UNIVERSITY OF SOUTHERN CALIFORNIA

Chapter 300.1

NIH Licensing Procedures

A. PURPOSE

This Manual Chapter sets forth procedures for licensing Public Health Service (PHS) inventions administered by the National Institutes of Health’s Office of Technology Transfer (NIH OTT).

B. BACKGROUND

The primary mission of PHS laboratories is to pursue new knowledge through the conduct and support of research to improve the health of the American people. Pursuant to the Stevenson-Wydler Technology Innovation Act of 1980 (Pub. L. No. 96-480) and the Federal Technology Transfer Act of 1986 (Pub. L. No. 99-502), as amended, Federal laboratories, including PHS research laboratories at the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC), were given a statutory mandate to ensure that new inventions in which the U.S. Government obtains an interest are transferred to the private sector and commercialized in an expeditious and efficient manner.

The ability and willingness of private sector technology transfer partners to commercialize new inventions can be critical to realizing the benefits of PHS-conducted research. For potential preventive, diagnostic, and therapeutic products, that willingness most often hinges on the transfer of PHS inventions through licensing of patent rights in the United States and foreign countries for the invention in question.

C. PROCEDURES

The following principles support PHS licensing policy:

– Negotiating non-exclusive or co-exclusive licenses whenever possible. This allows more than one company to develop products using a particular invention, products which may ultimately compete with each other in the marketplace. In such cases, non-exclusive or co-exclusive licenses may provide sufficient incentive to bring the Government invention to practical application.

– Negotiating and granting exclusive licenses in which the scope of exclusive rights is limited to that which is reasonably necessary to bring the invention to practical application or otherwise promote its utilization by the public. Such licenses may be directed to specific indications or fields of use, based on the license applicant's commercial development ability at the time of application.
Negotiating provisions for mandatory sublicensing by exclusive licensees, particularly where a broad exclusive license is granted. Thus, NIH OTT requires exclusive licensees to grant sublicenses to broaden the development possibilities when necessary for the public health.

Negotiating provisions for mandatory sublicensing by exclusive licensees of inventions made under a Cooperative Research and Development Agreement (CRADA), in view of the scope of the research plan and as provided under 15 U.S.C. § 3710a.

- Negotiating requirements for continuing availability of the invention for further research. Although an invention has been licensed for commercial development, NIH OTT seeks to maintain the availability of that invention for further research uses only by non-profit and for-profit entities. This advances science and stimulates further commercial development.

- Granting license rights only to fields of use for which the company has submitted an acceptable commercial development plan to bring the invention to practical application. NIH OTT typically does not grant license rights to venture capitalists, brokers, or other entities that are not in a position to develop the invention directly.

- Negotiating specific commercial development milestones and benchmarks with proposed licensees so that development can be assessed and monitored.

- Negotiating license execution royalties, minimum annual royalty payments, milestone payments, and reimbursement of patent expenses in addition to earned royalty payments. Requiring a company to pay royalties "out of pocket" to acquire and keep the invention ensures that a company is committed to developing the invention and has not licensed the invention merely for competitive advantage.

- Negotiating specific grounds for modification or termination of the license. The PHS model exclusive license specifies these grounds, including failure to meet commercialization benchmarks, failure to keep the licensed invention reasonably accessible to the public, and failure to reasonably meet unmet health care needs.

- Monitoring the commercial development activities of the licensees to determine compliance with the terms of the license agreement.

- Initiating administrative action to modify or terminate license rights where necessary.

D. EFFECTIVE DATE

The procedures set forth in this Manual Chapter are effective December 8, 2010, and supersede in their entirety the procedures in PHS Technology Transfer Policy Manual Chapter 300, which was first approved on October 25, 1995.
E. ADDITIONAL INFORMATION

For information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301) 496-7057 or http://www.ott.nih.gov/contact-us.