University of California OFFICE OF TECHNOLOGY TRANSFER

MEMO Operating Guidance No. 01-02 August 1, 2001

PATENT COORDINATORS CONTRACT AND GRANT OFFICERS VICE CHANCELLORS - RESEARCH/ADMINISTRATION ADMINISTRATIVE CONFLICT OF INTEREST COORDINATORS

SUBJECT: Managing Potential Conflicts of Interest in Licensing Under the California Political Reform Act

Dear Colleagues:

In a June 18, 2001 letter to Chancellors and Laboratory Directors (Exhibit A), Provost King and Senior Vice President Mullinix asked campuses and Laboratories to implement the requirements of California's Political Reform Act with regard to licensing University research results. To accomplish this, campuses and Laboratories were asked to establish local plans to ensure that intervening substantive review of University decisions relating to such licensing activities are carried out as required by the Act. To distinguish this from other intervening substantive review processes under the Act, intervening substantive review of licensing decisions will be referred to as Licensing Decision Review (LDR). LDR plans must provide for intervening review by an appropriately disinterested official or committee if an inventor or author participates in or influences University licensing decisions and has a disqualifying personal financial interest in those decisions as defined in the California Political Reform Act.

The Provost and Senior Vice President directed OTT to issue systemwide guidance for use by campuses and Laboratories in establishing their Licensing Decision Review plans. Accordingly, I am enclosing the new University of California Guidelines on Managing Potential Conflicts of Interest in Licensing (Exhibit B). These guidelines have been developed after extensive consultation with University Patent Coordinators, licensing personnel, Conflicts of Interest Coordinators, and representatives from OTT, the Office of Research Policy, and the Office of General Counsel. The guidelines address some of the most common issues concerning potential conflicts of interest in University licensing activity, and should be followed to implement the requirements of the California Political Reform Act. They are developed to clarify the roles of both inventors and 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. Also enclosed is Exhibit C, "Required Elements for Campus/Laboratory Plans for Licensing Decision Reviews," which outlines the elements that any local LDR process must include to be in compliance with the Political Reform Act. UC Form TT-100, "Inventor Statement Concerning Involvement in Licensing Decisions" (Exhibit D) must be used in accordance with the Guidelines.

Campuses and Laboratories have broad discretion in shaping their local LDR processes. As long as the enclosed Guidelines (Exhibits B) and the Required Elements (Exhibit C) are satisfied, some of the areas of local choice and flexibility include:

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- the extent to which inventors should be encouraged to participate in the licensing decision-making process;
- choice of conducting LDR by individual UC officials or by committee review;
- levels for reviews of varying rigor based on the level of inventor financial interest;
- nature of materials to be reviewed, instructions to reviewers, scope of potential remedies, and authority for final decisions.

For your information and as a reference I have also included OTT's own Plan for Carrying Out Licensing Decision Reviews (Exhibit F) including a sample notice that OTT will provide to inventors, "What Inventors Need to Know about Conflict of Interest in Licensing" (Exhibit E). I consider OTT's own plan an interim one until we have gained experience in this area. It may be revised from time to time based on our experience and feedback from inventors, campuses, and Laboratories. Campuses and Laboratories should feel free to incorporate any elements of the OTT plan, or to construct something quite different, as long local plans include all the Required Elements (Exhibit C). If campuses or Laboratories wish to have OTT occasionally conduct an LDR for an invention managed by the local licensing office in unique case circumstances, then the local LDR plan may provide for that option.

Finally, all sites--regardless of whether or not they have independent licensing offices--should indicate how they wish to handle LDRs of inventions that are under OTT management. These inventions may be covered by the local LDR process or by the OTT LDR plan (this will be the default). To the extent that local LDR plans will address cases for which OTT will be the authorized licensing office, those aspects of the LDR should be coordinated with OTT and agreed upon in a memorandum of understanding between the two offices.

Campus and Laboratory LDR plans should be submitted to my attention by October 31, 2001. If in developing these plans, you have any questions or need any policy or legal advice, please feel free to contact Joe Acanfora at (510) 587-6011 or Marty Simpson at (510) 987-9763.

berely

Alan B. Bennett Executive Director Research Administration and Technology Transfer

- Exhibit A Letter from Senior Vice Presidents King and Mullinix, June 18, 2001
- Exhibit B Guidelines on Managing Potential Conflicts of Interest in Licensing
- Exhibit C Required Elements for Campus/Laboratory Plans for Licensing Decision Reviews
- Exhibit D-UC Form TT-100, "Inventor Statement Concerning Involvement in Licensing Decisions"
- Exhibit E Sample Notice: "What Inventors Need to Know about Conflict of Interest in Licensing"
- Exhibit F OTT Plan for Carrying Out Licensing Decision Reviews
- cc: OTT Associate Directors and Managers Academic Conflict of Interest Coordinators

UNIVERSITY OF CALIFORNIA

OII Operating Memo No. 01-02 August 1, 2001 EXHIBIT A

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OFFICE OF THE PRESIDENT

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June 18, 2001

CHANCELLORS LABORATORY DIRECTORS

Dear Colleagues:

In December 1999, the Administrative Task Force to Review University Policies Pertaining to Outside Activities, Conflict of Commitment, Conflict of Interest and Related Issues released the second part of its two-part report. That report included a recommendation that the University require inventors to disclose any financial interest in potential licensees of their University inventions and that the University provide guidance to inventors and licensing staff about managing positive financial interests.

University experience with transferring research results to the private sector has shown that inventors are often the best source of marketing leads for potential licensees of their inventions. In addition, UC licensing staff and potential licensees sometimes rely on inventors and authors of copyrightable works to provide technical details about their research results and to become involved in determining a company's interest in a license. Yet under California law (the California Political Reform Act of 1974 and its regulations), UC inventors and authors normally must not participate in or attempt to influence University decisions involved in the licensing process, including the selection of licensees, when they have a financial interest in a potential licensee.

The Office of General Counsel has recently confirmed, however, that the Political Reform Act permits participation by an inventor with a financial interest in advising or making recommendations with respect to University licensing decisions, so long as there is an appropriate intervening review by a non-interested person or persons. Intervening review means there is another level of review before the final decision is approved. The review must be substantive, based on an independent assessment of the facts of the case. At its February 2001 meeting, the Technology Transfer Advisory Committee endorsed establishing, in accordance with requirements of the Political Reform Act, an intervening substantive review process for licensing decisions made at University licensing offices.

Intervening reviewers shall consider proposed decisions of licensing officials in light of the factual situation presented, good licensing practices such as exemplified in the University's Licensing Guidelines and the University's research and education objectives, including

consideration of any impacts on students. Reviewers should have the option of recommending approval of proposed licensing decisions, with or without modification or safeguards, or disapproval of such decisions, or proposing their own courses of action.

It is expected that the intervening substantive review process will not affect the majority of University licensing cases as it will be activated only in cases where an inventor or author with a financial interest in a candidate licensee will have a role in the licensing process.

Accordingly, we are asking campuses and Laboratories to develop and implement local plans to ensure the carrying out of required intervening substantive reviews of decisions relating to licensing University research results. Such plans must provide for intervening review by an appropriately disinterested official or committee if an inventor or author participates in or influences licensing decisions and has a financial interest in those decisions as defined in the California Political Reform Act. Development and implementation of such local plans must be coordinated with the systemwide Office of Technology Transfer (OTT) for those cases for which OTT will be the authorized licensing office. We have asked OTT Executive Director Bennett to issue by July 31 systemwide guidance for use by campuses and Laboratories in establishing their intervening substantive review plans.

Copies of campus and Laboratory plans should be submitted to the UCOP Office of Technology Transfer by October 31, 2001.

We appreciate your help in addressing this important technology transfer need. Once this review system is successfully established, we believe it will enable us to tap more fully the expertise and creativity of our inventors and authors and, at the same time, ensure that they may remain in compliance with the Political Reform Act.

Any questions about the new licensing review process should be directed to Associate Director Joe Acanfora at (510) 587-6011 or joe.acanfora@ucop.edu.

Sincerely,

C. Judson King

C. Judson King Provost and Senior Vice President--Academic Affairs

Joseph P. Mullinix enior Vice President--**Business and Finance**

cc: President Atkinson Members, President's Cabinet Academic Senate Chair Cowan Interim Vice Provost Coleman Executive Director Bennett Members, Technology Transfer Advisory Council

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, <u>http://patron.ucop.edu/ottmemos/docs/ott00-05.html</u>), 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, <u>http://patron.ucop.edu/ottmemos/docs/ott00-05.html</u>), 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.

Required Elements for Campus/Laboratory Plans for Licensing Decision Reviews (LDR) (August 1, 2001)

This document is a component of the guidelines 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 University technology licensing activity. Campus and Laboratory plans for Licensing Decision Reviews (LDR) (a form of intervening substantive review under the California Political Reform Act) must incorporate the following elements:

Licensing Professional Disqualification

Licensing Professionals (LP) who determine that they have a disqualifying personal financial interest in licensing decisions for an invention disclosure that has been assigned to them must disqualify themselves from participating in or attempting to influence any licensing decisions for that case and advise their supervisor of the need to relieve them from any case management responsibilities. The case must be re-assigned by the supervisor for management to another LP without a disqualifying personal financial interest in the licensing decisions.

Consultation with Inventors

In order to help to address and manage potential conflicts of interest in licensing decision issues, as soon as practical after an invention disclosure is received by the Authorized Licensing Office, the Licensing Professional shall:

- a) provide notice to inventors of the provisions of the State of California Political Reform Act of 1974 and the disqualification and disclosure requirements contained therein, and the University's policies and procedures for managing any potential conflicts of interest if an inventor has a disqualifying financial interest in a candidate licensee(s). Exhibit E, "What Inventors Need to Know about Conflicts of Interest in Licensing") is provided as one optional tool/sample for campuses and Laboratories use in advising inventors on this matter.
- b) determine the level of inventor involvement in licensing decision-making (e.g., in legal and policy terms, determine the role the Licensing Professional would like the inventor to play in "making, participating in making or influencing" any LP's decision concerning the invention, including selection of licensees and other decisions made in the course of commercializing the invention.) 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 the licensing decisions may be a factor in the considerations and ultimate

recommendations of a Licensing Decision Review body. In general, the role of the inventor in the licensing process should be kept to the minimum necessary to successfully achieve the University's objectives in marketing and licensing. Any approach, however, should not chill inventor involvement in patent prosecution which is necessary and often legally required.

c) consider reviewing with the inventor the applicability of the University Licensing Guidelines to the disclosed invention when appropriate (see OTT Guidance Memo No. 00-05, hhtp://patron.ucop.edu/ottmemos/docs/ott00-05.html). Degree of adherence to the Licensing Guidelines would be one factor in any subsequent Licensing Decision Review.

Inventor Disqualification

Upon identification by the Licensing Professional of candidate licensees (usually those entering Secrecy Agreements with the University), and where the LP wishes to have the inventor's involvement in the licensing decision-making process, the lead inventor should be asked to consider his or her involvement in the licensing decision-making process, considering the earlier notification about disqualification and disclosure requirements of the Political Reform Act.

The inventor may disqualify him or herself by formally asserting in writing that while having the disqualifying personal financial interest, he or she has not in the past nor will in the future make, participate in making, or attempt to influence a University decision concerning the subject invention, including the selection of a licensee(s), and other decisions made in the course of attempting to commercialize the invention. UC Form TT-100, Inventor Statement Concerning Involvement in Licensing Decisions, (www.ucop.edu/ott/tt-100) may be used for this purpose. Alternatively, simple non-participation in any and all licensing decisions, even without formal written self-disqualification, is sufficient to remain in compliance with the Act. Such action by the inventor should be taken in close coordination with the LP. A copy of any written disqualification should be kept in the invention case file.

Inventor Participation/Disclosure

When both the Licensing Professional and the inventor agree that the inventor should participate in University licensing decision-making, working with University licensing staff and/or with potential licensees, to accomplish the objective of commercializing the invention, or will be negotiating "across the table" from the University on behalf of a company in which the inventor has a disqualifying personal financial interest, the inventor would not disqualify him or herself. In this case, the inventor would be considered to be "making, participating in making or influencing" a LP's decision concerning licensing the invention. If the inventor has no disqualifying personal financial interest in candidate licensees, no financial disclosure is required. If however, an inventor who will be so involved 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 must be used for this purpose. When disqualifying

personal financial interest is disclosed in such a circumstance, a Licensing Decision Review of LP-proposed licensing decisions is required.

If, after initially completing Form TT-100, either the inventor develops a new or revised disqualifying personal financial interest in a candidate licensee or the LP identifies additional potential licensees, the inventor(s) must promptly provide to the LP a new Form TT-100 providing the relevant information.

On a case-by-case basis, Licensing Professionals may exercise their judgement in identifying and addressing any case where it is reasonably apparent that an inventor who is participating in licensing decisions has a disqualifying personal financial interest, but has not disclosed that interest. LPs may reiterate to the inventor the disclosure/disqualification requirements under the Act, may request a Licensing Decision Review, or take other case-specific actions.

Objective Licensing Professional Decision-Making

The Licensing Professional should conduct the licensing process 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 commercializing University research results should be based upon the education, research, and public service missions of the University and in accordance with the factual situation presented and good licensing practices as exemplified in the University Licensing Guidelines (see OTT Guidance Memo No. 00-05, http://patron.ucop.edu/ottmemos/docs/ott00-05.html). When an inventor has a disqualifying personal financial interest in a candidate licensee and does not disqualify him or herself from participation in the licensing process, the LP should ensure that sufficient documentation is available in the invention case file in the Authorized Licensing Office to provide an understanding of the objective business basis for the LP-proposed selection of a licensee(s), and for other licensing decisions made in the course of commercializing the invention.

Request for Licensing Decision Review

When an inventor has a disqualifying personal financial interest in a candidate licensee, and does not disqualify him or herself from participation in licensing decision-making, Licensing Decision Review (LDR) of the licensee selection and other licensing decisions is required. In such circumstances, the LP shall inform the appropriate LDR individual or committee as early in the process as appropriate of a LP-proposed decision to place a license with a particular company and of other proposed licensing decisions made in the course of commercializing the invention.

Submission of Information for Licensing Decision Review

At least, the following information shall be provided to the appropriate LDR individual or committee by the Licensing Professional proposing a licensing decision(s):

- a) A description of the licensing decision(s) to be made and of the LP-proposed decision(s), including an explanation of the basis or rationale for the proposed decision(s).
- b) Copies of, or the location of all relevant documentation supporting the proposed licensing decision(s).
- c) A copy of the Form TT-100 if any, disclosing the nature and level of any inventor disqualifying personal financial interest.
- d) A description of the inventor's involvement in the licensing process.
- e) Other information as required by the review body.

Conduct of Licensing Decision Review

The Licensing Decision Review body must be composed of qualified staff with appropriate expertise, knowledge and professional judgment, and 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 in view of the University Licensing Guidelines, the nature and level of the inventor(s)' disqualifying personal financial interest, and the education, research, and public service missions of the University.

In those cases where a license agreement involves the licensee's support of additional University research involving the inventor with the disqualifying personal financial interest, the LP must inform the inventor and the campus or Laboratory Contract and Grant Officer that financial disclosure and independent substantive review of financial interests under the University of California Policy on Disclosure of Financial Interest in Private Sponsors of Research may be required prior to execution of the license agreement. Any required Licensing Decision Review should be coordinated or combined with any required Independent Substantive Review Committee review as appropriate

Final Decisions

When a Licensing Decision Review is required under the Guidelines, the final decision-maker shall consider the recommendations of the Licensing Decision Review body before placing a license with a company in which the inventor has a disqualifying personal financial interest, or before otherwise implementing a licensing decision. The original Licensing Professional may serve as the final decision-maker if he or she agrees to accept and implement the recommendations of the Licensing Decision Review body in their entirety. However, if the original LP does not accept or does not wish to implement the recommendations of the Licensing Decision Review body be made in consideration of the recommendations of the Licensing Decision Review body be made in consideration of the recommendations of the Licensing Decision Review body by a University official with appropriate authority who is at least one level higher in the organization than the LP making the

original proposed decision, and who has not been influenced by the inventor(s) with a disqualifying personal financial interest.

Inventor / Author Statement Concerning Involvement in Licensing Decisions

Form TT-100 (August 2001)

This form is to be completed by University inventors/authors and submitted to the University Authorized Licensing Office in accordance with OTT Operating Guidance Memo No. 01-02 located at http://patron.ucop.edu/ottmemos/docs/ott01-02.html. It should be completed after discussions with the Licensing Professional responsible for managing the invention or work of authorship (herein, "invention"). Generally it is submitted:

- upon selection by the Licensing Professional of candidate licensees, and
- upon any change in a disclosed financial interest of an inventor in a candidate licensee.

itle of Inv	rention:	UC Case # (if known)	
	t:		
	l statement for this invention	Supplemental statement for this invention	
		a Political Reform Act to my involvement in University licensing	
(CHEC)		ert tile following.	
//	DISQUALIFICATION		
	influence a University licensing dec selection of a licensee(s), and other	not and do not intend to participate in making, or attempting to cision concerning the invention identified above, including the decisions made in the course of attempting to license this invention.	
	STOP HERE (No need to complete	e Section III below).	
//	ELIGIBILITY TO PARTICIPATE		
	I do not disqualify myself. I have, or wish to remain eligible to participate in or influence a University licensing decision concerning the invention identified above, including the selection of a licensee(s), and other decisions made in the course of attempting to license this invention. I understand all such University decisions will be subject to an intervening Licensing Decision Review by a disinterested official or committee.		
	COMPLETE SECTION III BELO	DW.	
		Date:	

	Inventor's/Author's Statement of Financial Interest in Candidate Licensee
Pro	vide the following information about this candidate licensee:
	Company Name (candidate licensee): Company location:
A.	Are you or a member of your immediate family a director, officer, trustee, or employee of, or do you hold any position of management in the company identified above?NoYesIf yes, identify specificposition (s):
B.	Do you, or does a member of your immediate family, have:
	1. An investment of \$2,000 or more in the company identified above?NoYesValue
	2. Income (including any payment, such as salary or consulting fees, or any loan or any gift) of \$320 or more received from the company identified above within the last 12 months? (Do not include any salary paid by the University with funds provided by the company). NoYes InterviewNo YesYes If yes, \$Value
C.	Will there be a current or future impact on the personal finances of you or your immediate family as a result of the licensing decision(s)?
I ha	ve used all reasonable diligence in preparing this Statement and to the best of my knowledge it is true and complete.
Sig	Date:
req emj	<u>s is a public document</u> . All of the information on this form will be available to any member of the public upon uest. This information is to be used to reveal to public scrutiny certain financial interests of public officials and ployees in order to disclose potential conflicts of interest and to aid in the prevention of actual conflicts of prest.

Sample Notice to Inventors: This notice will be used by the Office of Technology Transfer (OTT) as part of its acknowledgement sent to inventors of receipt of a Record of Invention. A comparable notice should be given to all campus or Laboratory inventors by Authorized Licensing Offices at the time of invention disclosure. This notice may be excerpted or adapted by campuses or Laboratories for their own use as they may choose. If the local notice is intended to be shared routinely with authors disclosing their works of authorship for licensing consideration, this sample notice should be modified accordingly.

What Inventors Need to Know about Conflicts of Interest in Licensing (August 1, 2001)

UC Policy and State Law Concerning Conflicts of Interest in Licensing

The University of California's policy on conflicts of interest provides that none of the University's "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." In addition to UC policy, University faculty and staff must comply with state statutes and regulations governing conflicts of interest, specifically the Political Reform Act of 1974 (the Act). The Act requires public officials to "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." (Gov. Code, § 81001, subd. (b).)

The Act and its implementing regulations apply to University licensing decisions. In other words, University inventors and University licensing staff must not allow their personal financial interests to influence their or other's University licensing decisions.

Guidelines on Managing Potential Conflicts of Interest in Licensing

Licensing decisions for the University are made by Licensing Professionals (LP) within authorized campus and Laboratory licensing offices. The work of the LP is sometimes aided by the inventor, who may be invited by the LP to work with University licensing staff and potential licensees to effectively commercialize University inventions.

Because 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, inventors must comply with the disqualification and disclosure requirements of the Act.

 The disqualification requirements of the Act require an inventor who has a disqualifying personal financial interest in a University licensing decision to refrain from participating in or influencing the decision. However, if the LP determines that the inventor's involvement is necessary to the decision, or if the inventor will negotiate "across the table" from the University on behalf of a company in which the inventor has a disqualifying personal financial interest, the inventor may participate so long as proposed University licensing decisions are reviewed by an independent body (a Licensing Decision Review). (Note: Under the Act, University negotiations with an inventor who is also the sole proprietor or who solely, or jointly, with his or her spouse, exercises sole direction and control of a candidate licensee may not trigger the need for Licensing Decision Review).

2. The disclosure requirements of the Act require the inventor to specifically disclose any disqualifying personal financial interest in the licensing decision when he or she is involved in a proposed University licensing decision.

How does an inventor disqualify him or herself?

If an inventor has a disqualifying personal financial interest in a University licensing decision, as early as at the time of invention disclosure--the inventor may disqualify him or herself by formally asserting in writing on Form TT-100 (available at <u>www.ucop.edu/ott/tt-100</u>) that he or she has not and will not in the future 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 licensing the invention. Alternatively, simple (and absolute) nonparticipation in all licensing decisions, even without formal written self-disqualification, would constitute an acceptable disqualification under the Act. Inventors who do not wish to be involved in the licensing decision-making process in any way do not have to complete any form, as long as they make their wishes clear to the Licensing Professional.

How does inventor become involved?

When an inventor is invited to be involved in a University licensing decision by the Licensing Professional, or intends to negotiate "across the table" from the University, inventor disclosure of any disqualifying personal financial interest must be made on Form TT-100, promptly upon request by the LP. In most cases, this would be upon identification by the LP of candidate licensees and prior to company signing of any Secrecy Agreement. If Form TT-100 indicates an inventor disqualifying personal financial interest, or if no Form TT-100 is completed by the inventor (and thus there is no definitive assertion, positive or negative, of the inventor's personal financial interest), 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. If inventors have any questions about how the disqualification/disclosure process should be carried out, the LP can provide assistance.

How does the licensing decision undergo review?

Licensing Decision Review means there is a review by a non-interested person or persons before the proposed licensing decision goes to the final decision-maker for approval. The review must be based on an independent review and assessment of the facts of the case and must be conducted by qualified staff with appropriate expertise, knowledge and professional judgment, who must independently check the Licensing Professional's original data, analysis, proposed selection of licensees, and other licensing decisions. This is necessary under the Act since the LP may have been influenced by the inventor with the disqualifying personal financial interest.

Who conducts the Licensing Decision Review?

Each campus and Laboratory and the Office of Technology Transfer 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 Licensing Decision Review. At OTT the nature of the licensing decision review will depend on the level of the inventor's personal financial interest in the potential licensee. Most Licensing Decision Reviews

will be conducted by another licensing official within the Office of Technology Transfer who has not been involved in the original proposed decision. More complex cases involving more significant inventor personal financial interests will be reviewed by an appropriate independent reviewer or by a committee appointed by the Executive Director or the Senior Vice President.

More detailed information and guidance on managing potential conflicts of interest in University licensing decisions are available at <u>http://patron.ucop.edu/ottmemos/docs/ott01-02.html</u>

Office of Technology Transfer (OTT) Office of the President (August 1, 2001)

Plan for Carrying Out Licensing Decision Reviews

Provost King and Senior Vice President Mullinix, in a June 18, 2001 letter to Chancellors and Laboratory Directors requested that each authorized University licensing office establish a process to carry out intervening substantive reviews of licensing decisions (hereinafter referred to as Licensing Decision Reviews) consistent with the requirements of the California Political Reform Act. The following process will be used by the UCOP Office of Technology Transfer (OTT) to carry out such Licensing Decision Reviews (LDR) for those inventions under OTT management unless other LDR plans have been mutually agreed upon under a Memorandum of Understanding for a specific campus' or Laboratory's cases managed by OTT. Based on its experience in carrying out LDRs, from time-to-time OTT may revise its LDR processes with input from campuses and Laboratories.

A. Notice to Inventors

Promptly upon receipt by the OTT of a record of invention form (ROI) or other invention disclosure, the OTT Prosecution Group will send an acknowledgment letter to each inventor which will incorporate a notice to inventors of the provisions of the State of California Political Reform Act of 1974 and the disqualification and disclosure requirements contained therein, "What Inventors Need to Know about Conflict-of-Interest in Licensing." The OTT notice will explain briefly the University's policies and procedures for managing any potential conflicts of interest if an inventor has a disqualifying personal financial interest in a candidate licensee(s) and will direct the inventor(s) to the OTT website for further information (http://patron.ucop.edu/ottmemos/docs/ott01-02.html).

B. Licensing Professional Disqualification

OTT Licensing Professionals (LPs) who determine that they have a disqualifying personal financial interest in licensing decisions for a case that has been assigned to them will disqualify themselves from case management responsibilities by notifying their supervisor of the situation. The OTT supervisor will re-assign the case for management to another LP without a disqualifying personal financial interest in the licensing decisions.

C. Consultation with Inventors

In order to help address concerns about potential conflicts of interest in licensing decisions, OTT Licensing Professionals in their early discussions with inventors will consider the appropriate level of inventor involvement in licensing decision-making for a

particular invention. If the OTT LP wishes to have inventor(s) involved in the licensing decision-making process, the LP will invite one or more inventors to be involved, considering the disqualification and disclosure requirements of the Political Reform Act. Alternatively, an inventor may become involved when the inventor negotiates "across the table" from an OTT LP on behalf of a candidate licensee in which the inventor has a disqualifying personal financial interest. 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 the licensing decisions may be a factor in the considerations and ultimate recommendations of any LDR body. In general, the role of the inventor in the OTT licensing decision-making process will be kept to the minimum necessary to successfully achieve the University's objectives in marketing and licensing inventions.

If the OTT Licensing Professional does not desire such inventor participation, the LP will advise the inventor not to participate in nor attempt to influence OTT licensing decisions.

In addition, OTT Licensing Professionals will, when they judge appropriate, review with the inventor the applicability of the University Licensing Guidelines (see OTT Guidance Memo No. 00-05, http://patron.ucop.edu/ottmemos/docs/ott00-05.html) to the disclosed invention.

D. Inventor Disqualification, Participation, and Disclosure

Upon identification by OTT Licensing Professionals of candidate licensees (usually those entering Secrecy Agreements with the University), the LP will send a letter or e-mail asking the inventor(s) either:

- not to participate in or attempt to influence any licensing decisions, or
- where invited to do so by the OTT LP, to participate and disclose any disqualifying personal financial interest in candidate licensees.

University Form TT-100, Inventor Statement Concerning Involvement in Licensing Decisions, will be used to solicit and obtain the necessary information. The OTT LP may include a copy of the form with any letter sent to the inventor or may choose to indicate in the letter or e-mail the website location for the form (<u>www.ucop.edu/ott/tt-100</u>) and ask that it promptly be returned to the OTT LP.

If the inventor chooses to disqualify him or herself, he will be asked to check the box "Self-Disqualification" on UC Form TT-100, thereby formally asserting that he or she has not in the past nor will in the future "make, participate in making, or attempt to influence" a University licensing decision concerning the subject invention, including the selection of a licensee(s), and other decisions made in the course of attempting to commercialize the invention. While simple non-participation in any and all licensing decisions, even without written self-disqualification, is sufficient to remain in compliance with the Act, a written assertion provides clear documentation of the inventor's choice not to participate. A copy of any written disqualification will be kept in the OTT invention case file.

Alternatively, when both the LP and the inventor agree that the inventor should participate in University licensing decision-making, the inventor will be asked to indicate any disqualifying personal financial interest in each candidate licensees. If the inventor has no such disqualifying interest, he or she would indicate no disqualifying financial interest on Form TT-100 for each candidate licensee. If however, an inventor who will be so involved has a disqualifying personal financial interest in any candidate licensee identified by the OTT Licensing Professional, that inventor is required under the Act to disclose his or her interest. The inventor will be asked to make this disclosure using Form TT-100 and to promptly return it to the OTT LP. When a disqualifying personal financial interest is disclosed in such circumstances, a Licensing Decision Review of LP-proposed licensing decisions is required and will be conducted be OTT.

The communication with the inventor will advise that if, after initially completing Form TT-100, either the inventor develops a new or revised disqualifying personal financial interest in a candidate licensee or the OTT Licensing Professional identifies additional candidate licensees, the inventor(s) must promptly provide to the OTT LP a new Form TT-100 providing the requested information.

On a case-by-case basis, OTT Licensing Professionals will exercise their judgment in identifying and addressing any case where it is reasonably apparent that an inventor who is participating in licensing decisions has a disqualifying personal financial interest, but has not disclosed that interest. In such cases, OTT LPs may reiterate to the inventor the disclosure/disqualification requirements under the Act, request an LDR of proposed licensing decisions for that case, or take other appropriate case-specific actions.

E. Objective LP Decision-Making

The OTT LP will conduct the licensing process 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 commercializing University research results technology will be based upon the education, research, and public service missions of the University and taking into account University Licensing Guidelines (see OTT Guidance Memo No. 00-05, http://patron.ucop.edu/ottmemos/docs/ott00-05.html). When an inventor indicates on Form TT-100 a disqualifying personal financial interest in a candidate licensee and does not disqualify him or herself from participation in the licensing process, the OTT LP will ensure that sufficient documentation is available in the OTT invention case file to provide an understanding of the objective business basis for the LP-proposed selection of a licensee(s), and for other licensing decisions and to support the review to be conducted by the LDR body.

F. When and How to Request Licensing Decision Review

When an inventor has a disqualifying personal financial interest in a candidate licensee, and participates in licensing decision-making, Licensing Decision Review of the proposed licensee selection and other proposed licensing decisions will be conducted by OTT. In such circumstances, the OTT Licensing Professional will advise his or her supervisor as early in the process as appropriate of a LP-proposed decision to place a license with a particular company and other proposed licensing decisions made in the licensing process and of the need to conduct a LDR. Preferably, the LDR will occur prior to the perspective licensee taking substantial actions in reliance upon the University's obligation to negotiate in good faith. The respective campus or Laboratory Patent Coordinator will be promptly advised of the situation.

G. Submission of Information for Licensing Decision Review

When a Licensing Decision Review is required, the OTT Licensing Professional who proposes the selection of a licensee or other University licensing decisions will provide at least, the following information to the appropriate LDR individual or committee:

- a) A description of the University licensing decision(s) to be made and of the LPproposed decision(s), including an explanation of the basis or rationale for the proposed decision(s).
- b) Relevant documentation supporting the proposed licensing decision(s) (including access to OTT case files as requested).
- c) A copy of all Form TT-100s, if any, disclosing the nature and level of any inventor disqualifying personal financial interest in all candidate licensees.
- d) A description of the inventor's involvement in the licensing process.
- e) Other information as requested by the LDR body.

H. OTT Licensing Decision Reviews

OTT will conduct required Licensing Decision Reviews of LP-proposed licensing decisions by a non-interested person or persons before such licensing decisions are approved or acted upon. OTT LDRs will be based on an independent consideration and assessment of the facts of the case in view of the University Licensing Guidelines, the nature and level of the inventor(s)' disqualifying personal financial interest, and the education, research, and public service missions of the University. The LDR body, will be composed of at least one qualified staff member with appropriate expertise, knowledge and professional judgment, and will 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. Licensing Decision Review will be conducted by OTT as described below.

Standard Level Licensing Decision Review

A *Standard Level Licensing Decision Review* will be conducted by OTT when the disqualifying personal financial interest disclosed by an inventor on Form TT-100 is:

- \$320 or more in income or gifts in the last 12 months, whichever is less; or
- the value of the personal equity interest or other investment in the proposed licensee is \$2,000 or more, or is five (5) percent or greater of ownership, whichever is less; or
- the inventor or a member of his or her immediate family is an employee or manager of the proposed licensee.

A *Standard Level LDR* will be conducted by an OTT staff member with appropriate expertise, knowledge and professional judgment who has not been influenced by the inventor(s) with a disqualifying personal financial interest. Normally this will be the OTT Licensing Manager for the OTT Licensing Group in which the Licensing Professional making the original licensing decision proposal is located. If that Licensing Manager is the LP making the original licensing decision proposal or has been influenced by the inventor(s) with a disqualifying personal financial interest, then the *Standard Level LDR* will be conducted by the Executive Director of OTT or by another OTT Licensing Professional to be appointed by the Executive Director of OTT. If the Executive Director of OTT is the LP making the original proposal licensing decision, or has been influenced by the inventor(s) with a disqualifying personal financial interest, then the *Standard Level LDR* will be conducted by the Senior Vice President – Business and Finance or by another individual who does not report to the Executive Director of OTT to be appointed by the Senior Vice President.

Special Level Licensing Decision Review

A *Special Level Licensing Decision Review* will be conducted by OTT when the disqualifying personal financial interest disclosed by an inventor on Form TT-100 is:

• \$50,000 or more in income or \$5,000 or more in gifts in the last 12 months, whichever is less; or

- the value of the personal equity interest or other investment in the proposed licensee is \$200,000 or more, or is eight (8) percent or greater of ownership, whichever is less; or
- the inventor or a member of his or her immediate family is a corporate officer (president, vice president, secretary, treasurer, director, trustee) of the proposed licensee; or
- the licensing decision will have a "personal financial effect" on the inventor (see discussion in Guidelines on Managing Potential Conflicts of Interest in Licensing).

A *Special Level LDR* will be conducted by an individual or committee with appropriate expertise, knowledge and professional judgment. Normally, a *Special Level LDR* will be conducted by the Executive Director of OTT or by another individual or committee appointed by the Executive Director. If the Executive Director of OTT is the Licensing Professional making the original proposal licensing decision, or has been influenced by the inventor(s) with a disqualifying personal financial interest, then the *Special Level LDR* will be conducted by the Senior Vice President – Business and Finance or by another individual or committee appointed by the Senior Vice President who does not report to the Executive Director of OTT. Any individual appointed solely or as a member of a committee to conduct a *Special Level LDR* must not have been influenced by the inventor(s) with a disqualifying personal financial interest. The respective campus or Laboratory Patent Coordinator will be consulted as to the appointment of a *Special Level Licensing Decision Review* body.

In those cases where a license agreement involves the licensee's support of additional University research involving the inventor with the disqualifying personal financial interest, the OTT Licensing Professional will inform the inventor and the campus or Laboratory Patent Coordinator and/or Contract and Grant Officer that financial disclosure and independent substantive review of financial interests under the University of California Policy on Disclosure of Financial Interest in Private Sponsors of Research may be required prior to execution of the license agreement. OTT will work with the campus Patent Coordinator in an attempt to coordinate or combine any required Licensing Decision Review with any required review by the local Independent Substantive Review Committee.

I. Final Decisions

When a Licensing Decision Review is required under the Guidelines on Managing Potential Conflicts of Interest in Licensing, the final OTT decision-maker will consider the recommendations of the LDR body before placing a license with a company in which the inventor has a disqualifying personal financial interest or before otherwise implementing a licensing decision. The original OTT Licensing Professional may serve as the final decision-maker if he or she agrees to accept and implement the recommendations of the Licensing Decision Review body in their entirety. However, if the original OTT LP does not accept or does not wish to implement the recommendations of the LDR body in their entirety, the final decision will be made in consideration of the recommendations of the LDR body by the OTT Licensing Manager for the OTT Licensing Group in which the Licensing Professional making the original proposed licensing decision is located. If that Licensing Manager is the Licensing Professional making the original licensing decision proposal or has been influenced by the inventor(s) with a disqualifying personal financial interest, then the final decision will be made by the Executive Director of OTT or by another OTT Licensing Manager to be appointed by the Executive Director of OTT. If the Executive Director of OTT is the Licensing Professional making the original proposed licensing decision, or has been influenced by the inventor(s) with a disqualifying personal financial interest, then the final decision will be made by the Senior Vice President - Business and Finance or by another individual who does not report to the Executive Director of OTT to be appointed by the Senior Vice President.

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University of California



MEMO Operating Guidance No. 01-02

Supplement 1 October 11, 2001

PATENT COORDINATORS CONTRACT AND GRANT OFFICERS VICE CHANCELLORS--RESEARCH ADMINISTRATION ADMINISTRATIVE CONFLICT OF INTEREST COORDINATORS

SUBJECT: Supplement to Managing Potential Conflicts of Interest in Licensing under the California Political Reform Act

OTT Operating Guidance Memo No. 01-02 (August 1, 2000) issued the new University of California Guidelines on Managing Potential Conflicts of Interest in Licensing (Exhibit B) for use by campuses and Laboratories in establishing their Licensing Decision Review (LDR) plans. The guidelines addressed some of the most common issues concerning potential conflicts of interest in University licensing activity and serve as a guide to implement the requirements of the California Political Reform Act. Also enclosed with that Memo were Exhibit C, "Required Elements for Campus/Laboratory Plans for Licensing Decision Reviews," which outlined the elements that any local LDR process must include to be in compliance with the Political Reform Act, and UC Form TT-100, "Inventor Statement Concerning Involvement in Licensing Decisions" (Exhibit D) to be used in accordance with the Guidelines. For information, I also included in that August 1 Guidance Memo OTT's own Plan for Carrying Out Licensing Decision Reviews (Exhibit F) including a sample notice that OTT would provide to inventors, "What Inventors Need to Know about Conflict of Interest in Licensing" (Exhibit E). All of the Exhibits to the August 1 issuance are included here for your convenience.

I stated at that time that I considered OTT's own plan an interim one until we had gained experience in this area and that it would be revised from time to time based on our experience.

Having gone through some early OTT implementation activities and already initiated several Licensing Decision Reviews, we wish to now modify certain elements of the package that was issued on August 1. The following Exhibits have been updated:

- Exhibit C Required Elements for Campus/Laboratory Plans for Licensing Decision Reviews
- Exhibit E Sample Notice: "What Inventors Need to Know about Conflict of Interest in Licensing"
- Exhibit F OTT Plan for Carrying Out Licensing Decision Reviews.

OTT Operating Memo No. 01-02 Supplement 1 October 11, 2001 Page 2

In each case, the document has been modified to reflect a change in the approach that OTT will take in asking inventors to complete Form TT-100. Each Exhibit will now indicate that at OTT, the most likely time that a Form TT-100 will be sent to an inventor will be just prior to the commencement of negotiations with a potential licensee(s), and only when the OTT Licensing Professional determines that the inventor has or will in the future be involved in University licensing decisions. The Licensing Professional will be required to complete and sign a new form for retention in the case file called Licensing Professional Statement of Influence. It is expected that this approach will minimize the administrative burden involved in addressing these matters, while helping to ensure that inventors are informed of and act in accordance with their obligations under the Political Reform Act.

Please be sure that you refer to the most current versions of all Exhibits as dated below.

Sincerely,

Alan B. Bennett Executive Director Research Administration and Technology Transfer

- Exhibit A Letter from Senior Vice Presidents King and Mullinix, June 18, 2001
- Exhibit B Guidelines on Managing Potential Conflicts of Interest in Licensing (August 1, 2001)
- Exhibit C Required Elements for Campus/Laboratory Plans for Licensing Decision Reviews (October 1, 2001)
- Exhibit D UC Form TT-100, "Inventor Statement Concerning Involvement in Licensing Decisions" (August 1, 2001)
- Exhibit E Sample Notice: "What Inventors Need to Know about Conflict of Interest in Licensing" (October 1, 2001)
- Exhibit F OTT Plan for Carrying Out Licensing Decision Reviews (October 1, 2001)
- cc: Managers Academic Conflict of Interest Coordinators Senior Vice President Mullinix OTT Associate Directors

UNIVERSITY OF CALIFORNIA

OTT Operating Memo No. 01-02 August 1, 2001 EXHIBIT A

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June 18, 2001

CHANCELLORS LABORATORY DIRECTORS

Dear Colleagues:

In December 1999, the Administrative Task Force to Review University Policies Pertaining to Outside Activities, Conflict of Commitment, Conflict of Interest and Related Issues released the second part of its two-part report. That report included a recommendation that the University require inventors to disclose any financial interest in potential licensees of their University inventions and that the University provide guidance to inventors and licensing staff about managing positive financial interests.

University experience with transferring research results to the private sector has shown that inventors are often the best source of marketing leads for potential licensees of their inventions. In addition, UC licensing staff and potential licensees sometimes rely on inventors and authors of copyrightable works to provide technical details about their research results and to become involved in determining a company's interest in a license. Yet under California law (the California Political Reform Act of 1974 and its regulations), UC inventors and authors normally must not participate in or attempt to influence University decisions involved in the licensing process, including the selection of licensees, when they have a financial interest in a potential licensee.

The Office of General Counsel has recently confirmed, however, that the Political Reform Act permits participation by an inventor with a financial interest in advising or making recommendations with respect to University licensing decisions, so long as there is an appropriate intervening review by a non-interested person or persons. Intervening review means there is another level of review before the final decision is approved. The review must be substantive, based on an independent assessment of the facts of the case. At its February 2001 meeting, the Technology Transfer Advisory Committee endorsed establishing, in accordance with requirements of the Political Reform Act, an intervening substantive review process for licensing decisions made at University licensing offices.

Intervening reviewers shall consider proposed decisions of licensing officials in light of the factual situation presented, good licensing practices such as exemplified in the University's Licensing Guidelines and the University's research and education objectives, including consideration of any impacts on students. Reviewers should have the option of recommending approval of proposed licensing decisions, with or without modification or safeguards, or disapproval of such decisions, or proposing their own courses of action.

It is expected that the intervening substantive review process will not affect the majority of University licensing cases as it will be activated only in cases where an inventor or author with a financial interest in a candidate licensee will have a role in the licensing process.

Accordingly, we are asking campuses and Laboratories to develop and implement local plans to ensure the carrying out of required intervening substantive reviews of decisions relating to licensing University research results. Such plans must provide for intervening review by an appropriately disinterested official or committee if an inventor or author participates in or influences licensing decisions and has a financial interest in those decisions as defined in the California Political Reform Act. Development and implementation of such local plans must be coordinated with the systemwide Office of Technology Transfer (OTT) for those cases for which OTT will be the authorized licensing office. We have asked OTT Executive Director Bennett to issue by July 31 systemwide guidance for use by campuses and Laboratories in establishing their intervening substantive review plans.

Copies of campus and Laboratory plans should be submitted to the UCOP Office of Technology Transfer by October 31, 2001.

We appreciate your help in addressing this important technology transfer need. Once this review system is successfully established, we believe it will enable us to tap more fully the expertise and creativity of our inventors and authors and, at the same time, ensure that they may remain in compliance with the Political Reform Act.

Any questions about the new licensing review process should be directed to Associate Director Joe Acanfora at (510) 587-6011 or joe.acanfora@ucop.edu.

Sincerely,

C. Judson King

Provost and Senior Vice President--Academic Affairs

Joseph P. Mullinix Senior Vice President--**Business and Finance**

cc: President Atkinson Members, President's Cabinet Academic Senate Chair Cowan Interim Vice Provost Coleman Executive Director Bennett Members, Technology Transfer Advisory Council

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

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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, <u>http://patron.ucop.edu/ottmemos/docs/ott00-05.html</u>), 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

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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, <u>http://patron.ucop.edu/ottmemos/docs/ott00-05.html</u>), and based upon the education, research, and public service missions of the University.

What does the Political Reform Act require regarding licensing decisions?

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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?

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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. <u>SELF-DISQUALIFICATION UNDER THE ACT</u>

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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?

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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

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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?

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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

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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 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.

Required Elements for Campus/Laboratory Plans for Licensing Decision Reviews (LDR)

This document is a component of the guidelines 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 University technology licensing activity. Campus and Laboratory plans for Licensing Decision Reviews (LDR) (a form of intervening substantive review under the California Political Reform Act) must incorporate the following elements:

Licensing Professional Disqualification

Licensing Professionals (LP) who determine that they have a disqualifying personal financial interest in licensing decisions for an invention disclosure that has been assigned to them must disqualify themselves from participating in or attempting to influence any licensing decisions for that case and advise their supervisor of the need to relieve them from any case management responsibilities. The case must be re-assigned by the supervisor for management to another LP without a disqualifying personal financial interest in the licensing decisions.

Consultation with Inventors

In order to help to address and manage potential conflicts of interest in licensing decision issues, as soon as practical after an invention disclosure is received by the Authorized Licensing Office, the Licensing Professional shall:

- a) provide notice to inventors of the provisions of the State of California Political Reform Act of 1974 and the disqualification and disclosure requirements contained therein, and the University's policies and procedures for managing any potential conflicts of interest if an inventor has a disqualifying financial interest in a candidate licensee(s). Exhibit E, "What Inventors Need to Know about Conflicts of Interest in Licensing") is provided as one optional tool/sample for campuses and Laboratories use in advising inventors on this matter.
- b) determine the level of inventor involvement in licensing decision-making (e.g., in legal and policy terms, determine the role the Licensing Professional would like the inventor to play in "making, participating in making or influencing" any LP's decision concerning the invention, including selection of licensees and other decisions made in the course of commercializing the invention.) 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 the licensing decisions may be a factor in the considerations and ultimate recommendations of a Licensing Decision Review body. In general, the role of the inventor

in the licensing process should be kept to the minimum necessary to successfully achieve the University's objectives in marketing and licensing. Any approach, however, should not chill inventor involvement in patent prosecution which is necessary and often legally required.

c) consider reviewing with the inventor the applicability of the University Licensing Guidelines to the disclosed invention when appropriate (see OTT Guidance Memo No. 00-05, hhtp://patron.ucop.edu/ottmemos/docs/ott00-05.html). Degree of adherence to the Licensing Guidelines would be one factor in any subsequent Licensing Decision Review.

Inventor Disqualification

Upon identification by the Licensing Professional of a candidate licensee(s) (usually prior to initiating negotiations with a company), and where the LP wishes to have the inventor's involvement in the licensing decision-making process, the lead inventor should be asked to consider his or her involvement in the licensing decision-making process, considering the earlier notification about disqualification and disclosure requirements of the Political Reform Act.

The inventor may disqualify him or herself by asserting in writing that while having the disqualifying personal financial interest, he or she has not in the past nor will in the future make, participate in making, or attempt to influence a University decision concerning the subject invention, including the selection of a licensee(s), and other decisions made in the course of attempting to commercialize the invention. UC Form TT-100, Inventor Statement Concerning Involvement in Licensing Decisions, (www.ucop.edu/ott/tt-100) may be used for this purpose. Alternatively, simple non-participation in any and all licensing decisions, even without written self-disqualification, is sufficient to remain in compliance with the Act. Such action by the inventor should be taken in close coordination with the LP. A copy of any written disqualification should be kept in the invention case file.

Inventor Participation/Disclosure

When both the Licensing Professional and the inventor agree that the inventor has or in the future should participate in University licensing decision-making, working with University licensing staff and/or with potential licensees, to accomplish the objective of commercializing the invention, or will be negotiating "across the table" from the University on behalf of a company in which the inventor has a disqualifying personal financial interest, the inventor would not disqualify him or herself. In this case, the inventor would be considered to be "making, participating in making or influencing" a LP's decision concerning licensing the invention. If an inventor who will be so involved 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 must be used for this purpose. When disqualifying personal financial interest of her interest is disclosed in such a circumstance, a Licensing Decision Review of LP-proposed licensing decisions is required.

If, after initially completing Form TT-100, an inventor who is so involved in LP licensing decisions either develops a new or revised disqualifying personal financial interest in a candidate licensee or the LP identifies additional potential licensees, the inventor must promptly provide to the LP a new Form TT-100 providing the relevant information.

On a case-by-case basis, Licensing Professionals may exercise their judgement in identifying and addressing any case where it is reasonably apparent that an inventor who is participating in licensing decisions has a disqualifying personal financial interest, but has not disclosed that interest upon request. LPs may reiterate to the inventor the disclosure/disqualification requirements under the Act, may request a Licensing Decision Review, or take other case-specific actions.

Objective Licensing Professional Decision-Making

University selection of licensees and other decisions made in the course of commercializing University research results should be based upon the education, research, and public service missions of the University and in accordance with the factual situation presented and good licensing practices as exemplified in the University Licensing Guidelines (see OTT Guidance Memo No. 00-05, http://patron.ucop.edu/ottmemos/docs/ott00-05.html). When an inventor has a disqualifying personal financial interest in a candidate licensee and does not disqualify him or herself from participation in the licensing process, the LP should ensure that sufficient documentation is available in the invention case file in the Authorized Licensing Office to provide an understanding of the objective business basis for the LP-proposed selection of a licensee(s), and for other licensing decisions made in the course of commercializing the invention.

Request for Licensing Decision Review

When an inventor has a disqualifying personal financial interest in a candidate licensee, and does not disqualify him or herself from participation in licensing decision-making, Licensing Decision Review (LDR) of the licensee selection and other licensing decisions is required. In such circumstances, the LP shall inform the appropriate LDR individual or committee as early in the process as appropriate of a LP-proposed decision to place a license with a particular company and of other proposed licensing decisions made in the course of commercializing the invention.

Submission of Information for Licensing Decision Review

At least, the following information shall be provided to the appropriate LDR individual or committee by the Licensing Professional proposing a licensing decision(s):

a) A description of the licensing decision(s) to be made and of the LP-proposed decision(s), including an explanation of the basis or rationale for the proposed decision(s).

- b) Copies of, or the location of all relevant documentation supporting the proposed licensing decision(s).
- c) A copy of the Form TT-100 if any, disclosing the nature and level of any inventor disqualifying personal financial interest.
- d) A description of the inventor's involvement in the licensing process.
- e) Other information as required by the review body.

Conduct of Licensing Decision Review

The Licensing Decision Review body must be composed of qualified staff with appropriate expertise, knowledge and professional judgment, and 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 in view of the University Licensing Guidelines, the nature and level of the inventor(s)' disqualifying personal financial interest, and the education, research, and public service missions of the University.

In those cases where a license agreement involves the licensee's support of additional University research involving the inventor with the disqualifying personal financial interest, the LP must inform the inventor and the campus or Laboratory Contract and Grant Officer that financial disclosure and independent substantive review of financial interests under the University of California Policy on Disclosure of Financial Interest in Private Sponsors of Research may be required prior to execution of the license agreement. Any required Licensing Decision Review should be coordinated or combined with any required Independent Substantive Review Committee review as appropriate

Final Decisions

When a Licensing Decision Review is required under the Guidelines, the final decision-maker shall consider the recommendations of the Licensing Decision Review body before placing a license with a company in which the inventor has a disqualifying personal financial interest, or before otherwise implementing a licensing decision. The original Licensing Professional may serve as the final decision-maker if he or she agrees to accept and implement the recommendations of the Licensing Decision Review body in their entirety. However, if the original LP does not accept or does not wish to implement the recommendations of the Licensing Decision Review body be made in consideration of the recommendations of the Licensing Decision Review body by a University official with appropriate authority who is at least one level higher in the organization than the LP making the original proposed decision, and who has not been influenced by the inventor(s) with a disqualifying personal financial interest.

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Inventor / Author Statement Concerning Involvement in Licensing Decisions

Form TT-100 (August 2001)

This form is to be completed by University inventors/authors and submitted to the University Authorized Licensing Office in accordance with OTT Operating Guidance Memo No. 01-02 located at http://patron.ucop.edu/ottmemos/docs/ott01-02.html. It should be completed after discussions with the Licensing Professional responsible for managing the invention or work of authorship (herein, "invention"). Generally it is submitted:

- upon selection by the Licensing Professional of candidate licensees, and
- upon any change in a disclosed financial interest of an inventor in a candidate licensee.

itle of Inv	rention:	UC Case # (if known)	
	t:		
	l statement for this invention	Supplemental statement for this invention	
		a Political Reform Act to my involvement in University licensing	
(CHEC)		ert tile following.	
//	DISQUALIFICATION		
	influence a University licensing dec selection of a licensee(s), and other	not and do not intend to participate in making, or attempting to cision concerning the invention identified above, including the decisions made in the course of attempting to license this invention.	
	STOP HERE (No need to complete	e Section III below).	
//	ELIGIBILITY TO PARTICIPATE		
	I do not disqualify myself. I have, or wish to remain eligible to participate in or influence a University licensing decision concerning the invention identified above, including the selection of a licensee(s), and other decisions made in the course of attempting to license this invention. I understand all such University decisions will be subject to an intervening Licensing Decision Review by a disinterested official or committee.		
	COMPLETE SECTION III BELO	DW.	
		Date:	

	Inventor's/Author's Statement of Financial Interest in Candidate Licensee
Pro	vide the following information about this candidate licensee:
	Company Name (candidate licensee): Company location:
A.	Are you or a member of your immediate family a director, officer, trustee, or employee of, or do you hold any position of management in the company identified above?NoYesIf yes, identify specificposition (s):
B.	Do you, or does a member of your immediate family, have:
	1. An investment of \$2,000 or more in the company identified above?NoYesValue
	2. Income (including any payment, such as salary or consulting fees, or any loan or any gift) of \$320 or more received from the company identified above within the last 12 months? (Do not include any salary paid by the University with funds provided by the company). NoYes InterviewNo YesYes If yes, \$Value
C.	Will there be a current or future impact on the personal finances of you or your immediate family as a result of the licensing decision(s)?
I ha	ve used all reasonable diligence in preparing this Statement and to the best of my knowledge it is true and complete.
Sig	Date:
req emj	<u>s is a public document</u> . All of the information on this form will be available to any member of the public upon uest. This information is to be used to reveal to public scrutiny certain financial interests of public officials and ployees in order to disclose potential conflicts of interest and to aid in the prevention of actual conflicts of prest.

Sample Notice to Inventors: This notice will be used by the Office of Technology Transfer (OTT) as part of its acknowledgement sent to inventors of receipt of a Record of Invention. A comparable notice should be given to all campus or Laboratory inventors by Authorized Licensing Offices at the time of invention disclosure. This notice may be excerpted or adapted by campuses or Laboratories for their own use as they may choose. If the local notice is intended to be shared routinely with authors disclosing their works of authorship for licensing consideration, this sample notice should be modified accordingly.

What Inventors Need to Know about Conflicts of Interest in Licensing (October 1, 2001)

UC Policy and State Law Concerning Conflicts of Interest in Licensing

The University of California's policy on conflicts of interest provides that none of the University's "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." In addition to UC policy, University faculty and staff must comply with state statutes and regulations governing conflicts of interest, specifically the Political Reform Act of 1974 (the Act). The Act requires public officials to "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." (Gov. Code, § 81001, subd. (b).)

The Act and its implementing regulations apply to University licensing decisions. In other words, University inventors and University licensing staff must not allow their personal financial interests to influence their or other's University licensing decisions.

Guidelines on Managing Potential Conflicts of Interest in Licensing

Licensing decisions for the University are made by Licensing Professionals (LP) within authorized campus and Laboratory licensing offices. The work of the LP is sometimes aided by the inventor, who may be invited by the LP to work with University licensing staff and potential licensees to effectively commercialize University inventions.

Because 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, inventors must comply with the disqualification and disclosure requirements of the Act.

 The disqualification requirements of the Act require an inventor who has a disqualifying personal financial interest in a University licensing decision to refrain from participating in or influencing the decision. However, if the LP determines that the inventor's involvement is necessary to the decision, or if the inventor will negotiate "across the table" from the University on behalf of a company in which the inventor has a disqualifying personal financial interest, the inventor may participate so long as proposed University licensing decisions are reviewed by an independent body (a Licensing Decision Review). (Note: Under the Act, University negotiations with an inventor who is also the sole proprietor or who solely, or jointly, with his or her spouse, exercises sole direction and control of a candidate licensee may not trigger the need for Licensing Decision Review). 2. The disclosure requirements of the Act require the inventor to specifically disclose any disqualifying personal financial interest in the licensing decision when he or she is involved in a proposed University licensing decision.

How does an inventor disqualify him or herself?

If an inventor has a disqualifying personal financial interest in a University licensing decision, as early as at the time of invention disclosure--the inventor may disqualify him or herself by formally asserting in writing on Form TT-100 (available at <u>www.ucop.edu/ott/tt-100</u>) that he or she has not and will not in the future 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 licensing the invention. Alternatively, simple (and absolute) nonparticipation in all licensing decisions, even without formal written self-disqualification, would constitute an acceptable disqualification under the Act. Inventors who do not wish to be involved in the licensing decision-making process in any way do not have to complete any form, as long as they make their wishes clear to the Licensing Professional.

How does an inventor become involved?

When an inventor is invited to be involved in a University licensing decision by the Licensing Professional, or intends to negotiate "across the table" from the University, inventor disclosure of any disqualifying personal financial interest must be made on Form TT-100, promptly upon request by the LP. In most cases, this would be upon identification by the LP of a candidate licensee(s) and prior to the commencement of University negotiations with the company. If Form TT-100 indicates that an inventor has a disqualifying personal financial interest, and if the inventor has been or will be involved in the LP's licensing decisions, the LP must initiate a Licensing Decision Review. If no Form TT-100 is completed by the inventor (and thus there is no definitive assertion, positive or negative, of the inventor's personal financial interest), and if the inventor has been or will be involved in the LP's licensing decisions, the LP, in his or her judgement, may determine that a Licensing Decision Review is appropriate. If inventors have any questions about how the disqualification/disclosure process should be carried out, the LP can provide assistance.

How does the licensing decision undergo review?

Licensing Decision Review means there is a review by a non-interested person or persons before the proposed licensing decision goes to the final decision-maker for approval. The review must be based on an independent review and assessment of the facts of the case and must be conducted by qualified staff with appropriate expertise, knowledge and professional judgment, who must independently check the Licensing Professional's original data, analysis, proposed selection of licensees, and other licensing decisions. This is necessary under the Act since the LP may have been influenced by the inventor with the disqualifying personal financial interest.

Who conducts the Licensing Decision Review?

Each campus and Laboratory and the Office of Technology Transfer 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 Licensing Decision Review. At OTT the nature of the licensing decision review will depend on the

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level of the inventor's personal financial interest in the potential licensee. Most Licensing Decision Reviews will be conducted by another licensing official within the Office of Technology Transfer who has not been involved in the original proposed decision. More complex cases involving more significant inventor personal financial interests will be reviewed by an appropriate independent reviewer or by a committee appointed by the Executive Director or the Senior Vice President.

More detailed information and guidance on managing potential conflicts of interest in University licensing decisions are available at http://patron.ucop.edu/ottmemos/docs/ott01-02.html

Office of Technology Transfer (OTT) Office of the President (October 1, 2001)

Plan for Carrying Out Licensing Decision Reviews

Provost King and Senior Vice President Mullinix, in a June 18, 2001 letter to Chancellors and Laboratory Directors requested that each authorized University licensing office establish a process to carry out intervening substantive reviews of licensing decisions (hereinafter referred to as Licensing Decision Reviews) consistent with the requirements of the California Political Reform Act. The following process will be used by the UCOP Office of Technology Transfer (OTT) to carry out such Licensing Decision Reviews (LDR) for those inventions under OTT management unless other LDR plans have been mutually agreed upon under a Memorandum of Understanding for a specific campus' or Laboratory's cases managed by OTT. Based on its experience in carrying out LDRs, from time-to-time OTT may revise its LDR processes with input from campuses and Laboratories.

A. Notice to Inventors

Promptly upon receipt by the OTT of a record of invention form (ROI) or other invention disclosure, the OTT Prosecution Group will send an acknowledgment letter to each inventor which will incorporate a notice to inventors of the provisions of the State of California Political Reform Act of 1974 and the disqualification and disclosure requirements contained therein, "What Inventors Need to Know about Conflict-of-Interest in Licensing." The OTT notice will explain briefly the University's policies and procedures for managing any potential conflicts of interest if an inventor has a disqualifying personal financial interest in a candidate licensee(s) and will direct the inventor(s) to the OTT website for further information (http://patron.ucop.edu/ottmemos/docs/ott01-02.html).

B. Licensing Professional Disqualification

OTT Licensing Professionals (LPs) who determine that they have a disqualifying personal financial interest in licensing decisions for a case that has been assigned to them will disqualify themselves from case management responsibilities by notifying their supervisor of the situation. The OTT supervisor will re-assign the case for management to another LP without a disqualifying personal financial interest in the licensing decisions.

C. Consultation with Inventors

In order to help address concerns about potential conflicts of interest in licensing decisions, OTT Licensing Professionals in their early discussions with inventors will consider the appropriate level of inventor involvement in licensing decision-making for a

particular invention. If the OTT LP wishes to have inventor(s) involved in the licensing decision-making process, the LP will invite one or more inventors to be involved, considering the disqualification and disclosure requirements of the Political Reform Act. Alternatively, an inventor may become involved when the inventor negotiates "across the table" from an OTT LP on behalf of a candidate licensee in which the inventor has a disqualifying personal financial interest. 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 the licensing decisions may be a factor in the considerations and ultimate recommendations of any LDR body. In general, the role of the inventor in the OTT licensing decision-making process will be kept to the minimum necessary to successfully achieve the University's objectives in marketing and licensing inventions.

If the OTT Licensing Professional does not desire such inventor participation, the LP will advise the inventor not to participate in nor attempt to influence OTT licensing decisions.

In addition, OTT Licensing Professionals will, when they judge appropriate, review with the inventor the applicability of the University Licensing Guidelines (see OTT Guidance Memo No. 00-05, http://patron.ucop.edu/ottmemos/docs/ott00-05.html) to the disclosed invention.

D. Inventor Disqualification, Participation, and Disclosure

Upon identification by OTT Licensing Professionals of the candidate licensee(s) with which the LP intends to enter negotiations, the LP will determine for each inventor whether the inventor already has, or in the future will be invited or allowed by the LP to participate in, or attempt to influence LP decisions made in the course of licensing the subject invention. The LP then will indicate that determination on the Licensing Professional Statement of Influence form (Attachment 1) as a record to be maintained in the OTT Negotiations File.

Inventors Not Participating

On the Licensing Professional Statement of Influence form, under the box "Disqualified from Participation", the LP will enter the name of each inventor who has not and who in the future will not be allowed by the LP to participate in, or attempt to influence LP decisions made in the course of licensing the subject invention.

Completion of UC Form TT-100 by inventors listed under "Disqualified from Participation" is not required. However, if inventors wish to disqualify themselves in writing, they may submit UC Form TT-100, checking the box "Disqualification" thereby asserting in writing that they have not in the past nor will in the future "make, participate in making, or attempt to influence" a University licensing decision concerning the subject invention, including the selection of a licensee(s), and other decisions made in the course

of attempting to commercialize the invention. While simple non-participation in any and all licensing decisions, even without such written self-disqualification, is sufficient to remain in compliance with the Act, a written assertion provides clear documentation of the inventor's choice not to participate. A copy of any written disqualification will be kept in the OTT invention case file.

Inventors Eligible to Participate

On the Licensing Professional Statement of Influence form, under the box "Eligible to Participate," the LP will enter the name of each inventor who already has or who in the future will be invited or allowed by the LP to participate in, or attempt to influence LP decisions made in the course of licensing the subject invention. The LP will send a letter or e-mail to each inventor listed here instructing them to disclose any disqualifying personal financial interests in candidate licensee(s) using University Form TT-100. The OTT LP may include a copy of the form with any letter sent to the inventor or may choose to indicate in the letter or e-mail the website location for the form <u>http://patron.ucop.edu/ottmemos/docs/tt1002.pdf</u> and ask that it promptly be returned to the OTT LP.

If an inventor has a disqualifying personal financial interest in any candidate licensee identified by the OTT Licensing Professional, that inventor is required under the Act to disclose his or her financial interest. The inventor will be asked to make this disclosure using Form TT-100 and to promptly return it to the OTT LP. When a disqualifying personal financial interest is disclosed in such circumstances, a Licensing Decision Review of LP-proposed licensing decisions is required and will be initiated be OTT.

The OTT communication with the inventor that requests disclosure of any disqualifying financial interest will advise the inventor that if, after initially completing Form TT-100, either the inventor develops a new or revised disqualifying personal financial interest in a candidate licensee or the OTT Licensing Professional identifies additional candidate licensees, the inventor(s) must promptly provide to the OTT LP a new Form TT-100 providing the updated information.

When an inventor who has or will be invited or allowed by the LP to participate in, or attempt to influence LP decisions does not disclose a financial interest, OTT Licensing Professionals on a case-by-case basis, will exercise their judgment in identifying and addressing any case where it is reasonably apparent that such an inventor appears to have a disqualifying personal financial interest. In such cases, OTT LPs may reiterate to the inventor the disclosure/disqualification requirements under the Act, request an LDR of proposed licensing decisions for that case, or take other appropriate case-specific actions.

E. Objective LP Decision-Making

The OTT LP will conduct the licensing process 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 commercializing University research results technology will be based upon the education, research, and public service missions of the University and taking into account University Licensing Guidelines (see OTT Guidance Memo No. 00-05, http://patron.ucop.edu/ottmemos/docs/ott00-05.html). When an inventor indicates on Form TT-100 a disqualifying personal financial interest in a candidate licensee and does not disqualify him or herself from participation in the licensing process, the OTT LP will ensure that sufficient documentation is available in the OTT invention case file to provide an understanding of the objective business basis for the LP-proposed selection of a licensee(s), and for other licensing decisions and to support the review to be conducted by the LDR body.

F. When and How to Request Licensing Decision Review

When an inventor has a disqualifying personal financial interest in a candidate licensee, and participates in licensing decision-making, Licensing Decision Review of the proposed licensee selection and other proposed licensing decisions will be conducted by OTT. In such circumstances, the OTT Licensing Professional will advise his or her supervisor as early in the process as appropriate of a LP-proposed decision to place a license with a particular company and other proposed licensing decisions made in the licensing process and of the need to conduct a LDR. Preferably, the LDR will occur prior to the perspective licensee taking substantial actions in reliance upon the University's obligation to negotiate in good faith. The respective campus or Laboratory Patent Coordinator will be promptly advised of the situation.

G. Submission of Information for Licensing Decision Review

When a Licensing Decision Review is required, the OTT Licensing Professional who proposes the selection of a licensee or other University licensing decisions will provide at least, the following information to the appropriate LDR individual or committee:

- a) A description of the University licensing decision(s) to be made and of the LPproposed decision(s), including an explanation of the basis or rationale for the proposed decision(s).
- b) Relevant documentation supporting the proposed licensing decision(s) (including access to OTT case files as requested).
- c) A copy of all Form TT-100s, if any, disclosing the nature and level of any inventor disqualifying personal financial interest in all candidate licensees.

- d) A description of the inventor's involvement in the licensing process.
- e) Other information as requested by the LDR body.

H. OTT Licensing Decision Reviews

OTT will conduct required Licensing Decision Reviews of LP-proposed licensing decisions by a non-interested person or persons before such licensing decisions are approved or acted upon. OTT LDRs will be based on an independent consideration and assessment of the facts of the case in view of the University Licensing Guidelines, the nature and level of the inventor(s)' disqualifying personal financial interest, and the education, research, and public service missions of the University. The LDR body, will be composed of at least one qualified staff member with appropriate expertise, knowledge and professional judgment, and will 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. Licensing Decision Review will be conducted by OTT as described below.

Standard Level Licensing Decision Review

A *Standard Level Licensing Decision Review* will be conducted by OTT when the disqualifying personal financial interest disclosed by an inventor on Form TT-100 is:

- \$320 or more in income or gifts in the last 12 months, whichever is less; or
- the value of the personal equity interest or other investment in the proposed licensee is \$2,000 or more, or is five (5) percent or greater of ownership, whichever is less; or
- the inventor or a member of his or her immediate family is an employee or manager of the proposed licensee.

A *Standard Level LDR* will be conducted by an OTT staff member with appropriate expertise, knowledge and professional judgment who has not been influenced by the inventor(s) with a disqualifying personal financial interest. Normally this will be the OTT Licensing Manager for the OTT Licensing Group in which the Licensing Professional making the original licensing decision proposal is located. If that Licensing Manager is the LP making the original licensing decision proposal or has been influenced by the inventor(s) with a disqualifying personal financial interest, then the *Standard Level LDR* will be conducted by the Executive Director of OTT or by another OTT Licensing Professional to be appointed by the Executive Director of OTT. If the Executive Director of OTT is the LP making the original proposal licensing decision, or has been influenced by the inventor(s) with a disqualifying personal financial interest, then the *Standard Level LDR* will be conducted by the Senior Vice President – Business and Finance or by

another individual who does not report to the Executive Director of OTT to be appointed by the Senior Vice President.

Special Level Licensing Decision Review

A *Special Level Licensing Decision Review* will be conducted by OTT when the disqualifying personal financial interest disclosed by an inventor on Form TT-100 is:

- \$50,000 or more in income or \$5,000 or more in gifts in the last 12 months, whichever is less; or
- the value of the personal equity interest or other investment in the proposed licensee is \$200,000 or more, or is eight (8) percent or greater of ownership, whichever is less; or
- the inventor or a member of his or her immediate family is a corporate officer (president, vice president, secretary, treasurer, director, trustee) of the proposed licensee; or
- the licensing decision will have a "personal financial effect" on the inventor (see discussion in Guidelines on Managing Potential Conflicts of Interest in Licensing).

A *Special Level LDR* will be conducted by an individual or committee with appropriate expertise, knowledge and professional judgment. Normally, a *Special Level LDR* will be conducted by the Executive Director of OTT or by another individual or committee appointed by the Executive Director. If the Executive Director of OTT is the Licensing Professional making the original proposal licensing decision, or has been influenced by the inventor(s) with a disqualifying personal financial interest, then the *Special Level LDR* will be conducted by the Senior Vice President – Business and Finance or by another individual or committee appointed by the Senior Vice President who does not report to the Executive Director of OTT. Any individual appointed solely or as a member of a committee to conduct a *Special Level LDR* must not have been influenced by the inventor(s) with a disqualifying personal financial interest. The respective campus or Laboratory Patent Coordinator will be consulted as to the appointment of a *Special Level Licensing Decision Review* body.

In those cases where a license agreement involves the licensee's support of additional University research involving the inventor with the disqualifying personal financial interest, the OTT Licensing Professional will inform the inventor and the campus or Laboratory Patent Coordinator and/or Contract and Grant Officer that financial disclosure and independent substantive review of financial interests under the University of California Policy on Disclosure of Financial Interest in Private Sponsors of Research may be required prior to execution of the license agreement. OTT will work with the campus Patent Coordinator in an attempt to coordinate or combine any required Licensing

Decision Review with any required review by the local Independent Substantive Review Committee.

I. Final Decisions

When a Licensing Decision Review is required under the Guidelines on Managing Potential Conflicts of Interest in Licensing, the final OTT decision-maker will consider the recommendations of the LDR body before placing a license with a company in which the inventor has a disqualifying personal financial interest or before otherwise implementing a licensing decision. The original OTT Licensing Professional may serve as the final decision-maker if he or she agrees to accept and implement the recommendations of the Licensing Decision Review body in their entirety. However, if the original OTT LP does not accept or does not wish to implement the recommendations of the LDR body in their entirety, the final decision will be made in consideration of the recommendations of the LDR body by the OTT Licensing Manager for the OTT Licensing Group in which the Licensing Professional making the original proposed licensing decision is located. If that Licensing Manager is the Licensing Professional making the original licensing decision proposal or has been influenced by the inventor(s) with a disqualifying personal financial interest, then the final decision will be made by the Executive Director of OTT or by another OTT Licensing Manager to be appointed by the Executive Director of OTT. If the Executive Director of OTT is the Licensing Professional making the original proposed licensing decision, or has been influenced by the inventor(s) with a disqualifying personal financial interest, then the final decision will be made by the Senior Vice President – Business and Finance or by another individual who does not report to the Executive Director of OTT to be appointed by the Senior Vice President.

Case #_____

LICENSING PROFESSIONAL STATEMENT OF INFLUENCE (October 1, 2001)

DISQUALIFIED FROM PARTICIPATION

The following inventors have not and will not be invited/allowed to participate in, or attempt to influence decisions made by me or other Licensing Professionals in the course of attempting to license the subject invention.

ELIGIBLE TO PARTICIPATE

The following inventors have or will be invited/allowed to participate in or attempt to influence decisions made by me or other Licensing Professionals in the course of licensing the subject invention. Each such inventor will be requested to complete and submit Form TT-100, "Inventor/Author Statement Concerning Involvement in Licensing Decisions." Licensing Decision Reviews will be requested and conducted in accordance with OTT Operating Guidance Memo No. 01-02.

Licensing Officer Signature

Licensing Officer Name

Date