

any State compensation program, under an insurance policy, or under any Federal or State health benefits program, or (2) by an entity that provides health services on a prepaid basis.

#### General Use of Grant Funds

States may use the HIV Care Grant funds to:

- Establish and operate HIV care consortia within areas most affected by HIV. The statute defines a consortium as an association of one or more public, and one or more nonprofit private health care and support service providers and community-based organizations operating within areas determined by the State to be most affected by HIV disease.

- Provide home- and community-based care services for individuals with HIV disease. Funding priorities must be given to entities that provide assurances to the State that they will participate in HIV care consortia if such consortia exist within the State, and will utilize the funds for the provision of home- and community-based services to low-income individuals with HIV disease.

- Provide assistance to assure the continuity of health insurance coverage for low-income (as defined by the State) individuals with HIV disease. The State must establish a program that assures that (1) funds will be targeted to individuals who would not otherwise be able to afford health insurance coverage, and (2) income, asset, and medical expense criteria will be established and applied by the State to identify those individuals who qualify for assistance, and information concerning such criteria shall be made available to the public.

- Provide treatments that have been determined to prolong life or prevent serious deterioration of health for low-income individuals with HIV disease.

A State must use at least 15 percent of its grant funds to provide health and support services to infants, children, women and families with HIV disease.

At least 75 percent of the fiscal year 1996 Title II grant awarded to a State must be obligated to specific programs and projects and made available for expenditure within 120 days of the receipt of the grant by the State.

#### Federal Smoke-Free Compliance

The Public Health Service strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

#### Executive Order 12372

It has been determined that the Title II HIV Care Grant Program is not subject to the provisions of Executive Order 12372 concerning inter-governmental review of Federal programs. The Catalog of Federal Domestic Assistance Number is 93.917.

Dated: October 29, 1996.

Ciro V. Sumaya,  
*Administrator.*

[FR Doc. 96-28217 Filed 11-1-96; 8:45 am]

BILLING CODE 4160-15-P

#### National Institutes of Health

##### Proposed Collection; Comment Request; Women's Health Initiative Observational Study

**SUMMARY:** In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, which provides for an opportunity for public comment on proposed data collection projects, the Office of the Director (OD), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**PROPOSED COLLECTION:** Title: Women's Health Initiative (WHI) Observational Study. Type of Information Collection Request: Revision OMB #0925-0414 Exp: 6/97 Need for Use of Information Collection: This study will be used by NIH to evaluate risk factors for chronic disease among older women by developing and following a large cohort of postmenopausal women and relating subsequent disease development to baseline assessments of historical, physical, psychosocial, and physiologic characteristics. In addition, the observational study will complement the clinical trial (which has received clinical exemption) and provide additional information on the common causes of frailty, disability and death for postmenopausal women, namely, coronary heart disease, breast and colorectal cancer, and osteoporotic fractures. Frequency of Response: On occasion. Affected Public: Individuals and physicians. Type of Respondents: Women, next of kin, and physicians office staff. The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual hours requested
OS Participants .....	100,000	1.06	.828	88,348
Next-of-Kin .....	2,682	1	.084	225
Physician's Office Staff .....	166	1	.084	14
Total .....				88,614

The annualized cost burden is: \$882,505.

The estimated annual Capital Costs, Operating Costs and/or Maintenance Costs is: \$10,342,000.

**REQUEST FOR COMMENTS:** Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection is necessary for the

proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of

information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

#### FOR FURTHER INFORMATION CONTACT:

To request more information on the proposed project or to obtain a copy of the data collection plan and instruments, contact: Dr. Loretta

Finnegan, Women's Health Initiative Program Office, 7550 Rockville Pike, Room 6A09, Bethesda, Maryland 20892-9110 or call non-toll-free number (301) 402-2900, or E-mail your request, including your address to: <FinnegaL@od31em1.od.nih.gov>.

**COMMENTS DUE DATE:** Comments regarding this information collection are best assured of having their full effect if received on or before January 3, 1997.

Dated: October 23, 1996.

Stephen Benowitz,

*Executive Officer, OD.*

[FR Doc. 96-28273 Filed 11-1-96; 8:45 am]

BILLING CODE 4140-01-M

### **National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (CRADA) for B-Cell Lymphoma Tumor Specific Antigen Studies**

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

**ACTION:** Notice.

**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 a Cooperative Research and Development Agreement (CRADA) with a pharmaceutical or biotechnology company. A major goal of the CRADA is to develop strategies to isolate B-cell lymphoma tumor specific antigen. The CRADA would have an expected duration of one (1) to five (5) years. The goals of the CRADA include the rapid publication of research results and the timely commercialization of any products, diagnostics and treatments that result from the research.

**ADDRESSES:** Proposals and questions about this CRADA opportunity may be addressed to Gary Cuchural, Office of Technology Development, National Cancer Institute-Frederick Cancer Research and Development Center, P.O. Box B, Frederick, MD 21702-1201, Telephone: (301) 846-5465, Facsimile: (301) 846-6820.

**EFFECTIVE DATE:** In view of the high interest in developing Anti-Cancer Vaccines in general, interested parties should notify the NCI Office of Technology Development in writing no later than December 4, 1996.

**SUPPLEMENTARY INFORMATION:** A major research goal of this CRADA is the

development of strategies for the isolation of lymphoma derived Ig protein, including for example, the molecular cloning of Ig variable regions for expression in eukaryotic and prokaryotic cells. Another major research goal of this CRADA is the development and implementation of procedures for the GMP production of Ig protein. GMP Ig protein will be produced in sufficient quantities to support vaccine formulation studies. Vaccine formulation studies with one of several carriers, final vaccine production, and/or testing may also be among the research goals of this CRADA.

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

1. Providing intellectual, scientific, and clinical expertise and experience to the research project.

2. Planning and conducting research studies and interpreting research results.

3. Publishing research results.

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

1. Providing intellectual, scientific, and regulatory expertise and experience to the research project.

2. Planning and conducting research studies and interpreting research results.

3. Providing support for CRADA-related research. Such support may include personnel and/or financial support to facilities scientific goals. Such support should include the availability of GMP manufacturing facilities for this effort, such support should also include assuming the cost of production of GMP Ig protein in sufficient quantities to support vaccine formulation studies. If vaccine formulation studies with one of several carriers, final vaccine production and/or testing are among the research goals of this CRADA, such support should also include assuming the cost of production of GMP vaccines in sufficient quantities to support these goals.

4. The experience and financial ability to support an IND.

5. 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 research and development of this technology. This ability 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.

2. The demonstration of adequate resources to perform the research,

development and commercialization 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, development and commercialization of this technology.

4. The demonstration of expertise in the commercial development, GMP production, marketing and sales of patient-specific 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 modifications, if any. These provisions govern the equitable 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 non-exclusive license 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 24, 1996.

Thomas D. Mays,

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

[FR Doc. 96-28275 Filed 11-1-96; 8:45 am]

BILLING CODE 4140-01-M

### **Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development.

**ADDRESSES:** Licensing information and a copy of the U.S. patent applications referenced below may be obtained by