

***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

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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.