

MEMO
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Guidance

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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 DEC's 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.

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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 DEC's 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