following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and of CLIA Exemption Under State Laboratory Programs and Supporting Regulations in 42 CFR 493.551–493.557; Form No.: HCFA-R–185 (OMB# 0938–0686); Use: The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation/licensure process is equal to or more stringent than those of CLIA. This information also provides a CLIA exemption of laboratories in a State that applies licensure requirements that are equal to or more stringent than those of CLIA; *Frequency:* Initial Application/as needed; *Affected Public*: Not-for-profit institutions, and State, Local, or Tribal Government; *Number of Respondents:* 22; *Total Annual Responses:* 11; *Total Annual Hours:* 2,112.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: October 19, 1998.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

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**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Notice of Opportunities for Cooperative Research and Development Agreements

National Cancer Institute: Opportunities for Cooperative Research and Development Agreements (CRADAs) for the development and evaluation of allogeneic whole melanoma cell vaccines based on the expression of shared tumor-associated antigens in association with GM–CSF as potential treatments for cancer.

**AGENCY:** National Institutes of Health, PHS, DHHS.

**ACTION:** Notice of Opportunities for Cooperative Research and Development Agreements.

**SUMMARY:** Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks Cooperative Research and Development Agreements (CRADAs) with pharmaceutical or biotechnology companies.

Any CRADA for the biomedical use of this technology will be considered. The CRADAs would have an expected duration of three (3) to five (5) years. The goals of the CRADAs include the rapid publication of research results and timely commercialization of products, diagnostics and treatments that result from the research. The CRADA Collaborators will have an option to negotiate the terms of an exclusive or nonexclusive commercialization license to subject inventions arising under the CRADAs.

**EFFECTIVE DATE:** Organizations must submit a proposal summary preferably one page or less, to NCI within two weeks from date of this publication. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents with whom initial discussions will have established sufficient mutual interest.

**ADDRESSES:** Proposals and questions about this CRADA opportunity may be addressed to Dr. Suzanne M. Frisbie, Technology Development & Commercialization Branch, National Cancer Institute, 6120 Executive Blvd., Suite 450, Rockville, MD 20852, Telephone: (301) 496–0477, Facsimile: (301) 402–2117.

**SUPPLEMENTARY INFORMATION:**

#### Technology Available

Using recombinant DNA technology, NCI has cloned a number of shared (commonly expressed) melanoma-associated antigens recognized by immune cells derived from melanoma patients and thought to be associated with tumor regressions in patients undergoing immunotherapy. These antigens include MART–1, gp100, gp75, tyrosinase, TRP–2, and others. NCI has extensive experience in the design and conduct of clinical trials to assess the potential efficacy of vaccine treatments, and has unique expertise in developing *in vitro* immunologic assays to monitor the results of such treatments. NCI has identified select cultured melanoma cell lines which express a plurality of shared melanoma antigens and desires to develop these cell lines, or similar cell lines, as allogeneic whole cell vaccines for the treatment of melanoma. Furthermore, based on extensive preclinical experimentation demonstrating the unique efficacy of whole tumor cell vaccines genetically engineered to secrete large amounts of the immunostimulatory cytokine GM–CSF, NCI desires to administer allogeneic whole melanoma cell vaccines engineered to secrete this cytokine. Published data document the importance of $CD4^+$ T helper cells in anti-tumor immune responses in the context of GM–CSF-secreting whole tumor cell vaccines. NCI has special expertise in defining T helper cell responses to human cancers and is on the forefront of developing biochemical and molecular cloning strategies for identifying novel MHC class II-restricted tumor antigens. Thus, the selected sponsor will collaborate in a project aimed to develop GM–CSF-secreting melanoma cell lines for use in human vaccination trials, to monitor the immunological effects of such vaccination, and to develop improved *in vitro* methods for characterizing T helper cell responses to such a vaccine.

The role of the National Cancer Institute in this CRADA may include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience related to human melanoma cell cultures expressing shared melanoma antigens.

2. Providing human melanoma cell cultures shown to express several shared melanoma antigens.

3. Engineering the cell cultures to secrete large quantities of human GM–CSF using a vector supplied by the CRADA Collaborator.

4. Conducting Phase I/II clinical trials in melanoma patients to evaluate the therapeutic efficacy of allogeneic whole melanoma cell vaccines expressing multiple shared melanoma-associated antigens in association with GM–CSF, using vaccines manufactured by the Collaborator.

5. Developing model *in vitro* systems to optimize methods to monitor T helper cell immunity based on nominal antigens in normal donors and cancer patients. Applying these model *in vitro* systems to study and characterize immune responses generated in vaccinated patients as part of the Phase I/II clinical trials.

6. Publishing research results.

The role of the CRADA Collaborator may include, but not be limited to:

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project.

2. Obtaining a background license in the appropriate fields of use to the relevant Government patent rights.

3. Providing an efficient vector for introducing the gene encoding human GM–CSF into select melanoma cell lines for vaccine development.

4. Manufacturing GMP certifiable GM–CSF-transduced whole melanoma cell vaccines for the conduct of Phase I/II clinical trials at the NCI, including all necessary pre-clinical safety information and preparation, filing, and maintaining of the Drug Master File or IND as required for gene therapy clinical studies.

5. Providing peripheral blood lymphocytes and serum from select vaccinated patients for *in vitro* use in NCI studies of T helper cell reactivities to shared melanoma antigens, if the Collaborator also sponsors clinical trials outside the NCI.

6. Providing technical and financial support to facilitate scientific goals and for further design of applications of the technology outlined in the agreement.

7. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but not be limited to:

1. The ability to collaborate with NCI on the research and development of this technology and obtain a background license to relevant NCI patent rights. The ability to collaborate with NCI can be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development. The licensing contact at the Office of Technology Transfer is Elaine Gese (301–496–7735).

2. The demonstration of adequate resources to perform the research and development of this technology (e.g. facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.

3. The willingness to commit best effort and demonstrated resources to the research and development of this technology, as outlined in the CRADA Collaborator's proposal.

4. The demonstration of expertise in the commercial development and production of products related to this area of technology.

5. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.

6. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.

7. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.

8. The willingness to accept the legal provisions and language of the CRADA with only minor modification, if any. These provisions govern the distribution of patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a license for research and other Government purposes to the Government when the CRADA Collaborator's employee is the sole inventor, or (2) the grant of an option to elect an exclusive or nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: October 15, 1998.

**Kathleen Sybert,**

*Acting Director, Office of Technology Development, National Cancer Institute, National Institutes of Health.*

[FR Doc. 98–28711 Filed 10–26–98; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

### National Toxicology Program; National Institute of Environmental Health Sciences (NIEHS); National Institute of Health (NIH) Notice of Meeting to Review the Corrositex® Assay as an Alternative Test Method for Assessing the Skin Corrosivity Potential of Chemicals; Request for Comments

**SUMMARY:** Pursuant to Public Law 103–43, notice is hereby given of a public meeting sponsored by the NIEHS and the National Toxicology Program (NTP), and coordinated by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the NTP Interagency Center for the Evaluation of Alternative Toxicology Methods (NICEATM). The agenda topic is the scientific peer review of the Corrositex® assay, which is proposed as an in vitro alternative toxicological test method for assessing the skin corrosivity potential of chemicals and products. The meeting will be held on January 21, 1999, at the Natcher Center, National Institute of Health, 45 Center Drive, Bethesda, MD, 20892. The meeting will take place from 8:30 a.m. to 5:30 p.m. and is open to the public.

#### Background

Public Law 103–43 directed the NIEHS to develop and validate alternative methods that can reduce or eliminate the use of animals in acute or chronic toxicity testing, establish criteria for the validation and regulatory acceptance of alternative testing methods, and recommend a process through which scientifically validated alternative methods can be accepted for regulatory use. Criteria and processes for validation and regulatory acceptance were developed in conjunction with 13 other Federal agencies and programs with broad input from the public. These are described in the document ''Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the Ad Hoc Interagency Coordinating Committee on the Validation of Alternative Methods'' NIH publication 97–3981, March 1997, which is available on the internet at http://ntp-server.niehs.nih.gov/htdocs/ICCVAM/ICCVAM htm. Additional information on ICCVAM and NICEATM can be found through the ICCVAM/NICEATM web site http://iccvam.niehs.nih.gov.

An Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) was