UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 302

PHS Policy for Preparing and Submitting Notices Regarding Licensing of PHS Inventions to the *Federal Register* for Publication

A. PURPOSE

This Manual Chapter establishes the Public Health Service (PHS) policy for the preparation, review, and publication of notices in the *Federal Register* relating to PHS inventions.

B. BACKGROUND

Notices relating to PHS technology transfer activities are published in the *Federal Register*. Publishing a notice that an invention is available for licensing is one of a number of marketing outreach methods employed to inform industry that particular PHS inventions are available for licensing. Also, publication of a notice that an invention is available for licensing serves to meet one of the requirements of 37 C.F.R. § 404.7 if an exclusive or partially exclusive license is ultimately granted. Additionally, if an exclusive or partially exclusive license is to be granted, 35 U.S.C. § 209 and 37 C.F.R. § 404.7 require that a notice of intent to grant such a license must be published in the *Federal Register*, and there must be an opportunity for submission of comments or objections to the proposed license following publication of such a notice.

C. POLICY

Consistent with 37 C.F.R. § 404.4, all PHS inventions that are available for licensing and for which a patent application has been filed, except those that were developed under the terms of a Cooperative Research and Development Agreement (CRADA), will be described in a notice published in the *Federal Register*. If an exclusive or partially exclusive license is contemplated, notice to that effect will be published in the *Federal Register* with opportunity for public comment and objections in accordance with 37 C.F.R. § 404.7. Such notice is not required for exclusive or partially exclusive licenses to inventions developed under the terms of a CRADA and to joint inventions under 35 U.S.C. § 202(e); or license agreements arising from the settlement of a patent dispute.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective December 8, 2010, and supersedes in its entirety the policy in PHS Technology Transfer Manual Chapter 302, which was first approved on September 30, 1994.

E. ADDITIONAL INFORMATION

For additional information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301) 496-7057 or http://www.ott.nih.gov/contactus/contact_us.aspx.