the individual being nominated, the basis for the individual’s nomination, and a statement bearing an original signature of the nominated individual that, if appointed, he or she is willing to serve as a member of the Council:

- Name, return address, and daytime telephone number at which the nominator may be contacted. Nominations from organizations must identify a principal contact person; and

- Copy of a current resume or curriculum vitae for the nominated individual.

Individuals can nominate themselves for consideration of appointment to the Council. All nominations must include the required information. Incomplete nominations will not be processed for consideration. The letter from the nominator and certification of the nominated individual must bear original signatures; reproduced copies of these signatures are not acceptable.

The Department is legally required to ensure that the membership of HHS federal advisory committees is fairly balanced in terms of points of view represented and the functions to be performed by the advisory committee. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on HHS federal advisory committees and, therefore, the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the Council. Appointment to the Council shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status. The Standards of Ethical Conduct for Employees of the Executive Branch are applicable to individuals who are appointed as members of the Council. Individuals being considered for appointment as public voting members will be required to complete and submit a report of their financial holdings. An ethics review must be conducted to ensure that individuals appointed as members of PACHA are not involved in any activity that may pose a potential conflict of interest for the official duties that are to be performed.

Dated: August 24, 2015.

B. Kaye Hayes,
Executive Director, Presidential Advisory Council on HIV/AIDS.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Public Consultation on Antimicrobial Resistance Rapid, Point-of-Care Diagnostic Test Challenge


SUMMARY: The U.S. Department of Health and Human Services (HHS) intends to hold a prize competition in which up to $20 million will be made available, subject to the availability of funds, for the delivery of one or more rapid, point-of-care diagnostics that may be used by health care providers to identify bacterial infections. The National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA) are sponsoring the prize competition and will convene a public consultation to seek comments regarding the technical criteria and performance characteristics of the diagnostic(s) for which the prize(s) will be offered.

DATES: The public consultation will be held on October 7, 2015, 3:30 p.m. to 3:30 p.m. PDT. Written comments can be submitted to the https://www.challenges.gov Web site for this competition beginning on October 1 at 8:30 a.m. EDT to October 6, 2015 at 5:00 p.m. EDT.

ADDRESSES: The public consultation will be held at the Marriott Marquis San Diego Marina, 333 West Harbor Drive, San Diego, California, 92101.

FOR FURTHER INFORMATION CONTACT: Robert W. Eisinger, Ph.D., National Institutes of Health, Division of Program Coordination, Planning, and Strategic Initiatives, Telephone: 301–496–2229, Email: Robert.eisinger@nih.gov.


In conformance to the above documents, the NIH and BARDA are sponsoring a prize competition, and the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) are contributing technical and regulatory expertise to develop the award evaluation process.

The aim of the prize competition is to incentivize the development of one or more in vitro diagnostic tests that would be of significant clinical and public health utility to combat the development and spread of antibiotic-resistant bacteria. For example, such a diagnostic test could be used by health care providers to identify bacterial infections in patients to help guide their decisions about the necessity of prescribing antibiotics, and if so, which antibiotics may be effective—thus promoting antibiotic stewardship. Another important diagnostic use could be to facilitate clinical trials for new antibacterial products by allowing for the enrollment of patient populations with specific infections, thus advancing the development of new antibacterial agents. The prize-winning diagnostic(s) must exhibit a set of predefined technical criteria and performance characteristics based on the intended use(s).

When exercising prize authority under the America COMPETES Act (http://www.gpo.gov/fdsys/pkg/PLAW–111publ358/html/PLAW–111publ358.htm), agencies are to “consult widely both within and outside the federal Government” when developing prize competitions. As such, HHS is seeking input from the medical, public health, and scientific communities; the pharmaceutical and medical diagnostic sectors; patients and other advocacy groups; and the public at-large in order to receive broad input on the type(s) of diagnostic(s) that may be developed in an appropriate time frame to be of significant utility in combating the development and spread of antibiotic-resistant bacteria. HHS has previously issued a Request for Information (RFI) to obtain comments on several topics as they pertain to a rapid, point-of-care diagnostic test(s) that could be developed in an appropriate time frame to be of significant clinical and public
health utility in combating the development and spread of antibiotic resistant bacteria. A prioritized list of 18 bacteria of highest concern can be found in Table 3 of the National Action Plan (https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf). Input received from the RFI and during the public consultation will be used by HHS to develop the technical criteria and performance characteristics of the diagnostic(s) for which the prize(s) will be offered. The design of the Challenge will take into account previous guidance obtained in the aforementioned National Strategy and National Action Plan to combat antibiotic resistant bacteria.

The agenda of the public consultation meeting will be devoted to presentations and discussions on the objectives and criteria for the antimicrobial diagnostic challenge competition. Presentations will focus on the need for rapid diagnostics to address antimicrobial resistance; development and use of rapid diagnostics for drug resistant microorganisms; pathogen/resistance markers identification versus phenotypic susceptibility; antibiotic stewardship in the clinical setting; and regulatory perspectives on rapid diagnostic development.

Any interested person may submit written comments to be considered during the public consultation to the discussion board for this Challenge accessible on https://www.challenge.gov. This statement should include your name, address, telephone number and when applicable, the business or professional affiliation. Written comments can be submitted from October 1, 2015 at 8:30 a.m. EDT to October 6, 2015 at 5:00 p.m. EDT.

This web-based discussion board also provides an open forum for discussion of this prize competition. The online community is open to the public and will allow for a broad and interactive discussion of the topics covered by this public consultation. This platform will allow users to submit ideas about a desired diagnostic test and to comment on the ideas that have been submitted by others.

Dated: September 1, 2015.
Lawrence A. Tabak,
Deputy Director, National Institutes of Health.

[FR Doc. 2015–22690 Filed 9–8–15; 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; NCI Omnibus R03 & R21 SEP–8.
Date: October 27–28, 2015.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Yisong Wang, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W240, Rockville, MD 20850, 240–276–7157, yisong.wang@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Omnibus R03 & R21 SEP–11.
Date: October 29, 2015.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Doubletree Hilton Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Reed A. Graves, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W264, Rockville, MD 20850, 240–276–6384, gravesr@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Omnibus R03 & R21 SEP–3.
Date: November 5–6, 2015.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Viatcheslav A. Soldatenkov, MD, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W254, Bethesda, MD 20892, 240–276–6378, soldatenkov@email.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Omnibus R03 & R21 SEP–1.
Date: November 9–10, 2015.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Doubletree Hilton Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Zhiqiang Zou, MD, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W242, Bethesda, MD 20892–8328, 240–276–6372, zouzhiq@ 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)

Melanie J. Gray,
Program Analyst, Office of Federal Advisory Committee Policy.
[FR Doc. 2015–22659 Filed 9–8–15; 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 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity.
Date: September 30, 2015.
Time: 1 p.m. to 2:30 p.m.
Agenda: To review and evaluate grant applications.