

## 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](mailto: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](http://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]

**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 "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

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solution testing clinical or contrived samples in 15 pages or less.

(6) An Appendix B with the standard operating procedures for the use of the solution submitted for Step 2 of the Challenge competition must be limited to 10 pages or less in length. If a longer Appendix is submitted, only the first 10 pages will be considered by the Technical Evaluation Panel and the Judging Panel.

(7) Submissions for Step 2 of the Challenge competition can be submitted to <http://www.cccinnovationcenter.com/challenges/antimicrobial-resistance-diagnostic-challenge/> beginning June 1, 2018. Submissions received after the deadline of September 4, 2018, at 11:59 p.m. ET will be disqualified and not evaluated by the Technical Evaluation Panel or Judging Panel.

(8) Solvers may submit corrections or additional materials in support of their Step 2 submissions so long as the NIH receives the materials by the deadline of September 4, 2018, at 11:59 p.m. ET. Corrections or additional materials for Step 2 will not be accepted or evaluated by the Technical Evaluation Panel or Judging Panel if they are received after September 4, 2018, at 11:59 p.m. ET.

(9) The NIH will perform an initial review of all submissions to ensure they are complete and within the scope of the Challenge competition. Submissions that are incomplete will be administratively disqualified and will not be evaluated by the Technical Evaluation Panel or the Judging Panel.

(10) A Solver may not be a federal employee of HHS (or any component of HHS) acting in their personal capacity.

(11) A Solver employed by a federal agency or entity other than HHS (or any component of HHS), should consult with an agency Ethics Official to determine whether the federal ethics rules will limit or prohibit the acceptance of a prize under this challenge.

(12) 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 2 that less competitive submissions will not be discussed by the Technical Evaluation Panel during the Panel's meeting.

(13) Members of the Technical Evaluation Panel for Step 1 are not eligible to participate in or contribute to any proposal for Step 2 and Step 3 of the Challenge competition.

(14) Any Solver is eligible for Step 2 of this Challenge competition. For example, if a Step 1 "Solver" was not identified as a semifinalist, he/she may still submit for Step 2 of this

competition and those who did not submit a Step 1 proposal may still submit a proposal for Step 2.

(15) All submissions for Step 2 and 3 must be in English.

For further information about the Antimicrobial Resistance Diagnostic Challenge competition, please contact Robert W. Eisinger, Ph.D., NIH, 301-496-2229 or by email [Robert.eisinger@nih.gov](mailto:Robert.eisinger@nih.gov).

Dated: April 27, 2017.

**Lawrence A. Tabak,**

*Deputy Director, National Institutes of Health.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Docket ID FEMA-2007-0008]

#### National Advisory Council; Meeting

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Committee management; notice of Open Federal Advisory Committee meeting.

**SUMMARY:** The Federal Emergency Management Agency (FEMA) National Advisory Council (NAC) will meet in person on May 23-25, 2017 in Tampa, FL. The meeting will be open to the public.

**DATES:** The NAC will meet Tuesday, May 23, 2017 from 8:00 a.m. to 5:00 p.m., Wednesday, May 24, 2017 from 8:30 a.m. to 5:00 p.m., and Thursday, May 25, 2017 from 8:30 a.m. to 1:00 p.m. Eastern Daylight Time (EDT). Please note that the meeting may close early if the NAC has completed its business.

**ADDRESSES:** The meeting will be held at The Barrymore Hotel Tampa Riverwalk located at 111 W. Fortune St., Tampa, FL 33602. It is recommended that attendees register with FEMA prior to the meeting by providing your name, telephone number, email address, title, and organization to the person listed in **FOR FURTHER INFORMATION CONTACT** below.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the person listed in **FOR FURTHER INFORMATION CONTACT** below as soon as possible.

To facilitate public participation, members of the public are invited to provide written comments on the issues

to be considered by the NAC listed in the agenda. The "Agenda" section below outlines these issues. The full agenda and any related documents for this meeting will be posted by Friday, May 19 on the NAC Web site at <http://www.fema.gov/national-advisory-council>. Written comments must be submitted and received by 5:00 p.m. EDT on May 12, 2017, identified by Docket ID FEMA-2007-0008, and submitted by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

- **Email:** [FEMA-RULES@fema.dhs.gov](mailto:FEMA-RULES@fema.dhs.gov). Include the docket number in the subject line of the message.

- **Fax:** (540) 504-2331. Please include a cover sheet addressing the fax to ATTN: Deana Platt.

- **Mail:** Regulatory Affairs Division, Office of Chief Counsel, FEMA, 500 C Street SW., Room 8NE, Washington, DC 20472-3100.

*Instructions:* All submissions received must include the words "Federal Emergency Management Agency" and the docket number for this action. Comments received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided.

*Docket:* For access to the docket to read comments received by the NAC, go to <http://www.regulations.gov>, and search for the Docket ID listed above.

A public comment period will be held on Wednesday, May 24 from 1:30 p.m. to 1:45 p.m. EDT. All speakers must limit their comments to 5 minutes. Comments should be addressed to the NAC. Any comments not related to the agenda topics will not be considered by the NAC. To register to make remarks during the public comment period, contact the individual listed in **FOR FURTHER INFORMATION CONTACT** by May 12, 2017. Please note that the public comment period may end before the time indicated, following the last call for comments.

**FOR FURTHER INFORMATION CONTACT:** Deana Platt, Designated Federal Officer, Office of the National Advisory Council, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472-3184, telephone (202) 646-2700, fax (540) 504-2331, and email [FEMA-NAC@fema.dhs.gov](mailto:FEMA-NAC@fema.dhs.gov). The NAC Web site is: <http://www.fema.gov/national-advisory-council>.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix.