RPAC Research Policy Analysis & Coordination
Office of Research & Graduate Studies
University of California, Office of the President

Memo

Operating Guidance

No. 14-01

February 4, 2014

To: Intellectual Property Managers
Contract & Grants Officers
Vice Chancellors for Research

Subject: Revised University Patent Policy Guidelines for Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects

This memo supersedes Operating Guidance Memos 96-03 and 05-03.

Background

Campus Contract and Grant Officers have asked for clear and flexible guidance in support of having drug and device investigations expeditiously placed at the University. University medical schools and other health-related research facilities, with their faculty's hospital and clinic affiliations and access to diverse patient populations, commonly conduct testing of new pharmaceutical and medical device products involving human patients. Drug and device testing provides a means by which University faculty, either directly or indirectly, can gain knowledge that increases their teaching skills and effectiveness. Such investigations also create a valuable point of contact between the academic and private research communities by which appropriate and valuable public service can be provided by the University in support of the development of new products for the general public good. Further, income provided for such studies is an integral part of the financial health of the University's medical centers.

When this guidance first issued as Guidance Memo No. 96-03 in 1996, the need for flexible University guidance in this area was considered and endorsed by University Contract and Grant Officers, Patent Coordinators, the Council on Research (COR), the University Technology Transfer Advisory Committee (TTAC), and the University Council on Research Policy (UCORP). UCORP asked that any guidance ensure that consideration be given to the intellectual contribution of clinical study investigators to the conception and development of the study protocol and to the interest of study investigators in benefiting from any resulting inventions. These guidelines, therefore, have been developed in consideration of these factors and are issued for use by University Contract and Grant Officers or others with authority to enter into drug and device testing agreements on behalf of The Regents.

A sponsor of University research is granted patent rights in accordance with Chapter 11 of the University Contract and Grant Manual. However, the University may confer greater patent rights to sponsors of drug and device studies, ranging from a free license to ownership of a narrow scope of specified inventions, if the research meets certain criteria. This memo provides the criteria under which the University may confer these greater patent rights to sponsors of studies that meet these criteria.

FDA-Regulated Studies

Guidance provided in this memo is directed to testing conducted under agreements with private commercial sponsors as a means of complying with the U.S. Food and Drug Administration (FDA) regulatory approval requirements.

FDA-regulated drug development studies typically move through the following phases:

> **Preclinical**: Animal and laboratory studies, not involving human patients, leading to the filing of an Investigational New Drug (IND) application.
>
> **Phase I**: Initial clinical test of new treatments on humans to study dose range, toxicity, schedule of agent or combination of agents or feasibility of combining treatment modalities. Patients typically number less than 100 and are volunteers.
>
> **Phase II**: Early controlled studies to assess efficacy and to further explore toxicity and appropriate dosage. Hundreds of individuals are usually involved and are typically hospitalized patients.
>
> **Phase III**: Building upon the results of earlier phase investigations, Phase III trials are expanded and well-controlled studies intended to further define effectiveness and safety and to establish the statistical significance of treatment. Generally, many thousands of patients, often at multiple locations, are involved in Phase III trials. Phase III results may lead to the approval of a New Drug Application (NDA). Following such approval, additional Phase III studies may be undertaken as part of the Phase IV program, exploring "unapproved" uses, dosages, and indications.
>
> **Phase IV**: Following approval of the NDA, surveillance of medical practice experiences with emphasis on rare untoward effects. Such trials could involve prospective multi-clinic Phase III trials or exploration of comparative features with competitive drugs.

Note: Observational, non-interventional studies are not included in the definition of any of the Phases above for purposes of this memo.

FDA-Regulated Medical Device Study

The FDA regulates medical devices under the Medical Devices Amendment of 1976. Medical devices are classified into Class I, II, and III.[1] Most devices that are not "significant risk" devices, which include those devices that are implanted or that cause or prevent life-threatening conditions, are considered "Class II devices," and require filing with the FDA under 510(k), Premarket Approval Notification procedures.

This approach is relatively simple, requiring only that device manufacturers establish that the subject device is "substantially equivalent to" a pre-1976 device, a device that has been reclassified from Class III to Class II or I, or a device that has been found to be substantially equivalent through the 510(k) premarket notification process. Those devices that are significant risk devices, however, are subject to a more rigorous FDA preclinical and clinical testing program. Specifically, Class III and some Class II devices require the filing of an Investigational Device Exemption (IDE), which, when approved, by the FDA, enables the device to be tested in a clinical study.

The results of device clinical studies may lead to Premarket Approval (PMA). Following such approval, the FDA may require additional testing of the device, either in the form of post-market

[1] Class I devices (e.g., elastic bandages, examination gloves, hand-held surgical instruments) typically present the lowest potential for harm and are simpler in design than Class II or III devices. Most Class I devices may be marketed without prior FDA permission.

surveillance or a Post-Approval Study. FDA required post-market surveillance and Post-Approval Studies are considered "FDA-Regulated Medical Device Studies" for purposes of this memo.

Note: Post-market studies that are not required by the FDA and observational, non-interventional studies are not considered "FDA-Regulated Medical Device Studies" for purposes of this memo.

Applicability of Guidelines

A sponsor of University research is usually granted patent rights in accordance with Chapter 11 of the University Contract and Grant Manual. However, the University may grant greater rights as described in "Guidelines for Negotiating Sponsor Rights to Clinical Study Inventions" for those studies that meet all of the following criteria:

1. The investigation to be undertaken is an FDA Phase I, II, III, or IV drug study or an FDA-Regulated Medical Device Study. Preclinical studies are specifically excluded.
2. A private sponsor provides its proprietary product and study protocol to the University for the investigation.
3. The cost of the investigation conducted according to the Sponsor's protocol is fully funded by the Sponsor and is not supported in whole or in part with other funds, including Federal funds.
4. There are no known third-party rights to intellectual property of The Regents that would be compromised by granting rights to the clinical trial sponsor.
5. All administrative requirements of the Requirements for Administration of Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects, issued jointly by Senior Vice Presidents Massey and Kennedy on February 3, 1995, have been satisfied.

Rights to inventions made under studies that do not meet all of the criteria above should be consistent with guidance provided in Chapter 11 of the University Contract and Grant Manual.

Intent of Guidance

The criteria identified above reflect the key concerns to the University in conferring patent rights in clinical studies:

a. The likelihood of an invention being created in the direct performance of the clinical study that utilizes the intellectual contributions of University employees and agents;
b. The benefit to subjects and the public from the University's participation in the clinical study.

a. The Likelihood of an Invention Being Created in the Direct Performance of the Clinical Study Utilizing the Intellectual Contributions of University Employees and Agents.

Criterion 1 requires that the investigation be an FDA Phase I-IV drug study or an FDA-Regulated Medical Device Study. The ability to confer greater patent rights is limited to such studies because the likelihood of inventions being created in the direct performance of research that utilizes the intellectual contributions of University employees and agents is low: sponsor-authored protocols of Phase I-IV FDA-regulated drug studies and FDA-Regulated Medical Device Studies are generally more prescribed than other sponsor-authored studies, such as preclinical research and observational studies, as the study design is limited to gathering data on issues prescribed by the sponsor in order to approve a drug or device for

specific commercial use. As a result, there is little room for the investigator to provide additional contributions as to the data collected or methods used.

Criterion 2 requires that the sponsor provide both the protocol and the proprietary product to the University. This requirement is also rooted in reducing the likelihood that an invention utilizes the intellectual contributions of University employees and agents. In the case where the sponsor provides both the protocol and product, any invention made in the direct performance most likely exclusively relies upon the intellectual contribution of the sponsor. However, if a University researcher authors the protocol, the University has contributed intellectually to the project, and therefore, the University should hold intellectual property rights to any invention made in the direct performance of such research and may grant rights to the other party in accordance with Chapter 11 of the University Contract and Grant Manual. If the sponsor authors the protocol, but does not provide the proprietary product to be studied to the University, the reason for not so providing may suggest that the study is observational, and therefore follows a less prescribed protocol, enabling the investigator to make his or her own independent intellectual contributions to the conduct of the study. For example, many registry studies[2] measure the long-term effects of a device after it has been implanted into a subject population. In such a case, the sponsor would not provide the product to the University, as it is already implanted in the subject. Other observational studies may similarly measure the effects of a study drug administered to a patient population in the course of such patients' care under a physician. Such studies rely upon investigators' contributions.

b. The Benefit to Subjects and the Public from the University's Participation in the Clinical Study.

In limiting the ability to confer greater patent rights to sponsors in FDA-regulated clinical studies and in studies in which the sponsor provides the University with the proprietary product to be studied, this memo intends to limit its application to studies that make new interventions available, and improve existing interventions, for the benefit of the public. The memo also intends to provide faculty with opportunities to gain knowledge and increase their teaching skills.

Guidelines for Negotiating Sponsor Rights to Clinical Study Inventions

Many clinical study sponsors have established long-standing contractual relationships with the University. Some sponsors find contractual silence acceptable or accept the standard University position as described in Chapter 11 of the University Contract and Grant Manual. In such cases, sponsors' interests can and should be readily accommodated. If a sponsor seeks greater rights than those described in Chapter 11 of the University Contract and Grant Manual, University Contract and Grant Officers or others with authority to enter into drug and device testing agreements on behalf of the Regents should be guided by this memo, as well as the interests of the study investigator. The attached Clinical Study PI Questionnaire is a sample form that may be used to obtain information from clinical study investigators that would be helpful in determining appropriate invention rights language and the investigators' interest in benefiting from intellectual property that may be developed during the course of the study.

[2] As defined by the Agency for Healthcare Research and Quality, a registry uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition or exposure.

University contracting officials must also ensure that they do not inadvertently enter into conflicting contractual obligations with other parties. Agreement terms that create the possibility of entering into conflicting obligations regarding inventions violate The University's Principles Regarding Rights to Future Research Results in University Agreements with External Parties. Applicability criteria 3 and 4, above, as well as future assignment of inventions, are intended to preclude that possibility. University policy does not allow an outright assignment of inventions to sponsors.

For clinical studies meeting all the criteria above, authorized University contracting officials may grant to sponsors any of a range of rights to inventions made in the direct performance of the study protocol, in accordance with the enclosed guidance. This guidance, along with sample language provided in the Rationale and Sample Contract Language, is provided to assist in developing and negotiating the appropriate invention rights clauses.

Contact:

Hillary Kalay
Hillary.Kalay@ucop.edu
(510) 987-0355

Wendy D. Streitz
Executive Director
Research Policy Analysis & Coordination

Attachments:

Rationale and Sample Contract Language (previously Enclosures A through E to Operating Guidance Memo No. 96-03)

Clinical Study PI Questionnaire (previously Enclosure F to Operating Guidance Memo No. 96-03)