Food Safety Modernization Act (FSMA or the Act), which relate to the functions of the Food and Drug Administration.

This authority may be redelegated. This authority will be exercised in accordance with the Department of Health and Human Services applicable policies, procedures, guideline, and regulations.

I hereby ratify and affirm any actions taken the Commissioner, or the Commissioner's subordinates, that involved the exercise of the authority delegated herein prior to the effective date of this delegation.

This delegation is effective upon date of signature.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2016–21504 Filed 9–7–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.

Date: October 5, 2016.

Time: 10:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 4H200A/B, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Maryam Feili-Hariri, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 5601 Fishers Lane, Rockville, MD 20852, 240–669–5026, *haririmf@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 2, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–21616 Filed 9–7–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Cellular Signaling and Regulatory Systems Study Section, September 29, 2016, 08:00 a.m. to September 29, 2017, 06:00 p.m., Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814 which was published in the **Federal Register** on August 31, 2016, 81 FR PG 60010.

The end date is September 29, 2016 instead of September 29, 2017. The meeting location remains the same. The meeting is closed to the public.

Dated: September 1, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–21514 Filed 9–7–16; 8:45 am]

BILLING CODE 4140–01–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; Training Grants.

Date: October 18, 2016.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2W200, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jeannette L. Johnson, Ph.D., National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2W200, Bethesda, MD 20892, 301–402–7705, *JohnsonJ9@NIA.NIH.GOV.*

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

Dated: September 1, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–21516 Filed 9–7–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

Authority: 15 U.S.C. 3719.

SUMMARY: Through the ''Antimicrobial Resistance Rapid, Point-of-Need Diagnostic Test'' Challenge (the ''Challenge''), the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA) of the Office of the Assistant Secretary for Preparedness and Response (ASPR) are searching for novel and innovative *in vitro* diagnostic tests that would rapidly inform clinical treatment decisions and be of potential significant clinical and public health utility to combat the development and spread of antibiotic resistant bacteria. Tests of interest will provide novel, innovative solutions for use in inpatient and/or outpatient settings. The goal of the challenge is to identify a diagnostic test that when utilized would lead to more rapid clinical decision making such that antibiotic use and/or outcomes of patients infected with resistant pathogens are fundamentally improved compared to current standard of care, and/or reduce transmission of resistant pathogens such that population infection rates significantly decrease. The Challenge competition seeks to incentivize a broad range of scientists, engineers, and innovators to develop diagnostic tests that would enable health care providers to make more informed decisions on appropriate antibiotic use and infection prevention.

This Challenge, structured in three steps, will complement existing BARDA and NIH research portfolios by reaching

out to a diverse population of innovators and solvers, including not only those from academic institutions, but also those from research and development communities in the private sector and others who are outside biomedical disciplines. The NIH and the BARDA believe this Challenge will stimulate investment from both public and private sectors in rapid, point-of-need *in vitro* diagnostic assay research and product development, which, in turn, could lead to the development of more sensitive, accurate, robust, and cost-effective assay approaches and devices for clinical diagnosis.

DATES:

Step 1 Submission period begins: September 8, 2016.
Step 1 Submission period ends: January 9, 2017, 11:59 p.m. ET
Step 1 Judging Period: January 10, 2017, to March 26, 2017
Step 1 Up to 20 highest ranked proposals Semi-finalists Announced: March 27, 2017
Step 2 Submission period begins: March 28, 2017
Step 2 Submission period ends: September 4, 2018, 11:59 p.m. ET
Step 2 Judging Period: September 5, 2018–November 30, 2018
Step 2 Up to 10 Semi-finalists Announced: December 3, 2018
Step 3 Submission period begins: December 4, 2018
Step 3 Submission period ends: January 3, 2020, 11:59 p.m. ET
Step 3 Judging Period: May 1, 2020–July 1, 2020
Step 3 Winner(s) Announced: July 31, 2020

The NIH and the BARDA may shorten the submission period for Steps 2 and 3 and adjust dates for judging and winner(s) announcement if the Step 1 winners' feasibility assessments suggest shorter Step 2 and 3 submission periods are possible. The NIH and the BARDA will announce any changes to the timeline by amending this **Federal Register** notice no later than January 3, 2017. Administrative aspects of this Challenge will be managed by Capital Consulting Corporation.

FOR FURTHER INFORMATION CONTACT:

Robert W. Eisinger, Ph.D., NIH, 301–496–2229 or by email *robert.eisinger@nih.gov.*

SUPPLEMENTARY INFORMATION:

Statutory Authority to Conduct the Challenge: This Challenge is consistent with and advances the mission of the Department of Health and Human Services to identify and support research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis. The NIH and BARDA are conducting this competition under the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358), codified at 15 U.S.C. 3719.

Subject of Challenge: On September 18, 2014, the President issued *Executive Order 13676* on Combating Antibiotic-Resistant Bacteria, and announced the Administration would hold the Antimicrobial Resistance Challenge, as described in the accompanying White House Fact Sheet. The development and use of rapid, point-of-need, and innovative diagnostic tests for identification and characterization of resistant bacteria was a goal identified in the National Strategy for Combating Antibiotic-Resistant Bacteria released in September 2014 and addressed in the National Action Plan for Combating Antibiotic-Resistant Bacteria released in March 2015.

In conformance with the above plans and directives, the NIH and the BARDA are sponsoring a Challenge competition, with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) contributing technical and regulatory expertise to develop the award evaluation process.[1]

There are two clinical scenarios in which a diagnostic test is expected to have a significant impact on antibiotic stewardship:

(1) *Outpatient setting.* Outpatient settings include physician offices, clinics, urgent care centers, and emergency rooms, as these offer healthcare services without hospital admission. These settings are often the first point of contact between patients and providers and play an increasingly important role in the delivery of healthcare services. Providers in this setting often need to make decisions on the use of antibiotics based on immediately observable information. Therefore the ability to rapidly determine if a patient needs antibiotic therapy, and which antibiotic would be efficacious to treat the infection using clinically relevant samples is of primary importance.

(2) *Inpatient setting.* Inpatient settings include hospitals and other settings in which patients are admitted for more than 24 hours. Patients admitted with serious infections such as sepsis and pneumonia require prompt bacterial detection, identification, and susceptibility for selecting appropriate antibiotic treatment. The ability to differentiate among many bacterial strains using many different sample types is critical. Additionally, hospital-acquired infections are a major concern in these settings, and the ability to determine if patients are infected with drug resistant microorganisms is critical for both treatment and infection control.

Currently available *in vitro* diagnostics have not sufficiently addressed the needs in each of these settings. Therefore a diagnostic that could advance the state-of-the-art in a reliable, cost-effective way would provide the healthcare community a significant advantage in combating antibiotic resistance. An additional benefit of an *in vitro* diagnostic would be to facilitate clinical trials for new antibacterial products by allowing enrollment of patient populations with specific infections, thus advancing the development of new antibacterial agents.

In this Challenge, the NIH and the BARDA are seeking proposals for the 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.

The prize-winning *in vitro* diagnostic(s) must meet a set of predefined technical criteria and performance characteristics based on the intended use(s), as described further below. Solutions submitted to this Challenge should have the potential to significantly improve clinical decision making compared to the current standard of care. Solutions also should be novel, innovative, rapid, and appropriate for use at the point-of-need. Ultimately the solution should be an *in vitro* diagnostic assay(s) that can:

- Improve antibiotic decision making by health care providers and be effective in reducing inappropriate use of antibiotics
- demonstrate a clinically significant advance in diagnostic test performance and address gaps or deficiencies in current capabilities that may include, but are not limited to:
  - → Ease of use;
  - → time to result;
  - → significant advances in sensitivity and specificity; and
  - → ability to process a broad range of specimen types.

[1] The NIH has engaged Capital Consulting Corporation to manage certain administrative aspects of this challenge, such as registration, as described below, under 15 U.S.C. § 3719(l).

Solutions describing existing, well-established and/or currently supported approaches, especially commonly used strategies are not of interest unless a compelling case is made that potentially clinically significant, quantifiable advances are achievable and/or the methods and measures are used in unique combinations that have not been previously tested together for the detection/diagnosis of drug resistant bacteria. Examples of breakthroughs in this arena could allow health care providers to:

(1) More rapidly identify/detect the specific etiology drawn from a differential diagnosis of a particular clinical syndrome caused by any of the 18 drug resistant bacteria of highest concern which can be found in Table 3 of the National Action Plan for Combating Antibiotic Resistant Bacteria released in 2015;

(2) more rapidly identify/detect, and characterize antibiotic susceptibility of at least one of the 18 drug resistant bacteria of highest concern which can be found in Table 3; and

(3) detect biomarkers that would inform patient management decisions such as need for antibiotics or severity of infection.

Eligibility Rules for the Challenge

1. *To Participate.* This Challenge is open to any ''Solver'' where ''Solver'' is defined as an individual, a group of individuals (*i.e.,* a team), or an entity. Whether singly or as part of a group or entity, each individual participating in the Challenge must be 18 years of age or older. We welcome solutions from individuals, teams, and entities from all U.S. sources, including the public sector, private sector, and nonprofit groups.

Eligibility to participate in Step 2 of the Challenge is not dependent on participation in Step 1 of the Challenge and being selected as a ''Step 1 Semi-finalist.'' If a ''Solver'' did not participate in Step 1, he/she must follow the requirements listed in the ''To Win'' section of this announcement in order to submit a solution at Step 2. Step 1 Semi-finalists are any individual, team, and/or entity whose solution received a meritorious rating based on the judging criteria. Eligibility to participate in Step 3 of the challenge is conditioned upon participation in Step 2 of the Challenge and being selected as a ''Step 2 Semi-finalist.''

2. *Eligibility to Win.* To be eligible to win a prize under this Challenge, the Solver—

- Shall have registered to participate in the Challenge under the rules promulgated by the NIH as published in this Notice.
- Shall submit a letter of intent outlining the proposed *in vitro* diagnostic assay/assay system and its intended use.
- Shall have complied with all the requirements set forth in this Notice.
- In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States; and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States. *Note:* Individuals who are non-U.S. citizens and nonpermanent residents may participate as a member of a team that otherwise satisfies the eligibility criteria, but will not be eligible to win a monetary prize (in whole or in part); however, their participation as part of a winning team, if applicable, may be recognized when results are announced.
- In the case of an individual, he/she may not be an employee of the NIH, ASPR, CDC, or FDA; an individual involved in formulation of the Challenge and/or serving on the technical evaluation panel; any other individual involved with the design, production, execution, distribution, or evaluation of this Challenge; or members of the individual's immediate family (specifically, a parent, step-parent, spouse, domestic partner, child, sibling, or step-sibling).
- An individual, team, or entity that is currently on the Excluded Parties List (*https://www.epls.gov/*) will not be selected as a Semi-finalist or prize winner.
- In the case of an entity, may not be a federal entity; and in the case of an individual, may not be a federal employee acting within the scope of his or her employment.
- Federal employees otherwise permitted to participate in the Challenge shall not work on their submission during assigned duty hours. *Note:* Federal ethical conduct rules may restrict or prohibit federal employees from engaging in certain outside activities, so any federal employee not excluded under the prior paragraph seeking to participate in this Challenge outside the scope of employment should consult his/her agency's ethics official prior to developing a submission.
- HHS employees may not work on their applications or submissions during assigned duty hours. Commissioned Corps officers are excluded from this competition since they are on active duty at all times.
- Federal grantees may compete but may not use federal funds to develop America COMPETES Act challenge applications unless consistent with the purpose of their grant award. If a grantee using federal funds wins the competition, the award needs to be treated as program income for purposes of the original grant in accordance with applicable Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.[2]
- Federal entities are not eligible to compete in a prize competition.
- Federal contractors are eligible to participate, but may not use federal funds from a contract to develop submissions for an America COMPETES Act prize competition or to fund efforts in support of an America COMPETES Act prize competition. Costs associated with such activities are unallowable and are not allocable to government contracts.
- An individual shall *not* be deemed ineligible to win because the individual used federal facilities or consulted with federal employees during the Challenge provided that such facilities and/or employees, as applicable, are made available on an equitable basis to all individuals and teams participating in the Challenge.

All questions regarding the Challenge should be directed to Dr. Robert Eisinger, identified above, and answers will be posted and updated as necessary at the Web site of the Challenge administered for NIH by Capital Consulting Corporation at *http://www.cccinnovationcenter.com/challenges/antimicrobial-resistance-diagnostic-challenge/* under ''Frequently Asked Questions.'' Questions from Solvers that may reveal proprietary information related to solutions under development may be addressed in the Capital Consulting Corporation project room, an online secure and confidential communication forum.

Submission Requirements: The Challenge has three steps (following registration and submission of a Letter of Intent), and specific submissions for each step.

[2] 2 CFR 200, ''Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards'' supersedes OMB Circular A–21, *Cost Principles for Educational Institutions,* OMB Circular A–87, *Cost Principles for State, Local, and Indian Tribe Governments,* OMB Circular A–110, *Uniform Administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations,* and OMB Circular A–122, *Cost Principles for Non-Profit Organizations.*

Step 1 (Theoretical)—Step 1 of the Challenge requires a written proposal that describes a potentially clinically significant, new, innovative, and cost effective, point-of-need *in vitro* diagnostic test for use in either an inpatient or outpatient setting that could allow health care providers to significantly inform clinical treatment decisions and be of significant clinical and public health utility to combat the development and spread of antibiotic resistant bacteria. For example:

(1) More rapidly identify/detect the specific etiology drawn from a differential diagnosis of a particular clinical syndrome caused by any of the 18 drug resistant bacteria of highest concern which can be found in Table 3 of the National Action Plan for Combating Antibiotic Resistant Bacteria released in 2015;

(2) more rapidly identify/detect, and characterize antibiotic susceptibility of at least one of the 18 drug resistant bacteria of highest concern which can be found in Table 3; and

(3) detect biomarkers that would inform patient management decisions such as need for antibiotics or severity of infection.

The Step 1 Submission shall include:

1. A description sufficiently detailed for evaluation of the proposed solution in 10 pages or less including the next 4 bullets, 8.5 x 11 inch page, 10-point or greater Arial, Palatino Linotype, or Georgia font and one inch margins including:

- A one-paragraph executive summary that clearly states the clinically significant concern being addressed and the specific intended use of the proposed diagnostic device;
- A description of the proposed *in vitro* diagnostic, and the development approach, challenges, and risks;
- A ''State-of-the-Art'' statement that describes: (1) Approaches currently in use (if any); (2) clearly explains how the methods and measures proposed will outpace/outperform current advancements; (3) will provide a useful tool for rapid clinical decision making; and (4) potentially quantifiable improvements beyond existing capabilities;
- A description of how Solvers plan to complete Step 2, including methods and technologies key to implementation. This should include estimated timeframe, supporting precedents, and a feasibility assessment and description of the Solver's ability to execute the proposed solution, including any unique resource(s) that may be needed. If relevant, the assessment of feasibility should also address Protections for Humans Subjects, compliance with policies related to the use of Vertebrate Animals, biosafety issues, and use of methods/technologies covered by patents or other intellectual property protection, as applicable;
- All Step 1 Submitters also will need to provide an Executive Summary for public posting on the AMR Diagnostic Test Challenge Web site. Proprietary information should not be included in the Executive Summary, since this will be accessible to the general public.

2. Optional Appendices describing existing, unpublished experimental data (if available) that support the proposed solution may be included. Please note that while a page limit is not placed on appendices, it is recommended that applicants be concise and include only relevant data in support of the solution. All information that is confidential/proprietary should be so indicated.

Step 2 (Delivery of Prototype and Analytical Data)—All Step 1 Semi-finalists will be eligible to participate as Step 2 Solvers in the second step of the Challenge to produce data generated using their solution and may include analytical and clinical data. In addition, entries will be accepted for Step 2 from Solvers that have not previously entered a submission for Step 1. However, if a Solver did not participate in Step 1, he/she must follow the requirements listed in the ''To Win'' section of this announcement. Step 2 Solvers will develop the proposed diagnostic solution(s) of Step 1 of the Challenge and submit (in the Step 2 submission) a prototype device and data supporting the ability of the *in vitro* diagnostic device to meet the target product profile (TPP) for analytical and performance characteristics in non-clinical testing (*i.e.,* contrived specimens, panels, etc.), as well as confirmation of analytical performance (*e.g.,* limit of detection, interference, inclusivity, etc.)

Additional details on submission requirements for Step 2 of the Challenge will be available to Step 2 Solvers no later than 30 days after the Step 1 Semi-finalists are announced.

At a minimum, the Step 2 submission shall include:

1. *Execution:* Description of the successful generation of a prototype diagnostic test(s) that is based on the Step 1 solution, which may also include innovations, essential alterations in the original proposed plan, and/or technical or analytical challenges experienced or anticipated. Any changes from the original design (Step 1 solution) should be documented and explained.

2. *Data:* At a minimum, a summary of the analytical performance (limit of detection, inclusivity and exclusivity testing) demonstrated by non-clinical testing (*i.e.,* contrived specimens or panels), and demonstrated progress or plans to achieving the target product profile.

3. *Detection of New Analyte/Biomarker:* The Solvers should provide data to the judges that demonstrate the utility or potential utility of the test for clinical management. The extent and scope of these data are up to the Solver. The judges will assess the strength of these data in projecting the potential impact of the diagnostic test.

Step 3 (Performance testing in CLIA-Certified Laboratories)—All Step 2 Semi-finalists will be eligible to participate in Step 3. Solvers in the third step of the Challenge will have their solutions (prototypes) evaluated in 2 independent CLIA-certified laboratories. The cost for the CLIA-certified laboratory testing will be incurred by the Challenge Sponsor, not the Solvers. This will permit an assessment of the performance of prototype *in vitro* diagnostics confirmed by independent testing. Step 3 Solvers will execute their proposed solution(s) to Step 2 of the Challenge and submit (in the Step 3 submission) sufficient numbers of their solutions (prototype platforms and diagnostic test kits/reagents) for testing. The testing in these two independent laboratories will ensure the solution(s) demonstrate usability, stated time to result, appropriate analytical sensitivity/specificity by non-clinical and/or clinical testing (*i.e.,* contrived specimens or panels of drug resistant bacteria), as well as confirmation of analytical performance (*e.g.,* limit of detection, interference, inclusivity, reproducibility, etc.) reported in the data submitted by solver in Step 2.

Additional details on submission requirements for Step 3 of the Challenge will be available to Step 3 Solvers no later than 30 days after the Step 2 Semi-finalists are announced.

The Step 3 submission requires each semi-finalist to submit:

1. *Project Description:* Detailed description of materials, methods, personnel, resources, and schedule. Any changes from the original design (Step 2 solution) should be documented and explained.

2. *Execution:* The Solvers selected for Phase 3 must provide two prototype instruments and sufficient numbers of the diagnostic test(s) based on the Step 2 solution for testing by the two CLIA-

laboratories, as well as methodology/protocols to perform diagnostic testing using the prototypes.

Registration and Submission Process for Solvers: To register and submit for this Challenge, Solvers may access the registration and submission platform from any of the following:

- Access the *www.challenge.gov* Web site and search for ''Antimicrobial Resistance Rapid, Point-of-Need Diagnostic Test.''
- Access the Antimicrobial Resistance Rapid, Point-of-Need Diagnostic Test Web site; a registration link for the Challenge can be found on the landing page under ''Challenge Description.''
- Access the Web site of the Challenge administered for NIH by Capital Consulting Corporation at *http://www.cccinnovationcenter.com/challenges/antimicrobial-resistance-diagnostic-challenge/*.

Amount of the Prize

Step 1: Up to $50,000 per semi-finalist (maximum of 20 semi-finalists)
Step 2: up to $100,000 per semi-finalist (maximum of 10 semi-finalists)
Step 3: equal to or greater than $18,000,000 to be divided among a maximum of 3 awardees based on the number of prizes awarded to Step 1 and 2 semi-finalists from a total pool of $20,000,000.

As determined by the judges, the number of prizes will be determined for the Step 1 and 2 Semi-finalists and Step 3 winner(s) from a total pool of $20,000,000.

The NIH and the BARDA reserve the right to cancel, suspend, and/or modify this Challenge at any time through amendment to this **Federal Register** notice. In addition, the NIH and the BARDA reserve the right to not award any prizes if no solutions are deemed worthy. The award approving official for Step 3 of this Challenge is the Secretary, Department of Health and Human Services (HHS).

Basis upon Which Winners Will Be Evaluated: Solutions for all steps of the Challenge will be evaluated by a Technical Evaluation Panel using the criteria and rating scales describe below. Additionally, the BARDA scientific staff and the NIH scientific staff from the various NIH Institutes and Centers (ICs), including the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) of the NIH Office of the Director, will review highly rated solutions for scientific alignment with the National Action Plan for Combating Antibiotic Resistant Bacteria goal for a rapid, point-of-need diagnostic test that has the ability or potential to improve clinical decision making such that antibiotic use and/or outcomes of patients infected with drug resistant pathogens are fundamentally improved compared to current standard of care and/or reduce transmission of drug resistant pathogens. Specific examples could include allowing health care providers to: (1) Rapidly identify/detect one or more of the 18 drug resistant bacteria of highest concern which can be found in Table 3 of the National Action Plan for Combating Antibiotic Resistant Bacteria or (2) detect biomarkers that would inform patient management decisions, such as need for antibiotics or severity of infection.

The Judging Panel will determine which of the diagnostic test solutions are of relevance to the BARDA's and NIH's missions, and the degree of innovation advancing existing clinical diagnostics. Three judges, comprising senior leadership from the BARDA and the NIH, will use the technical and programmatic evaluations to determine the Step 1 semi-finalists, those Solvers in Step 1 who are deemed meritorious; the Step 2 semifinalists, those Solvers in Step 2 who are deemed meritorious; and the Step 3 prize winner(s). Prizes will be approved by the Secretary, Department of Health and Human Services.

Step 1 (Theoretical)—The Technical Evaluation Panel will use the following criteria and rating scales for evaluating proposed solutions with high scores reflecting the mostly highly rated solutions:

1. *Innovation.* Clearly demonstrates novel and innovative technology and/or approaches outpacing the current state-of-the-science.

2. *Clinical significance.* Implementation of the proposed *in vitro* diagnostic test supports improved clinical decision making and thus decreases antibiotic resistance.

3. *Diagnostic Performance.* The proposed *in vitro* diagnostic test is anticipated to have performance characteristics (*e.g.,* sensitivity, specificity) relevant to its intended use and consistent with and support by proposed approaches and prior evidence.

4. *Feasibility.* Likelihood, based on scientific concept, existing data, technological capability, and resources that the proposed *in vitro* diagnostic test can be successful as a commercial diagnostic system.

5. *Time to test result.* The proposed *in vitro* diagnostic test produces actionable results (from the time that a sample is collected from a patient to the time that the result is available to the healthcare provider) relevant to its intended use (inpatient, outpatient, reduction in time compared to existing methods).

6. *Setting and Ease of Use.* The proposed *in vitro* diagnostic test is intended for use in inpatient and/or outpatient settings. The proposed solution should account for: A settings particular availability of equipment and personnel, that will affect what specimens can be collected (*i.e.,* sample matrix), stored, processed, and analyzed; what level of training is required to operate the device; what disposable materials are required; and how dependent the test will be on other types of equipment. These factors may affect an *in vitro* diagnostic test's ease of use or otherwise limit its utility. Plan for advancing to Step 2 of the competition.

Step 2 (Delivery of Prototype and Analytical Data)—Additional details on evaluation criteria will be provided later. Step 2 submissions must provide a clear description of how experiments were conducted (including use of appropriate controls, instrument calibration, etc.), how the data were collected, and how analytical performance was assessed. Step 2 submissions must include all requisite scientific and technical details including materials, methods, protocols, and devices to demonstrate successful execution of the proposed solution. Has test reproducibility been demonstrated? What improvements and/or innovations were implemented above and beyond what was proposed in Step 1?

The Technical Evaluation Panel will use the following criteria and rating scales for evaluating proposed Step 2 solutions, with high scores reflecting the mostly highly rated solutions.

1. *Innovation.* Must be clearly novel and innovative technology representing an advance beyond the current state-of-the-science.

2. *Clinical significance.* Clinical significance of the diagnostic use and likelihood that implementation would contribute to decreasing antibiotic resistance.

3. *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.

4. *Feasibility.* Likelihood, based on scientific concept, existing data, technological capability, and resources that the proposal can be successful at the end of Step 3 of this competition. Time to test result. The development of an effective *in vitro* diagnostic test that rapidly produces results (from the time

that a sample is collected from a patient to the time that the result is available to the healthcare provider) relevant to its intended use (inpatient, outpatient, reduction in time compared to existing methods). It is anticipated that all proposals will have a maximum result time of 90 minutes.

5. *Setting and Ease of Use.* The settings or venues in which the proposed point-of-need *in vitro* diagnostic test may be most needed for combating antibiotic resistance. The development of an effective *in vitro* diagnostic test that is easy to use in either an inpatient and/or outpatient setting. The proposed solution should require limited, if any, specimen processing. Test complexity, as assessed by applicability for over-the-counter, outpatient (*i.e.,* CLIA-waived), or hospital-based settings (*i.e.,* moderately complex CLIA laboratories) will be considered. Recognizing that diagnostics often require specialized equipment for sample storage, processing and/or analysis, considerations about how such specialized equipment may affect an *in vitro* diagnostic test's ease of use or otherwise limit its utility.

6. *Sample matrix.* The development of an effective *in vitro* diagnostic test that uses human samples (*e.g.,* blood, urine, sputum, tissue fluid, multiple or other sample specimens).

7. *Throughput.* Methods that describe the ability to process more than one specimen simultaneously.

8. *Data Content.* Methods that promote the collection and integration of multiple types of data (*e.g.,* biochemical, physiologic, morphological, or 'omics-level analyses) on diagnostics for one or more of the 18 drug resistant bacteria referenced previously or differentiates between viral and bacterial infections will be rated more favorably.

Step 3 (Performance testing)—Step 3 submitters must provide the diagnostic device(s), any ancillary devices, procedure for using the device and interpreting the results, and controls for testing. Specimen panels will be provided by the Challenge sponsors.

The Technical Evaluation Panel will use the following criteria and rating scales for evaluating proposed Step 3 solutions, with high scores reflecting the mostly highly rated solutions:

1. Must be clearly novel and innovative technology representing an advance beyond the current state-of-the-science.

2. Likelihood of improving the use of antibiotics in patients.

3. *Diagnostic performance.* The performance characteristics (*e.g.,* sensitivity, specificity, positive predictive value, and negative predictive value) of the *in vitro* diagnostic test using the prototype and likely impact of the performance on utility in combating antibiotic resistance.

4. *Sample matrix.* The development of an effective *in vitro* diagnostic test that uses human samples (*e.g.,* blood, urine, sputum, tissue fluid, multiple or other sample specimens).

5. *Time to test result.* The development of an effective *in vitro* diagnostic test that rapidly produces results. Specifically, 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).

6. *Setting and Ease of Use.* The settings or venues in which the proposed point-of-need *in vitro* diagnostic test may be most needed for combating antibiotic resistance. 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, considerations about how such specialized equipment may affect an *in vitro* diagnostic test's ease of use or otherwise limit its utility.

As part of the evaluation process, the panel may request a demonstration of the technology.

Additional Requirements

Each individual (whether participating singly or in a group) or entity agrees to follow all applicable federal, state, and local laws, regulations, and policies.

Each individual (whether participating singly or in a group) or entity participating in this Challenge must comply with all terms and conditions of these rules, and participation in this Challenge constitutes each such participant's full and unconditional agreement to abide by these rules. Winning is contingent upon fulfilling all requirements herein.

Intellectual Property: By submitting the Submission, each Solver warrants that he or she is the sole author and owner of any copyrightable works that the Submission comprises, that the works are wholly original with the Solver (or is an improved version of an existing work that the Solver has sufficient rights to use and improve), and that the Submission does not infringe any copyright or any other rights of any third party of which Solver is aware.

To receive an award, Solvers will *not* be required to transfer their exclusive intellectual property rights to the NIH or ASPR. Instead, Solvers must grant to the federal government a *nonexclusive license* to practice their solutions and use the materials that describe them. To participate in the Challenge, each Solver must warrant that there are no legal obstacles to providing a nonexclusive license of Solver's rights to the federal government. This license must grant to the United States government a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States throughout the world any invention made by the Solvers that covers the Submission. In addition, the license must grant to the federal government and others acting on its behalf, a fully paid, nonexclusive, irrevocable, worldwide license in any copyrightable works that the Submission comprises, including the right to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly said copyrightable works.

Liability and Indemnification: By participating in this Challenge, each Solver agrees to assume any and all risks and waive claims against the federal government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise. By participating in this Challenge, each Solver agrees to indemnify the federal government against third party claims for damages arising from or related to Challenge activities.

Insurance: Based on the subject matter of the Challenge, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, or property damage, or loss potentially resulting from competition participation, Solvers are not required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.

Privacy, Data Security, Ethics, and Compliance: Solvers are required to identify and address privacy and security issues in their proposed projects and describe specific solutions for meeting them. In addition to complying with appropriate policies, procedures, and protections for data that ensures all privacy requirements and institutional policies are met, use of data should not allow the identification

of the individual from whom the data was collected.

Solvers are responsible for compliance with all applicable federal, state, local, and institutional laws, regulations, and policies. These may include, but are not limited to, Health Information Portability and Accountability Act (HIPAA) protections, Department of Health and Human Services (HHS) Protection of Human Subjects regulations, and Food and Drug Administration (FDA) regulations. If approvals (*e.g.,* from an Institutional Review Board) will be required to initiate project activities in Step 2, it is recommended that Solvers apply for approval at or before the Step 1 submission deadline. The following links are intended as a starting point for addressing potentially applicable regulatory requirements but should not be interpreted as a complete list of resources on these issues:

HIPAA

Main link: *http://www.hhs.gov/ocr/privacy/index.html.*

Summary of the HIPAA Privacy Rule: *http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html.*

Summary of the HIPAA Security Rule: *http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html.*

Human Subjects—HHS

Office for Human Research Protections: *http://www.hhs.gov/ohrp/index.html.*

Protection of Human Subjects Regulations: *http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.*

Policy & Guidance: *http://www.hhs.gov/ohrp/policy/index.html.*

Institutional Review Boards & Assurances: *http://www.hhs.gov/ohrp/assurances/index.html.*

Human Subjects—FDA

Clinical Trials: *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm.*

Office of Good Clinical Practice: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018191.*

Consumer Protection—Federal Trade Commission

Bureau of Consumer Protection: *http://business.ftc.gov/privacy-and-security.*

Challenge Judges: Senior leadership of the DPCPSI of the Office of the Director of NIH; the National Institute of Allergy and Infectious Diseases (NIAID), NIH; and BARDA, ASPR.

Acknowledgements

The Antimicrobial Resistance Diagnostic Working Group would like to thank the following Subject Matter Experts for providing guidance as BARDA and NIH staff developed this Challenge.

NIAID staff including Ann Eakin, Ph.D. and Randall Kincaid, Ph.D.

FDA staff including Steven Gitterman, M.D., Ph.D. and Jennifer Ross, Ph.D., J.D.

CDC staff including Jean Patel, Ph.D., D (ABMM).

Dated: August 3, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016–21328 Filed 9–7–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 a meeting of the Board of Scientific Counselors, National Institute of Mental Health.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF MENTAL HEALTH, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Mental Health.

Date: September 26–28, 2016.

Time: September 26, 2016, 1:20 p.m. to 5:15 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Porter Neuroscience Research Center, Room GE610/640, Building 35A Convent Drive, Bethesda, MD 20892.

Time: September 26, 2016, 6:00 p.m. to 8:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Time: September 27, 2016, 9:00 a.m. to 4:40 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Porter Neuroscience Research Center, Room GE610/640, Building 35A Convent Drive, Bethesda, MD 20892.

Time: September 28, 2016, 8:40 a.m. to 4:50 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Porter Neuroscience Research Center, Room GE610/640, Building 35A Convent Drive, Bethesda, MD 20892.

Contact Person: Jennifer E. Mehren, Ph.D., Scientific Advisor, Division of Intramural Research Programs, National Institute of Mental Health, NIH, 35A Convent Drive, Room GE 412, Bethesda, MD 20892–3747, 301–496–3501, *mehrenj@mail.nih.gov.*

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

Dated: September 1, 2016.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–21619 Filed 9–7–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Cancer Prevention Fellowship Program Fellowship Program and Summer Curriculum Applications

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 17, 2016 page 39679 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.