

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 400

PHS Cooperative Research and Development Agreement Policy

A. PURPOSE

The purpose of this Public Health Service (PHS) Technology Transfer Manual Policy Chapter is to set forth the policy for Cooperative Research and Development Agreements (CRADAs) within PHS laboratories.¹

B. BACKGROUND

The primary mission of PHS research laboratories is to pursue new knowledge through the conduct and support of research to improve the public health. In pursuit of its mission, PHS supports a broad spectrum of research approaches, ranging from basic laboratory research to clinical research. This continuum of research activities creates a synergism essential to the effective advancement of knowledge. The synergy that exists among these research approaches is dependent upon the ability of PHS investigators to discuss and explore new ideas freely and openly.

The Federal Technology Transfer Act (FTTA) of 1986, and Executive Order No. 12591, mandated PHS to encourage and facilitate collaborations, including CRADAs, among Federal laboratories, state and local governments, universities, the private sector, particularly small businesses, and other entities in order to assist in the transfer of federal technology to the marketplace. The intent of Congress in authorizing CRADAs was to promote national technological competitiveness and the rapid transfer of innovations to the marketplace.²

C. POLICY

1. General

Each PHS laboratory may enter into CRADAs “with other Federal agencies; units of State or local government; industrial organizations (including corporations,

¹ “Laboratory (-ies),” as used in this chapter, refers to “laboratory (-ies)” as described in the Federal Technology Transfer Act (FTTA) of 1986, 15 U.S.C. § 3701 et seq. As such, within the PHS, the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) are each a “laboratory.”

² See 15 U.S.C. § 3702.

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).” 15 U.S.C. § 3710a(a)(1).

2. Consistent with 15 U.S.C § 3710a, the following principles apply to PHS CRADAs:

a. Ensuring Research Freedom

PHS investigators generally are free to choose the subject matter of their research, consistent with the mission(s) of their PHS Agency (or Institute or Center) and the research programs of their laboratories. This policy applies to CRADAs as well, and laboratories and investigators have complete discretion to decline a CRADA collaboration.

b. CRADA Funding

PHS laboratories are authorized to accept, retain, and use funds, personnel, services, and property from a collaborating party and to provide personnel, services, and property to a collaborating party. 15 U.S.C. § 3710a(b)(3)(A). A CRADA is not intended to be the principal means of funding PHS research but may be used to defray the costs of the PHS CRADA research.

c. Scientific Communication and Dissemination of Research Results

It is fundamental to the mission of PHS that research results, including CRADA research results, be published and discussed at public fora.

d. Requirement of Intellectual Contribution by Collaborator

PHS CRADAs are authorized only with collaborators who will make significant intellectual contributions to the research project. Essential research materials or technical resources provided by the Collaborator that are not otherwise reasonably available to PHS can constitute such contributions.

e. Avoidance of Conflict of Interest

Conflicts of interest--actual or apparent--must be addressed and resolved in the review and approval of CRADAs.

f. Licensing of CRADA Subject Inventions

Pursuant to 15 U.S.C. § 3710a(b)(1), a PHS CRADA will typically provide the collaborating party with an exclusive option to negotiate an exclusive or a

nonexclusive license to PHS rights in CRADA subject inventions.³ These licenses should be consistent with applicable Agency policies, e.g., with respect to NIH licenses, the Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice (the “NIH Research Tools Policy”), 64 Fed. Reg. No. 68 72,090-72,096 (Dec. 23, 1999) and Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18,413-18,415 (Apr. 11, 2005), and other applicable policies.

g. Fair Access to CRADA Opportunities

The policy of PHS is to facilitate the development of CRADAs with a wide range of organizations. Consistent with PHS’s mission and in consideration of the preferences established by the FTTA, PHS will provide outside organizations a fair opportunity to pursue collaborative opportunities.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective February 11, 2021 and supersedes in its entirety the policy in PHS Technology Transfer Manual Chapter 400, which was first approved on January 25, 1996 and subsequently approved March 8, 2012.

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/contactus/contact_us.aspx. For more information specific to the Food and Drug Administration, contact TechTransfer@fda.hhs.gov. For more information specific to the Centers for Disease Control and Prevention contact tto@cdc.gov.

³ CRADA Subject Invention means any Invention of any party to the CRADA conceived or first actually reduced to practice in the performance of the CRADA Research Plan.