including packaging grant announcements and application kits. Makes recommendations to the Director/NIDILRR regarding allocation of NIDILRR program funds for current and future budget years. Coordinate and collaborates with Office of Research Sciences program staff in the preparation of the annual spending plan and facilitate the implementation of the plan to ensure compliance with established departmental guidance. Provides administrative support in the monitoring of grants and cooperative agreements, and facilitates the administrative execution of interagency agreements.

Administers NIDILRR evaluation activities to improve the effectiveness of NIDILRR’s research activities. This includes collaboration with NIDILRR’s senior management to define and facilitate the conduct of analyses of program and budget data as well as focused, special program evaluation activities. In its evaluation function, it coordinates with CPE to prepare planning and evaluation documents required by ACL, HHS, OMB and Congress.

II. Delegations of Authority: All delegations and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further re-delegations.

III. Funds, Personnel and Equipment: Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies and other resources.

Dated: May 27, 2015.

Sylvia M. Burwell, Secretary.

[FR Doc. 2015–13351 Filed 6–1–15; 8:45 am]
BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

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 meeting.

The 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. 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 on Aging Special Emphasis Panel; Mitochondrial ROS and Aging.

Date: July 9, 2015.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elaine Lewis, Ph.D., Scientific Review Branch, National Institute On Aging, Gateway Building, Suite 2C212, MSC–9205, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–7707, elainelewis@nia.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866. Aging Research, National Institutes of Health, HHS)

Dated: May 27, 2015.

Melanie J. Gray, Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–13149 Filed 6–1–15; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Correction for Announcement of Requirements and Registration for: "Harnessing Insights From Other Disciplines To Advance Drug Abuse and Addiction Research" Challenge

The National Institutes of Health (NIH) is correcting a notice previously published in the Federal Register on May 26, 2015 (80 FR 30084) and titled "Announcement of Requirements and Registration for: "Harnessing Insights From Other Disciplines To Advance Drug Abuse and Addiction Research" Challenge." The notice announced a National Institute on Drug Abuse (NIDA) challenge soliciting ideas on how to adapt specialized knowledge from other disciplines to inform new directions and discoveries in drug abuse and addiction research.

NIH is amending the submission date for the challenge from June 22, 2015 to June 30, 2015, the Judging period from June 23, 2015–July 17, 2015 to July 1, 2015–July 24, 2015, and winners announced date from July 30, 2015 to August 6, 2015.

For further information about the Challenge, please contact Emily Einstein, Ph.D. Science Policy Branch, NIDA, Phone 301–443–6071, email: emily.einstein@nih.gov.

Dated: May 27, 2015.

Nora D. Volkow, Director, National Institute on Drug Abuse National Institutes of Health.

[FR Doc. 2015–13348 Filed 6–1–15; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement for Request for Comment for: Antimicrobial Resistance Rapid, Point-of-Care Diagnostic Test Challenge

Authority: 15 U.S.C. 3719

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 successful 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 seek public comments regarding the technical criteria and performance characteristics of the diagnostic(s) for which the prize(s) will be offered.

DATES: Submission Period begins June 2, 2015, 9:00 a.m. EST. Submission Period ends 5 p.m. EST July 17, 2015.

ADDRESSES: Comments can be sent to https://www.challenge.gov.

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.

identification and characterization of resistant bacteria was a goal identified in the National Strategy for Combating Antibiotic-Resistant Bacteria released in September 2014 (https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf) and addressed in the National Action Plan for Combating Antibiotic-Resistant Bacteria released in March 2015 (https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf). 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 in combating 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 enrichment 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, 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.

At this time, HHS is seeking comments on the topics identified below 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). The comment period will open for 45 days from the publication of this request for information (RFI). Input received during this 45-day comment period and during the subsequent 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. Comments may be submitted to the discussion board for this Challenge accessible on https://www.challenge.gov.

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 RFI. 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. Comments may include, but are not limited to, the following topic areas:

1. Purpose. The purpose(s) or function(s) a rapid, point-of-care in vitro diagnostic test that would be of significant utility to the clinical and public health communities in combating antibiotic resistance. Comments may reflect considerations about in vitro diagnostic tests that distinguish between bacterial and viral infections, or that identify specific bacterial pathogens and/or their drug susceptibility in patients.

2. Characterizing drug susceptibility. The development of an effective in vitro diagnostic test that can identify whether bacterial pathogens are resistant and/or sensitive to certain clinically relevant antibiotics, and thus would be of significant utility in combating antibiotic resistance. Examples may be provided.

3. Sample matrix. The development of an effective in vitro diagnostic test that identifies pathogens by testing human samples (e.g., blood, urine, sputum, tissue fluid, multiple or other sample specimens). Comments may include what type or types of samples would be most relevant in identifying pathogens and/or antibiotic susceptibility.

4. Speed. The development of an effective in vitro diagnostic test that rapidly produces results. Comments may reflect considerations about what would be the maximum acceptable time-to-result for an in vitro diagnostic test to be of significant utility (i.e., from the time that a sample is collected from a patient to the time that the result is available to the healthcare provider).

5. Setting. The settings or venues in which the proposed point-of-care in vitro diagnostic test may be most needed for combating antibiotic resistance.

6. Ease-of-use. The development of an effective in vitro diagnostic test that is easy to use. Recognizing that diagnostics often require specialized equipment for sample storage, processing and/or analysis, comments also may include considerations about how such specialized equipment may affect an in vitro diagnostic test’s ease of use or otherwise limit its utility. Comments may include considerations about the nature and extent of training that would be necessary to operate and obtain results from the proposed in vitro diagnostic test.

7. Diagnostic performance. The performance characteristics (e.g., sensitivity, specificity, positive predictive value, and negative predictive value) required of the proposed in vitro diagnostic test in order for it to have significant utility in combating antibiotic resistance.

8. Tradeoffs. Any inherent tradeoffs associated with the performance characteristics/parameters described in connection with your previous comments and priority of the characteristics/parameters, if applicable.

9. Cost. The development of an effective in vitro diagnostic test that is not cost prohibitive for its intended purpose. Cost and cost considerations may include what price or price range would be desirable to support the widespread adoption of an in vitro diagnostic test that will be effective in combating antibiotic resistant bacteria.

10. Other characteristics. Additional characteristics of the proposed in vitro diagnostic test that would be of significant value.

11. Key technologies. The specific technologies or disciplines, current or nascent, which would lend themselves to the development of a successful in vitro diagnostic test including, for example, what special considerations, advantages, and disadvantages may be associated with each technology/discipline. Comments on what timeframe would be considered reasonable for the development and licensure of a successful in vitro diagnostic test are also welcome.
12. Interest. Major factors that may influence a person’s decision to compete in the prize competition described in this information request.

13. Use. Identification of who is likely to purchase and/or use the type of in vitro diagnostic tests being targeted by this prize competition and how or where such a purchaser or user is most likely to use the in vitro diagnostic test. Examples may be provided (e.g., patient/self-diagnosis, guiding prescriptive decisions, etc.).

14. Barriers. Major barriers that may impede development of the proposed in vitro diagnostic test (e.g., technical or research driven; financial or regulatory; infrastructure or resource based). Comments may reflect considerations about what potential solutions, if any, may be available to overcome such barriers and the level of difficulty associated with implementing any such solution in the U.S. and/or globally.

Dated: May 26, 2015.
Lawrence A. Tabak,
Deputy Director, National Institutes of Health.

[FR Doc. 2015–13113 Filed 6–1–15; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; PAR–13–007: Nucleomics Tools.

Date: June 29, 2015.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20051.

Contact Person: Thomas Beres, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1114, MSC 7890, Bethesda, MD 20892, 301–435–3565, svedam@csr.nih.gov.


Date: June 29, 2015.
Time: 8:00 a.m. to 6:00 p.m.
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