A. PURPOSE

This Manual Chapter sets forth the policy for the receipt and distribution of Royalties received by the Public Health Service (PHS) through the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and the U.S. Food and Drug Administration (FDA) from licensing inventions in which the U.S. Government has an ownership interest.

B. BACKGROUND

The primary mission of PHS research laboratories is to pursue new knowledge through the conduct and support of research to improve the public health. This mission is advanced by PHS’s fostering fundamental creative discoveries, innovative research strategies, and their applications as a basis to advance significantly the Nation’s capacity to protect and improve health. To accomplish its mission and goal to significantly improve public health some research results must be transferred to the private sector for subsequent commercial development and manufacture in order to make available to the public new or improved products and services. The licensing of inventions is generally an effective means for the transfer of such research results to the private sector.

Under the Stevenson-Wydler Technology Innovation Act of 1980, as amended, Congress established that helping U.S. businesses to speed the development of new products and processes is a responsibility of each federal agency. To further this objective, Congress has included incentives for researchers to participate in the technology transfer process that will promote and support the expeditious transfer of Federally-owned inventions. These incentives are realized through the distribution of Royalties by PHS to inventors and to research and training programs within PHS.

C. POLICY

PHS generally seeks to patent and license biomedical technologies when a patent will facilitate and attract investment by commercial partners for further research and commercial development of the technology. PHS seeks to obtain a fair financial return on the public’s investment in the development of the technology through royalty-bearing licenses and payment of patent expenses. Royalties received under a license allows the
PHS to provide appropriate incentives to inventors and other laboratory employees who increased the value of a licensed invention and also to support scientific exchange, education, and research within PHS. Royalties are distributed by PHS in accordance with 15 U.S.C. 3710c.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective March 8, 2012 and supersedes in its entirety the policy in PHS Technology Transfer Manual Chapter 311, which was first approved on January 23, 2002.

E. ADDITIONAL INFORMATION

For more information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301) 594-7700 or http://www.ott.nih.gov/contact-us