reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 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.)

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–29341 Filed 11–14–96; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Board of Scientific Advisors, National Cancer Institute meeting which was published in the Federal Register (61 FR 55811) on October 29, 1996 to change the location and time of the meeting.

The Board was scheduled to meet in Building 31C, Conference Room 10 at 8:30 a.m. on November 21 and 22. The location and times have been changed to Building 31, Conference Room 6, at 8 a.m. on November 21 and 22.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–29344 Filed 11–14–96; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Scientific and Commercial Development of Fusion Proteins That Include Antibody and Non-Antibody Portions

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (DHHS) seeks one or more companies that can collaboratively pursue the pre-clinical and clinical development of Fusion Proteins That Include Antibody and Non-Antibody Portions. The following disease states are of interest: neoplasia, arteriosclerosis, tumor vascularization, fibrotic diseases, psoriasis and wound healing. The National Cancer Institute, Laboratory of Cellular and Molecular Biology has developed an assay system to identify receptor agonists and antagonists using fusion protein technology. The selected sponsor will be awarded a CRADA with the National Cancer Institute for the co-development of agents identified using the fusion protein technology.

ADDRESSES: Questions about this opportunity may be addressed to Jeremy A. Cubert, M.S., J.D., Office of Technology Development, NCI, 6120 Executive Blvd. MSC 7182, Bethesda MD 20892–7182, Phone: (301) 496–0477, Facsimile: (301) 402–2117, from whom further information may be obtained.

DATES: In view of the important priority of developing new agents for the treatment or prevention of cancer, interested parties should notify this office in writing no later than [FR: insert date 60 days after date of publication]. Respondents will then be provided an additional 30 days for the filing of formal proposals.

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 amendments (including 104 P.L. 133) and Executive Order 12591 of October 10, 1987 to collaborate on the specific research project described below.

The Government is seeking one or more companies which, in accordance with the requirements of the regulations governing the transfer of agents in which the Government has taken an active role in developing (37 CFR 404.8), can further develop the identified compounds and related diagnostic methods through Federal Food and Drug Administration approval and to a commercially available status to meet the needs of the public and with the best terms for the Government. The government has applied for domestic and foreign patent applications directed to Fusion Proteins That Include Antibody and Non-Antibody Portions.

The Fusion Proteins comprise an IgG sequence covalently joined at the IgG hinge and Fc domain to a non-antibody effector domain such as a ligand, toxin, or receptor. The effector domain or IgG non-antibody portion may be linked to a heterologous signal peptide to facilitate secretion. The resulting fusion protein exhibits the effector properties of both the antibody and non-antibody portions. Applications of this technology include development of diagnostic methods to monitor binding and expression of a protein of interest *in vitro, in vivo* and *in situ* (i.e. immunohistochemistry). In addition, the technology can be used to identify agonists and antagonists that modulate the binding of an effector molecule to its target. Fusion proteins may also be employed as a therapeutic to deliver radiation, a cytotoxic agent or a drug directly to a target cell.

The LCMB, Division of Basic Sciences, NCI is interested in establishing a CRADA with one or more companies to assist in the development of diagnostic, screening and therapeutic applications of the technology. The Government will provide all available expertise and information to date and will jointly pursue pre-clinical and clinical studies as required, giving the company full access to existing data and data developed pursuant to the CRADA. The successful company will provide the necessary scientific, financial and organizational support to establish clinical efficacy and possible commercial status of subject compounds and/or diagnostic and therapeutic applications.

The expected duration of the CRADA will be two (2) to five (5) years.

The role of the National Cancer Institute, includes the following:

1. Construction of fusion proteins comprising a molecule of interest covalently joined to an IgG hinge and FC antibody regions.
2. Expression and harvesting of the resulting fusion protein from conditioned medium of a suitable transfectant such as NIH 3T3 cells.
3. Develop a screen of ligand-HFc on receptor or receptor-HFc on ligand to identify putative agonists and antagonists.
4. Conduct in vitro studies to identify putative agonists and/or antagonists by screening libraries of compounds.
5. Conduct in vitro and in vivo studies to characterize the properties of putative agonists and/or antagonists.
6. Evaluation of test results.
7. Preparation of manuscripts for publication.
8. Relevant Government intellectual property rights are available for licensing through the Office of Technology Transfer, National Institutes of Health. For further information contact Susan Rucker, J.D., NIH Office of Technology Transfer, 6011 Executive Blvd, Suite 325, Rockville, MD 20852, Phone: (301) 496–7056 (ext. 245); Facsimile: (301) 402–0220.

The role of the collaborator company, includes the following:

For agonist/antagonist screening:

1. Provide growth factor or receptor cDNA clones for fusion protein construction if not available in NCI/LCMB clone bank.

2. Scale-up production of fusion proteins constructed by NCI if required.

3. Conduct in vitro studies to identify putative antagonists/agonists by screening libraries of compounds.

4. Conduct in vitro and in vivo studies to characterize the properties of putative antagonists/agonists.

5. Conduct clinical studies of best candidates.

For ligand-mediated histochemical experiments:

1. Test conditioned medium for suitability in histochemical experiments.

2. Screen tumor samples or biopsies for reactivity.

3. Conduct clinical studies of diagnostic test.

Criteria for choosing the company include its demonstrated experience and commitment to the following:

1. Scientific expertise in and demonstrated commitment to the treatment of neoplasia, arteriosclerosis, fibrotic diseases and related disorders.

2. Scientific expertise in and demonstrated commitment to the development of drug delivery systems.

3. Experience in preclinical and clinical drug development.

4. Experience and ability to produce, package, market and distribute pharmaceutical products.

5. Experience in the monitoring, evaluation and interpretation of the data from investigational agent clinical studies under an IND.

6. A willingness to cooperate with the NCI in the collection, evaluation, publication and maintaining of data from pre-clinical studies and clinical trials regarding the subject compounds.

7. Provide defined financial and personnel support for the CRADA to be mutually agreed upon.

8. An agreement to be bound by the DHHS rules involving human and animal subjects.

9. The aggressiveness of the development plan, including the appropriateness of milestones and deadlines for preclinical and clinical development.

10. Provisions for equitable distribution of patent rights to any CRADA inventions. Generally the rights of ownership are retained by the organization which is the employer of the inventor, with (1) an irrevocable, nonexclusive, royalty-free license to the Government and (2) an option for the collaborator to elect an exclusive or nonexclusive license to Government owned rights under terms that comply with the appropriate licensing statutes and regulations.

Dated: November 4, 1996.

Thomas D. Mays,

Director, Office of Technology Development, OD, NCI.

[FR Doc. 96–29346 Filed 11–14–96; 8:45 am]

BILLING CODE 4140–010–M

National Heart, Lung, and Blood Institute; Division of Lung Diseases, Phase II or Phase III Clinical Trails

The National Heart, Lung, and Blood Institute Acute Respiratory Distress Syndrome Network, a group of 10 academic medical centers consisting of 24 hospitals with expertise in clinical research relating to acute adult lung injury, invites letters of interest by December 1, 1996 from private sector companies who have developed novel therapies for acute lung injury and/or acute respiratory distress syndrome (ARDS) and who are interested in collaborating in Phase II or Phase III clinical trials. Letters of interest will not be viewed as a formal commitment, but are invited as a first step in exploring possible future collaborations. Information submitted will be treated as strictly confidential. Letters of interest should include a proposal regarding the nature of possible interactions with the ARDS Network. Network investigators and NHLBI staff will select agents for study based on scientific interests, novelty, feasibility, and availability. It is anticipated that clinical trials of agents selected will be initiated as early as 1997, but later starting dates will also be considered. Letters should be sent by December 1, 1996 to Dorothy Berlin Gail, Ph.D., Director, Lung Biology and Disease Program, Division of Lung Diseases, NHLBI, 6701 Rockledge Drive Room 10100, Bethesda, Maryland 20892–7952.

Dated: November 7, 1996.

Sheila E. Merritt,

Executive Officer, NHLBI.

[FR Doc. 96–29345 Filed 11–14–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 United States Code Appendix 2), notice is hereby given of the following meeting:

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel.

Date: December 3–5, 1996.

Time: 8 am–5 pm, December 3, 8 am–5 pm, December 4, 8 am to adjournment, December 5.

Place: Doubletree Hotel, 1750 Rockville Pike, Rockville MD 20852.

Contact Person: Mary V. Nekola, Ph.D., Scientific Review Administrator, NIDCD/DEA/SRB, EPS Room 400C, 6120 Executive Boulevard, MSC 7180, Bethesda MD 20892–7180, 301–496–8683.

Purpose/Agenda: To review and evaluate program project applications. The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6) Title 5, United States Code. The applications and/or proposals and the discussion could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

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

(Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Communication Disorders)

Dated: November 6, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–29250 Filed 11–14–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 United States Code Appendix 2), notice is hereby given of the following meeting:

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel.

Date: November 26, 1996.

Time: 3 pm to adjournment.

Place: 6120 Executive Blvd., Room 400C, Rockville, Maryland (telephone conference call).

Contact Person: Craig A. Jordan, Ph.D., Scientific Review Administrator, NIDCD/DEA/SRB, EPS Room 400C, 6120 Executive Boulevard, MSC 7180, Bethesda, MD 20892–7180, 301–496–8683.

Purpose/Agenda: To review and evaluate contract proposals.

The meeting will be closed in accordance with the provisions set forth in sections 552(c)(4) and 552(c)(6) Title 5, United States Code. The applications and/or proposals and the discussion could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.