makers in understanding the practice of organ donation nationwide. Results of the survey will be reported confidentially, either in the aggregate or stripped of individual identifiers. *Frequency of Response:* Once. *Affected Public:* Business or other for-profit; Not-for-profit institutions; Federal Government. *Type of Respondents:* OPOs. 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 burden hours requested
OPOs (directors of procurement or executive directors)	62	1	0.5	31
Total	62			31

The annualized cost to respondents is estimated at; $3,000,00. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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 of information 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.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, D.C. 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. David Wendler, Department of Clinical Bioethics, DCB, CC, NIH, Building 10, Room 1C 118, 9000 Rockville Pike, Bethesda, MD 20892–1156, or call non-toll-free number (301) 435–8726 or e-mail your request, including your address to: dwendler@nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before May 10, 1999.

Dated: March 16, 1999.

David K. Henderson,

Deputy Director, Warren G. Magnuson Clinical Center, National Institutes of Health.

[FR Doc. 99–8670 Filed 4–7–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Cooperative Research and Development Agreement (CRADA) Opportunity to Develop a Library of New cDNA Clones Derived From Mouse Stem Cells

AGENCY: NIA, NIH, DHHS.

ACTION: Notice.

SUMMARY: The Laboratory of Genetics, in the National Institute on Aging (NIA), is seeking at least one collaborator to participate in a Cooperative Research and Development Agreement (CRADA) to develop uses for a growing library of new cDNA clones. The Laboratory of Genetics has been collecting the cDNA clones from mouse embryonic tissues. A current first cohort of 15,000 unique genes, with an average length of 1.5 kb, includes more than 40% that are previously unknown by comparison with all entries in dbEST (2/1/99); subsequent additional cohorts, aiming at more uniformly full-length clones and including comparable fractions of additional previously unknown genes, are in development. The NIA is interested in developing this unique cDNA library into a variety of prognostic, diagnostic, and therapeutic applications.

This opportunity is not necessarily limited to a single collaborator or a single CRADA; all viable proposals that are consistent with the mission of the NIA and the goals of the Laboratory of Genetics will be considered. If more than one acceptable CRADA proposal is received, NIA may require that each research plan be crafted to protect against overlap. The term of each CRADA will be up to five (5) years.

DATES: Interested parties should notify the National Cancer Institute's Technology Development & Commercialization Branch, in writing, of their intent to file a formal proposal no later than May 24, 1999. Formal proposals must be submitted to this office no later than June 7, 1999.

ADDRESSES: Inquiries and proposals regarding this opportunity should be addressed to Bruce D. Goldstein; NCI Technology Development & Commercialization Branch; Suite 450, 6120 Executive Blvd.; Rockville, Maryland, 20852 (Tel. # 301–496–0477, FAX # 301–402–2117). Scientific inquiries should be addressed to Dr. David Schlessinger, Chief; NIA Laboratory of Genetics, 5600 Nathan Shock Drive; Baltimore, Maryland, 21224 (Tel. # 410–558–8337, FAX # 410–558–8331). Copies of the PHS Model CRADA are available.

SUPPLEMENTARY INFORMATION: A CRADA is the anticipated joint agreement to be entered pursuant to the Federal Technology Transfer Act of 1986, as amended by the National Technology Transfer and Advancement Act (Pub. L. 104–113 (Mar. 7, 1995)) and by Executive Order 12591 of April 10, 1987.

A CRADA is an agreement designed to enable certain collaborations between Government laboratories and non-Government laboratories. It is not a grant, and is not a contract for the procurement of goods/services. THE NIA IS PROHIBITED FROM TRANSFERRING FUNDS TO A CRADA COLLABORATOR. Under a CRADA, the NIA can offer the selected collaborator(s) access to facilities, staff, materials, and expertise. The collaborator(s) may contribute facilities, staff, materials, expertise, and funding to the collaboration. A CRADA collaborator may elect an option to an exclusive or non-exclusive license to Government intellectual property rights

arising under the CRADA, and may qualify as a co-inventor of new technology developed under the CRADA. Any party is eligible to participate; however, as between two or more sufficient, overlapping research proposals (where the overlap cannot be cured), the NIA, as specified in 15 U.S.C. 3710a(c)(4), will give special consideration to small businesses, and will give preference to business units located in the U.S. that agree to manufacture CRADA products in the U.S.

The NIA's principal objectives for this CRADA opportunity are the rapid publication of research findings, and the timely commercialization of prognostic, diagnostic, or therapeutic products. In particular, under the present proposal, the specific goals of the CRADA may include, but are not necessarily be limited to, the development of the following technology:

- Development of one or more diagnostic assays using gene arrays;
- Creation of pharmaceutical compositions derived from specific cDNA sequences; and
- Development of improved informatics concerning the analysis of expression of cDNA sequences identified by NIA.

Collaborators are encouraged to recommend additional applications and technologies to be developed in their written proposals.

Policy Considerations

The rapid advancement of many important avenues of biomedical research depend on the ready access to high quality clones and sequences of mammalian cDNA. The NIA acknowledges that, to provide commercial parties an incentive to develop a technology into a product, patent applications sometimes must directly claim a genetic sequence or clone so that a related diagnostic, prognostic, or therapeutic invention will be adequately protected. At the same time, the NIA is concerned that patent applications claiming clones and their associated sequences ''per se''—in other words, in the absence of a demonstrated diagnostic, prognostic, or therapeutic function—could have a chilling effect on other research into products that will benefit the public health. Consequently, the NIA is committed, wherever possible, to making such per se cDNA libraries, clones, and sequences publicly available, without restriction, in a timely manner (for example, by placing them in public databases and repositories). All successful collaborators will acknowledge NIA's policy and will take meaningful steps to accommodate it wherever possible.

Party Contributions

The role of NIA may include the following:

(1) Plan research studies, interpret research results, and, with the collaborator, jointly publish the conclusions;

(2) Provide collaborator with access to mouse-embryonic cDNA clones, sequence information, and other research data (both already collected and yet to be collected);

(3) Provide staff, expertise, & materials for the development and testing of promising products; and

(4) Provide work space and equipment for testing of any prototype compositions developed.

The role of the successful collaborator will include the following:

(1) Provide significant intellectual, scientific, and technical expertise in the development and manufacture of relevant products;

(2) Plan research studies, interpret research results, and, with NIA, jointly publish the conclusions;

(3) Provide to NIA a supply of materials, access to necessary proprietary technology and/or data, and as necessary for the project, staff and funding in support of the research goals; and

(4) Provide resources to develop and market any promising products.

Other contributions may be necessary for particular proposals.

Selection Criteria

Proposals submitted for consideration should address, as best as possible and to the extent relevant to the proposal, each of the following qualifications:

(1) Expertise:

A. Expertise in developing and producing high quality pharmaceutical compositions;

B. Demonstrated ability to secure national marketing and distribution of its products (international distribution a plus);

C. Demonstrated expertise in informatics, and in handling of arrays of clones and genes; and

D. Demonstrated intellectual ability in the prediction and verification of diagnostic, prognostic, and/or therapeutic products based on sequences and genetic properties.

(2) Reliability as a research partner:

A. Produces quality products in a timely manner (for example, as demonstrated by a history of meeting benchmarks in licenses);

B. Indications of high levels of satisfaction by industry with the collaborator's products; and

C. Commitment to supporting the advancement of scientific research, as evidenced by a willingness to publish research results in a prompt manner, and a willingness to be bound by DHHS and PHS policies regarding:

(i) the public distribution of unmodified genetic sequences and pure research tools,

(ii) the care and handling of animals, and

(iii) testing in human subjects.

Proposals MUST address the collaborator's policy on the handling of intellectual property rights in, and the public dissemination of, cDNA sequences, clones, and libraries to be developed under a prospective CRADA.

(3) Physical Resources:

A. An established headquarters, with office space and equipment;

B. Access to the organization during business hours by telephone, facsimile, courier, U.S. Post, e-mail, the World-Wide-Web, and other evolving technologies; and

C. Sufficient financial and material resources to support, at a minimum, the anticipated activities of the CRADA to meet the needs of NIA under the proposal.

Dated: March 19, 1999.

Kathleen Sybert,

Director, Technology Development & Commercialization Branch, National Cancer Institute, National Institutes of Health.

[FR Doc. 99–8672 Filed 4–7–99; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice if hereby given of a meeting of the Director's Council of Public Representatives.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Director's Council of Public Representatives.

Date: April 21, 1999.

Time: 8:30 am to 4:00 pm.

Agenda: Among topics proposed for discussion are: (1) Health disparities in the U.S.; (2) clinical trials database on Internet;