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