status so that this information can be integrated into appropriate treatment decisions that can improve patient outcomes. POC PT/INR testing is increasingly being viewed as a testing modality with performance expectations similar to that of traditional laboratory testing. From a regulatory standpoint, POC PT/INR devices have been reviewed and cleared for prescription use under appropriate professional supervision or prescription home use (patient self-testing), depending on the claimed intended use. For this workshop, both settings will be open for discussion.

II. Topics for Discussion at the Public Workshop

This public workshop will consist of presentations covering the topics listed in this document. Following the presentations, there will be a moderated panel discussion where participants will be asked to provide their perspectives. The workshop panel discussion will focus on identifying potential solutions to address the scientific and regulatory challenges associated with POC PT/INR devices. In advance of the meeting, FDA plans to post a discussion paper outlining FDA's current thinking on the various topics mentioned in the following list, and invite comment on this from the community.

Topics to be discussed at the public workshop include, but are not limited to, the following:

- Current regulatory process involved with the clearance of POC PT/INR devices.
- Current benefit/risk balance of POC PT/INR devices.
- Technological differences amongst marketed POC PT/INR devices, advantages and limitations of each technology, and comparability of test results obtained using different technologies.
- Challenges associated with correlating results from whole blood POC PT/INR devices to conventional plasma-based laboratory tests.
- Appropriate study design for validation and usability studies from the perspectives of the Agency, manufacturers and end users to help improve our understanding of the accuracy, reliability and safety of POC PT/INR devices.
- Types of quality control and the test system elements assessed by the controls.
- Challenges associated with different sample matrices (venous, fingerstick, arterial).

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m., March 10, 2016. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Office of Communication and Education, 301–796–5661, email: *Susan.Monahan@fda.hhs.gov* no later than March 4, 2016.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan (contact for special accommodations) to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. The Webcast link will be available on the workshop Web page after March 10, 2016. Please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available 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.* A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

Dated: February 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–03153 Filed 2–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel Career Development Program in Emergency Care Research (K12).

Date: March 10, 2016.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington, DC/Rockville 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Stephanie J. Webb, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892, 301–435–0291, *stephanie.webb@nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Pathophysiology and Treatment of Bicuspid Aortic Valve Disease.

Date: March 11, 2016.

Time: 9:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Chang Sook Kim, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7188, Bethesda, MD 20892–7924, 301–435–0287, *carolko@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: February 10, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–03121 Filed 2–16–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 Cancer Institute Special Emphasis Panel; Omnibus SEP–12.

Date: March 15, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, Downtown, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Timothy C. Meeker, MD, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W624, Rockville, MD 20850, 240–276–6464 *meekert@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Planning Grants for Global Research Infrastructure in Non-Communicable Disease.

Date: April 27–28, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Marriott Courtyard Gaithersburg Washingtonian Center, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Michael B. Small, Ph.D., Chief, Program & Review Extramural Staff Training Office, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W412, Bethesda, MD 20892–9750, 240–276–6438 *smallm@mail.nih.gov*.

(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: February 10, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–03124 Filed 2–16–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of In Vitro Diagnostics for the Detection of Diseases or Pathogenic Agents

AGENCY: National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), that the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), at the National Institutes of Health, Department of Health and Human Services, is contemplating the grant to Altra Tech, Ltd. (''AltraTech''), a company incorporated under the laws of the Ireland, having an office in Shannon, Ireland, an exclusive patent commercialization license to practice the following inventions embodied in the following patent applications: US Provisional Patent Application No.60/846,354, entitled, ''(S,S)-trans-1,2-cyclopentane Diamine-modified and Gamma-lysine-modified Peptide Nucleic Acids as Probes for Nucleic Acid Detection: Synthesis and Applications,'' filed 22 Sep 2006 [HHS Ref No. E–308–2006/0–US–01]; US Provisional Patent Application No. 60/896,667, entitled, ''Synthesis of Trans-tert-butyl-2-aminocyclopentylcarbamate,'' filed 23 Mar 2007 [HHS Ref No. E–308–2006/1–US–01]; International Application PCT/US2007/020466, entitled, ''Synthesis of Trans-tert-butyl-2-aminocyclopentylcarbamate,'' filed 21 Sep 2007 [HHS Ref No. E–308–2006/2–PCT–01]; US Patent Application No. 12/441,925, filed 21 Sep 2007, [HHS Ref No. E–308–2006/2–US–02]; US Patent Application No. 12/409,159, entitled, ''Cross-Coupled Peptide Nucleic Acids for Detection of Nucleic Acids of Pathogens,'' filed 23 Mar 2009 [HHS Ref No. E–308–2006/3–US–01]; US Patent No. 9,156,778, entitled, ''Cross-Coupled Peptide Nucleic Acids for Detection of Nucleic Acids of Pathogens,'' issued 13 Oct 2015 [HHS Ref No. E–308–2006/3–US–02]; US Provisional Patent Application No. 61/684,354, entitled, Cyclopentane-peptide Nucleic Acids for Qualitative and Quantitative Detection of Nucleic Acids,'' filed 17 Aug 2012 [HHS Ref No. E–260–2012/0–US–01]; International Application PCT/US2013/055252, filed 16 Aug 2013 [HHS Ref No. E–260–2012/0–PCT–02]; European Patent Application No. 13753962.3, filed 11 Feb 2015, [HHS Ref No E–260–2012/0–EP–03]; Korea Patent Application No. 10–2015–7006286, filed 11 Mar 2015, [HHS Ref No E–260–2012/0–KR–04]; US Patent Application No. 14/421,732, filed 13 Feb 2015, [HHS Ref No E–260–2012/0–US–05]; US Provisional Patent Application No. 61/333,442, filed 11 May 2010, [HHS Ref No E–129–2010/0–US–01]; International Patent Application No. PCT/US2011/036090, filed 11 May 2011, [HHS Ref No. E–129–2010/0–PCT–02]; European Patent Application No. 11721899.0, filed 11 May 2011, [HHS Ref No. E–129–2010/0–EP–03]; and US Patent Application No. 13/697,123, filed 9 Nov 2012, [HHS Ref No. E–129–2010/0–US–04].

The patent rights in these inventions have been assigned to the United States of America. AltraTech is seeking a worldwide territory for this license. The field of use may be limited to exclusive use of the licensed patent rights limited to the development and sale of *trans*-cyclopentane-modified peptide nucleic acids (PNA) in a diagnostic test system incorporating AltraTech's proprietary sample preparation and AltraTech's proprietary semiconductor sensor technology for the detection of infectious diseases or pathogenic agents including viruses and microorganisms.

DATES: Only written comments or applications for a license (or both) which are received by the Technology Advancement Office, NIDDK, on or before March 3, 2016 will be considered.

ADDRESSES: Requests for copies of the patent application, patents, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Patrick McCue, Ph.D., Senior Licensing and Patenting