

in the organization, financing, and delivery of health care services.

The Council is composed of public members appointed by the Secretary. These members are: Robert A. Berenson, M.D.; F. Marion Bishop, Ph.D.; Linda Burnes Bolton, Dr. P.H.; John W. Danaher, M.D.; Helen Darling, M.A.; Nancy J. Kaufman, M.S.; William S. Kiser, M.D.; Robert M. Krughoff; Risa J. Lavizzo-Mourey, M.D.; W. David Leak, M.D.; Harold S. Luft, Ph.D.; Barbara J. McNeil, M.D.; Walter J. McNerney, M.H.A.; Edward B. Perrin, Ph.D.; Louis F. Rossiter, Ph.D.; Albert L. Siu, M.D.; and Ellen B. White, M.B.A.

There also are Federal ex officio members. These members are: Administrator, Substance Abuse and Mental Health Services Administration; Director, National Institutes of Health; Director, Centers for Disease Control and Prevention; Administrator, Health Care Financing Administration; Commissioner, Food and Drug Administration; Assistant Secretary of Defense (Health Affairs); and Chief Medical Director, Department of Veterans Affairs.

II. Agenda

On Tuesday, May 16, 1995, the open portion of the meeting will begin at 12:30 p.m. with the call to order by the Council Chairman. The Administrator, AHCP, will update the status of current Agency issues and program initiatives. The meeting will adjourn at 5:30 p.m.

On Wednesday, May 17, 1995, the open portion of the Council meeting will resume at 8:30 a.m. with a discussion of the AHCP grant application review process. The open meeting will adjourn at 10:15 a.m. The Council will begin the closed portion of the meeting to discuss the AHCP grant portfolio from 10:15 a.m. to 12:00 p.m. The meeting will then adjourn at 12:00 p.m.

Agenda items are subject to change as priorities dictate.

Dated: April 19, 1995.

Clifton R. Gaus,

Administrator.

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National Institutes of Health

National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Scientific and Commercial Development of Monoclonal Antibodies for the Therapy and/or Diagnosis of Cancer

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Advertisement.

SUMMARY: The Laboratory of Tumor Immunology and Biology (LTIB), National Cancer Institute is seeking pharmaceutical or biotechnology collaborator(s) which can effectively pursue the scientific and commercial development of a panel of monoclonal antibodies generated against tumor associated antigens for use in the therapy and/or diagnosis of a range of human cancers. The primary focus of these collaborations will be the development and commercialization of a panel of monoclonal antibodies consisting of two major groups: (A) Monoclonal antibodies directed against the pancarcinoma antigen, TAG-72. TAG-72 is expressed on a range of human carcinomas including colorectal, gastric, pancreatic, ovarian, endometrial, breast, non-small cell lung, and prostate. Monoclonal antibody CC49 is the prototype monoclonal antibody of this group. Humanized and other genetically engineered variants of monoclonal antibody CC49 have already been developed. (B) Monoclonal antibodies directed against human carcinoembryonic antigen, which is expressed on the following carcinomas: colorectal, pancreatic, gastric, non-small cell lung, and breast carcinoma. The prototype for this group of monoclonal antibodies is COL-1. (C) Additionally, it may likely be a further goal of these collaborations to develop novel recombinant forms of these monoclonal antibodies.

It is anticipated that because of the magnitude, diversity, and expense of these proposed research projects the collaboration(s) may take the form of multiple CRADAs. The collaboration(s) will involve all aspects of diagnostic and/or therapeutic development from basic scientific inquiry to late stage clinical trials which selected sponsor(s) will be required to partially support. The selected sponsor(s) will collaborate in the development of one or more of the following diagnostic or therapeutic forms of these monoclonal antibodies: (1) Radiolabeled monoclonal antibodies (diagnostic (oncologic imaging) and/or therapeutics); (2) Drug and/or toxin

conjugated monoclonal antibodies; (3) Pro-drug conjugated monoclonal antibodies; (4) Unconjugated monoclonal antibodies (including bifunctional forms).

Sponsors will be selected based upon their ability to collaborate with NCI for the development of any of these therapeutic or diagnostic forms in accordance with the corporate role and selection criteria outlined below. It is emphasized that selection of a collaborator will not be dependent upon an entity's ability to perform the largest portion of the research project. Rather, a collaborator will be selected based upon the scientific merit and intellectual contributions brought to each individual project(s). Potential collaborators are, therefore, urged to submit proposals which focus on particular area(s) of expertise in a well-organized and precise manner which clearly outlines a development and commercialization plan. Finally, it is also possible that logical extensions of these research protocols may be considered as potential collaborative projects. Accordingly, proposals must address the requested criteria and protocols, but in addition, may include any additional unique development projects relating to the core technology.

The term of the CRADA(s) is anticipated to be three (3) to five (5) years.

ADDRESSES: Inquiries and proposals regarding this opportunity should be addressed to either Michael Christini or Mark Noel (Tel #301-496-0477, Fax #301-402-2117), Office of Technology Development, National Cancer Institute, Building 31, Room 4A49, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

DATES: Proposals must be received at the above address by 5 p.m. June 26, 1995.

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 to collaborate on the specific research project described below. Under the present proposal, the Government is seeking collaborator(s), which in accordance with the requirements of the regulations governing the transfer of technology in which the Government has taken an active role in developing (37 CFR 404.8), can further develop this technology to a commercially available status to best meet the needs of the public.

This technology has been the focal point of much research and