

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 606A

NIH Contractor Procedures for Requests for Reconsideration and Appeals of Certain Extramural Waiver Decisions

A. PURPOSE

This Manual Chapter describes the procedures for a request for reconsideration and appeal of an NIH decision denying: (1) a request for waiver of the U.S. manufacturing requirement, under 35 U.S.C. § 204, in exclusive licenses to use or sell a Contractor's Subject Invention in the United States; and (2) a request for permission by a nonprofit Contractor¹ to assign title to a Subject Invention² to a third party.

B. BACKGROUND

The NIH decision or determination concerning the denial of a Contractor's request for waiver of the U.S. manufacturing requirement or permission for third party assignment³ is final unless the procedures for requests for consideration and appeals set forth below are initiated.

C. NIH CONTRACTOR PROCEDURES

1. Requests for Reconsideration

- a. A NIH Contractor may request reconsideration of an NIH determination denying a request for waiver of the U.S. manufacturing requirement or permission for third party assignment 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.

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). For the purpose of this chapter, Contractor also includes a third party assignees of extramural subject inventions developed by nonprofit contractors.

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 Request for assignments of title to third parties are also referred to as requests for waiver of the prohibition against third party assignment of title.

- 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.

2. Appeals

- a. A Contractor who has received an adverse determination on a request for reconsideration of a denial of a request for waiver of the U.S. manufacturing requirement or a request for third party assignment 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 NIH Contractor procedures set forth in this Manual Chapter are effective June 20, 2013, and supersede in their entirety the NIH Contractor procedures in PHS Technology Transfer Manual Chapter 606, which was first approved on March 26, 1998.

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>.