DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 National Advisory Mental Health Council.

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 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/or proposals 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 Advisory Mental Health Council.

Date: May 25, 2017.

Open: 9:00 a.m. to 12:15 p.m.

Agenda: Presentation of the NIMH Director's Report and discussion of NIMH program.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Closed: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Jean G. Noronha, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9609, 301–443–3367, *jnoronha@mail.nih.gov*.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml.,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: April 28, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–08938 Filed 5–2–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

The National Institutes of Health (NIH) is correcting a notice previously published in the **Federal Register** on September 8, 2016 (81 FR 62150), 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 competition that 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 NIH is correcting and clarifying several components of Step 2 of the Challenge competition including:

(1) The letter of intent must be submitted by August 3, 2018, at 11:59 p.m. ET, for all ''Solvers'' planning to submit for the Step 2 (Delivery of Prototype and Analytical Data) stage of the competition.

(2) The prototype in vitro diagnostic device is not to be provided with the submission. The September 8, 2016, announcement incorrectly stated that the device was to be included as part of the submission for Step 2.

(3) The Technical Evaluation Panel will use the following 4 criteria for evaluating the Step 2 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 solutions based on eight criteria.

(4) A description sufficiently detailed and organized by sections for evaluation in the technical review and programmatic assessment of the proposed solution in 15 pages or less including the next 6 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 detailed description of the proposed in vitro diagnostic, and the development approach, challenges, and risks;
- One section addressing each of the 4 criteria listed above;
- One section providing a summary of the data, using the in vitro diagnostic device and the Standard Operating Procedures described in Appendix B, 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;
- Photographs of the in vitro diagnostic prototype device and a video not to exceed 5 minutes (in accordance with the NIH interim policy for submitting a video as NIH application materials *https://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-141.html*) demonstrating the status of the development and actual use of the device in testing contrived or clinical specimens;
- Address the NIH Human Subjects Protections and Inclusion of Women, Children, and Minorities policies, as well as biohazards policies (*https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-078.html*), if applicable.

(5) An Appendix A, provide additional data and tables to support the data summary and performance claims based on the use of the proposed