A. PURPOSE

This Manual Chapter provides guidance to the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) when deciding whether or not to file patent applications on Government owned inventions.

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 NIH, 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 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.

C. CRITERIA

The decision of whether or not to file a patent on an NIH or FDA invention requires the consideration of several factors to determine if a patent is necessary to encourage a commercial partner to invest in the product development of a technology for the public’s benefit.

- The decision may depend on whether there is a reasonable expectation of at least one commercial or public health use that can be enhanced by patenting.

- The decision typically requires consideration of the costs and benefits of obtaining protection. Even if NIH or FDA determines that a technology is patentable, it may decline to expend public funds and seek patent protection due to low public health or commercial priority. Where the market is small or non-existent, offering a license to a patent may not be sufficient to encourage investment by the private sector in some inventions. The commercial
market for an invention may be an important factor in the decision; however, programmatic goals relating to small markets (for example, rare and neglected diseases) may suggest that patent protection is warranted.

- When the public benefit of an invention can best be realized without patent protection, patent protection should not be sought. For example, some technologies may be distributed most effectively through non-patent licensing, such as software and biological materials. Also, some technologies can be utilized immediately through publication alone, with no further research or development needed, such as new methods of performing surgical procedures. Patents covering either category of invention could impede broad dissemination or rapid utilization of the technology.

- In accordance with a longstanding tradition of scientific freedom, PHS research results are to be published rapidly and broadly. Publication of research is not to be significantly delayed for the purpose of filing patent applications on patentable subject matter.

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.