

Guidelines for Faculty Inventors Involved with Start-Up or Other Companies Licensing Technology That They have Developed at the University: Managing Potential Conflicts of Interest Arising from the Licensing of the Technology

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I. Preamble

A. The University Welcomes Start-Up Companies Involving Faculty

UCLA and the University of California welcome the opportunity to license to start-up companies in general and inventor start-ups in particular. Licensing to start-up companies based in California allows us to meet our mandate to favor small businesses and California-based businesses that employ Californians and support the state economy. In addition, when the technology is developed at UCLA using federal funding, promoting start-ups satisfies federal interests and directives.

When UCLA licenses to inventor start-ups, it has the satisfaction of supporting entrepreneurial enterprise at UCLA and, often, of providing employment opportunities for our graduate students. Licensing to start-ups also provides a pathway for the development of early stage technology and may fulfill a faculty member's long-term research goal of developing a specific product that solves an important societal problem.

Not only does UCLA favor start-ups because they are small businesses and are based in California, it favors them because this allows technologies to be developed that would otherwise never see the market place. Often the technology doesn't interest large established companies such as big Pharma, as it's too early in the development stage, the market is too small, there are too many competing products, or the technology doesn't fit with the current interests of a large company. A start-up company will often take on an early stage invention in which a large company is not interested and develop it to a point where a large company will seriously consider taking it on. Start-ups may be willing to develop technologies with relatively small markets or profit margins. Start-ups are frequently less risk-averse. In addition, they are usually more focused and therefore less likely to drop a project because the management changes research direction.

Intellectual Property that results from sponsored research at UCLA must become the property of The Regents unless The Regents expressly relinquish the rights to the intellectual property. After fulfilling his or her obligation to disclose the intellectual property, the faculty member may a) choose to leave it to the University to oversee the translational development of the technology for the marketplace, or b) consider forming or becoming involved in the formation of a start-up company that, as indicated below, can compete for the license. However, faculty may not use a consulting agreement to develop intellectual property at a company nor can they transfer intellectual property resulting from sponsored research at UCLA to an entity outside of UCLA; the transfer of the intellectual property to the company must involve a license agreement to the company by The Regents.

B. Balancing the Mission of the University with its Desire to Encourage Start-Up Companies Involving Faculty

While the University encourages start-up companies involving faculty, it must do so in a way that does not compromise its core mission and in a way that fits within certain

boundaries dictated by University policies and regulations. This places some restrictions on both University-Company interactions and Company-Faculty interactions.

II. Guidelines Relevant to Licensing

A. The University Must Balance its Desire to Encourage Entrepreneurship with its Goal of Getting Technology to Market

While the University wants to encourage entrepreneurial spirit and recognize the commitment, determination, and vision of faculty start-ups, it must balance its desire to encourage start-up companies against the ultimate goal of advancing the technology to the market place. UCLA will not automatically license the invention rights to a faculty start-up company because UCLA must be reasonably satisfied that it is placing the technology with the entity most likely to develop products in a timely manner. Technology invented at UCLA must be made available to all potential licensees and UCLA must treat the inventor start-up as it would any candidate licensee. If, for instance, the technology is late stage and there are one or more potential licensees for the invention and the licensee(s) can demonstrate a quick and reasonably certain route to the marketplace, it may make the most sense for UCLA to license to the established entity. Also, if there is a conflict among the co-inventors regarding the start-up company, the University may determine that it is best to go the established company route.

B. What the University Expects from a Start-up with Respect to Licensing University Technology

If the situation is right and the University determines that the technology might best be licensed to a company linked with a faculty member, UCLA will ask the faculty member and the start-up company for some of the following:

1. UCLA will require that a company be formed. UCLA may not issue a license to an individual. The start-up company must show that it has the resources or the ability to obtain the resources to develop the product in a timely manner. UCLA recognizes that 'timely' varies with the stage of the technology.
2. UCLA will ask the start-up company to identify the product to be sold and will ask for a development plan and timeline.
3. In the license agreement, UCLA will require the start-up company to pay patent costs, licensing fees and ultimately royalties, as with any commercial entity. UCLA will also require that the start-up company adhere to a development timetable that encompasses diligent efforts to bring the product to market and may include milestones that require the company to raise the necessary capital to fund the development of the technology.

The same requirements outlined above would apply to any other company.

C. *What the University Must Do Before Executing a License with a Faculty-Owned Start-Up Company.*

In 2001, the University issued guidance on Managing Potential Conflicts of Interest in Licensing under the California Political Reform Act. In brief, this UC guidance reminded the campuses that inventors were often the best source of leads to potential licensees but at the same time had conflicts of interest that had to be acknowledged. The guidance indicates that in some instances employees must disqualify themselves from “making, participating in making or influencing a University decision.” It also indicates that when employees with a financial interest do not disqualify themselves from involvement in such decisions, a review of the licensee selection and other licensing decisions must take place. (See OTT Operating Guidance Memo 02-02, August 1, 2001, for a description of this Licensing Decision Review process at: <http://patron.ucop.edu/ottmemos/docs/ott01-02.html>). In discussions with the faculty inventor(s), the UCLA Licensing Officer will ask the inventor(s) to disclose financial interests in the company(ies) to which they are considering licensing the technology. The form UCLA TT100 is used for this purpose. (http://www.research.ucla.edu/researchpol/forms/Form_TT_100_UCLA.doc)

This Licensing Decision Review should be handled under the process established within the campus Office of Intellectual Property and Industry Sponsored Research (OIP-ISR). Unless the license agreement also includes support for continued research by one or more of the inventors at UCLA, there is no need for additional review prior to execution of the license. Additional review by the campus Conflict of Interest Review Committee (CIRC) should be limited to those situations in which support for research is planned. See Section IV below.

D. *What the University Will Not Do*

The University will not:

1. Provide funding or find funding for the company.
2. Provide business expertise (e.g. writing business plans or helping to raise seed money), beyond what is available to faculty from internal resources such as programs offered at the Anderson School of Management, and events put together by the OIP-ISR. For information on programs available at the UCLA Anderson School of Management, such as the internship program for business plan development, contact the Harold Price Center for Entrepreneurial Studies (310-825-2985). For OIP-ISR contacts/events, see the OIP-ISR website <http://www.research.ucla.edu/oipa/> or contact Earl Weinstein at 310-794-0558.
3. Negotiate with the faculty member. The faculty member must identify a representative to handle the licensing negotiations for the start-up company. This may be another person working for the start-up who does not have a conflict of interest with the University. Or it may be someone such as a CEO or an attorney hired specifically to represent the start-up company in the negotiations.

4. Act as an agent in any way for the company.
5. Treat the faculty start-up company differently from other licensees. If the Faculty start-up fails to meet diligence provisions or make payments, the company risks losing the license, as would any other licensee.

E. Other Considerations Relevant to Licensing

1. Conducting Additional Research at UCLA

a. General Considerations

The licensing of technology owned by The Regents to a faculty-owned company does not preclude the faculty inventor from conducting additional research on the technology in his or her laboratory or office under sponsorship from the company (or other sponsors). It is only when inventions are released back to the inventor(s) who patents them as individuals that additional use of University resources (including space, University-managed funding, personnel, etc.) is prohibited. (see: http://www.ucop.edu/ott/genresources/pat-pol_97.html, Statement of Policy, B 1 and 2)

Company sponsored research in the lab of the faculty member must comply with various University rules relevant to covering the costs of research, student participation, open publication of results, ownership of intellectual property, etc. Such proposals are reviewed by the campus CIRC prior to their acceptance. See Section IV below.

b. SBIR and STTR Grants

When the anticipated funding is derived from a federal Small Business Innovation Research (SBIR) or Small Business Technology Transfer Program (STTR) grant to the company, special reviews are required to ensure that campus research resources are being appropriately used and to minimize conflict of interest and conflict of commitment concerns. *UCLA Guidelines for Faculty Participation in SBIR and STTR Programs* issued by the Vice Chancellor for Research in 2002 outlines some of the ways in which this is accomplished. These guidelines indicate that the Principal Investigator for the company and the Principal Investigator for the UCLA portion of the work should be different individuals. The guidelines also indicate that bringing work into the UCLA laboratory of the company owner requires special permission from the Dean. For more details about conducting portions of SBIR or STTR grants on campus see: http://www.research.ucla.edu/researchpol/memos/sbir_memo.pdf.

Section IV below provides additional information about research support.

2. UCLA Equity

Under some circumstances, the University will accept equity as it recognizes that technologies are often offered to potential licensees at an early stage of development when small or start-up companies may find it difficult to fund both development costs and licensing costs. The University can accept equity only in lieu of fees, not in lieu of royalties or patent cost reimbursement. The University is also limited by UC policy to accepting no more than a 10% share of any company. Acceptance of equity requires a review of the agreement and approval by the Office of the President. (See the *Policy on Accepting Equity When Licensing University Technology*: <http://www.ucop.edu/ott/genresources/equi-pol.html>)

3. Faculty Member's Equity

The University anticipates that faculty involved in the formation of a start-up company will hold equity in the company. The University appreciates that the absolute amount of equity owned by the faculty member and the percentage of the company owned by the faculty member may vary widely depending upon a host of factors such as the number of company founders, the magnitude of the faculty member's personal financial investment in the company, the maturity of the company (i.e., the percentage ownership may be very high during the early stages of the company's development but substantially lower during later stages as the initial equity level is diluted in subsequent rounds of financing), the amount of financing required to develop the product, the potential size of the product's market, and other economic factors. Essentially the same conflict of interest issues apply whether the amount of equity or percentage ownership is high or low.

III. Guidelines Relevant to Faculty Participation in the Start-Up

The University recognizes that outside professional activities may be a valuable contribution to the University and to the faculty member's professional growth. However, such activities must be undertaken in a manner that is a) consistent with the faculty member's performance of his/her University responsibilities, and b) does not create or appear to create a conflict of commitment with the faculty member's commitment to the University.

A. Board Membership

Faculty often serve on the Board of Directors of start-up companies with which they are involved. Prior written approval is not required for such service (University of California Academic Personnel Manual Chapter 025 (APM 025)). Nevertheless, such activity is counted toward the 39/48 (9-month/12-month calendar) annual day limit on outside consulting activities. Such activities are expected to be reported annually using APM 025 Appendix C ("Report of Category I and II Compensated Outside Professional

Activities and Additional Teaching Activities for the Fiscal Year Ending June 30, _____").

B. *Holding a Position as Company Officer and/or Salaried Employee*

1. Company Officer

Service as a Company officer may be appropriate provided the time commitment required does not exceed University policy. Executive or managerial positions (in for-profits or not-for-profits) are considered Category I activities: those activities that "are likely on their face to raise issues of conflict of commitment" (APM 025). Faculty who want to accept executive or managerial positions are expected to make a written request to the Chancellor or the Chancellor's designee and receive prior written approval (APM 025).

2. Salaried Employee

Establishing a relationship as a salaried employee outside of the University is also considered a Category I activity and requires the same kind of prior written approval as accepting an executive or managerial position (APM 025).

3. Uncompensated Outside Activities

APM 025 also indicates that faculty members may occasionally undertake outside professional activities - including consulting - without compensation. It goes on to indicate that if the Chair or Dean feel that these faculty are failing to meet their University obligations, then the Chancellor's designee can use the guidelines in APM 025 for compensated outside professional activities to address these possible conflicts of commitment.

4. Mechanism for Obtaining Written Permission

The written request and approval for executive/managerial and/or salaried positions is done using APM 025 Appendix B ("Prior Approval for Compensated outside Professional Activities (Category I) or for Involving Students in Outside Professional Activities").

N.B. The Vice Chancellor's written approval for APM 025 should be rendered to the OIP-ISR. As part of its review process, the UCLA CIRC expects to see a copy of an approved Appendix B when the Investigator discloses a salaried or executive position in an outside organization.

C. *Time Limits on Outside Activities*

APM 025 indicates that a full-time faculty member with an academic year appointment (9 month appointment) may normally engage in up to 39 days per fiscal year of

compensated outside activities. Full-time faculty on a fiscal year (year round) appointment may engage in compensated outside activities up to 48 days per year. Part-time faculty time limits are pro-rated based on the percentage of the appointment. Days cannot be carried forward from one year to the next but the Chancellor may grant an exception to these time limits when, in the Chancellor's opinion, the activity benefits the University.

APM 025 also indicates that under certain circumstances the University can grant a leave to a faculty member who anticipates that any compensated or uncompensated professional or non-professional activity would interfere with the performance of University activities. Those leaves are normally for up to 2 years.

D. Compensation for Outside Activities

Compensation for outside activities is determined by market forces and may be at a rate that is higher or lower than the faculty member's University salary.

E. Relevant University Documents

Relevant University policies and rules may be found in the following documents:

UC Regents Standing Order 103.1(b) indicates that faculty members shall not allow outside employment to interfere with their primary University responsibilities. This statement is short and general. It applies to all UC employees including faculty. (See: <http://www.universityofcalifornia.edu/regents/bylaws/so1031.html>)

The University of California Academic Personnel Manual Chapter 025 ("Conflict of Commitment and Outside Activities of Faculty Members") provides much more specific guidance. (See: <http://www.ucop.edu/acadadv/acadpers/apm/apm-025-07-01.pdf#search=%22University%20of%20california%20apm%20025%22>). The introduction to APM 025 indicates that the policy was issued "...to affirm faculty responsibilities as members of the University of California and provide mechanisms to ensure that those activities" [compensated or not] "... do not interfere with fulfillment of those responsibilities".

In June 2006, Vice Provost Kathryn Atchison issued an Interim Guide to Faculty Consulting Activities (See: <http://www.ucla.edu/evc/policies/0606-faculty-consulting.pdf>). It also provides written guidance about time limits on outside activities.

A memo to faculty from Dean Gerald Levey and Sr. Associate Dean Donald Becker outlines the ways in which the Health Science Compensation Plan is implemented. It includes specific guidance about the way that non-cash compensation such as stock, founder's stock, and stock options are to be handled. (See: <http://www.deans.medsch.ucla.edu/academic/planproc.doc> and <http://www.ucop.edu/ott/genresources/unindrel.html>)

IV. Research Support for Laboratory of Faculty Member

One of the missions of the University is to contribute to California's economic growth through research activities. Consistent with this, Company sponsorship of University research is encouraged. However, care should be taken to avoid conflicts of interest, particularly when the companies are start-ups that have licensed the Principal Investigator's intellectual property.

A. Nature of the Research

Research to be undertaken in the faculty member's laboratory should be appropriate for the University setting. Very routine procedures or tests that are readily available at commercial entities outside the University are generally not appropriate.

B. Cost of the Research

When for-profit sponsors are involved, it is expected that the Company will reimburse the University for all costs (direct and appropriate indirect costs) of the research. Sponsorship of the research will generally provide the sponsoring company with an option to license inventions arising from the research. The Industry Sponsored Research Group of the OIP-ISR will review the research proposal to insure that all reasonable direct and indirect costs are included before the application is submitted to make sure that the company is fully underwriting the research.

C. Conflicts of Interest

The proposal for Company sponsored research in a University laboratory when the faculty member has a financial relationship with the Company requires review by the CIRC prior to acceptance of the research support. Under State of California regulations and UCLA policy, the personal financial interests of the Principal Investigator and other Investigators are reviewed by the campus CIRC. In conducting the review, the CIRC takes into consideration the nature and magnitude of the disclosed financial interests, the faculty member's role in the proposed research, and the nature of the research.

In the past, the Committee has generally approved acceptance of contracts and grants to support this kind of research provided mechanisms are in place for reducing or managing the conflicts of interest. These mechanisms may include such measures as full disclosure of financial interests in publications and presentations in which the research is reported; disclosure of the financial interests to students and trainees working on the project, or periodic reporting of research progress and inventions resulting from the study. In some instances, the Committee may require that the work be reviewed by an oversight committee or that the inventor's role in the research be modified. While the great majority of conflicts of interest inherent in these proposals can be managed, in rare instances certain activities may be deemed not to be in the best interest of the University. Special considerations apply if the research involves a clinical trial (see below).

D. Student and Post-doctoral Fellow Participation

Student and post-doctoral participation in Company-sponsored research is encouraged provided the research activities are appropriate for training. Before involving a trainee in the research, it is necessary that the faculty member disclose to the trainee that the research is funded by a company in which the faculty member holds an interest. Highly routine activities with little or no training value are not appropriate for trainees.

“Students must be able to choose research topics for educational reasons without being overly influenced by the need to advance investigations of direct interest to a particular firm; they must be protected against the premature transmittal of research results; and they must be advised objectively on career choices.” (UC *Guidelines on University-Industry Relations*: <http://www.ucop.edu/ott/genresources/unindrel.html>). This is especially important when the research is sponsored by a company in which the faculty mentor/supervisor has a financial interest.

To insure that the research is appropriate for a trainee, the faculty member should obtain the written permission of the faculty member’s immediate administrative superior (Division Chief, Department Chair, Dean, etc., as appropriate, or his/her designee who must be independent of the company). The administrative superior/designee should oversee the appropriateness of the trainee’s research project, and he/she should meet with the trainee and review the project and the work accomplished by the trainee on an annual basis and issue a letter to the faculty member and trainee attesting to the appropriateness of the research.

E. Publication of the Results of Research

While there are few absolutes in this arena, one of them is that faculty members, post-doctoral fellows, and students must be free to publish the results of all research conducted at the University. While sponsors may not dictate the terms of publication nor be given the right to suppress publications, they may be given advance notice of planned publications or presentations and opportunities to review them to ensure that proprietary data that they provide to the researchers is not inadvertently disseminated. Sponsors may also be granted a brief delay in publication to allow time for the filing of patent protection of intellectual property.

F. Ownership of Intellectual Property Arising out of Company-Sponsored Research at the University

The University owns the rights to all Intellectual Property arising out of research at the University. In the case of Company-sponsored research, the research contract generally provides the Company with a time-limited ‘first right to negotiate a license’ from the University to the intellectual property arising from the research. The University must be careful to not make promises to a company that might violate rights of other companies sponsoring research in similar technological space.

Faculty often wonder why IP rights remain with the university when a start-up company is created. The UC firmly holds that the faculty right to continue research is critical to a strong teaching and research program. While everyone hopes that a start-up company will be an enormous success, many start-up companies do not succeed. To give the faculty member a second chance and to assure that the right to use and continue to build upon a discovery remains constant for the faculty and graduate students, the university maintains ownership of the intellectual property. Only the right to commercialize the technology is licensed to the company. Thus, in the event the company fails, is sold, or is broken into subsidiaries, the IP rights for the faculty member remain. Through these rights, the faculty member will realize the inventor share rights to royalty income.

V. Special Considerations for Human Clinical Trials Conducted at UCLA

A. Faculty Conflicts of Interest

The conduct of clinical trials at UCLA by the faculty member(s) who invented the drug, device or process to be tested in human research participants is not encouraged. Approval to do so would only occur under special circumstances, for example, when the faculty member has special expertise in the use of the technology or where the technology is clearly of exceeding low risk of causing harm to the patients. In such cases, the CIRC would need to determine if the benefit of the faculty member being involved outweighs the potential negative consequences of the faculty member's involvement. When the inventor or developer of the drug/device/technology being studied or tested has any financial interest in the commercial development of the drug/device/technology, he/she should not participate in patient recruitment or consenting and should have very limited or no involvement in data analysis or interpretation of results. Such individuals may participate in other aspects of such research or testing, subject, however, to conditions imposed by the campus. For example, the prohibition from direct participation with subjects and data collection, analysis or transmittal would not exclude the faculty member's laboratory from providing a test done in his/her laboratory on blinded samples submitted by the Principal Investigator of the study (which cannot be the faculty member).

Clinical trials at UCLA of technology developed by a faculty member at UCLA may be conducted by another faculty member at UCLA who has no financial interests in the company and who is not directly connected to the faculty member that is involved in the company. An outside data safety monitoring board may be required.

B. Institutional Conflicts of Interest

Since UC policy on "Accepting Equity When Licensing University Technology" was issued in 1996, the campus CIRC has also been expected to review any clinical trial or comparable product testing for a company in which the University holds equity that was acquired as part of a technology-licensing transaction. At then-Executive Vice Chancellor Rory Hume's request, application of this policy has been broadened to

include *any* research to be conducted at UCLA if The Regents hold equity that was acquired as part of a technology-licensing transaction. This review is conducted whether or not the Principal Investigator or others involved in design, conduct or reporting of the research have personal financial interests in the sponsor.

To insure the utmost protection of research subjects, if The Regents have a financial interest by way of the intellectual property or ownership in the company, the approval of an IRB not associated with the University should be obtained by the institutional IRB following its own approval.