

SUMMARY: The National Cancer Institute seeks a company to collaboratively pursue the preclinical and clinical development of an orally administered cytologic sampler for the early detection of esophageal cancer. The National Cancer Institute has preclinical data and evidence that currently available sampling devices need to be and can be improved. Thus, the overall goal of this research project is to develop an improved cytologic sampler for the early detection of esophageal cancer.

ADDRESSES: Inquiries and statements of interest regarding this opportunity should be addressed to Rita Khanna, Technology Development and Commercialization Branch, National Cancer Institute, Executive Plaza South, Suite 450, 6120 Executive Blvd., Rockville, MD 20852 (Tel. # 301-496-0477 Fax # 301-402-2117).

DATE TO RESPOND: In view of the important priority of developing an orally administered cytologic sampler for the early detection of esophageal cancer, interested parties should notify this office in writing no later than thirty (30) days from date of publication of this announcement.

SUPPLEMENTARY INFORMATION: Cooperative Research and Development Agreement or "CRADA" means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of October 10, 1987 as amended by the National Technology Transfer Advancement Act of 1995. The goal of this CRADA will be to collaborate on the specific research project described below. Under the present proposal, the Government is seeking a collaborator, who can develop an improved cytologic sampler to a marketable status to meet the public need for the early detection of esophageal cancer. The expected duration of the CRADA will be four years.

Currently, the most widely used esophageal screening method is to obtain a cytologic sample of the esophageal mucosa using an inflatable balloon or an encapsulated sponge. Although cytologic screening of asymptomatic high-risk individuals remains a promising method for the early detection of curable squamous esophageal dysplasia and cancer, a recent study by the NCI Division of Cancer Prevention and Control showed that current cytologic samplers had a low sensitivity for identifying these lesions.

Under a CRADA, the NCI can offer the selected collaborator access to facilities, staff, materials, and expertise. The

collaborator may contribute facilities, staff, materials, expertise and funding to the collaboration. the NCI CANNOT CONTRIBUTE FUNDING. The 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.

The role of the National Cancer Institute, the Division of Clinical Sciences under the CRADA will include the following:

1. Providing intellectual expertise in the form of cytologic and histologic evaluation of biological samples for preneoplastic and neoplastic lesions;
2. Making suggestions regarding sampler design based on its clinical experience with existing cytologic samplers;
3. Arranging field studies to test the efficacy of new samplers;
4. Evaluating each of the active studies as they progress to ensure that the appropriate questions are being addressed and to ensure that the studies are modified as required based on the developing data; and
5. Providing technological considerations for patient safety, position and comfort.

The role of the successful corporate partner under the CRADA will include the following:

1. Understanding the biological and physiological obstacles that need to be overcome and contributing its expertise in innovative engineering toward overcoming these obstacles;
2. Providing proven competence to carry out the work of developing an improved cytologic sampler;
3. Providing technical support including design concepts, engineering analysis, detailed design, fabrication management and contribution to experimental design;
4. Performing studies to assess the physical properties of new designs in an effort to improve patient tolerance and design efficacy; and
5. Commercializing the resulting device including providing the necessary resources.

Criteria for choosing the collaborating company will include the following:

1. Experience in aspects of innovative engineering necessary for the development of cytologic samplers;
2. Scientific expertise and demonstrated commitment to the development of cytologic samplers;
3. Willingness to cooperate with the NCI in the collection and evaluation of data;
4. Experience and track record of taking such products to market;

5. Nature of resources to be contributed to the collaboration;

6. Willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the distribution of patent rights to CRADA inventions. Generally, the right 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 of inventor;

7. Willingness to cooperate with the National Cancer Institute in the timely publication of research results;

8. Level of financial support the CRADA Collaborator will provide for CRADA-related Government activities; and

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

Dated: April 9, 1999.

Kathleen Sybert,

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

[FR Doc. 99-9758 Filed 4-16-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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 the public in accordance with the provisions set forth in section 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 discloser of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial

Review Group Population Research Subcommittee.

Date: May 5, 1999.

Time: 10:00 AM to 5:00 PM.

Agenda: To be reviewed evaluate grant applications.

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

Contact Person: Jon M. Ranhand, Health Scientist Administrator, Division of Scientific Review, National Institute of Child Health, and Human Development, 6100 Executive Blvd., Room 5E01, MSC 7510, Bethesda, MD 20892, (301) 435-6884. (Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: April 13, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-9667 Filed 4-16-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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 Institute of Child Health and Human Development Special Emphasis Panel Use of Nimodipine in the Management of Service Preeclampsia.

Date: April 26, 1999.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: 6100 Executive Blvd., DSR Conf. Rm., Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Hameed Khan, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Room 5E01, Bethesda, MD 20892, (301) 496-1485.

The 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. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: April 13, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel HIV Vaccine Production: Part C FDA Submissions.

Date: April 26, 1999.

Time: 12:00 PM to 3:00 PM.

Agenda: To review and evaluate contract proposals.

Place: Solar Building, Room 4C07, 6003 Executive Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Dianne E. Tingley, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Solar Building, Room 4C07, 6003 Executive Boulevard MSC 7610, Bethesda, MD 20892-7610, 301/496-0818.

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. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 13, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 section 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel HIV Vaccine Production: Part A in response to DAIDS-99-21.

Date: April 29, 1999.

Time: 8:30 AM to 5:00 PM.

Agenda: To review and evaluate contract proposals.

Place: Hyatt Arlington, The Gallery Room, 1325 Wilson Boulevard, Arlington, VA 22209.

Contact Person: Dianne E. Tingley, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Solar Building, Room 4C07, 6003 Executive Boulevard MSC 7610, Bethesda, MD 20892-7610, 301/496-0818.

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. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 13, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy, NIH.

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