MEMO
Operating Guidance
No. 96-3
January 31, 1996

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

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.

The need for flexible University guidance in this area has been 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 interim guidelines, therefore, have been developed in consideration of these factors and are issued for immediate use by University Contract and Grant Officers or others with authority to enter into drug and device testing agreements on behalf of The Regents. Final guidance will be issued later this year after campuses have assessed their experiences operating under these interim guidelines.

FDA-Regulated Studies

Guidance provided in this memo is directed to testing conducted under agreements with private 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 often 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.

The FDA also regulates medical devices under the Medical Devices Amendment of 1976. 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. Those devices that are significant risk devices, however, are subject to a more rigorous FDA preclinical and clinical testing program.

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.

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, however, 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. Enclosure F provides 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.

In addition, University contracting officials must ensure that they do not inadvertently enter into conflicting contractual obligations with other parties. Applicability criteria 3 and 4, above, are intended to preclude that possibility.

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 interim guidance. This guidance, along with sample language, is provided to assist in developing and negotiating the appropriate invention rights clauses.

Please contact your OTT Campus Liaison representative if you have questions or would like further assistance.
Additional comments regarding this OTT Operating Guidance Memo should be submitted to Joe Acanfora at OTT by May 31, 1996, after which this guidance will be issued in final form.

Refer Questions to: Joe Acanfora  
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Sincerely,

Joe Acanfora  
Manager, Sponsor/Campus Liaison

Enclosures:  
A - Time-limited first right to negotiate a royalty-bearing license  
B - Contractual silence  
C - Time-limited first right to negotiate either a royalty-free, non-exclusive license or a royalty-bearing license, at sponsors’ discretion  
D - Time-limited first right to negotiate a royalty-free exclusive license  
E - Assignment of ownership (title)  
F - "Clinical Study PI Questionnaire"