UNITED STATES PUBLIC HEALTH SERVICE
TECHNOLOGY TRANSFER PROCEDURE MANUAL

Chapter No. 313.1

NIH Office of Technology Transfer Procedures for Communication with PHS Technology Development Coordinators about Licensing of PHS Inventions

A. PURPOSE

This Manual Chapter establishes the National Institutes of Health Office of Technology Transfer’s (NIH OTT) procedures for communication with Public Health Service (PHS) Technology Development Coordinators (TDC(s)) regarding the licensing of PHS inventions administered by NIH OTT.

B. BACKGROUND

Each Agency, the Institutes, Centers, Divisions, Bureaus, or other comparable components within each Agency (collectively, Agency/IC), shall designate a TDC who serves as its liaison with NIH OTT. Effective communication between NIH and TDCs is important to the licensing process.

Collaborative research among NIH scientists occasionally yields inventions to which more than one Agency/IC contributed inventive activity. In these cases of joint inventorship the Agency/IC(s) typically agree that one Agency/IC will assume primary responsibility for the invention and will serve as the “Lead Agency/IC” for licensing communications with NIH OTT. NIH OTT also informs the non-lead Agency/IC(s) of certain licensing activities relevant to their joint inventions, as described below, usually by providing to their respective TDCs a “cc” on communications about these inventions. The TDC of the Lead Agency/IC (“Lead TDC”) is responsible for soliciting input from non-lead TDC(s) and for communicating the final TDC decision to NIH OTT.

C. PROCEDURES

1. Publication of Notices in the Federal Register Regarding Licensing of PHS Inventions administered by NIH OTT:

   a. Abstracts of new inventions to be included in a Federal Register notice are forwarded by the NIH OTT Division of Technology Development and Transfer (DTDT) to the appropriate TDC, or, for joint inventions, to the Lead TDC, for review and solicitation of comments from inventor(s) and the TDC (or Lead TDC). The TDC, or for joint inventions, the Lead TDC, is expected to respond within two weeks.
b. Abstracts for continuation-in-part applications (CIPs), further filings based on priority applications, or previously filed inventions to be included in an “Availability for Licensing” notice are written by DTDT in consultation with the TDC or, for joint inventions, the Lead TDC, and, where appropriate, the inventor, and are forwarded by DTDT to the TDC (or Lead TDC) for review and comment as noted in item a. above.

c. In some cases, DTDT may prepare a notice regarding the availability of an invention or a group of inventions for licensing, e.g., when conducting a special promotion for the invention(s). In these cases the notice is forwarded to the appropriate TDC, or for joint inventions, the Lead TDC, for review and solicitation of comments from the inventor(s) and the TDC (or Lead TDC). Response by the TDC, or for joint inventions, the Lead TDC, is requested within two weeks.

d. When an Agency/IC expresses an interest in seeking licensees or collaboration partners, for example, under a CRADA, for the further development and commercialization of an invention or a group of related inventions, the content of the notice is developed jointly by DTDT and the appropriate TDC, or for joint inventions, the Lead TDC. The notice may be drafted by either office; however, approval by the TDC, or for joint inventions, Lead TDC, is required before the notice is routed through DTDT for publication.

2. Receipt of Licensing Applications: The NIH OTT database system automatically generates an email to the appropriate TDC(s) to indicate that a license application has been received for a particular invention.

3. Determinations related to Proposed Exclusive or Partially Exclusive Licenses:

a. NIH OTT shall provide to the appropriate TDC(s), or in cases of joint inventions, to the Lead TDC with cc to the non-Lead TDC(s), a Preliminary Determination Memorandum, which, as sent to the TDC(s), shall outline the proposed course of action related to the licensing of the invention. Memos will contain sufficient information that sets forth NIH OTT’s recommendations, e.g., market data, the license applicant and its capabilities, the proposed field of use and the proposed territory. If the TDC, or in cases of joint inventions, the Lead TDC, provides no objections to NIH OTT within ten business days of the TDC’s receipt of the Preliminary Determination Memorandum, DTDT shall prepare a “Notice of Intent to Grant” an exclusive or partially exclusive license for publication in the Federal Register.

b. A Final Determination Memorandum, which reviews any issues raised during the notice period, e.g., the receipt of an objection to the proposed grant of an exclusive license, shall be sent to the appropriate TDC, or in cases of joint inventions, to the Lead TDC with cc to the non-Lead TDC(s).
4. Determinations related to PHS inventions made under CRADAs:
   a. At the request of the TDC, or in cases of joint inventions, the Lead TDC, DTDT will determine whether an invention made under a CRADA is a CRADA Subject Invention and, therefore, subject to the reporting and licensing provisions of the CRADA. If the TDC (or Lead TDC) requests this determination prior to the filing of a patent application, DTDT may provide an initial determination to the TDC, or in cases of joint inventions, to the Lead TDC with cc to the non-Lead TDC(s), but a final determination cannot be created unless patent claims are filed and reviewed in light of the CRADA research plan.
   b. Prior to finalizing its determinations, DTDT shall consult with the appropriate TDC(s), as necessary, to obtain any additional relevant information.

5. License Documents: Once a license agreement is fully executed and in receipt by DTDT, the NIH OTT Royalties Administration Unit shall send a copy of the fully executed license agreement and, as necessary, related documentation, to the appropriate TDC(s).

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 Manual Chapters 302, 304 and 306, which were first approved on September 30, 1994, and the procedures in Chapter 305, which were first approved on August 10, 1995.

E. ADDITIONAL INFORMATION

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