

concomitant use with an inhibitor of HMG-CoA reductase (statin) to reduce triglycerides, non-high density lipoprotein cholesterol, apolipoprotein B, low-density lipoprotein cholesterol, total cholesterol, and very low density lipoprotein cholesterol in adults with mixed dyslipidemia and coronary heart disease (CHD) or a CHD risk equivalent.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 30, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 20, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 23, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Stephanie L. Begansky at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee

meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 13, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-20111 Filed 8-16-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH Cooperative Research and Development Agreement Program: Invitation To Solicit Nonclinical and Clinical Research Proposals From NIH Intramural Research Program Scientists

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Office of Technology Transfer (OTT), Office of the Director (OD), the National Institutes of Health (NIH), invites industry organizations (including corporations, partnerships, limited partnerships, and industrial development organizations); public and private foundations and nonprofit organizations to solicit research proposals from scientists across the NIH Intramural Research Program (IRP) for multiple focused research projects under a the NIH Cooperative Research And Development Agreement (CRADA) Program. This CRADA Program is an extension of collaboration opportunities solicited by NIH or developed on a one-on-one basis. As such, it is consistent with PHS Technology Transfer policy and the public health mission of the NIH. These collaboration opportunities are structured under the authority of 15 U.S.C. 3710a—Cooperative Research and Development Agreements. Note that the CRADA mechanism does not permit the transfer of funds from the NIH to a collaborator but does permit the collaborator to provide funding to the NIH researcher.

FOR FURTHER INFORMATION CONTACT: Ann Hammersla, J.D., Director, Division of Policy, Office of Technology Transfer, NIH, 6011 Executive Blvd., Suite 325, Rockville, MD 20852; Email: hammerslaa@od.nih.gov.

SUPPLEMENTARY INFORMATION: The NIH Wide CRADA Program is a means for a single collaborative research partner to coordinate a number of focused research projects across the IRP of the NIH Institutes and Centers (ICs). The CRADA Program will be driven by the collaborator's interest to solicit research proposals from NIH IRP scientists in multiple ICs for highly focused collaborative research in areas of mutual interest. NIH investigators' proposals responsive to a solicitation will be reviewed by their IC's Scientific Director to assure that: (1) The proposed project advances the mission of that IC, (2) the scientist has the resources to complete his or her part of the project, and (3) the IC supports the use of the investigator's time and resources. Once the research proposal is approved by the IC Scientific Director, the NIH IRP scientist(s) will submit to the soliciting organization the non-confidential, non-binding research proposal. NIH research proposals selected by the organization will be developed more fully and if appropriate under confidentiality agreements governing the confidentiality and use of such additional information. The collaboration will be governed by CRADA terms that address intellectual property rights, publications, and reporting obligations using the model CRADA as a basis for negotiation, see: www.nih.gov/forms_model_agreements/forms_model_agreements.aspx.

For each collaboration, the CRADA will include a specific Research Plan, which delineates the scope of the NIH and collaborator's research to be conducted and establishes benchmarks to chronicle its progress. The CRADA will include a description of the resources to be contributed by the collaborator (e.g., scientific expertise, R&D support, proprietary materials, and funding), and the NIH IC (e.g., scientific expertise, R&D support, and proprietary materials). The CRADA statute does not permit the NIH to provide funding to a collaborator. The NIH is willing to work with each collaborator to establish a CRADA template agreement to be used by any IC interested in collaborating under this type of CRADA Program.

NIH Criteria for Submitting a Summary Research Proposal to a Collaborator's Solicitation

Alignment with NIH IC scientific mission and identified public health objectives;

Advancement of NIH IRP scientist's ongoing research or an extension of that research; and

Availability of NIH resources sufficient to conduct the research project.

Dated: August 13, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013-20046 Filed 8-16-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Brachyury Tumor Associated Antigens as Cancer Vaccines for Colorectal Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to Bavarian Nordic Immunotherapeutics (“BNIT”) located in Mountain View, CA, USA.

Intellectual Property: U.S. Provisional Patent Application No. 61/701,528 [HHS Ref. No. E-054-2011/0-US-01] filed September 17, 2012, entitled “Methods and Compositions for the Treatment of Cancer,” as well as all international applications, continuation applications and divisional applications.

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use will be limited to the use of Licensed Patent Rights for development of pox virus-based immunotherapeutics for colorectal cancer.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before September 18, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Sabarni K. Chatterjee, Ph.D., M.B.A. Licensing and Patenting Manager, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325,

Rockville, MD 20852-3804; Telephone: (301) 435-5587; Facsimile: (301) 435-4013; Email: *chatterjeesa@od.nih.gov*.

SUPPLEMENTARY INFORMATION: Cancer immunotherapy is a recent approach where tumor associated antigens (TAAs), which are primarily expressed in human tumor cells and not expressed or minimally expressed in normal tissues, are employed to generate a tumor-specific immune response. Specifically, these antigens serve as targets for the host immune system and elicit responses that result in tumor destruction.

The technology relates to the development of cancer vaccines utilizing pox virus vectors encoding proteins involved in regulating the epithelial-to-mesenchymal transition (EMT) during vertebrate development, as a cancer antigen. Dr. Jeffrey Schlom et al. at NCI have demonstrated for the first time that a T-box transcription factor and a molecule implicated in EMT, namely the Brachyury protein, appears to be highly expressed in metastasizing tumor cells, and could be a potential target for human T-cell mediated cancer immunotherapy, such as for tumors of the lung, intestine, stomach, kidney, bladder, uterus, ovary, testis, colon and chronic lymphocytic leukemia.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 13, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013-20057 Filed 8-16-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD); Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. A portion of this 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 for the review and discussion of grant applications. 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: National Advisory Child Health and Human Development Council.

Date: September 19, 2013.

Open: September 19, 2013, 8:00 a.m. to 12:00 p.m.

Agenda: The agenda will include: 1) Update on program issues; 2) Report of the Director, NICHD; 3) Report of the Scientific Director, NICHD; and 4) Other business of the Council.

Closed: September 19, 2013, 1:00 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Center Drive, C-Wing, Conference Room 6, Bethesda, MD 20892.

Contact Person: Yvonne T. Maddox, Ph.D., Deputy Director, Eunice Kenney Shriver National Institute of Child Health and Human Development, NIH, 9000 Rockville Pike MSC 7510, Building 31, Room 2A03, Bethesda, MD 20892, (301) 496-1848.

Any interested person may file written comments with the committee by forwarding the statement to the contact person listed on this notice. The statement should include the name, address, telephone number, and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles, will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.