

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 306

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

A. PURPOSE

This Technology Transfer Policy Manual Chapter establishes the policy of an Institute/Center (IC) of the National Institutes of Health (NIH), the Food and Drug Administration (FDA), or the Centers for Disease Control and Prevention (CDC), each an “Agency” and collectively “Agencies,” for licensing an invention that is made under a Cooperative Research and Development Agreement (CRADA).

B. BACKGROUND

The Federal Technology Transfer Act (FTTA) of 1986 (as amended) permits the Directors of Agencies to enter into CRADAs with other Federal agencies, units of State or local government, industrial organizations (including corporations, partnerships, and limited partnerships, and industrial development 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)).

Pursuant to entering into a CRADA, the FTTA gives the Agency the authority to grant, or agree to grant in advance, patent licenses or assignments, or options thereto, to the collaborating party for any invention made in whole or in part by an Agency’s employee under the CRADA (see 15 U.S.C. § 3710a(b)(1)). An invention made in whole or in part by an Agency’s 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

Pursuant to 15 U.S.C. § 3710a(b)(1), a CRADA negotiated by an Agency will typically provide the collaborating party with an exclusive option to negotiate an exclusive or a nonexclusive license to the Government’s interest in CRADA Subject Inventions.

After an Agency receives an invention report from its employee or the collaborating party, the Agency will determine if the invention is a CRADA Subject Invention and the collaborating party will be notified of this determination. A patent application will typically be filed by the Agency or the collaborating party, in accordance with the terms of the CRADA. Should the collaborating party exercise its exclusive option to negotiate a license for the CRADA Subject Invention, the Agency will negotiate a license to the Government’s rights in the CRADA

Subject Invention 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, 35 U.S.C. § 207-209, and 37 C.F.R. § 404. Public notice of the intent to grant an exclusive or partially exclusive license is not required for a CRADA Subject Invention, 35 U.S.C. § 209(e).

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective November 17, 2022, and supersedes in its entirety the policy in PHS Technology Transfer Manual Chapter 306, which was approved on December 8, 2010.

E. ADDITIONAL INFORMATION

For additional information on this Manual Chapter, contact the Office of Technology Transfer, NIH, nihott@mail.nih.gov or the Division of Technology Transfer and Innovation Policy, Office of Science Policy National Institutes of Health, NIH, SciencePolicy@od.nih.gov. For CDC contact tto@cdc.gov. For FDA contact techtransfer@fda.hhs.gov