A. PURPOSE

This Manual Chapter establishes the NIH Office of Technology Transfer's (NIH OTT) procedures for proper review and disposition of requests by an inventor to leave title in NIH inventions in which the U.S. Government has an ownership interest (NIH Intramural Inventions).

B. BACKGROUND

Under the Federal Technology Transfer Act of 1986 (FTTA), as amended and set forth in 15 U.S.C. § 3710d and 37 C.F.R. Part 501, a Government employee who is an inventor may request that the Government leave title in the invention to the employee. If the Government has insufficient interest in the invention to obtain or retain the right, title, and interest to a patent therein or to otherwise promote commercialization, the agency employing the inventor has the discretion to decide to leave title in the invention to the inventor. HHS regulations (45 C.F.R. Part 7), authorize the PHS to determine the appropriate disposition of the Government interests in a PHS Intramural Invention.

NIH OTT has been delegated the authority to determine whether to leave title in an NIH Intramural Invention to an inventor. The following procedures are to be followed in processing and responding to such requests for leaving title.

C. CRITERIA and PROCEDURES

Criteria:

1. For inventors presently subject to the ethics laws and regulations applicable to federal employees, leaving title is appropriate only if the agency has determined either that the inventor’s ownership of rights in the invention will not constitute a conflict of interest (real or apparent), or that the resulting conflict has been resolved.

2. Consistent with 37 C.F.R. § 501.6, NIH OTT will consider any criteria related to the commercialization potential and the ultimate benefit to the public of an Intramural Invention in determining whether to retain title of the invention. Such criteria include (but are not limited to) the following:

   a. whether the public health, NIH Institute/Center (IC) mission, or financial potential of the invention requires investment of Government funds in patenting and licensing
b. whether the invention can reasonably be commercialized through a non-patent license or material transfer agreement;

c. whether the invention can reasonably be commercialized through publication of the invention;

d. whether leaving title would reasonably be expected to inhibit broad dissemination and application of the invention; or

e. whether it is otherwise in the best interest of the Government or the public health to release the technology to the general public free of patent.

If any criteria related to the commercialization of a Government-owned invention can be answered in the affirmative, then the leaving title is not appropriate.

**Procedures:**

1. An inventor who wishes to request that PHS leave title to the Government’s interest must submit a written request through the Technology Development Coordinator (TDC) of the pertinent IC. The request must contain the following elements:

   a. **Rationale:** The request must provide an explanation of how leaving title to the inventor (rather than abandoning the patents on the technology) will benefit the public health, along with any information relevant to the analysis of the Criteria listed above.

   b. **Conflict of Interest:** The request must include a statement by the IC Ethics Coordinator or Deputy Ethics Coordinator indicating one of the following:

      i. The inventor is presently not (or shortly will no longer be) subject to the ethics laws and regulations applicable to federal employees; or

      ii. A brief description of how any potential conflict of interest (real or apparent) will be resolved by the IC and the inventor.

**Note:** For inventions with at least two employees as co-inventors, each employee requesting leaving title must separately request it.

2. The TDC will seek concurrence or non-concurrence in the inventor’s request to leave title from officials at the inventor’s IC, as applicable, and will communicate the IC’s position on the request to the NIH OTT. If the invention arose from more than one IC, the requesting-inventor’s TDC will arrange for a coordinated recommendation from all ICs.

3. Factors that the NIH OTT will consider in recommending that a request to leave title be granted include the Criteria cited above, the ability of the inventor to file with the Patent and Trademark Office in a timely manner, and the IC recommendation.

4. NIH OTT may elect to specify that its grant of a request to leave title is contingent upon certain conditions, responsibilities, and/or restrictions.

5. If the NIH OTT recommendation is not in accordance with the IC recommendation, the Director, NIH OTT (or designee) will initiate a dialogue with the (lead) TDC to determine the action to be taken. The Director, NIH OTT will make the final decision.
6. Consistent with 37 C.F.R. § 501.7, the NIH OTT will prepare a transmittal letter addressed to the inventor, with a copy to the (lead) TDC, indicating the disposition of the request. If the request is granted, the NIH OTT will send to the inventor a document containing a royalty-free, nonexclusive license to the Government to practice the invention, along with any conditions, responsibilities, and/or restrictions (discussed above). If the NIH OTT has elected to include additional such terms, these will be listed in the document.

7. The grant of the request is effective upon receipt of the executed document by the NIH OTT. The NIH OTT will send a copy of the executed document to the TDC(s).

D. EFFECTIVE DATE

The procedures set forth in this Manual Chapter are effective September 23, 2013, and supersede in their entirety the procedures in PHS Technology Transfer Manual Chapter 202, which was first approved on January 23, 1997 and revised on June 17, 2010.

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.