University of California
OTT
OFFICE OF TECHNOLOGY TRANSFER
Office of the President

MEMO
Operating Guidance

No. 99-5
September 28, 1999

PATENT COORDINATORS
CONTRACT AND GRANT OFFICERS

Subject: Intellectual Property and Data Restrictions in NIH Agreements

In recent months, several campuses have inquired about deviations from the standard FAR Patent Rights clauses seen in agreements from the National Institutes of Drug Abuse (NIDA). Under Federal grants, contracts and cooperative agreements, the University's standard Bayh-Dole rights are prescribed in FAR Clause 52.227-11, "Patent Rights – Retention by the Contractor (Short Form)." The recent NIDA agreements, however, have included a modified version of FAR Patent Rights Clause 52.227-13, "Patent Rights--Acquisition by the Government," which gives title to subject inventions to "NIDA or to a Collaborating party designated by NIDA." In addition, the NIDA contracts raise serious problems with publication and data ownership. We want to alert you to the nonstandard clauses that are being used by some programs within the National Institutes of Health (NIH). Below is a summary of the issues under two proposed NIDA agreements we have encountered recently.

The first case involved pre-clinical testing of compounds to determine their absorption, distribution, metabolism and excretion (ADME) properties. No other research was expected to be conducted on these compounds. The second case, which is currently being reviewed by the University, involves Phase I and II clinical trials to evaluate the clinical utility of candidate compounds for treatment of drug abuse and addiction. The compounds for both studies were to be provided, via NIDA, by third party collaborators, including "pharmaceutical companies, academia, and other private sector parties."

In the first case, NIH Director Varmus approved a Determination of Exceptional Circumstances (DEC) to the Bayh-Dole Act, permitting NIDA to require that title to University-developed inventions be assigned to either NIDA or the third party collaborator. The primary justification for the DEC was the third party collaborators' reluctance to submit compounds to the program without assurance that their intellectual property rights would be preserved. NIH also indicated that the DEC would facilitate "the rapid, efficient and least expensive development of new therapies." Acceptance of the ownership provisions under this DEC raises serious concerns for the University and requires an exception to University patent policy. In this case, the program entailed conducting pre-clinical pharmacokinetic testing studies on compounds, rather than basic research on publicly available compounds. Furthermore, NIDA had indicated that it had preexisting contractual obligations to the third party collaborators. Finally, in response to our inquiry, the Council on Governmental Relations (COGR) pointed out that NIDA had been issuing DECs for these pre-clinical ADME studies for many years without objection from the university community. For these reasons, OTT approved an exception to University Patent Policy for this specific case. We would also be inclined to approve an exception in the second case due to the clinical trial nature of the project.

1111 Franklin Street, 5th Floor, Oakland, California 94607-5200
tel: (510) 587-6000 fax: (510) 835-3705

In both cases, however, OTT identified additional serious problems concerning publication and data ownership. The Rights in Data-Special Works clause (FAR52.277-17 (d)) that was included in both agreements requires permission from NIDA for any publication of data produced in the performance of the contract. Furthermore, the Use of Data clause states that the University does not own the data and does not allow the investigator to retain a copy of the data or use it for any purpose. NIDA was unwilling to negotiate any changes to these clauses. Although OTT had approved an exception for the patent policy deviation, the first campus chose not to accept the award because of the data and publication clauses.

The campus Vice Chancellors for Research subsequently brought this issue to the attention of the systemwide Council on Research (COR). After a COR discussion, the nine Vice Chancellors for Research sent a letter to Vice Provost Shelton, who forwarded it to NIH Director Varmus, objecting to the data and publication terms of the NIDA agreement and declaring an "unwillingness to accept grants or contracts for our campuses under such terms." Copies of both letters are attached for your reference.

The UC system is not alone in its objection to the NIH restrictions on academic freedom and patent rights. Under a very large NCI award, four other universities have taken a strong stand against these same restrictions. Engaging the assistance of COGR, they have tried unsuccessfully over the past several years to come to resolution with the NIH. As a result of these discussions, however, COGR began work with NIH to draft policy and procedures on the criteria and process for issuing DECs under NIH programs. The draft policy has not yet been issued and we continue to monitor COGR's work with NIH on this matter.

As campuses review NIH agreements, please be aware that nonstandard clauses occasionally may be used, and each such situation needs to be carefully reviewed on a case-by-case basis. OTT is willing to assist campuses in this review and consider exception to UC patent policy as appropriate.

If you have any questions regarding this material, please contact Wendy Streitz at (510) 987-9108.

Sincerely

Joe Acanfora
Associate Director

Enclosures:
1. February 2, 1999 letter from Vice Chancellors of Research to Vice Provost Shelton
2. February 23, 1999 letter from Vice Provost Shelton to Director Varmus

cc: Executive Director Feuerborn
Senior Vice President Kennedy
OTT Associate Directors and Managers

UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • RIVERSIDE • SAN DIEGO • SAN FRANCISCO

SANTA BARBARA • SANTA CRUZ

OFFICE OF THE PROVOST AND SENIOR VICE PRESIDENT—
ACADEMIC AFFAIRS

OFFICE OF THE PRESIDENT
1111 Franklin Street
Oakland, California 94607-5200

February 2, 1999

Robert N. Shelton
Vice Provost
Office of Research
1111 Franklin Street, 11th Floor
University of California
Oakland, CA 94607-5200

Dear Robert:

We, the Vice Chancellors for Research of the nine University of California campuses, support the decision of the University of California, San Francisco campus not to accept the terms of a National Institute of Drug Abuse (NIDA) contract that requires Institute permission for publication of experimental results and that reserves the right to restrict the availability to the investigator of the data generated.

The following excerpts of the Special Contract Requirements from NIDA RFP N01DA-8-8086 are unacceptable to the University of California:

CLAUSE, Rights in Data-Special Works (FAR52.227-17)

(d) Release and use restrictions. . . .The Contractor shall not use for purposes other than the performance of this contract, nor shall the Contractor release, reproduce, distribute, or publish any data first produced in the performance of this contract, nor authorize others to do so, without written permission of the Contracting Officer.

CLAUSE, Use of Data (Special Clause C)

Data collected under this contract are not the property of the Contractor. The Contractor is not allowed to retain any copies of data generated under the contract. On or before contract expiration, the contractor shall deliver (or otherwise dispose per the Contracting Officer's directives) all data, including raw databases, tapes, software programs used to interpret or manipulate data, weight calculations files, data collection forms, file definitions, various edited databases, generated under this contract to the Project Officer. . .

Furthermore, we declare our unwillingness to accept grants or contracts for our campuses under such terms.

Sincerely,

Joseph Cerny
Vice Chancellor for Research

Richard Attiyeh
Vice Chancellor for Research

Kevin Smith
Vice Chancellor for Research

Zach Hall
Associate Vice Chancellor for Academic Affairs

Frederic Y.M. Wan
Vice Chancellor For Research

France Córdova
Vice Chancellor for Research

C. Kumar Patel
Vice Chancellor for Research

James Gill
Associate Vice Chancellor

Harry W. Green, II
Vice Chancellor for Research

UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • RIVERSIDE • SAN DIEGO • SAN FRANCISCO

SANTA BARBARA • SANTA CRUZ

OFFICE OF THE PROVOST AND SENIOR VICE PRESIDENT—
ACADEMIC AFFAIRS

OFFICE OF THE PRESIDENT
1111 Franklin Street
Oakland, California 94607-5200

February 23, 1999

Harold E. Varmus, M.D.
Director
National Institutes of Health
126, Building 1
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Varmus:

I am writing with respect to the terms of an RFP (# N01DA-9-8086) recently issued by the National Institute of Drug Abuse (NIDA). The proposed contract contained restrictions that make it unacceptable to the University of California (UC), restrictions that the Institute refused to negotiate. Because of the seriousness of the restrictive clauses and the unfortunate precedent that they set and because of the apparent inflexibility of the Institute with respect to the issues at stake, I believe it important that the University of California state its position. In short, we object to these restrictions in the strongest possible terms.

The first of the restrictions requires permission or approval from NIDA for any publication of the data resulting from the contract. Although third-party review of the data prior to publication is not objectionable to us and is commonly included in UC contracts, third-party permission is unacceptable to us. Such a restriction strikes at the base of a core academic principle, that of free publication and access to information. The second restriction is also oppressive, as it prevents the investigator from retaining a copy of the data or for using it for any other purpose.

These restrictions are a barrier to participation by any University of California campus. Each of the Research Vice Chancellors, at all nine campuses of the University of California, has signed the enclosed statement signifying their opposition to these policies and their unwillingness to accept contracts containing them on their campuses. I believe that many other academic institutions will also find them problematic.

I respectfully request that these policies be carefully reviewed and revised. I do not believe that the National Institutes of Health, as a public agency, should exert this kind of chilling influence on the free exchange of scientific information.

Sincerely,

Robert N. Shelton
Vice Provost for Research

Enclosure

cc: Provost King