

exclusively in-licensed check point inhibitor with Ad-Her2 and ME-TARP vaccine within the Licensed Patent Rights.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before April 6, 2016 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. Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504E-mail: chatterjeesa@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns the identification of immunogenic peptides within TARP, and their use to create an anti-cancer immune response in patients. By introducing these peptides into a patient, an immune response against these cancer cells can be initiated by the peptides, resulting in treatment of the cancer. A phase I clinical trial in stage D0 prostate cancer patients is nearing completion. Initial results indicate a statistically significant decrease in the slope of PSA for 48 weeks after vaccination.

Additionally, a novel vaccine candidate using recombinant adenoviruses expressing the extracellular (EC) and transmembrane (TM) domains of human HER2 (HER2ECTM) are also being developed that is within the scope of the field of use licensed to Midissia. The recombinant adenovirus expresses a chimeric fiber protein having the adenovirus type 35 (Ad5) shaft and knob domains, which facilitates transduction of human dendritic cells by the recombinant HER2ECTM expressing adenovirus. The vaccine candidate, namely, AdHer2ECTM can potentially be used to treat patients with Her2 expressing tumors. Clinical studies with this adenovirus based vaccine is currently being planned.

Both technologies have the potential of being developed into a vaccine for several cancer indications or for the treatment of any cancer associated with increased or preferential expression of TARP and Her 2/neu.

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 part 404.7. The prospective exclusive license may be

granted unless within fifteen (15) 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 part 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: March 16, 2016.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016-06374 Filed 3-21-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 Board of Scientific Counselors, NIDDK.

The meeting will be open to the public as indicated below, with attendance limited to space available. 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.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDDK

Date: April 14-15, 2016.

Open: April 14, 2016, 8:00 a.m. to 8:15 a.m.

Agenda: Introductions and Overview.

Place: National Institutes of Health, Porter Neuroscience Research Center, Building 35A Convent Drive, Rooms 620/630, Bethesda, MD 20892.

Close: April 14, 2016, 8:15 a.m. to 4:40 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Porter Neuroscience Research Center, Building 35A Convent Drive, Rooms 620/630, Bethesda, MD 20892.

Close: April 15, 2016, 8:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Porter Neuroscience Research Center, Building 35A Convent Drive, Rooms 620/630, Bethesda, MD 20892.

Contact Person: Michael W. Krause, Ph.D., Scientific Director, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Health, Building 5, Room B104, Bethesda, MD 20892-1818, (301) 402-4633, mwkrause@helix.nih.gov.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, 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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 15, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-06336 Filed 3-21-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request: Cancer Genomics Cloud Pilots Survey (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 13,

2016, Vol. 81 pp.1633 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health (NIH), may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Anthony Kerlavage, NCI CBIIT, Program Manager, 9609 Medical Center Drive, Room 1W-436, Rockville, MD 20850 or call non-toll-free number 240-276-5190 or email your request, including your address to: anthony.kerlavage@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Cancer Genomics Cloud Pilots Survey, 0925-NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Center for Biomedical Informatics and Information Technology (CBIIT), in collaboration with the Center for Cancer Genomics at the National Cancer Institutes (NCI) in the National Institutes of Health (NIH), is coordinating a program to develop three Cancer Genomics Cloud Pilots to help meet the research community's needs to access and analyze high quality, large-

scale cancer genomic data and associated clinical information. The goal of this effort is to develop an innovative, cost-effective model for computational analysis of biological data and provide broader yet secure access to genomic data that NCI generates. Cloud computing will be a valuable tool to support studies related to the mechanisms of cancer. This capability will be equally valuable to other NCI scientific areas, including clinical trials and other types of patient-focused research. In order to understand the utility and value of the tools being developed, the NCI has developed a survey instrument to capture feedback from the cancer research community. The information collected as part of this survey process will be used exclusively by the NCI to determine future funding of cloud technology projects.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 375.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Cloud Pilot Survey	Principal Investigator	1500	1	15/60	375
Totals	1500	1500	375

Dated: March 14, 2016.

Karla Bailey,

Project Clearance Liaison, National Cancer Institute, NIH.

[FR Doc. 2016-06332 Filed 3-21-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute, Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the meeting of the President's Cancer Panel.

The meeting will be open to the public, with attendance limited to space available. 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: President's Cancer Panel.

Date: June 10, 2016.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: Examining the Cancer Drug Cost and Access Landscape.

Place: New York Hilton Midtown, 1335 Avenue of the Americas, New York, NY 10019.

Contact Person: Abby B. Sandler, Ph.D., Executive Secretary, President's Cancer Panel, Special Assistant to the Director, NCI Center for Cancer Research, 9000 Rockville Pike, Building 31, Room B2B37, MSC 2590, Bethesda, MD 20892-8349, 301-451-9399, sandlera@mail.nih.gov.

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/pcp/index.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 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, National Institutes of Health, HHS)

Dated: March 16, 2016.

Melanie Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-06335 Filed 3-21-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Final Action Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

AGENCY: National Institutes of Health (NIH), HHS.

ACTION: Notice of changes to the *NIH Guidelines*.