

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 studies² 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.

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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)

Rationale and Sample Contract Language
Attachment to RPAC Memo No. 14-01

A. Time-limited first right to negotiate a royalty-bearing license

This is the standard University position on granting invention rights to research sponsors pursuant to Chapter 11 of the University Contract and Grant Manual.

Generally, the earlier the phase of the clinical study, Phases I and II drug studies, and the greater the involvement of the University investigator in the development of the drug or device study protocol, the more likely it is that the investigator and the University will have made creative and intellectual contributions to the study. The University's standard patents rights position as described in Chapter 11 of the Contract and Grant Manual would be appropriate in these circumstances.

Sample Language

All rights to inventions or discoveries arising from the performance of the study protocol under this Agreement shall belong to the University and shall be disposed of in accordance with University policy. To the extent that the University shall have the legal right to do so, University shall offer to sponsor(s), in accordance with the provisions of the following paragraph, a time-limited right to negotiate an exclusive (or co-exclusive where there are more than one study sponsor), royalty-bearing license, to make, use and sell any patentable inventions conceived and first actually reduced to practice in the direct performance of the study protocol under this Agreement, for the term of any patent thereon.

University shall promptly disclose to Sponsor(s) any such inventions arising under this Agreement. Sponsor(s) shall hold such disclosure on a confidential basis and will not disclose the information to any third party without consent of the University. Sponsor(s) shall advise the University in writing within sixty (60) days of disclosure to sponsor(s) whether or not it wishes to secure a commercial license. If Sponsor(s) elect to secure a license, Sponsor(s) shall assume costs associated with securing and maintaining patent protection for such inventions, whether or not a patent issues. Sponsor(s) shall have ninety (90) days from the date of election to conclude a license or option agreement with the University. Such period may be extended by mutual agreement. Said license shall contain reasonable terms and shall require diligent performance by Sponsor(s) for the timely commercial development and early marketing of such inventions, and include Sponsor(s)' continuing obligation to pay patent costs. If such agreement is not concluded in said period, University has no further obligation to Sponsor(s). If Sponsor(s) elects not to secure such license, rights to the inventions disclosed hereunder shall be disposed of in accordance with University policies, with no further obligation to the Sponsor(s).

Nothing contained in the Agreement shall be deemed to grant either directly or by implication, estoppel, or otherwise any license under any patents, patent applications, or other proprietary interest to any other inventions, discovery or improvement of either party.

B. Contractual Silence

Some sponsors will accept contractual silence in order to avoid a problematic negotiation of intellectual property rights. Contractual silence would allow ownership of inventions to be determined by U.S. patent law with no contractual obligations on the University to license inventions in which it would have an ownership interest. The earlier the phase of the clinical study, e.g. Phases I and II, and the greater the involvement of the University investigator in the development of the study protocol, the more likely it is that the investigator and the University will have made creative and intellectual contributions to the study. Contractual silence would be acceptable in these circumstances.

Sample Language

There would be no patent rights language included in the agreement.

C. Time-limited first right to negotiate either a royalty-free non-exclusive license or a royalty-bearing exclusive license, at sponsor's discretion

This approach would be most appropriate for later-phase clinical studies, e.g. Phase III drug studies, and for those drug or device studies for which the University investigator had little-to-no involvement in the conception and development of the study protocol. The language below will satisfy many clinical study sponsors because it provides them with free commercial access to the University's interest in inventions made in the direct performance of the protocol. Under this approach, the University would either non-exclusively license resulting inventions to the sponsor on a royalty-free basis with the University retaining the right to license non-sponsor companies on a royalty-bearing basis; or exclusively license the sponsor on a royalty-bearing basis, depending upon the licensing rights selected by the trial sponsor. There would be little likelihood that such an arrangement would provide significant royalty income to the University or inventors. Prior to its acceptance by the University, the authorized University contracting official must advise the Principal Investigator of the consequences of such "royalty-free" sponsor rights and consider the PI's interest in benefiting from any resulting invention. 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.

Sample Language

All rights to inventions or discoveries arising from the performance of the study protocol under this Agreement shall belong to the University and shall be disposed of in accordance with University policy. To the extent that the University shall have the legal right to do so, University shall offer to Sponsor(s), in accordance with the provisions of the following paragraph, a time-limited right to negotiate either an exclusive (or co-exclusive where there are more than one study Sponsor), royalty-bearing license; or a non-exclusive, royalty-free license, at Sponsor's discretion, to make, use and sell any patentable inventions made in the direct performance of the study protocol under this Agreement, for the term of any patent thereon.

University shall promptly disclose to Sponsor(s) any such inventions arising under this Agreement. Sponsor(s) shall hold such disclosure on a confidential basis and will not disclose the information to any third party without consent of the University. Sponsor(s) shall advise the University in writing within sixty (60) days of disclosure to Sponsor(s) whether or not it wishes to secure a commercial license, and whether it desires such license to be exclusive (co-exclusive) or non-exclusive. If Sponsor(s) elect to secure a license, Sponsor(s) shall assume costs associated with securing and maintaining patent protection for such inventions, whether or not a patent issues. Sponsor(s) shall

have ninety (90) days from the date of election to conclude a license or option agreement with the University. Such period may be extended by mutual agreement. Said license shall contain reasonable terms and shall require diligent performance by Sponsor(s) for the timely commercial development and early marketing of such inventions, and include Sponsor(s)' continuing obligation to pay patent costs. If such agreement is not concluded in said period, University has no further obligation to Sponsor(s). If Sponsor(s) elects not to secure such license, rights to the inventions disclosed hereunder shall be disposed of in accordance with University policies, with no further obligation to the Sponsor(s).

Nothing contained in the Agreement shall be deemed to grant either directly or by implication, estoppel, or otherwise any license under any patents, patent applications, or other proprietary interest to any other inventions, discovery or improvement of either party.

D. Time-limited first right to negotiate a royalty-free, exclusive license

Under Phase III and some Phase IV drug studies, and those drug and device studies involving little investigator involvement in the conception and development of the protocol, it is unlikely that the investigator and the University would make creative or intellectual contributions to the study. Under such circumstances, the trial sponsor would probably consider a royalty-free, exclusive license to be most appropriate. Such an arrangement would preclude any royalty income to the University or inventors.

Prior to its acceptance by the University, the authorized University contracting official must advise the Principal Investigator of the consequences of such "royalty-free" sponsor rights and consider the PI's interest in benefiting from any resulting invention for which he or she made an inventive contribution. 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 such inventions.

Sample Language

All rights to inventions or discoveries arising from the performance of the study protocol under this Agreement shall belong to the University and shall be disposed of in accordance with University policy. To the extent that the University shall have the legal right to do so, University shall offer to Sponsor(s), in accordance with the provisions of the following paragraph, a time-limited right to negotiate an exclusive (or co-exclusive where there are more than one study sponsor), royalty-free license to make, use and sell any patentable inventions made in the direct performance of the study protocol under this Agreement, for the term of any patent thereon.

University shall promptly disclose to Sponsor(s) any such inventions arising under this Agreement. Sponsor(s) shall hold such disclosure on a confidential basis and will not disclose the information to any third party without consent of the University. Sponsor(s) shall advise the University in writing within sixty (60) days of disclosure to Sponsor(s) whether or not it wishes to secure a commercial license, and whether it desires such license to be exclusive (co-exclusive) or non-exclusive. If Sponsor(s) elect to secure a license, Sponsor(s) shall assume costs associated with securing and maintaining patent protection for such inventions, whether or not a patent issues. Sponsor(s) shall have ninety (90) days from the date of election to conclude a license or option agreement with the University. Such period may be extended by mutual agreement. Said license shall contain reasonable terms and shall require diligent performance by Sponsor(s) for the timely commercial development and early marketing of such inventions, and include Sponsor(s)' continuing obligation to pay patent costs. If Sponsor(s) elects not to secure such license, rights to the inventions disclosed hereunder

shall be disposed of in accordance with University policies, with no further obligation to the Sponsor(s).

Nothing contained in the Agreement shall be deemed to grant either directly or by implication, estoppel, or otherwise any license under any patents, patent applications, or other proprietary interest to any other inventions, discovery or improvement of either party.

E. Assignment of Ownership (Title)

Under Phase III and some Phase IV drug studies and those drug and device studies involving little investigator involvement in the conception and development of the protocol, it is unlikely that the investigator and the University would make creative or intellectual contributions to the study. Under such circumstances, some trial sponsors would seek assignment of title to the Sponsor. Such an arrangement would preclude any royalty income to the University or inventors. Further, assignment of ownership could interfere with a University investigators' ability to pursue further research involving the assigned invention.

Prior to its acceptance by the University, the authorized University contracting official must advise the Principal Investigator of the consequences of granting the sponsor's right to obtain title to any resulting invention and consider the PI's interest in benefiting from or pursuing further research involving the assigned invention. 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 any resulting invention for which he or she made an inventive contribution.

Sample Language

Option 1

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 Sponsor. In instances in which Sponsor desires to secure protection on such inventions, the Principal Investigator will cooperate, at Sponsor's expense for all out-of-pocket costs, with the Sponsor for the purpose of filing and prosecuting patent applications, the cooperation to include the execution of any and all lawful papers which may be deemed necessary by Sponsor for the filing and prosecution of applications and for assignment of the same to Sponsor, including all declarations, oaths, specifications, and instruments of assignments for filing and recordation in the U.S. and foreign patent offices.

To the extent that the Principal Investigator or other University employees develop an invention, other than in the direct performance of Sponsor's study protocol, Sponsor acknowledges that such inventions shall be the sole property of the University. To the extent that the University has the legal right to do so and to the extent that Sponsor pays all direct and indirect costs of the research conducted under this Agreement, Sponsor shall be given a time-limited first right to negotiate an exclusive, royalty-bearing license to make, use and sell such patentable inventions conceived and first actually reduced to practice in the performance of the work conducted under this Agreement.

Nothing contained in the Agreement shall be deemed to grant either directly or by implication, estoppel or otherwise any license under any patents, patent applications, or other proprietary interest to any other inventions, discovery or improvement of either party.

Option 2

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 Sponsor. In instances in which Sponsor desires to secure protection on such inventions, the Principal Investigator will cooperate, at Sponsor's expense for all out-of-pocket costs, with the Sponsor for the purpose of filing and prosecuting patent applications, the cooperation to include the execution of any and all lawful papers which may be deemed necessary by Sponsor for the filing and prosecution of applications and for assignment of the same to Sponsor, including all declarations, oaths, specifications, and instruments of assignments for filing and recordation in the U.S. and foreign patent offices.

To the extent that the Principal Investigator or other University employees develop an invention, other than in the direct performance of Sponsor's Protocol, Sponsor acknowledges that such inventions shall be the sole property of the University. To the extent that the University has the legal right to do so and to the extent that Sponsor pays all direct and indirect costs of the research conducted under this Agreement, Sponsor shall be given a time-limited first right to negotiate an exclusive, royalty-bearing license to make, use and sell such patentable inventions conceived and first actually reduced to practice in the performance of the work conducted under this Agreement in accordance with the following provisions.

University shall promptly disclose to Sponsor any such inventions arising under this Agreement. Sponsor shall hold such disclosure on a confidential basis and will not disclose the information to any third party without consent of the University. Sponsor shall advise the University in writing within sixty (60) days of disclosure to Sponsor whether or not it wishes to secure a commercial license (Election Period). Sponsor shall have ninety (90) days from the date of election to conclude a license or option agreement with University (Negotiation Period). In the event that it is necessary in the opinion of University to file any patent application to protect the invention during the Election or Negotiation Periods, Sponsor shall promptly reimburse patent costs incurred by University during such period. Said license shall contain reasonable terms, shall require the diligent performance by Sponsor for the timely commercial development and early marketing of such inventions, and include Sponsor's obligation to reimburse University's patent costs.

If Sponsor elects not to secure such license or fails to notify University within the Election Period, rights to the inventions disclosed hereunder shall be disposed of in accordance with University policies with no further obligation to Sponsor.

Nothing contained in the Agreement shall be deemed to grant either directly or by implication, estoppel, or otherwise any license under any patents, patent applications, or other proprietary interest to any other inventions, discovery or improvement of either party.

Option 3

Inventions made in the direct performance of the Sponsor's study protocol shall be the sole property of Sponsor. In instances in which Sponsor desires to secure protection on such inventions, the Principal Investigator will cooperate, at Sponsor's expense for all out-of-pocket costs, with the Sponsor for the purpose of filing and prosecuting patent applications, the cooperation to include the execution of any and all lawful papers which may be deemed

necessary by Sponsor for the filing and prosecution of applications and for assignment of the same to Sponsor, including all declarations, oaths, specifications, and instruments of assignments for filing and recordation in the U.S. and foreign patent offices.

Nothing contained in the Agreement shall be deemed to grant either directly or by implication, estoppel, or otherwise any license under any patents, patent applications, or other proprietary interest to any other inventions, discovery or improvement of either party.

Clinical Study PI Questionnaire
Attachment to Operating Guidance Memo No. 14-01

PI Name:

Project Title:

Reference:

The rights of sponsors to inventions arising from clinical studies performed at the University can be the subject of challenging negotiations between the University and study sponsors. The University's negotiating position is defined by policy guidelines, which include consideration of the University Principal Investigator's:

- degree of involvement in the conception and intellectual development of clinical study protocol; and
- interest in benefitting from possible commercial exploitation of inventions arising from the study that are unanticipated new uses or modifications of the study drug or device.

Your answers to the following questions will help University contracting officials negotiate the appropriate disposition of intellectual property rights.

1. It is my understanding that the subject study is:

- an FDA-regulated preclinical or animal study
- an FDA-regulated human-subject clinical drug study - Phase _____ (if known)
- an FDA-regulated human-subject clinical device study
- NOT an FDA-regulated study
- do not know

2. Describe your degree of involvement in the conception and/or your intellectual contribution to the development of the study protocol:

- None
- Not Significant
- Significant - **Please Describe:**

The University typically attempts to negotiate rights in inventions such that research sponsors have a first right to negotiate a license to commercialize inventions arising from that research. The University and its inventors could potentially receive financial consideration from any commercial exploitation of such inventions. However, clinical study sponsors occasionally insist on royalty-free rights to commercialize, or full ownership of inventions arising from such clinical studies. Under those circumstances, the University and its inventors would receive no financial consideration from commercial exploitation of such inventions.

3. Indicate below the circumstances under which you would be willing to participate in the subject study:

I would not participate in this clinical study unless the University secured rights to financial consideration for University inventors from study inventions for which they made an inventive contribution.

The University should seek to secure rights to financial consideration for University inventors from study inventions for which they made an inventive contribution, but I would still participate in the study if the University did not succeed in obtaining such rights.

I feel that the University should NOT seek to secure any financial consideration for University inventors from study inventions for which they made an inventive contribution.

I have no opinion on this matter.

Comments: