UNITED STATES PUBLIC HEALTH SERVICE
TECHNOLOGY TRANSFER PROCEDURE MANUAL

Chapter No. 603.1

NIH Internal Procedures Regarding Requests for an Inventor to Acquire Title in an Extramural Invention

A. PURPOSE

This Manual Chapter establishes procedures for the National Institutes of Health’s (NIH) review and disposition of requests to allow an NIH Contractor’s employee-inventors to acquire title to extramural inventions for which the NIH Contractor elects not to retain title.

B. BACKGROUND

When a Contractor elects not to retain rights in a Subject Invention, the Government, as represented by a PHS Agency, may receive title to the Subject Invention, as provided under 35 U.S.C. § 202(c)(2). If a Contractor does not elect to retain title to a Subject Invention or the Contractor otherwise waives title to the Government, the Federal agency (NIH) may consider and after consultation with the Contractor grant requests for retention of rights by the inventor subject to the provision of 35 U.S.C. § 200 et al. See 35 U.S.C. § 202(d). The Contractor may also request, on behalf of its employee-inventor, permission from the PHS Agency for the employee-inventor to acquire title.

The NIH Office of Technology Transfer (NIH OTT) has been delegated the authority to consider and grant requests for transfer of rights to the inventor under 35 U.S.C. § 202(d) when the Government has insufficient interest in the invention to obtain the right, title, and interest therein (35 U.S.C. § 202 (c)(2)). The following procedures are to be followed to consider and respond to such requests.

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1 Under 35 U.S.C. § 201(c) and 37 C.F.R. § 401.2(b), as expanded by Executive Order 12591 (Apr. 22, 1987), a “Contractor” means any person, business firm, or nonprofit organization that is a party to a Funding Agreement. A “Funding Agreement” means any contract, grant, or cooperative agreement (but not a Cooperative Research And Development Agreement as defined under 15 U.S.C. § 3710a).

2 “Subject Invention” is formally defined in 35 U.S.C. § 201 as “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement…”.

3 For purposes of making this request, the “Contractor” may be either the Contractor or an employee-inventor of the Contractor subject to 35 U.S.C. § 202(d).
C. PROCEDURES

1. Expedited Requests

When a requester alerts OER that an irretrievable loss of all rights will occur within sixty (60) days of the requester’s submission of a waiver request to OER, OER may notify NIH OTT and the NIH Institute/Center (IC) of the need for expedited processing.

2. Transmission of Requests from the OER

Within five (5) business days, or one (1) business day for a request for expedited processing, of receiving all required items from the requester, the OER will provide the complete waiver package, including an inventor waiver checklist to both NIH OTT’s designated staff, and the Technology Development Coordinator (TDC) of the funding IC(s), or the TDC’s designee. If more than one IC funded the Subject Invention, OER will send a copy to the TDC for each of these ICs. The NIH OTT and the IC(s) will review the request to acquire title concurrently.

3. IC Evaluation of Whether the NIH Should Take Title to the Invention

a. Each of the funding ICs must recommend whether or not the government (as represented by the NIH) should take title to the Subject Invention. If the IC recommends denying the request, the IC should provide a case-specific rationale.

Examples of reasons include the following:

i. The circumstances surrounding the technology at the time of the IC’s review suggest that the public interest will best be served by taking title to the invention in order to ensure the invention is utilized in particular ways that meet public health needs that the inventor(s) cannot satisfy;

ii. The circumstances surrounding the technology at the time of the IC’s review suggest that the public interest will best be served by taking title to the invention in order to dedicate the patent rights to the public; and

iii. The technology so closely complements the IC’s portfolio of its other inventions such that not taking title will substantially compromise the IC’s efforts to develop the existing portfolio.

b. In the event the IC recommends that the NIH take title, the IC should indicate it will assume responsibility both for patent costs (if any) and for taking appropriate actions. If circumstances would allow the IC to address its needs by taking only partial title with a limited scope and allowing the inventor(s) to retain the remainder, such an approach is preferable to taking full title. For example, the IC may have a need to develop certain specific embodiments of a platform technology, but would have no objection to allowing the inventor to develop the remaining embodiments.

c. Optionally, the IC may include with its recommendation any comments and/or
additional information relevant to the waiver request.

d. The TDC will convey its recommendation to both NIH OTT’s and OER’s designated points of contact within twenty (20) business days, or ten (10) business days for an expedited processing request, of receiving the waiver package from OER. In exceptional circumstances, the TDC may request additional time from the NIH OTT before the IC’s response is due, and the NIH OTT will respond to the TDC’s request within three (3) business days and will copy OER.

e. When the IC recommends NIH take title (full or partial), the package must include a specific existing Common Account Number (CAN) if costs for patent prosecution may be charged.

4. OTT Evaluation of the Request

a. OTT shall consider all of the ICs recommendations that funded the Subject Invention on whether the NIH should or should not take title. The NIH OTT will determine whether the NIH should take title or grant the inventor’s or Contractor’s request to transfer title to the inventor. If NIH OTT’s intended decision varies from the IC recommendation, then the Director, NIH OTT (or designee) will initiate a dialogue with the (lead) TDC. The Director, NIH OTT (or designee) will make the final decision.

b. Each granted waiver request shall: (1) be subject to reservation by the Government of a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government, and, (2) Preference for United States industry as set fort at 35 U.S. C. § 204. NIH may also impose upon the inventor at least those conditions that would apply to a small business firm contractor. (37 C.F.R. 401.9)

c. The determination to grant or deny approval of the request, along with any specific conditions and/or limitations, will be communicated by NIH OTT to OER within five (5) business days of receiving the recommendations from all ICs. Within five (5) business days of OER receiving OTT’s determination, OER can send to OTT its comments and/or edits. OTT will seriously consider OER’s comments and/or edits and will issue its final determination within five (5) business days of receiving OER’s comments.

5. Transmission of the Determination from OER to the Contractor and Inventor(s)

Within five (5) business days after receiving NIH OTT’s final determination (absent extenuating circumstances and notification to NIH OTT), OER will communicate the final NIH determination as prepared by OTT to the Contractor(s) and the Inventor(s) and will send, at the same time of sending the final determination to the Contractor(s) and the Inventor(s), a copy of OER’s correspondence to OTT. OER will maintain the original request, all of OER’s related documents, and those documents submitted by the requester through iEdison.
6. **Requests for Reconsideration**

   a. Upon receipt of a request for reconsideration of an NIH decision denying a request for an inventor to acquire title to an extramural invention, OER shall transmit the request to NIH OTT within five (5) business days. If NIH OTT first receives a request for reconsideration it shall transmit the request to OER within five (5) business days.

   b. NIH OTT shall review the case and make a decision regarding action to be taken. NIH OTT may seek advice and information from any source, including OER; the Contractor; the NIH funding Institute or Center; NIH OTT employees; the NIH Office of the General Counsel; or other NIH employees.

   c. NIH OTT shall provide OER with a draft of the NIH decision prepared by OTT and will seriously consider OER’s comments with respect to its proposed determination.

   d. Within fifty (50) calendar days of receiving the request for reconsideration, or, if additional information is required, within fifty (50) days of NIH receiving such additional information, NIH OTT shall transmit the final NIH decision to OER.

   e. Within five (5) business days of receiving NIH OTT's final decision, OER will communicate the NIH decision to the Contractor and will send a copy to the NIH OTT.

7. **Appeals**

   a. OER shall transmit the request to the NIH Office of Technology Transfer (NIH OTT) within five (5) business days. If NIH OTT first receives a request for appeal it shall transmit the request to OER within five (5) business days.

   b. The Deputy Director for Intramural Research and the Deputy Director for Extramural Research may confer with respect to consideration of the appeal.

   c. The NIH Director shall make the final decision of any appeal.

   d. Within five (5) business days of receiving the NIH decision from the NIH Director, NIH OTT will communicate the NIH decision to the Contractor and will send a copy to OER.

   e. Judicial review is available as the law permits.

D. **EFFECTIVE DATE**

The NIH procedures set forth in this Manual Chapter are effective September 23, 2013, and supersede in their entirety all NIH procedures in the PHS Technology Transfer Manual Chapter 603, which was first approved on December 18, 2003. This Manual Chapter is not intended to create any right or benefit, substantive or procedural, enforceable at law by a
E. ADDITIONAL INFORMATION

For additional information on this Manual Chapter and related NIH policies, contact the NIH Office of Technology Transfer, (301) 496-7057, or http://www.ott.nih.gov/contact-us, or the NIH Office of Extramural Research, Division of Extramural Inventions & Technology Resources, (301) 435-1986, Edison@nih.gov, or http://inventions.nih.gov.