

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 202

Leaving Title to Inventors for PHS Inventions

A. PURPOSE

This Manual Chapter establishes the policy and procedures for the review and disposition of requests by an inventor to leave title to their invention when they have an obligation to assign their rights to the U.S. Government as represented by an Institute or Center (IC) of the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC) or Food and Drug Administration (FDA), all agencies within the Department of Health and Human Services (HHS) and constituting the Public Health Service. This Chapter applies to such inventors regardless of whether their primary work assignment was in an intramural, extramural, or a central program of a PHS agency where an invention was made.

B. BACKGROUND POLICY

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, an inventor who has assigned rights in their invention to the US Government may request that the Government leave title in the invention with them.

When an inventor requests title to their invention, the technology transfer office at the Agency/IC¹ where the invention was made (or other delegated evaluating office) will consider criteria related to the commercialization potential and the ultimate benefit to the public of an PHS Invention in determining whether to retain title to the invention or grant the request. Such criteria include, but are not limited to, the following:

- a. whether the public health, Agency/IC mission, or financial potential of the invention no longer requires investment of Government funds in patenting and licensing efforts;
- b. whether the invention can reasonably be commercialized through a non-patent license or material transfer agreement;
- c. whether publication of the invention would reasonably be expected to lead to commercialization of the invention;
- d. whether leaving title would reasonably be expected to provide 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 public, free of any patents.

¹ This Chapter also covers those inventors whose inventions have been assigned to the Government by a third party, even though the inventors never had any obligation to assign their inventions directly to the Government.

After weighing these factors, the Agency/IC technology transfer office has the discretion to leave title in the invention to the inventor.² That office may consult with other Agency/IC technology transfer offices including any applicable technology transfer service centers.

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 any resulting conflict has been resolved.
2. For inventions where the Government has received assignment of rights from more than one inventor, waiver of rights to any requesting inventor, and not others, must be limited to the requesting-inventor's rights and must not diminish the rights of the co-inventor(s) not requesting a waiver to share in any royalties received by an Agency/IC as a result of licensing the invention. To waive all Government rights, all co-inventors must individually request waivers.

Procedures:

1. An inventor requesting an Agency/IC waive title to the Government's interest in their invention must submit a written request to the Agency/IC Technology Development Coordinator (TDC) where the invention was made and to that Agency/IC's ethics office. The request must contain at least the following elements:
 - a. Rationale: an explanation of how leaving title to the inventor, rather than abandoning issued or pending patents on the technology, will benefit the public, along with any information relevant to the analysis of the criteria above.
 - b. Management: if the Government requires the inventor to file a patent application pursuant to 37 C.F.R. § 501.7, an explanation of the inventor's ability to manage the patents/application(s) at the US Patent and Trademark Office.
 - c. Conflict of Interest: a statement to be evaluated by the Agency/IC ethics official regarding 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 Agency/IC and the inventor.
2. Each IC/Agency ethics requirements may include additional criteria. If the waiver request clears the ethics review, the TDC will seek concurrence for their recommended response to waiver request from the appropriate IC/Agency officials, as applicable, and then will communicate the Agency/IC's position to the inventor.

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3. If the technology transfer office at the Agency/IC where the invention was made utilizes a technology transfer service center at another Agency/IC, and the service center recommendation is not in accordance with that of the Agency/IC TDC, the two parties or their designees will initiate a dialogue in an attempt to come to an agreed upon response to the waiver. If they cannot come to agreement, the Agency/IC TDC where the invention was made will draft the final recommendation to their Agency/IC, pointing out the unresolved concerns of the service center.
4. If the invention arose from more than one Agency/IC, the TDC managing the request will arrange for a coordinated recommendation from other relevant Agency/ICs. For such joint inventions, each inventor requesting title and working in an Agency/IC must independently request and receive clearance from the ethics official where they work.
5. The Agency/IC technology transfer office may elect to specify that its grant of a request to leave title be conditioned upon certain conditions, obligations, responsibilities, and/or restrictions authorized by 37 C.F.R. § 501.7.
6. The Agency/IC TDC will convey the Agency/IC's final decision in a letter to the inventor and, if the invention was made jointly with another Agency/IC, will send a copy to the other TDC(s), and to any technology transfer service center that might manage the invention. If the waiver request is granted, the Agency/IC technology transfer office will send to the inventor documents to acknowledge any conditions, obligations, responsibilities, and/or restrictions on the inventor and to grant a royalty-free, nonexclusive license to the Government to practice the invention.
7. The grant of the request is effective upon receipt of the executed document by the Agency/IC technology transfer office, which will in turn send copies to other offices having an ownership interest or management responsibilities for the invention.

D. EFFECTIVE DATE

The procedures set forth in this Manual Chapter are effective October 14, 2021 and supersede in their entirety the procedures in PHS Technology Transfer Manual Chapters 202 and 202.1, which were first approved on January 23, 1997.

E. ADDITIONAL INFORMATION

For additional information on this Manual Chapter, contact the Office of Technology Transfer, NIH, nihott@mail.nih.gov or the Division of Technology Transfer and Innovation Policy, Office of Science Policy National Institutes of Health, NIH, SciencePolicy@od.nih.gov. For CDC contact tto@cdc.gov. For FDA contact techtransfer@fda.hhs.gov.