

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 is 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;

and (3) models of public participation in NIH priority setting and other activities.

Place: National Institutes of Health, Building 31, C Wing, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Anne Thomas, Director, Office of Communications and Public Liaison, Office of the Director, National Institutes of Health, 9000 Rockville Pike, Building 1, Room 344, Bethesda, MD 20892, (301) 496-4461.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program, National Institutes of Health, HHS)

Dated: April 1, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-8663 Filed 4-7-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel Interdisciplinary Studies in the Genetic Epidemiology of Cancer.

Date: May 3-4, 1999.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Ray Bramhall, PhD., Scientific Review Administrator, Special

Review, Referral and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Blvd, Rockville, MD 20892, (301) 496-3428.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 1, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-8659 Filed 4-7-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel PAR-98-023 SMALL GRANTS PROGRAM FOR CANCER EPIDEMIOLOGY.

Date: April 28, 1999.

Time: 7:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Holiday Inn, Bethesda, MD 20017.

Contact Person: Michael B. Small, Mph, PhD, Scientific Review Administrator, National Cancer Institute, Division of Extramural Activities, 6130 Executive Blvd., Room 643, Bethesda, MD 20892 301-496-7929.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399,

Cancer Control, National Institutes of Health, HHS)

Dated: April 1, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Advisory Committee to the Director, National Cancer Institute.

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: Advisory Committee to the Director, National Cancer Institute.

Date: April 19, 1999.

Time: 2:30 p.m. to 3:30 p.m.

Agenda: The purpose of the meeting will be to update the Committee on the progress of the NCI working groups.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Room 11A10, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Susan J. Waldrop, Executive Secretary, National Institutes of Health, National Cancer Institute, Office of Science Policy, Bethesda, MD 20892, 301/496-1458.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 1, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

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