

**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.