would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Collaborative Applications: Behavioral Genetics and Epidemiology.

Date: February 6, 2019.

Time: 8:45 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave. NW, Washington, DC 20037.

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435–1712, *ryansj@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the partial Government shutdown of December 2018.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 18, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00179 Filed 1–28–19; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Cellular and Molecular Biology of Glia Study Section.

Date: February 7–8, 2019.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Lorien Hotel & Spa, 1600 King Street, Alexandria, VA 22314.

Contact Person: Linda MacArthur, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4187, Bethesda, MD 20892, 301–537–9986, *macarthurlh@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the partial Government shutdown of December 2018.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 18, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00187 Filed 1–28–19; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: Immunology Integrated Review Group; Transplantation, Tolerance, and Tumor Immunology Study Section.

Date: February 4–5, 2019.

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

Agenda: To review and evaluate grant applications.

Place: Sir Francis Drake Hotel, 450 Powell Street at Sutter, San Francisco, CA 94102.

Contact Person: Jin Huang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4199, MSC 7812, Bethesda, MD 20892, 301–435–1230, *jh377p@nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the partial Government shutdown of December 2018.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 18, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00188 Filed 1–28–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice To Announce of Requirements and Registration for ''Antimicrobial Resistance Rapid, Point-of-Need Diagnostic Test'' Challenge

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) is supplementing and amending a Notice previously published in the **Federal Register** on September 8, 2016 titled ''Announcement of Requirements and Registration for ''Antimicrobial Resistance Rapid, Point-of-Need Diagnostic Test'' Challenge.'' This Notice serves to provide additional details to Step 2 Semi-finalists of the submission requirements and review criteria for Step 3 (Performance Testing in CLIA-certified Laboratories) of this Challenge.

DATES: On or before Monday, November 4, 2019, 11:59 p.m. ET: Step 3 Letter of Intent is due. Only Step 2 Semi-finalists are eligible to submit a Letter of Intent. On or before Friday, January 3, 2020, 5:00 p.m. ET: The submissions from the Step 2 Semi-finalists for Step 3 are due. Submissions received after the deadline of January 3, 2020, at 5:00 p.m. ET will be disqualified and not evaluated by the CLIA-certified laboratories, the Technical Evaluation Panel, or Judging Panel.

Important note: The Step 3 submission must be received by January 3, 2020. Plan to send the submission so it arrives on or before January 3, 2020. In effect, a post-mark date of January 3, 2020, is not sufficient; the submission must be received by that date.

ADDRESSES: The Letter of Intent and Step 3 submission must be submitted to Capital Consulting Corporation no later than the due dates cited above. The letter of intent must be submitted on *http://www.cccinnovationcenter.com/challenges/antimicrobial-resistance-diagnostic-challenge/.*

FOR FURTHER INFORMATION CONTACT: Robert W. Eisinger, Ph.D., NIH, 301–

496–2229 or by email *Robert.eisinger@nih.gov.*

SUPPLEMENTARY INFORMATION: On September 8, 2016, the National Institutes of Health (NIH) published a Notice in the **Federal Register** titled ''Announcement of Requirements and Registration for ''Antimicrobial Resistance Rapid, Point-of-Need Diagnostic Test'' Challenge.'' The Notice announced the Antimicrobial Resistance Rapid, Point-of-Need Challenge may result in the awarding of $20 million dollars for the successful development of new, innovative, accurate, and cost-effective in vitro diagnostic tests that would rapidly inform clinical treatment decisions and be of significant clinical and public health utility to combat the development and spread of antibiotic resistant bacteria and improve antibiotic stewardship. The Notice provided information on submission requirements for Step 3 of the Challenge and indicated that additional details on submission requirements for Step 3 will be made available after the Step 2 Semi-finalists are announced. This Notice serves to provide additional details to Step 2 Semi-finalists of the submission requirements and review criteria for Step 3 (Performance Testing in CLIA-certified Laboratories) of this Challenge.

The NIH is supplementing and amending several components of Step 3 of the Challenge including:

(1) The letter of intent must be submitted by Monday, November 4, 2019, at 11:59 p.m. ET, for all Step 2 Semi-finalists planning to submit for the Step 3 (Performance Testing in CLIA-certified Laboratories) stage of the Challenge. A list of Step 2 Semi-finalists can be found at *http://www.cccinnovationcenter.com/challenges/antimicrobial-resistance-diagnostic-challenge/.*

(2) The Technical Evaluation Panel will use the following 4 criteria for evaluating the Step 3 submissions and the test results from the two CLIA-certified laboratories' analysis of the Step 3 prototype submissions, including: (a) Innovation; (b) clinical significance; (c) diagnostic performance and feasibility; and (d) sample matrix/setting and ease of use/throughput. These criteria were defined in the September 8, 2016, announcement; however, the announcement incorrectly stated that the Panel will evaluate the in vitro diagnostics (solution) based on six criteria.

(3) Each solution will be tested by two CLIA-certified laboratories against standard FDA-approved in vitro assays using a panel of reference (or well-characterized) pathogens, clinical specimens, and/or contrived samples to demonstrate usability, stated time to result, appropriate analytical sensitivity/specificity, as well as confirmation of analytical performance (*e.g.,* limit of detection, interference, inclusivity, reproducibility, etc.) reported in the data submitted by the Step 2 Semi-finalist.

(4) Step 2 Semi-finalists will submit:

a. Sufficient numbers of their diagnostic tests based on the Step 2 solutions for independent testing by both CLIA-certified laboratories, as well as methodology/protocols to perform diagnostic testing using the prototypes. These materials must be received on or before January 3, 2020, at 5:00 p.m. ET by Capital Consulting Corporation, Suite 100, 11821 Parklawn Drive, Rockville, MD 20852. At a future date, the NIH will provide additional information about the specific number of test kits that each Step 2 Semi-finalist will need to provide for CLIA-certified laboratory testing. Submissions received after the deadline of January 3, 2020, at 5:00 p.m. ET will be disqualified and not evaluated by the CLIA-certified laboratories, the Technical Evaluation Panel, or the Judging Panel.

b. A description sufficiently detailed and organized by sections for evaluation in the technical evaluation and programmatic assessment of the proposed solution in 10 pages or less including the next 8 bullets, 8.5″ x 11″ inch page, 10-point or greater Arial, Palatino Linotype, or Georgia font and one-inch margins including:

- A title of the proposed solution;
- A one-paragraph executive summary that will be posted on the Challenge website after the ''Winners'' are announced in July 2020. The Executive Summary must not contain any proprietary information since the website is open to the public;
- A statement as to the source of funds that were used to develop their solution submitted for Step 3 of the Challenge;
- A detailed description of the proposed in vitro diagnostic and the claims of performance using specific types of biospecimens/samples;
- A description of any changes from the original design (Step 2 solution) must be documented and explained;
- One section providing a summary of the data, using the in vitro diagnostic device and the Standard Operating Procedures described in Appendix A, generated with either clinical or contrived samples compared to existing standard techniques demonstrating the performance characteristics (*e.g.,* limits of detection, sensitivity, specificity, and other characteristics that demonstrate test performance to support detection of biomarkers or analytes). The September 8, 2016, announcement incorrectly stated that diagnostic performance characteristics included positive predictive value and negative predictive value;
- A video not to exceed 15 minutes demonstrating the status of the development and actual use of the device in testing contrived or clinical specimens;
- A section addressing applicable HHS Human Subjects Protections regulations and NIH Inclusion of Women, Children, and Minorities policies, as well as biohazards policies (*https://grants.nih.gov/grants/guide/notice-files?NOT-OD-12-141.html*), if applicable.

(5) An Appendix A with the standard operating procedures for the use of the solution submitted for Step 3 of the Challenge must include all steps to prepare test specimen/sample, perform the assay, and interpret the results.

(6) An Appendix B provide additional data and tables to support the data summary and performance claims based on the use of the proposed solution testing clinical or contrived samples in 5 pages of less.

(7) Each Step 2-Semi-finalist may submit corrections in support of their Step 3 submission within the page limitations cited above as long as Capital Consulting Corporation receives the materials by the deadline of January 3, 2020, at 5:00 p.m. ET. Corrections for Step 3 will not be accepted or evaluated by the CLIA-certified laboratories, Technical Evaluation Panel, or Judging Panel if they are received after January 3, 2020, at 5:00 p.m. ET.

(8) The NIH will perform an initial review of all submissions to ensure they are complete and within the scope of the Challenge. Submissions that are incomplete or outside of the scope of the Challenge will be administratively disqualified and will not be evaluated by the CLIA-certified laboratories, the Technical Evaluation Panel, or the Judging Panel. Disqualified submissions will not be returned to the Step 2 Semi-finalist.

(9) The NIH and Assistant Secretary for Preparedness and Response/Biomedical Advanced Research and Development Authority may determine that based on the number of submissions received for Step 3 that less competitive submissions will not be discussed by the Technical Evaluation Panel during the Panel's meeting.

(10) Members of the Technical Evaluation Panel for Step 1 or Step 2 are not eligible to participate in or

contribute to any proposal for Step 3 of the Challenge.

(11) Only Step 2 Semi-finalists are eligible for Step 3 of this Challenge.

(12) All submissions for Step 3 must be in English.

(13) No submissions will be returned to the submitters.

(14) The remainder of the provisions from the September 8, 2016, **Federal Register** Notice (81 FR 62150) not amended here still apply.

Dated: January 11, 2019.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2019–00218 Filed 1–28–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2018–0076]

Homeland Security Advisory Council

AGENCY: Office of Partnership and Engagement (OPE), Department of Homeland Security (DHS).

ACTION: Notice of open teleconference federal advisory committee meeting; cancellation.

SUMMARY: On December 27, 2018 (83 FR 66724–66725) the Department of Homeland Security (DHS) published a notice announcing that a meeting of the Homeland Security Advisory Council (HSAC) was to take place on Thursday, January 31, 2019 via teleconference. Due to the lapse in appropriations for the Department of Homeland Security, DHS is cancelling the January 31, 2019 meeting.

FOR FURTHER INFORMATION CONTACT: Mike Miron at *HSAC@hq.dhs.gov* or 202–447–3135.

SUPPLEMENTARY INFORMATION: None.

Dated: January 23, 2019.

Matthew Hayden,

Deputy Assistant Secretary, Private Sector Office.

[FR Doc. 2019–00258 Filed 1–28–19; 8:45 am]

BILLING CODE 9110–9B–P