

**UNIVERSITY OF CALIFORNIA GUIDELINES
ON MANAGING POTENTIAL
CONFLICTS OF INTEREST IN LICENSING
(August 1, 2001)**

POLICY

President Saxon, in his June 23, 1980 memorandum to Chancellors and Laboratory Directors, stated that the University's overall policy on conflict of interest is that "none of its faculty, staff, managers, or officials shall engage in any activities which place them in a conflict of interest between their official activities and any other interest or obligation." Over the years a variety of specialized policies and guidelines have been issued in recognition of the need for further direction in this and in related areas of ethical standards and codes of conduct.

These guidelines are issued by the Office of Technology Transfer, UCOP at the request of Provost King and Senior Vice President Mullinix in their June 18, 2001 letter to Chancellors and Laboratory Directors in which they asked each site to implement the requirements of California's Political Reform Act with regard to licensing University research results. These guidelines address University decisions made in the course of licensing activities, and not matters of patent prosecution.

GUIDELINES

The Political Reform Act of 1974 ("Act") and its accompanying regulations set forth complex and comprehensive rules designed to assure that public officials "perform their duties in an impartial manner, free from bias caused by their own financial interests or the financial interests of persons who have supported them." The rules apply to public officials at all levels of government in California, from the Governor on down to city officials, and include University faculty and UC administrators. The Act creates the Fair Political Practices Commission ("FPPC") to interpret and enforce its provisions.¹

These guidelines address some of the most common concerns regarding potential conflicts of interest in University licensing activity, and shall be followed to implement the requirements of the Act. They are developed to clarify the roles of both inventors and

¹ The Act is found in the California Government Code at section 81000, et seq. The implementing regulations regarding conflict of interest are found at California Code of Regulations, title 2, section 18700 et seq. A violation can result in agency discipline or a civil fine. (Gov. Code, § 91000 et seq.)

licensing professionals and to assist them in complying with the Act. The guidelines also apply to authors whose works will be licensed by the University. For purposes of these guidelines and related documents, "inventors" is meant to include "authors" and "inventions" is meant to include "works of authorship", where applicable.

The conflict of interest coordinators at the Office of the President, the campuses, and the Laboratories; and attorneys at the Office of General Counsel will do their best to answer additional questions with respect to compliance with the Act and should be able to provide guidance about most common situations. The law and regulations are complex, however, and only the State Fair Political Practices Commission itself can offer a definitive interpretation of the Act.

I. UNIVERSITY LICENSING DECISIONS

Why does the University license inventions?

The University licenses its inventions to encourage the practical application of the results of research for the broad public benefit; to address the needs of sponsors of University research; to build research partnerships with industry to enhance the research and educational experience of researchers and students; and to generate royalty income for the further support of research and education; and to provide an incentive for inventor faculty retention and support of the University technology transfer program.

Who makes licensing decisions for the University?

Licensing Professionals (LP) within University authorized licensing offices (ALOs) are charged to license University inventions. They have the responsibility to make complex licensing decisions based upon a multiplicity of facts and circumstances by applying their professional expertise and experience.

LPs must conduct the technology transfer process, including patenting, marketing, and licensing in a manner that supports the principles of openness, objectivity and fairness in decision-making. University selection of licensees and other decisions made in the course of licensing University research results must be made in accordance with the Act, with University Licensing Guidelines (see OTT Guidance Memo No. 00-05, <http://patron.ucop.edu/ottmemos/docs/ott00-05.html>), and based upon the education, research, and public service missions of the University.

What is the role of inventors in making licensing decisions?

Licensing Professionals sometimes ask University inventors to work closely with University licensing staff and candidate licensees and even to involve themselves in

companies that are candidate licensees to help effectively commercialize University inventions. This 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. Any involvement of inventors, however, must be in accordance with the Act, with University Licensing Guidelines (see OTT Guidance Memo No. 00-05, <http://patron.ucop.edu/ottmemos/docs/ott00-05.html>), and based upon the education, research, and public service missions of the University.

What does the Political Reform Act require regarding licensing decisions?

Because both Licensing Professionals and inventors may have the opportunity to influence University licensing decisions in ways that could lead to personal gain or give advantage to companies in which they have a financial interest, LPs and the inventors must be aware of and in compliance with the Act. Generally, LPs and inventors are prohibited from "making, participating in making or influencing a University decision," including selection of licensees and other decisions made in the course of commercializing University research results, if they have a personal financial interest in the decision, unless certain specific actions are taken.

In order to comply with the Act, when a University employee has a personal financial interest in a decision concerning a candidate licensee of an invention, either

- i) that employee must disqualify him or herself from "making, participating in making or influencing a University decision" concerning that invention, including selection of licensees and other decisions made in the course of commercializing the invention; or
- ii) when that employee does not disqualify him or herself from involvement in such decisions, a Licensing Decision Review of the licensee selection and other licensing decisions must occur.

The Political Reform Act will permit participation in negotiating, advising or making recommendations with respect to any University decision, including those related to licensing, so long as there is appropriate review by non-interested persons or persons. The Act requires an intervening review--in other words, another level of review before the work product goes to the final decision-maker for approval. A Licensing Decision Review is a form of intervening substantive review as required by the Act. For further information about the Licensing Decision Review see "What is Licensing Decision Review?" below.

What exactly is a Disqualifying Personal Financial Interest?

The Political Reform Act states that a public official has a disqualifying personal financial interest in a decision if it is reasonably foreseeable that the decision will have a material

financial effect,² distinguishable from its effect on the public generally, on the University employee, a member of his or her family, or on any of the following:

- i) Any business entity in which the public official has a direct or indirect investment worth \$2,000 or more.
- ii) Any real property in which the public official has a direct or indirect interest worth \$2,000 or more.
- iii) Any source of income, other than gifts and other than loans by a commercial lending institution in the regular of business on terms available to the public without regard to official status, aggregating \$500 or more in value provided to, received by or promised to the public official within 12 months prior to the time when the decision is made.
- iv) Any business entity in which the public official is a director, officer, partner, trustee, employee, or holds any position of management.
- v) Any donor of, or any intermediary or agent for a donor of, a gift or gifts aggregating \$320 or more in value provided to, received by, or promised to the public official within 12 months prior to the time when the decision is made.

In relation to i) and ii) above, a LP or inventor has an indirect investment or interest if the investment or interest is owned by his/her spouse or dependent child, by an agent on his/her behalf, or by a business entity or trust in which he/she, his/her agents, spouse, and dependent children own a 10 percent or greater interest.

Membership on a scientific advisory committee is not in itself a disqualifying personal interest as defined in (iv) above. However, any payment for serving on the advisory board, including reimbursement for travel, accommodations or food, is potentially a disqualifying personal interest as defined in (iii) or (v) above.

The inventor's share of royalty income paid to a University inventor by the University relating to the licensing of his or her invention is not considered to be a disqualifying personal interest of the inventor in the licensee of that invention.

² In general, it is prudent to assume that an effect will be material if a University decision will have *any* financial impact. The definition of "material financial effect" is the subject of complex regulations. You should consult your local Conflict of Interest Coordinator or the Office of General Counsel for advice.

What is a Personal Financial Effect?

Financial effects on a University employee or a member of his or her immediate family are called "personal financial effects." Personal financial effects are considered a sixth form of disqualifying personal financial interest. Thus, a public official has a disqualifying personal financial interest in his or her current and *future* personal finances and those of his or her immediate family. A government decision will have an effect on this interest if the decision will result in the personal expenses, income, assets, or liabilities of the official or his or her immediate family increasing or decreasing. A *reasonably foreseeable* financial effect on a public official's personal finances is considered material under the Act if it is at least \$250 in *any* 12-month period. For example, an employee may intend to start a company in order to commercialize his or her invention but perhaps does not currently have an interest in the company simply because it has not yet been established. Nevertheless, under the Act the employee could not participate in any way in University decisions related to licensing this invention because the official has a disqualifying personal financial interest in his or her own future personal finances (unless there is intervening substantive review - see Section III below).

When does a Licensing Professional or inventor "make" a University licensing decision?

Under the Act, a University employee "makes" a decision when, acting within the authority of his or her office, that employee votes on a matter, appoints a person, obligates or commits the University to any course of action, or enters into any contract on behalf of the University. It is important to recognize that a decision can also be made when one determines not to act, unless the determination not to act is the choice of disqualification (see Section II below). Thus a LP, for example, cannot proceed to make a decision even if that LP excludes from consideration as a potential licensee a serious candidate in which he or she has a disqualifying personal financial interest.

When does a Licensing Professional or inventor "participate" in the making of a University licensing decision?

An inventor or Licensing Professional participates in making a University decision when, acting within the authority of his or her position, he or she negotiates regarding the decision; or when the inventor or LP advises or makes recommendations to the University decision maker, by conducting research or making any investigation which requires the exercise of judgment on the individual's part and the purpose of which is to influence the decision; or when the inventor, for example, prepares or presents any report, analysis or opinion to University employees which requires the exercise of judgment and the purpose of which is to influence the University decision. Additionally, it is important to understand that a University employee does not "participate" in a University decision

when he or she interacts with external decision-makers, for example, scientists or officials of candidate licensees.

When does a Licensing Professional or inventor attempt to use his or her official position to influence a University licensing decision?

An inventor or Licensing Professional attempts to use his or her official position to influence a University decision if, for the purpose of influencing the decision, that person contacts, appears before, or otherwise attempts to influence any officer, employee, or consultant of the University. This includes a situation where the inventor negotiates "across the table" from the University on behalf of a company in which he or she has a disqualifying personal financial interest.^{3 4} An inventor may, however, communicate with the general public or the press without violating this provision. An individual also is not "attempting to influence" a decision when the contribution to the decision-making process is only technical or "ministerial" as explained below. Additionally, it is important to understand that a University employee does not "participate" in a University decision when he or she interacts with external decision-makers, for example, scientists or officials of candidate licensees.

Are there certain technical advisory actions that are not considered to be "participating in the making of or influencing a decision"?

Some Licensing Professional or inventor contributions to the licensing process are primarily technical advice and do not constitute "participation in" or "attempting to influence" a governmental decision under the Act. They are called "ministerial." An action is ministerial, even if it requires considerable expertise and professional skill, if there is no discretion with respect to the outcome. Thus an inventor can provide technical or scientific *information* about an invention where necessary without being considered to be participating in a government decision. This exception, however, does not apply to technical tasks such as most data gathering or analysis in which the employee makes professional judgments which can affect the ultimate decision in question.

II. SELF-DISQUALIFICATION UNDER THE ACT

³ The State regulation makes a specific exception, however, when the inventor or his or her immediate family wholly own the business entity or the inventor exercises sole direction and control or the inventor and his or her spouse jointly exercise sole direction and control over the business entity. Under such circumstances, the Act's exemption would allow such involvement without considering it to be an attempt to influence.

⁴ The Licensing Professional may require that a candidate licensee not use a University employee to negotiate a license agreement on behalf of the company except when an employee on his or her immediate family solely owns the company, or the employee solely, or jointly, with his or her spouse exercise sole direction and control over the company.

When is disqualification required as a result of a personal financial interest?

An inventor or Licensing Professional may not “make, participate in making, or in any way attempt to use [his or her] official position to influence” a University decision which will foreseeably have a material financial effect on the inventor or LP, on a member of that person's immediate family, or on the source of that interest (for example, a candidate licensee). The inventor or LP is disqualified for a period of 12 months following any point in time in which the interest exists, unless there is Licensing Decision Review.

What is the obligation under the Act of a University official with a financial interest?

If a Licensing Professionals or inventor determines that he or she has a disqualifying personal financial interest, that person may disqualify him or herself from making a University decision, and must refrain from participating in any way in the decision, and must not use his or her official position to influence any other University employees with respect to the matter. The determination not to act may be accompanied by disclosure of the disqualifying interest, but disclosure is not required.

When and how does a Licensing Professional disqualify him or herself from involvement in licensing decisions?

The LP should formally disqualify him or herself by notifying his or her supervisor that he or she has a disqualifying personal interest in the licensing decision, and that he or she formally disqualifies him or herself from case management responsibilities.

When and how does an inventor disqualify him or herself from involvement in licensing decisions?

The inventor may disqualify him or herself by formally asserting in writing that he or she will not (as long as a disqualifying personal financial interest exists) make, participate in making, or attempt to influence a University licensing decision concerning the invention, including the selection of a licensee(s), and other decisions made in the course of attempting to commercialize the invention. Alternatively, the inventor may choose simple and absolute nonparticipation in all licensing decisions, even without formal written self-disqualification. This is sufficient to remain in compliance with the Act. Any such self-disqualification action should be taken in close coordination with the LP.

Whether or not the inventor has a disqualifying personal financial interest is important as early as the time the invention disclosure form (the Record of Invention or ROI) is completed. If the inventor has a disqualifying personal financial interest in a candidate licensee for the invention that is disclosed, he or she should make the self-disqualification decision when disclosure of the invention is made. If, on the other hand, the inventor with such an interest chooses *not* to disqualify him or herself, that inventor should

preferably disclose the financial interest at this time--and certainly prior to the signing of any Secrecy Agreement with a candidate licensee. (See "When and how does an inventor disclose his or her financial interest in a candidate licensee?" below).

Who manages the invention after disqualification?

When a Licensing Professional disqualifies him or herself from management of an invention, the case would then be assigned by the LP's supervisor for management to another LP without a disqualifying personal financial interest in the decision.

When an inventor disqualifies him or herself from involvement in licensing decisions, any scientific or other advice determined necessary by the LP would be obtained from other co-inventors if available, other University scientists, or other sources with appropriate expertise.

III. INVENTOR INVOLVEMENT IN LICENSING DECISIONS

Is there any way in which an inventor can remain involved in licensing decision-making?

When an inventor has a disqualifying personal financial interest, it is sometimes determined useful or necessary by the Licensing Professional for the inventor to be involved in the licensing decision-making process as his or her expertise and input may be important to successful licensing and technology transfer. In such cases, the LP may determine that it is beneficial for the inventor--despite the existence of an interest--to work closely with the LP and with potential licensees, or to be directly involved with companies that are potential licensees. An inventor sometimes becomes involved by negotiating "across the table" from the University on behalf of a company in which the inventor has a disqualifying personal financial interest.

The Office of General Counsel has determined that the Political Reform Act will permit participation by an inventor, even where that inventor has a disqualifying personal financial interest, in advising, influencing, or making recommendations with respect to a University licensing decision, *so long as there is appropriate intervening substantive review*, called a Licensing Decision Review. Thus, when an inventor with a disqualifying personal financial interest in a potential licensee, is invited by the LP to participate in licensing decisions, and does not disqualify him or herself from participation, Licensing Decision Review of the licensee selection and other licensing decisions is required under the Act. Both the LP and the inventor must be agreeable to any inventor involvement, understanding that the extent to which the inventor participates in or influences licensing decisions may be a factor in the considerations and ultimate recommendations of the Licensing Decision Review body.

In general, the role of the inventor in licensing decisions should be kept to the minimum necessary to successfully achieve the University's objectives in licensing University research results for the public benefit.

When and how does an inventor disclose his or her financial interest in a candidate licensee?

When an inventor with a disqualifying personal financial interest in a candidate licensee has not and will not be "making, participating in making or influencing" a licensing decision, no financial disclosure is required. When an inventor *without* such a financial interest makes, participates in making or influences a licensing decision, again, no disclosure is required. If, however, an inventor who will be participating in the licensing decision-making activity has a disqualifying personal financial interest in any candidate licensee identified by the LP, that inventor is required under the Act to disclose his or her interest. Form TT-100, Inventor Statement Concerning Involvement in Licensing Decisions, must be used for this purpose. When such a financial interest is disclosed in such a circumstance, a Licensing Decision Review of LP-proposed licensing decisions is required. A Form TT-100 must be completed by the inventor, indicating whether or not he or she has any financial interest, for each company for which there is a Secrecy Agreement.

Inventor disclosure of financial interest on Form TT-100 should be made promptly upon request by the Licensing Professional. In most cases, this would be upon identification by the LP of candidate licensees and prior to the signing of any Secrecy Agreement. If no Form TT-100 is completed by the inventor, and if the inventor has been or will be involved in the licensing decision, the LP may determine that a Licensing Decision Review is appropriate.

What is Licensing Decision Review?

Licensing Decision Review means there is another level of review by a non-interested 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 LP-proposed selection of licensees and other licensing decisions were made and make its independent recommendations concerning the decisions.

Who conducts the Licensing Decision Review?

Each UC 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, and must be filed with the OTT.

How does this Licensing Decision Review relate to Independent Substantive Review Committee (ISRC) reviews of financial interest in private sponsors of research?

In those cases where the Licensing Professional determines that a condition of a license agreement will require the licensee's support of additional research by the University involving the inventor with the disqualifying personal financial interest, the LP must inform the appropriate University Contract and Grant Officer that disclosure and review of financial interests under the University of California Policy on Disclosure of Financial Interest in Private Sponsors of Research is required.

Disclosure would be made on UC Form 730U and any required independent substantive review would be conducted by the local Independent Substantive Review Committee (ISRC) prior to execution of the license agreement requiring future research funding. Any required intervening substantive reviews of the licensing decision should be coordinated or combined with the ISRC review as appropriate. If it is not possible to secure approval by the ISRC of the proposed additional research prior to the execution of the license agreement, any license agreement requirement that the licensee support additional research involving the inventor with the disqualifying personal financial interest, could be made conditional upon the ISRC's future approval of such research by incorporating an appropriate "escape" provision in the license agreement in the event that the ISRC does not approve such research.