The registrar will also accept payment by major credit cards (VISA/American Express/MasterCard only). For more information on the meeting, or for questions on registration, contact PDA (see **FOR FURTHER INFORMATION CONTACT**).

B. Accommodations

Attendees are responsible for their own accommodations. To make reservations, contact the Renaissance Washington Hotel (see **ADDRESSES**) and reference ''the 2016 PDA/FDA Joint Regulatory Conference'' to receive the PDA group rate. Room rates are: Single: $305 plus 14.5 percent State and local taxes. Requests will be processed on a first-come, first-served basis.

Transcripts: As soon as a transcript is available, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov*.

Dated: March 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–06366 Filed 3–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences, Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Evaluation of the U01 Engineered Nanomaterials (ENMs) Grant Applications.

Date: April 4, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Chapel Hill Hotel, 1 Europa Drive, Chapel Hill, NC 27517.

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, (919) 541–0670, *worth@niehs.nih.gov*.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Small Business Innovation Research (SBIR) Applications Teleconference Review.

Date: April 7, 2016.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS, Keystone Building, 530 Davis Drive, Suite 3118, Research Triangle Park, NC 27709, (Telephone Conference Call).

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, (919) 541–0670, *worth@niehs.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: March 15, 2016.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–06337 Filed 3–21–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development and Commercialization of Cancer Immunotherapy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This 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 Midissia Therapeutics (''MIDISSIA'') located in San Francisco, California, USA.

Intellectual Property

United States Provisional Patent Application No. 60/476,467, filed June 5, 2003, entitled ''Immunogenic Peptides and Peptide Derivatives For The Treatment of Prostate And Breast Cancer Treatment'' [HHS Reference No. E–116–2003/0–US–01]; International Patent Application No. PCT/US2004/17574 filed June 2, 2004 entitled ''Immunogenic Peptides and Peptide Derivatives or The Treatment of Prostate And Breast Cancer Treatment'' [HHS Reference No. E–116–2003/0–PCT–02]; United States Patent No.7,541,035, issued June 2, 2009, entitled ''Immunogenic Peptides and Peptide Derivatives For The Treatment of Prostate And Breast Cancer Treatment'' [HHS Reference No. E–116–2003/0–US–03]; United States Patent No. 8,043,623, issued 25 Oct 2011, entitled ''Immunogenic Peptides and Peptide Derivatives For The Treatment of Prostate And Breast Cancer Treatment'' [HHS Reference No. E–116–2003/0–US–04]; United States Provisional Patent Application No. 61/915,948, filed December 13, 2013, entitled ''Multi-Epitope TARP Peptide Vaccine and Uses Thereof'' [HHS Reference No. E–047–2014/0–US–01]; International Patent Application No. PCT/US2014/070144 filed December 12, 2014 entitled ''Multi-Epitope TARP Peptide Vaccine and Uses Thereof'' [HHS Reference No. E–047–2014/0–PCT–02]; and all continuation applications, divisional applications and foreign counterpart applications claiming priority to the US provisional application no. 61/915, 948 and U.S. Provisional Application No. 62/248,964 filed October 30, 2015 titled ''Compositions and Methods for the Treatment of HER2-Expressing Solid Tumors'' [HHS Reference No. E–187–2015/0–US–01] and continuation applications, divisional applications and foreign counterpart applications claiming priority to the US provisional application no. 62/248,964.

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 may be limited to the use of Licensed Patent Rights for the following:

(1) Development and commercialization of a therapeutic cancer vaccine specifically in combination with Licensee's proprietary or exclusively in-licensed vectors/adjuvants and ME–TARP;

(2) Development and commercialization of a combination product using Licensee's proprietary or

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 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,