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 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 in their entirety, the final decision must 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.