

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 200

Policy on the Filing of Patent Applications for PHS Inventions

A. PURPOSE

This Manual Chapter sets forth the policy for the filing of patent applications on technologies developed by the Public Health Service (PHS).

B. BACKGROUND

The primary mission of PHS research laboratories is to pursue new knowledge through the conduct and support of research to improve the health of the American people. Pursuant to the Stevenson-Wydler Act of 1980 (PL 96-480) and the Federal Technology Transfer Act of 1986 (PL 99-502) as amended, Federal laboratories, including PHS research laboratories at the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC) were given a statutory mandate to ensure that new technologies in which the U.S. Government obtains an interest are transferred to the private sector and commercialized in an expeditious and efficient manner.

The ability and willingness of private sector partners to commercialize inventions can be critical to realizing the benefits from PHS-conducted research. Patent protection on U.S. Government owned inventions in the United States and foreign countries can be a crucial incentive for the private sector to develop new products and services to realize public health benefits.

Accordingly, the PHS has established the following policy regarding U.S. and foreign patent protection for PHS-owned technology.

C. POLICY

Most technologies developed at the PHS are made available to the public without securing patent protection by publications in scientific journals, public presentations, online resources, and, for most tangibles like software and biological materials, through licenses for commercial development or research.

PHS may determine that it is necessary to seek patent protection on its inventions when doing so would facilitate the commercial development of products or services that will benefit the public health, or when a patent will advance any other PHS objective. The decision to file

will also be informed by other PHS policies as appropriate, including, for example, the NIH Policies on research tools¹ and genomic inventions.²

The decision to pursue a patent on inventions made under a Cooperative Research and Development Agreement (CRADA) will be informed by the terms of the CRADA, the relevant statutory requirements, and the principles of this Policy Chapter.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective June 17, 2010, and supersedes in its entirety the policy in the PHS Technology Transfer Manual Chapter 200, which was first approved on October 25, 1995.

E. ADDITIONAL INFORMATION

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

¹ “NIH Principles and Guidelines for Sharing of Biomedical Resources – Final” (December 1999), available online at http://www.ott.nih.gov/policy/research_tool.aspx.

² “Best Practices for the Licensing of Genomic Inventions: Final Notice” (April 2005), available online at http://www.ott.nih.gov/policy/lic_gen.aspx.