

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

Hundreds of 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. For more on making determinations regarding the grant of nonexclusive licenses, see Technology Transfer Policy Manual Chapter 304. 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 merit, and all statutory and regulatory requirements are met.

For licensing inventions made under a Cooperative Research and Development Agreement (CRADA), see Technology Transfer Policy Manual Chapter 306.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective October 23, 2024, and supersedes in its entirety the policy in PHS Technology Transfer Manual Chapter 305, which was approved on June 20, 2013.

E. ADDITIONAL INFORMATION

For additional information on this Manual Chapter, contact the NIH Office of Technology Transfer at nihott@mail.nih.gov. For more information specific to Food and Drug Administration, contact TechTransfer@fda.hhs.gov. For CDC contact tto@cdc.gov.