United States Public Health Service
Technology Transfer Manual
Chapter No. 401

PHS Policy for Promoting Fair Access to
Cooperative Research and Development Agreement Opportunities

A. PURPOSE

The purpose of this Public Health Service (PHS) Technology Transfer Manual Chapter is to establish guidelines for PHS Federal Laboratories to promote fairness in the process of initiating and developing a Cooperative Research and Development Agreement (CRADA).

B. BACKGROUND

The purpose of the Federal Technology Transfer Act of 1986 (FTTA) is to facilitate the transfer of commercially-useful technologies from the Federal Laboratories into the private sector as expeditiously as possible, for the purpose of strengthening U.S. competitiveness in high technology. A primary means of attaining this goal is through collaborations utilizing CRADAs. These agreements are intended to increase research and development interactions among Federal Laboratories and one or more other parties, including units of state or local government, public and private foundations, non-profit organizations, and private industry organizations. CRADAs involve joint participation in collaborative research projects, including the provision of personnel, services, and property. In addition, the collaborating organization, but not the Federal Government, may provide funding.

The FTTA gives the Federal Laboratories authority to negotiate terms and conditions of CRADAs with a wide range of parties. Although the legislation does not require that CRADAs must be competed, the law specifies that "special consideration" shall be given to small business firms and consortia involving small business firms, and preference be given to business units located in the United States which agree that products resulting from the CRADAs shall be manufactured substantially in the United States. FTTA gives no guidance as to how "special consideration" is to be given to small business. However, Federal Laboratories, in the process of executing CRADAs, should take into account the spirit of the law, the definition of "small business" set forth in the Small Business Act at 15 U.S.C. 631 et seq. and the implementing regulations of the Administrator of the Small Business Administration at 13 C.F.R. ' 121.

Congress was knowledgeable of the ways in which scientific collaborations arise, and intended that the policies governing CRADAs not impede the collaborative process. For that reason,

CRADAs were explicitly excluded from the policies governing federal procurement, and the FTTA is silent on the requirement to provide fair access. The Federal Laboratories, therefore, have considerable flexibility in determining how and with whom to enter into collaborations. However, the manner in which collaborators are selected is important to both the reality and appearance of fairness.

C. POLICY

The policy of the PHS is to facilitate the development of CRADAs with the private sector through a process that will promote fairness of access and attentiveness to the preferences established by the FTTA.

PHS distinguishes between providing general access for all qualified organizations to opportunities for CRADAs in the agencies, and providing a particular organization the opportunity to compete for a specific CRADA. Each PHS Federal Laboratory should strive to demonstrate that no entity is excluded *prima facie* from the possibility of being a CRADA partner, but it is neither necessary nor acceptable to require that each CRADA proposal or opportunity be advertised. PHS does not require public notification of the intent to initiate a CRADA with a particular collaborator, nor does it require that the basis of a particular CRADA shall have been the subject of a prior public announcement.

Many productive CRADAs between government and industry scientists have grown from informal collaborations, and it is essential that this avenue of CRADA development continue and be encouraged. PHS policy is not intended to inhibit the traditional means of CRADA development from scientific collaborations, but to promote participation in CRADAs by a wide range of organizations, many of which do not have established relationships with PHS scientists.

D. GUIDELINES

There are many ways to meet the goal of providing fair access. One important means is by restricting the scope of CRADAs to provide increased opportunities. Other methods include making available to the public compilations of CRADA opportunities, areas of ongoing research, and scientists potentially interested in CRADAs; scientific publications and presentations at meetings; participation by scientists, technology managers, and administrators in industry fora; and advertising requests for CRADA partners for development of a specific technology.

CRADAs should be restricted in scope to the greatest extent possible. The intent is to deter a sole CRADA partner from obtaining intellectual property rights to a broad area of PHS research or a multiple use technology. This will enable several companies to have CRADAs in narrowly defined research areas, which potentially would increase competition in product development. The number of CRADAs a particular company already has with the Federal Laboratory may be considered during the CRADA review process, but is not a de facto prohibition on new CRADAs with that company (there should not be any prior restrictions on the total number of CRADAs with one company).

This section sets forth the types of activities that PHS Federal Laboratories should undertake to provide access to CRADA opportunities. Laboratories also may implement other appropriate means of promoting fairness of access which are not specifically mentioned here.

1. Public Notification Activities

PHS Federal Laboratories encourage formal collaborations with outside organizations under CRADAs. Through the widespread availability of scientific publications and public presentations from the PHS Laboratory, companies are made aware of potential CRADA opportunities, and this is a powerful fair access tool. Companies interested in collaborating with PHS scientists typically are vigilant of their scientific activities. These companies actively follow public scientific meetings, the scientific literature, clinical activities newsletters, pharmaceutical trade publications, the Official Gazette of the Patent and Trademark Office, the *Federal Register*, and myriad sources of timely information on current scientific activity. Suggested additional public notification activities are described below.

a. Routine Publication

Each PHS Laboratory should implement a process for periodically informing outside parties of available collaborative opportunities and for encouraging access to the Federal Laboratories by industry. PHS Laboratories are encouraged to use at least one of the following activities on a regular basis:

(i) General Announcements

Publish an announcement which generally outlines the types of research opportunities available for collaboration and identifies a central point for interested parties to contact. General announcements may be made

through the National Technology Transfer Center; *Federal Register*; scientific, professional, and trade journals; and association publications.

(ii) Industry Collaboration Forum

Conduct or participate in an Industry Collaboration Forum to bring together interested PHS Laboratory scientists and private sector company or other outside representatives. PHS Laboratories which sponsor symposia on their intramural research programs which are open to the public, such as the National Institutes of Health (NIH) Research Day, could extend the duration and invite industry to attend a special session which would include those scientists interested in potential CRADA collaborations.

(iii) Directory Listing

Develop a directory listing of potential PHS Laboratory scientist collaborators, areas of research interests, and PHS patents available for licensing.

(iv) Electronic Network Listing

Publish the information specified in Directory Listings on one or more electronic bulletin boards or Internet locations for general public access. This method has major advantages, such as timeliness of information, lower cost to the agencies, and rapid access by the public.

b. Special Announcements

Under certain circumstances, a PHS Laboratory may decide that its interests are best served by making a special announcement of a CRADA opportunity. Such circumstances include the following examples:

(i) A PHS Laboratory initiates a major research effort and seeks collaborations with private sector organizations in an area that may or may not be a topic of a current routine announcement.

(ii) A PHS Laboratory holds proprietary rights in a technology developed without industry collaboration, and seeks a CRADA partner to develop the technology as a commercial product.

Special announcements should describe the specific purpose of the collaboration and should provide interested organizations the opportunity to submit proposals. Announcements may be made in the *Federal Register*; scientific, professional, and trade journals; association publications; press releases or other appropriate media.

General guidance on when public notification activities might be initiated by the PHS Laboratory are included in the Appendix.

2. Training Program

Each PHS Laboratory should establish an ongoing training and education program to ensure that PHS Laboratory scientists are informed about the FTTA and are aware of the preferences for small and U.S. businesses outlined in the law.

Since the FTTA permits and encourages new types of relationships to bridge industry and government research, the training program should also include guidance on CRADA relationships which might be subject to conflict of interest regulations.

3. Internal Review Process

Each PHS Laboratory should establish an internal CRADA review process at a level above the organizational unit of the principal investigator. This process should ensure that CRADAs are reviewed for their scientific value and for the suitability of the selected collaborator.

a. Documentation

The documentation which forms the CRADA record should include an indication of why the particular outside collaborator was selected, such as expertise, special ability to bring to market unique ideas, or proprietary resources. The documentation also should include a description of the actions of the Federal Laboratory which led to the selection of the collaborator. The documentation should be reviewed as part of the CRADA process by the PHS scientist=s ethics officer.

b. Prior Relationships

Previous collaborations between an agency scientists and staff of a potential CRADA partner, including paid consultation, should not de facto preclude a CRADA with that company. However, under 18 U.S.C. Section 208, a PHS scientist may not discuss a potential CRADA until any current personal financial interest or outside activity with the organization is terminated. The agency review of such a proposed CRADA, including a review by the scientist's ethics officer, should have an analysis of any prior relationships, taking into account the natural evolutions of collaborations in the scientific community, and the investment the proposed CRADA partner may have in a technology by virtue of a pre-existing collaboration. If the agency scientist had an arrangement with the company which was not part of his official duties, and the proposed CRADA partner is not the only capable company, then to avoid the appearance of conflict of interest or unfair access the proposed CRADA may be advertised, and selection of the CRADA partner made without regard to the prior relationship.

c. Selection Criteria

In those cases where the Federal Laboratory elects to advertise a particular CRADA opportunity, special effort should be made to provide fair access to all respondents. Specific selection criteria may be developed, and these criteria should be applied rigorously and fairly to all applicants. Care should be taken to assure that criteria do not unnecessarily exclude small business applicants.

E. EFFECTIVE DATE

The policies and procedures set forth in this Manual Chapter are effective immediately.

F. ADDITIONAL INFORMATION

For more information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301) 496-7057. Questions on entering into a particular CRADA may be directed to the appropriate PHS Technology Development Coordinator.

APPENDIX

Public Notification Guidance

Conditions which exist prior to advertisement:	**Notification:** Routine	Special
No proprietary rights exist. Research area may or may not have been routinely advertised. A CRADA collaborator has been identified.	*No*	*No*
No proprietary rights exist. Research area might support a CRADA, but none is currently envisioned. No collaborator is actively sought.	*Maybe*	*No*
No proprietary rights exist. Research area is of active interest to the Federal Laboratory. A CRADA would be of potential benefit, but no collaborator has been identified.	*Yes*	*Maybe*
No proprietary rights exist. Research area is of urgent interest to the Federal Laboratory. A CRADA is actively sought, but no collaborator has been identified.	*Yes*	*Yes*
Federal Laboratory has exclusive proprietary rights. A CRADA is necessary for development. A collaborator has been identified.	*No*	*Maybe*
Federal Laboratory has exclusive proprietary rights. A CRADA is necessary for development. A collaborator is to be actively sought, but none has been identified.	*Yes*	*Yes*
Private organization has exclusive proprietary rights or other essential resources not otherwise available. Federal Laboratory is sought as collaborator.	*No*	*No*