interest, the Conflict Avoidance Form will be countersigned by the head of the unit by which such person is employed or by the appropriate dean or administrator in the School in which they are enrolled.
4. Based on conclusions drawn from review of the above information, the relevant committee, office or administrator will institute any monitoring, review or reporting mechanisms or other actions that may be deemed appropriate to address a potential conflict of interest on the part of the individual having a Close Financial Interest, such as:
  1. reduction or elimination of such individual's equity ownership;
  2. ongoing (annual) reporting by that individual on the relation, if any, of his/her university research or other University activities to the licensee company and how the potential for conflict is being managed; and/or
  3. monitoring of the future research or other University activities of the individual.

## Footnotes

<sup>1</sup>To be sure, the relationship between the University and private enterprise in the context of academic research has raised a number of other questions in addition to those relating to conflict of interest in licensing, around which various schools have established policies. This statement, however, only deals with the issues related to licensing.

<sup>2</sup>Faculty of Arts and Sciences, Policies Relating to Research and Other Professional Activities Within and Outside the University (1982, as last amended in 2000), Policy Statement of Conflicts of Interest (1975) which applies to the Governing Boards and senior administrative officers of the University, and Harvard University Statement on Outside Activities of Holders of Academic Appointments (2000).

<sup>3</sup>Statement of Policy in Regard to Inventions, Patents and Copyrights (November 3, 1975, as last amended and restated on February 4, 2008 as the “Statement of Policy in Regard to Intellectual Property”).

<sup>4</sup>References to personal gain include gain for the individual, family and/or household members, business associates, etc.

<sup>5</sup>A Close Financial Interest includes equity, the option to obtain equity, or the promise of equity in the prospective licensee company, or a long-term, exclusive or otherwise significant consulting arrangement with the prospective licensee company. An equity position will not be considered a Close Financial Interest unless: (a) the equity represents a significant share of the company (a holding of over 5% of the company’s stock would be presumed to be significant; holdings of less than 5% will require case-by-case consideration) or (b) the proposed license or the Inventor’s, Author’s or other individual’s future research is likely to have a significant impact on the value of the stock. A relatively small number of shares of a large publicly-held company will not be considered a Close Financial Interest, but a small number of shares in a start-up or privately held company is likely to be considered a Close Financial Interest. A Close Financial Interest shall be considered to exist whether the above relationship is with the Author, Inventor or other Harvard faculty member, employee or student, or with members of his/her immediate family and/or household.

<sup>6</sup>In the Faculty of Arts and Sciences, the Committee on Professional Conduct; in some Faculties, the Dean or the Dean’s representative may be designated rather than a Committee. Generally, reporting to the Faculty Committee is accomplished by reporting to the Committee’s administrative staff or to the Chair of the Committee.

## Harvard University Conflict Avoidance Statement

Name: [ ]

Department/Faculty: [ ]

Licensed Technology: [ ]

Licensee Company/Address: [ ]

Because of the license granted by Harvard to the above company and my Close Financial Interest in this firm, I acknowledge the potential for a possible conflict of interest between the performance of my research, teaching, administrative or other obligations at Harvard and my personal financial interests and/or contractual or other obligations to this firm. Therefore, I will not:

1. involve students or post-doctoral fellows at Harvard in research and development projects for the company without the prior approval of the dean or the dean's designee;
2. restrict or delay general access to information from Harvard research;
3. alter the scope or direction of my Harvard research, if any, or the Harvard research of others; and/or
4. alter performance of my obligations to Harvard, whether by action or inaction, in order to materially benefit the company.

In addition, in order to avoid the appearance of a conflict, I will attempt to differentiate clearly between the intellectual directions of my Harvard research, if any, and my contributions to the company. To that end, I will report annually (i) to my department head (and/or faculty supervisor) and to the chairperson of the appropriate Faculty committee or, (ii) to the appropriate Harvard committee, office or administrator the general nature of my activities on behalf of the company and how those differ from my Harvard research or, if I am not engaged in the performance of research at Harvard, how such activities relate to the performance of my obligations to Harvard.

Finally, I understand that Faculty policy may require me to disclose that I have a financial interest in the company in any publications or public statements I make presenting research results related to this license.

Signature/Date: [ ]

Acknowledged by department head/Date: [ ]

Acknowledged by faculty supervisor (for research staff, students and post-docs)/Date: [ ]

Acknowledged by chairperson of Faculty committee (if required)/Date: [ ]

Acknowledged by head of unit in which employed (for non-research staff)/Date [ ]

Acknowledged by dean (or his/her designee) of school in which enrolled (for non-research students)/Date [ ]