

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 606

PHS Policy for Handling Appeals of Certain Extramural Waiver Decisions

A. PURPOSE

This Manual Chapter describes the PHS policy for handling appeals of denials of the following extramural waiver decisions: (1) requests 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) requests for permission by a nonprofit Contractor¹ to assign title to a Subject Invention² to a third party.

B. BACKGROUND

Denials of requests for waiver of the U.S. manufacturing requirement and permission for third party assignment³ are governed by this chapter.

C. POLICY

It is the policy of PHS to expeditiously and fairly review all appeals of decisions concerning denials of requests for waiver of the U.S. manufacturing requirement and for permission to assign title to a Subject Invention to a third party, as provided under 37 C.F.R. § 401.11(b)(3) and (b)(4), respectively. The Contractor that originally requested the waiver is the only entity eligible to appeal the denial of such a request.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective June 20, 2013, and supersedes in its entirety the policy in PHS Technology Transfer Manual Chapter 606, which was first approved on March 26, 1998.

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.

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>.