
THE UNIVERSITY OF CALIFORNIA
Office of the Associate Vice President

CONTRACT AND GRANT MEMO

April 10, 1979

No. 33-79

The following policy and procedure item remains in effect until subsequently incorporated into the Contract and Grant Manual, or until specifically cancelled.

PROPRIETARY DATA LEGEND FOR PROTECTION OF SENSITIVE DATA SUBMITTED IN (a) RESEARCH PROPOSALS AND (b) MEMORANDA OF UNDERSTANDING AND AGREEMENT RELATING TO REQUESTS FOR APPROVAL OF RECOMBINANT DNA RESEARCH UNDER NIH GUIDELINES

There are two situations, other than publication, where University investigators are likely to describe patentable concepts in a manner which may jeopardize future individual, sponsor, and/or University patent rights. These are (a) research proposals and (b) Memoranda of Understanding and Agreement (MUA's) or other registrations used to certify compliance to NIH Guidelines covering research in the recombinant DNA area. In the interest of protecting patent rights in these two situations the following information is provided for your use and for dissemination to investigators.

The Freedom of Information Act (5 U.S.C. 552) requires disclosure of all Government records upon request. An exemption exists for research protocols and designs, but only if the information not to be released is specified or if a general notice is given.

Research Proposals Containing Proprietary Data and Potentially Patentable Concepts

With regard to the preparation of research proposals, investigators should either (a) withhold sensitive or enabling information where possibly patentable concepts are described, or (b) include in the proposal a Proprietary Data legend based on the model shown below, specifying the paragraphs and pages which contain potentially patentable concepts and proprietary data.

MUA's and other Recombinant DNA Registrations

C & G Memo 9-77, Section I-2 explained the requirement under NIH's recombinant DNA Guidelines (July 7, 1976 Federal Register) for the preparation of MUA's when recombinant DNA research is contemplated either as part of a new proposal or in subsequent phases of the award. In effect, the MUA provides to NIH or other Federal funding agencies an institution's certification that the recombinant DNA

research project complies with the NIH Guidelines.

NIH's revised Guidelines (December 22, 1978 Federal Register) contain additional institutional responsibilities, including the requirement for institutions that receive NIH funds for recombinant DNA research to register all recombinant DNA projects, irrespective of the source of funding. Moreover, paragraph IV-D-2-g of the revised Guidelines encourages institutions to open Institutional Biosafety Committee (IBC) meetings to the public whenever possible, consistent with protection of privacy and proprietary interests. Paragraph IV-D-2-H requires that Institutions make available to the public upon request all minutes of IBC meetings and any documents submitted to or received from funding agencies, including MUA's and funded research proposals.

In view of the above requirements, the preparation of MUA's and other recombinant DNA registrations must include the Proprietary Data legend for protection because Federal approval is contingent upon full disclosure of the precise methodology, media and/or microorganisms that will be employed to carry out the research and because copies of MUA's and other documents bearing this sensitive data must be made available to the public upon request in the absence of the Proprietary Data legend.

Model Proprietary Data Legend

The following legend is to be used in (a) all research proposals where proprietary data and potentially patentable concepts are disclosed; and (b) all MUA's or recombinant DNA registrations.

Proprietary Data

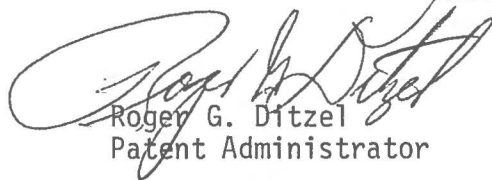
Portions (or insert paragraphs and pages when known) of this document may contain proprietary information which, if disclosed, could lead to loss of intellectual property rights. Before this proposal (or MUA) is released on a nonconfidential basis to persons outside the Government (or private sponsor) other than outside reviewers requested by the Government (private sponsor) to evaluate this proposal on a confidential basis, the Agency (or private sponsor) is requested to contact the author to ascertain what portions, if any, are deemed to be proprietary and to withhold from disclosure or place a restrictive legend on same in such manner as to protect the intellectual property rights of the author and the author's employer.

The above Proprietary Data legend should be inserted on the document's cover page, or, if the private sponsor or the Federal Agency has published instructions concerning the treatment of privileged or confidential information in proposals, this legend should be inserted in the manner so prescribed.


A promise of confidentiality by the Government or by a private sponsor in and of itself may not prevent disclosure. But because the Proprietary Data legend may deter indiscriminate disclosure, its consistent use is strongly recommended in the situations described above.

Refer: J. Opalka, 2-4777
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