

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 305

PHS Policy for Making Determinations Regarding the Grant of Exclusive or Partially Exclusive Commercialization Licenses

A. PURPOSE

This Manual Chapter establishes the Public Health Services (PHS) policy for making determinations as to whether or not to grant an exclusive or a partially exclusive commercialization license to PHS inventions.

B. BACKGROUND

Several hundred applications for licenses to PHS inventions may be received each year. Many of these applications request exclusive or partially exclusive commercialization licenses. Federal law (35 U.S.C. § 209) and regulations (37 C.F.R. § 404.7) set forth specific requirements that must be met before an exclusive or partially exclusive license may be granted. This chapter sets forth the policy to be followed to ensure that proper determinations are made, in light of the applicable Federal law and regulations, with respect to the grant of exclusive or partially exclusive commercialization licenses.

C. POLICY

It is PHS policy to grant nonexclusive licenses to PHS inventions to responsible individuals, companies, non-profit organizations, or other entities that demonstrate the financial and technical ability to develop the invention where the development of the invention will be furthered by granting a license, and doing so advances the interest of PHS and the public. While the award of a nonexclusive license is preferred, exclusive, co-exclusive, or partially exclusive commercialization licenses may be awarded in accordance with 15 U.S.C. § 3710a or 35 U.S.C. § 209 and 37 C.F.R. § 404.7, when circumstances warrant and all statutory and regulatory requirements are met.

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 305, which was first approved on August 10, 1995 and revised on December 8, 2010.

E. ADDITIONAL INFORMATION

For more information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301) 496-7057 or <http://www.ott.nih.gov/contact-us> .