# PUBLIC HEALTH SERVICE
# CENTERS FOR DISEASE CONTROL AND PREVENTION
# POLICY STATEMENT ON
# COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS
# AND INTELLECTUAL PROPERTY LICENSING

This Statement sets forth the policies of the Public Health Service and the Centers for Disease Control and Prevention (CDC) on various aspects of cooperative research and intellectual property licensing. These policies apply to the negotiation of CDC Cooperative Research and Development Agreements (CRADAs). License agreements for intellectual property rights to inventions developed under a CRADA or through the CDC intramural research programs, whether negotiated by NIH, CDC or the National Technical Information Service on its behalf, will also incorporate these policies. This Statement may be revised from time to time as PHS and CDC considers appropriate.*

To implement the Federal Technology Transfer Act of 1986, (FTTA, 15 U.S.C. at § 3710), Executive Order 12591 of April 10, 1987 orders Federal laboratories to assist universities and the private sector in broadening our national technology base by moving new knowledge from the research laboratory into the development of new products and processes. While Federal patent law (35 U.S.C. at §§ 200-212) authorizes the licensing of Government-owned patent rights, the FTTA seeks to facilitate technological collaboration at an earlier stage. Thus, the FTTA authorizes Federal laboratories to enter into CRADAs and to agree to grant intellectual property rights in advance to collaborators for inventions made in whole or part by Federal employees under the CRADA. Besides assisting in the transfer of commercially useful technologies from Federal laboratories to the marketplace, CRADAs make outside resources more accessible to Federal laboratories.

CDC, an agency of PHS within the Department of Health and Human Services (DHHS), is among the world's preeminent biomedical research organizations. Its general mission is to conduct biomedical and behavioral research that will lead to the better health of the American people. For the CDC investigator, this agency mission prescribes the exploration of ideas, the communication of ideas and information to colleagues, and a responsibility for the prompt and accurate publication of findings. Under the FTTA, 15 U.S.C. at § 3710a(a)(2), technology transfer, consistent with mission responsibilities, is also a responsibility of each laboratory science and engineering professional. To support its mission, CDC has developed an interdisciplinary and synergistic research environment that promotes the free exchange of ideas and information. In order to safeguard the collegiality and integrity of, as well as public confidence in, the CDC research programs, the following cooperative research and technology transfer policies have been adopted.

## 1. RESEARCH FREEDOM

CDC investigators generally are free to choose the subject matter of their research, consistent with the mission of their Institute and the research programs of their Laboratories. No CRADA or license agreement may contravene this freedom.

*Questions or comments about this Statement and requests for updated versions should be directed to the CDC Technology Transfer Office at (404)639-6270. This Statement is effective on an interim basis.

## 2. RESEARCH POLICY

CDC research results generally are disseminated freely through publication in the scientific literature and presentations at public fora. Brief delays in this dissemination of research results may be permitted under a CRADA as necessary in order to file corresponding patent or other intellectual property applications. CDC considers the filing of such applications to be an important component of its research efforts.

## 3. COOPERATIVE RESEARCH AND DEVELOPMENT UNDER A CRADA

As defined by the FTTA, 15 U.S.C. § at 3710a(d)(1), a CRADA means any agreement between one or more Federal laboratories and one or more non-Federal parties, under which the Government provides personnel, services, facilities, equipment, or other resources (but not funds), and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts. Cooperative research and development activities are intended to facilitate the transfer of Federally funded research and development for use by State and local governments, universities, and the private sector, particularly small business.

## 4. CDC CRADAS

As adopted by CDC, a CRADA is a standardized agreement intended to provide an appropriate legal framework for, and to expedite the approval of, cooperative research and development projects. The use of CRADAs is encouraged for cooperative efforts because they permit CDC to accept, retain, and use funds, personnel, services, and property from collaborating parties and to provide personnel, services, and property to collaborating parties. CDC may permit investigators to enter into CRADAs with collaborators who will make a significant intellectual contribution to the research project undertaken or who will contribute essential research materials or technical resources not otherwise reasonably available. While CDC welcomes contributions to its gift funds for research purposes, it does not view CRADAs as a general funding source or a mechanism for sponsored research. This approach to implementing the FTTA has been chosen in order to maintain the public's confidence in CDC through maintaining an independence from reliance on industry funding.

## 5. SELECTION OF COLLABORATORS UNDER A CRADA

Collaborations under a CRADA may be suggested by potential collaborators or by CDC investigators. Generally, the decision to initiate the approval process for a CRADA is made by the involved CDC investigator and Laboratory Chief based on scientific considerations and the desire for the public to benefit from the commercialization of particular CDC research. For some cooperative projects, where the development and commercialization potential is more immediate relative to the basic research aspects, CDC may seek a collaborator(s) which has both scientific expertise and commercialization capabilities. In certain areas of research, *e.g.*, where the Government has the intellectual lead or where both scientific and commercialization capabilities are deemed essential at the outset, CDC may competitively seek a collaborator through *Federal Register* notification. The PHS has also developed policy guidelines for ensuring fairness of access to PHS laboratories such as CDC in the process of initiating and developing CRADAs.

## 6. PROPRIETARY OR CONFIDENTIAL INFORMATION AND MATERIALS

CDC recognizes that an effective collaborative research program may require the disclosure of proprietary information to CDC investigators. Although agreements to maintain confidentiality are permitted under a CRADA, collaborators should limit their disclosure of proprietary information to the amount necessary to carry out the research plan of the CRADA. The mutual exchange of confidential information, *e.g.*, patient data, should be similarly limited. CDC also recognizes that cooperative research may require the exchange of proprietary research materials. Such materials may be used only for the purposes specified in the research plan set forth in the CRADA. All parties to the CRADA will agree to keep CRADA research results confidential to the extent permitted by law until they are published in the scientific literature or presented at a public forum.

## 7. TREATMENT OF DATA AND RESEARCH

*Products Produced under a CRADA:* The CDC investigator and the collaborator will agree to exchange all data and research products developed in the course of research under a CRADA whether developed solely by CDC, jointly with the collaborator, or solely by the collaborator. In general, tangible research products developed under a CRADA will be shared equally by the parties to the CRADA. All parties to a CRADA will be free to utilize such data and research products for their own purposes. Data and research products developed solely by the collaborator may be designated as proprietary by the collaborator when they are wholly separable from the data

and research products developed jointly with CDC investigators; however, except as may be afforded through intellectual property rights that require public disclosure of the protected subject matter (*e.g.*, patents), CDC will not agree to exclude others from utilizing or commercializing the data or research products developed solely by CDC investigators or jointly with the collaborator under a CRADA.

## 8. OWNERSHIP AND LICENSING OF CDC INTELLECTUAL PROPERTY RIGHTS

Pursuant to the FTTA, 15 U.S.C. at § 3710a(b)(2), a Federal laboratory is authorized to own and license patent rights to inventions made in whole or part by its employees under a CRADA. The term "invention" is defined at § 3703(9) to mean any invention or discovery which is or may be patentable or otherwise protected under Title 35 or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (PVPA), 7 U.S.C. § 2321 *et seq*. The patent law, 35 U.S.C. at § 207, authorizes the ownership and licensing of intramural inventions. Executive Order 12591 at § 1(b)(1)(B) further authorizes the transfer of Government intellectual property rights. Although the FTTA speaks broadly of the transfer of "technology," CDC does not have statutory authority to license (or to agree to limit dissemination of) technology developed in whole or part by its investigators under a CRADA unless a patent, PVPA certificate or other intellectual property application has been filed for that technology. CDC will retain the Government ownership interest in, but not license rights to, all intellectual property rights to inventions developed solely through intramural research or developed in whole or in part by its investigators under a CRADA.

## 9. GENERAL LICENSING POLICY

CDC recognizes that under the FTTA and the patent licensing law to which it refers, Congress and the President have chosen to utilize the patent system as the primary mechanism for transferring Government inventions to the private sector. The importance of patents to commercialization in the biomedical field is further reflected by the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417). A fundamental principle of the patent system is that the owner of a patent have a time-limited "right to exclude others from making, using, or selling the [patented] invention." The reason for such a period of exclusivity is to encourage industry to invest the resources necessary to bring an invention from the discovery stage through subsequent development, clinical trials, regulatory approvals, and ultimately into commercial production. CDC accordingly is willing to grant exclusive commercialization licenses under its patent or other intellectual property rights in cases where substantial additional risks, time and costs must be undertaken by a licensee prior to commercialization. Under a CRADA, CDC is also willing to agree to grant exclusive commercialization licenses in advance to collaborators. CDC will attempt, however, to license its intramural inventions nonexclusively in cases where an invention reflects a relatively more advanced stage in its commercial development, *e.g.*, when an CDC investigator invents a patentable new therapeutic use for a known and FDA-approved compound.

Federal laboratories are authorized to negotiate license agreements for Government-owned patent rights in intramural inventions pursuant to 35 U.S.C. § 207. Although § 207 does not apply to intellectual property license agreements authorized by the FTTA for inventions made under a CRADA, CDC has adopted the following approach of § 207 for all license agreements:

> Each Federal Agency [may] ... grant nonexclusive, exclusive, or partially exclusive licenses under Federally owned patent applications, patents, or other forms of protection ... on such terms and conditions ... as determined appropriate in the public interest.

CDC has determined it to be appropriate in the public interest to grant nonexclusive research licenses and either exclusive or nonexclusive commercialization licenses to DHHS-owned intellectual property rights according to the plan discussed below.

## 10. GOVERNMENT INTELLECTUAL PROPERTY RIGHTS

For inventions developed wholly by CDC investigators or jointly with a collaborator under a CRADA, CDC is required by the FTTA at 15 U.S.C. § 3710a(b)(2) to retain at least a nonexclusive, irrevocable, paid-up license to practice the invention or to have the invention practiced throughout the world by or on behalf of the U. S. Government. When granting exclusive or partially exclusive licenses to CDC intramural inventions, 35 U.S.C. § 208, as implemented by 37 C.F.R. § 404.7(2)(i), requires the reservation of similar Government rights. CDC will not assert an ownership right in inventions made solely by a collaborator under a CRADA, but will require the grant of a research license, as described below, to the Government for inventions made wholly by a collaborator under a CRADA.

## 11. RESEARCH LICENSES

CDC will reserve the right under any CRADA and intellectual property license to grant nonexclusive licenses to make and to use the invention for purposes of research involving the invention itself, and not for purposes of commercial manufacture or in lieu of purchase as a commercial product for use in other research. The purpose of the research license is to facilitate basic academic research. CDC intends to consult with any involved commercialization licensee(s) before granting research licenses to commercial entities.

## 12. COMMERCIALIZATION LICENSES

CDC is willing to consider requests for nonexclusive or exclusive commercialization licenses to intellectual property rights to inventions developed under a CRADA or in the course of intramural research, pursuant to applicable statutes and regulations. Under a CRADA, CDC generally will grant a time-limited option to negotiate, in good faith, the terms of a license that fairly reflects the relative contributions of the parties, the risks incurred by the collaborator, and the costs of subsequent research and development needed to bring the results of CRADA research to the marketplace. CDC contemplates the drafting of a model invention license to serve as the starting point for license negotiations. It is contemplated further that such a model will reduce negotiations essentially to matters of execution fees, royalty rates, and minimum annual royalties. Royalty rates will be based on product sales and the rates conventionally granted in the field identified in the CRADA's research plan for inventions with reasonably similar commercial potential. Royalty rates generally will not exceed a rate within the range of 5 - 8 % for exclusive commercialization licenses. Contingent royalty schemes based on, *e.g.*, patent issuance or nonissuance, and clauses treating the stacking of royalties or packaging of other inventions developed under the CRADA may be provided. Exclusive licensees will be expected to reimburse CDC for intellectual property related expenses, and may be permitted to offset such reimbursement against future product royalties.

## 13. NONEXCLUSIVE COMMERCIALIZATION LICENSES

Unless a request for exclusive commercialization license is made under a CRADA or submitted for an intramural invention, CDC will attempt to license its inventions nonexclusively. Such nonexclusive licenses generally will follow the guidelines of 37 C.F.R. Part 404.

## 14. EXCLUSIVE COMMERCIALIZATION LICENSES

All CDC exclusive commercialization licenses will require the submission by a prospective licensee of an acceptable development and commercialization plan as described by 35 U.S.C. § 209(a) and subsequent, periodic reports on utilization of the invention as described by § 209(f)(1). All such plans and reports will be treated in confidence and as privileged from disclosure under the Freedom of Information Act. Modification provisions as described by § 209(f)(2)-(4) may apply. In appropriate cases, CDC may also reserve the right to grant separate exclusive commercialization licenses in various fields of use. The remaining provisions of 35 U.S.C. §§ 200-212 will also apply to licenses to CDC intramural inventions.

CDC also considers the following provisions for exclusive commercialization licenses to be necessary and appropriate in the public interest:

(i) the exclusive licensee must pledge its reasonable best efforts to commercialize a licensed invention and the development and commercialization plan mentioned above may serve as the measure of such efforts;

(ii) CDC shall have the right, after notice and opportunity to cure, to terminate or render nonexclusive any license granted: *1)* if the licensee is not reasonably engaged in research, development, clinical trials, manufacturing, marketing, sublicensing, or other activities reasonably necessary to the expeditious commercial dissemination of the licensed invention; or *2)* when the licensee cannot reasonably satisfy unmet health and safety needs;

(iii) in order to maximize the commercialization of the licensed invention in other fields of use not utilized by the exclusive licensee through ongoing development, manufacturing or sublicensing, CDC reserves the right to require the licensee to grant sublicenses to responsible applicants, on reasonable terms, in such other fields of use, unless the licensee can reasonably demonstrate that such a sublicense would be contrary to sound and reasonable business practice and the granting of the sublicense would not materially increase the availability to the public of the licensed invention; and

(iv) exclusive licensees to DHHS inventions, whether developed under a CRADA or through

intramural research, must agree to not unreasonably deny requests for sublicense or cross license rights from future CRADA collaborators when the possibility of acquiring such derivative rights is necessary in order to permit a proposed cooperative research project with CDC to go forward, and the exclusive licensee has been given a reasonable opportunity to join as a party to the proposed CRADA

## 15. COMPLIANCE UNDER A CRADA WITH OTHER POLICIES

For research conducted pursuant to a CRADA, collaborators must agree to comply with PHS and CDC policies and guidelines concerning, *e.g.*, human subjects research, the use of research animals including nonwild chimpanzees, recombinant DNA and other policy statements as may be promulgated from time to time.

## 16. WAIVERS

CDC will consider requests to modify any of the foregoing policies in special cases where public health exigencies or commercial situations warrant such a modification. Modifications dealing with business terms such as royalties are not decided by the CDC investigators and should be discussed with the appropriate CDC technology management personnel.

## 17. SPECIAL CONSIDERATION AND PREFERENCE UNDER A CRADA

CDC will give special consideration to entering into CRADAs with small business firms and consortia involving small business firms, and will give preference to business units located in the United States which agree to manufacture substantially in the United States products which embody inventions developed in the course of research under CRADAs.