UNITED STATES PUBLIC HEALTH SERVICE
TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 300

PHS Licensing Policy

A. PURPOSE

This Manual Chapter sets forth the policy for licensing inventions owned in whole or in part by the United States (US) Government, as represented by the Public Health Service (PHS).

B. BACKGROUND

The primary mission of PHS laboratories is to pursue new knowledge through the conduct and support of research to improve the health of the American people. Pursuant to the Bayh-Dole Act of 1980 (PL 96-517), the Stevenson-Wydler Technology Innovation Act of 1980 (PL 96-480), and the Federal Technology Transfer Act of 1986 (PL No. 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 inventions and discoveries in which the US Government obtains an interest are transferred to the private sector and commercialized in an expeditious and efficient manner.

The ability and willingness of parties with an interest in improving public health, including the private sector, to commercialize new inventions can be critical to realizing the benefits of PHS-conducted research and development. This typically requires a robust licensing program for PHS inventions.

C. POLICY

PHS generally seeks to license inventions that it manages when a license will facilitate and attract investment by partners for further research and commercial development of the invention. A license is often necessary when the invention is directed to a preventive, diagnostic, or therapeutic product. Licensing may also be necessary to encourage a partner to make important materials or products available for research use.

PHS often licenses inventions that have been patented. Patent protection generally is not sought by PHS where further research and development is not necessary to realize the invention's primary use, and future preventive, diagnostic, or therapeutic uses are not reasonably anticipated. For example, PHS will typically not seek patent protection for materials that serve only as research tools, e.g., transgenic mice, or cell lines, because such materials can be either licensed effectively without patent protection under royalty-bearing

materials license agreements, or distributed through non-royalty bearing material transfer agreements. In most cases, the public interest is best served by ensuring that research tools are widely available to both academic and commercial scientists to advance further scientific discovery.

In addition, some inventions may be transferred most expeditiously through publication, and PHS may determine for any given invention and circumstance that patenting and licensing is unnecessary and could inhibit broad dissemination and application of the invention.

In contrast, for inventions with potential preventive, diagnostic, therapeutic, or those that may involve significant development or risk, licensing of patent rights is typically the primary vehicle for transferring the invention. Due to the importance of effective licensing, particularly patent licensing, to the development and availability of new products arising from PHS inventions, the PHS licensing program is governed by the following principles in marketing, negotiating, executing, and monitoring licenses to PHS inventions:

- The PHS licensing program is consistent with the Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice (the "NIH's Research Tools policy"), 64 Fed. Reg. 72,090 (Dec. 23, 1999) and Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18,413 (Apr. 11, 2005).

- PHS seeks to ensure development of each invention for the broadest number of possible applications to maximize the availability of the invention to the public.

- PHS seeks to ensure that a licensee obtains the appropriate scope of rights necessary to develop a potential application of the invention. This enables as many licensees as possible to obtain commercial development rights, resulting in the potential for concurrent development of many potential applications and the further promotion of the invention's utilization by the public. PHS enhances public access to the benefits of its invention by fostering the development of competing products for the same or similar applications where feasible.

- PHS seeks to ensure expeditious development of the licensed invention.

- PHS seeks to ensure that licensees developing inventions are obligated to bring them to practical application and make the benefits of the invention reasonably accessible to the public.

- PHS seeks to ensure that products produced through the use of the invention in the United States are manufactured substantially in the United States unless domestic manufacture is not commercially feasible.

- PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.

- PHS seeks to obtain a fair financial return on the public's research investment through negotiating royalty-bearing licenses and obtaining payment of patent expenses from licensees.

- PHS seeks to negotiate and obtain public benefits from licensees consistent with expeditious commercial development and accessibility of the invention.

- PHS considers license applications in view of applicant's compliance with prior and/or existing obligations to PHS, which may include payments, reports, or adherence to performance benchmarks.

- PHS monitors the performance of its licensees and ensures that any licensed PHS invention is developed in accordance with the licensee's plan for development. In the event that a licensee has substantially failed to meet its license obligations, PHS may modify the license to replace an exclusive license with a non-exclusive one, narrow the field(s) of use, modify performance benchmarks, and/or terminate the license to allow PHS to license the invention to other partners.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective January 11, 2024, and supersedes in its entirety the policy in PHS Technology Transfer Policy Manual Chapter 300, which was approved on December 08, 2010.

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.