

[Note: When you are in the hospital and your HMO decides that you do not need to be there any longer, you can ask for immediate review by a Peer Review Organization (PRO). If you ask for a immediate review, you can stay in the hospital at no charge during the review. The review usually takes at least 24 hours.]

The Appeals Process

Your HMO is required to notify you when it denies, reduces or terminates services or payment for services. (Whether or not you have written notification, you may appeal.) The HMO must also provide you with written information about your appeal rights and the process you must follow, including time frames for each step.

The appeals process begins with your written request to the HMO asking it to review the denial, reduction or termination. If the HMO does not reverse its decision, the appeal automatically goes next to an independent review organization that contracts with Medicare to review HMO denials. If the review organization does not decide fully in your favor, you may request a hearing from Medicare.

If you need help in deciding whether to appeal, or if you have questions regarding what you must do to appeal, you can contact your local or State Insurance Counselling and Assistance (ICA) Program. Call the Medicare Hotline at 1-800-638-6833 to get the number of the ICA in your area.

Complaints About Quality

If you have complaints about the quality of care you have received by your HMO or any of its providers, including hospitals, skilled nursing facilities and home health agencies, you can complain to your HMO or a Peer Review Organization (PRO). PROs are groups of doctors and health care professionals that monitor the quality of care provided to Medicare beneficiaries. Call the Medicare Hotline or your ICA to get the number of the PRO serving your area (See Part IV: Where to Go For Help). The PRO will investigate your complaint.

Other Complaints

If you have other complaints about the HMO, such as physician demeanor or adequacy of the facilities, contact your HMO directly. Your HMO must have written procedures, including time frames, for investigating these types of complaints (also called grievances). The HMO representatives will review these complaints and notify you in writing of their conclusions.

Part IV: Where To Go for Help

What You Need To Do if You Believe Your HMO Is Not Meeting Its Obligations or May Be Violating Your Rights

- Complain directly to the HMO. You must write to your HMO asking it to reconsider its decision to deny, reduce or terminate care, coverage or payment. Every HMO is required to have a process to handle complaints, and the HMO must give you detailed information on how to file a complaint.

- Contact your local or State Insurance Counselling and Assistance Program (ICA) which has been set up to assist Medicare beneficiaries in resolving problems with, or answering questions about, their Medicare benefits. To obtain the phone number of your ICA, you can call the Medicare toll-free Hotline at 1-800-638-6833 or your local area Agency on Aging office. To obtain the number of your local aging office, you can call 1-800-677-1116 (the Eldercare locator number).

- Contact the HHS Office of Inspector General through its toll-free Hotline at 1-800-HHS-TIPS (1-800-447-8477), or contact the HCFA Medicare toll-free Hotline at 1-800-638-6833. Contacting one of these offices about improper practices will not resolve your individual problem, but may help to stop any improper practices.

Quiz Yourself

There are several important questions you should ask yourself regarding HMO participation.

Do you know:

- What lock-in into an HMO means?
- The role of your primary care doctor?
- How the HMO's referral process works?
- The HMO's rules and responsibilities about paying for emergency and out-of-area urgent care?
- Whether HMO enrollment is a good choice for you if you travel or are out of the HMO service area for long periods of time?
- How to disenroll from an HMO?
- How to complain if you have a problem?

Dated: October 18, 1996.

Michael Mangano,

Principal Deputy Inspector General.

[FR Doc. 96-28377 Filed 11-14-96; 8:45 am]

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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 of the national Cancer Institute Initial Review Group:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: Subcommittee A—Cancer Center Subcommittee.

Date: December 18–19, 1996.

Time: 8 a.m.

Place: The Bethesda Ramada, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: David E. Maslow, PhD., 6130 Executive Blvd., Room 643A, Bethesda, Md 20892, Telephone: 301-496-2330.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions 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.

(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. 96-29340 Filed 11-14-96; 8:45 am]

BILLING CODE 4140-01-M

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 of the National Cancer Institute Initial Review Group:

Agenda/Purpose: To review and evaluate grant applications.

Name of Subcommittee: Subcommittee D—Clinical Studies.

Date: December 12–13, 1996.

Time: 8 a.m.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Martin H. Goldrosen, PhD., National Cancer Institute, NIH, Executive Plaza North, Room 635C, 6130 Executive Boulevard, MSC 7405, Bethesda, MD 20892-7405, Telephone: 301/496-7930.

The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and the discussions could

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.