

# UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

## Chapter No. 306

### PHS Policy for the Licensing of Inventions Made Under Cooperative Research and Development Agreements

#### A. PURPOSE

This Manual Chapter establishes the Public Health Service (PHS) policy for licensing an invention that is made under a Cooperative Research and Development Agreement (CRADA).

#### B. BACKGROUND

The Federal Technology Transfer Act of 1986 (FTTA) permits Federal laboratories to enter into CRADAs with other Federal agencies, units of State or local government, industrial organizations, public and private foundations, nonprofit organizations (including universities), or other persons (including licensees of inventions owned by the Federal agency). *See* 15 U.S.C. § 3710a(a)(1). The FTTA further provides that the Federal laboratory “may grant, or agree to grant in advance, to a collaborating party licenses or assignments, or options thereto, in any invention made in whole or in part by a laboratory employee under the [CRADA].” 15 U.S.C. § 3710a(b)(1). An invention made in whole in part by a laboratory employee and/or a collaborating party that is conceived or first actually reduced to practice in performance of the CRADA is a “CRADA Subject Invention.”

#### C. POLICY

A CRADA negotiated by PHS will typically provide the collaborating party with an exclusive option to negotiate an exclusive or a nonexclusive license to CRADA Subject Inventions made in whole or in part by a PHS employee(s).

PHS, following its determination that an invention is a CRADA Subject Invention(s) made in whole or in part by a PHS employee(s), shall license the Government’s rights in the CRADA Subject Invention(s) in accordance with the applicable provisions of the CRADA. However, all licenses granted shall be consistent with applicable laws and regulations, including 15 U.S.C. § 3710a.

#### 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 306, which was first approved on September 30, 1994.

## **E. ADDITIONAL INFORMATION**

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