

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 605

PHS Policy Regarding Requests for Permission to Assign Title to Extramural Subject Inventions Developed by PHS Nonprofit Contractors to Third Parties

A. PURPOSE

This Manual Chapter establishes the policy of the Public Health Service (PHS) for review and disposition of requests for permission by a nonprofit Contractor¹ to assign title to Subject Inventions² to a third party, also referred to as requests for waiver of the prohibition against third party assignment of title.

B. BACKGROUND

For all nonprofit Contractors, 35 U.S.C § 202(c)(7) requires that the Funding Agreement include, among other terms, a prohibition of assignment of any Subject Invention to third parties without the approval of the funding agency “except where such assignment is made to an organization which has as one of its primary functions the management of inventions (provided that such assignee shall be subject to the same provisions as the contractor).”

C. POLICY

The PHS will follow 35 U.S.C. § 202(c)(7) in making determinations regarding requests for permission to assign title to Subject Inventions to third parties. The Bayh-Dole Act presumes that the Contractor, particularly a nonprofit Contractor, is in the best position to develop its own inventions. Accordingly, PHS policy is to waive the prohibition on assignments only upon a strong and timely showing by the Contractor that assigning the Subject Invention to a third party will further the goals of the Bayh-Dole Act and advance public health significantly better than licensing it exclusively, or that assignment is otherwise substantially in the public interest, as reasonably determined by PHS.

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...”.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective September 20, 2012, and supersedes in its entirety the policy in the PHS Technology Transfer Manual Chapter 605, which was first approved March 26, 1998. 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, 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>.