

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 603A

NIH Contractor Procedures Regarding Inventor Requests to Acquire Title in Extramural Inventions

A. PURPOSE

This Manual Chapter establishes the procedures to allow an NIH Contractor's¹ 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 Invention², 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.³

C. NIH CONTRACTOR PROCEDURES

1. A request for an inventor to acquire title must be submitted to the NIH Office of Extramural Research (OER). See <https://s-edison.info.nih.gov/iEdison/nihprocs.jsp> . Such submission must provide supporting information for the request.
2. Factors to be considered by NIH in making a determination may include:
 - a. The nature of the technology;
 - b. The explanation of why the waiver is necessary for commercialization of the

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).

technology;

- c. The explanation of how the public interest will be protected after assignment of title to the inventor(s), including, for example, through:
 - i. Agreement by the inventor(s) that the Subject Invention(s) will remain bound by and subject to all of the Government rights reserved under applicable laws and regulations as if the assignee was the original NIH Contractor;
 - ii. Agreement by the inventor(s) that the use and transfer of the Subject Invention(s) will conform with all of the HHS, PHS, NIH applicable policies concerning broad public access to research results (e.g., data, materials);
 - iii. Remedies for failure to comply with conditions placed on the assignment; and
 - iv. Disposition of the technology in the event the inventor(s) enters bankruptcy, dissolution, or is otherwise unable or unwilling to commercialize the technology.
3. Each granted waiver request shall 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. In addition, consistent with statutes, regulations, and HHS, PHS, NIH applicable policies, NIH retains sole discretion to add additional conditions, requirements, and/or restrictions (either generally or case-specific) that NIH deems appropriate.
4. The waiver will become effective upon receipt of confirmatory signatures from both the NIH Contractor and the inventor(s) accepting all terms and conditions of the waiver approval.
5. Requests for Reconsideration
 - a. An NIH Contractor may request reconsideration of an NIH denying a request for an inventor to acquire title to an extramural invention by submitting a written request to the NIH Office of Extramural Research (OER) within thirty (30) calendar days after the notice of denial is sent to the Contractor.
See <https://s-edison.info.nih.gov/iEdison/nihprocs.jsp> .
 - b. The request for reconsideration shall concisely state the grounds for reconsideration and include copies of all pertinent documents. NIH may require submission of additional information or documentation.
 - c. Within sixty (60) calendar days of receiving the request for reconsideration, or, if additional information or documentation from the Contractor is required, within sixty (60) calendar days of receiving such additional information, NIH shall send a final determination to the Contractor.

6. Appeals

- a. A Contractor who has received an adverse determination on a request for reconsideration of a denial of a request for an inventor to acquire title to an extramural invention may appeal of such determination pursuant to 37 C.F.R. § 401.11(b)(3) or (b)(4), respectively.
- b. The Contractor shall file a written appeal to the NIH Office of Extramural Research, Office of Policy for Extramural Research Administration, Division of Extramural Inventions and Technology Resources (OER/OPERA/DEITR) no later than thirty (30) calendar days from the receipt of an adverse decision concerning a request for reconsideration.
- c. The appeal shall concisely state the grounds for appeal and include copies of all pertinent documents. The appeal must include concise arguments as to why the decision of the NIH should be rejected or modified. Appellants shall not be entitled to an adversary hearing.
See <https://s-edison.info.nih.gov/iEdison/nihprocs.jsp> .
- d. Within sixty (60) calendar days of receiving the appeal, or, if additional information from the Contractor is required, within sixty (60) days of receiving such information, NIH shall send a final determination to the Contractor.
- e. Judicial review is available as law permits.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective September 23, 2013, and supersedes in their entirety the NIH Contractor procedures in PHS Technology Transfer Manual Chapter 603, which was first approved on December 18, 2003 and revised on September 20, 2012. This Manual Chapter is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any other persons.

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>.