UC Davis Principal Investigator's Statement
Exception to University of California Policy
for Clinical Study Contracts

The University's intellectual property policy includes consideration of the University Principal Investigator's degree of involvement in the conception and intellectual development of a clinical study protocol. It also takes into consideration the Principal Investigator's interest in benefiting from possible commercial exploitation of inventions arising from the study that are modifications of the study drug or device as well as unanticipated new uses of the study drug or device. The University usually attempts to negotiate intellectual property rights in inventions such that research sponsors have a first right to negotiate a license to commercialize any new inventions and/or improvements to existing inventions arising from that research. Under that policy the University and its inventors potentially could receive financial consideration from any commercial exploitation of such inventions.

However, clinical study sponsors frequently insist on royalty-free rights to commercialize, or full ownership of, inventions (new or modifications of the study drug or device) arising from such clinical studies. Under those circumstances, the University and its inventors would receive no financial consideration from commercial exploitation of such inventions.

The University has made an exception to its intellectual property policy for clinical trial agreements that meet certain criteria (see Directive 96-053 dated April 9, 1996, Policy on Clinical Research Studies, and page two of this form). Under this exception the University will give royalty-free commercialization rights or ownership of inventions or improvement invention made in the direct performance of the study protocol to the Sponsor (the pharmaceutical or medical device company). Therefore, even though the University Principal Investigator may make a new invention or improve the study drug or device, neither the University or the Principal Investigator would benefit from that invention or improvement invention.

Please sign below indicating that you have read and understand this exception to University policy.

_____
Principal Investigator's Signature

Name: _____
Title: _____
Department _____

Date: _____

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Clinical study contracts have all of the following characteristics*:

A. Human subjects are utilized in the study and **the sponsor** (pharmaceutical company or any intermediary contract research organization) **provides a proprietary protocol** that has been tested and developed for the drug/device in accord with FDA regulations**, has obtained FDA approval to proceed to clinical trial, and has been issued an investigational drug or device number**.

B. **Sponsor accepts liability for adverse subject injuries related to the study**. The University will not agree to bill third-party insurance companies for injuries directly resulting from participation in the study. The University will not agree to restrict human subjects on the basis of medical insurance coverage or on the subject's ability to pay.

C. Sponsor agrees to indemnify, defend, and hold harmless the University from any claim or costs of injury or damage arising out of performance of the study, except when the claim or cost is due to the University's negligence or failure to comply with the study protocol. Contract research organizations may substitute evidence of indemnification by the manufacturer of the drug or device.

D. Sponsor retains invention rights in accordance with UC policy. **To the extent that Sponsor has authored the study protocol to be conducted under this agreement, and has designed and structured the manner in which the work is to be conducted, all inventions made in the direct performance of the study protocol shall be the sole property of the Sponsor. To the extent that the Principal Investigator or other University employees develop an invention, independently from their work on the Sponsor's study protocol, Sponsor acknowledges that such inventions shall be the sole property of the University**.

E. Sponsor agrees to not use the University's name without prior written approval except to identify University as a study site when required to do so by law.

F. Sponsor agrees to not restrict the right of the University to publish. Except as required by law, the University will use reasonable efforts to protect "confidential and proprietary" information for a period of up to five years after the end of the contract. University may publish study results and will provide for manuscript review 30 days prior to publication. Sponsor will have no editorial rights over manuscripts, but may comment on implications of publication timing for multiple site studies.

G. Sponsor agrees to pay all costs, direct and indirect. No other source of funds, e.g., Federal, State, or University, is used to conduct the clinical study. Uniform pricing is used, based on the number of patients enrolled, the number of trials completed, the number of exams, etc. An internal budget identifying anticipated costs by the usual categories of personnel benefits, supplies, other, and indirect costs is included with the documentation forwarded to the Sponsored Programs Office; however, spending of award by budget category is discretionary. There is limited accountability to the Sponsor for funds with no requirement to return unused funds.

H. Deliverables are defined as completed case report forms or the equivalent.

* Directive No. 96-053