collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

All written comments will be available for public inspection on Regulations.gov.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Comment Due Date: Your comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

Dated: February 20, 2015.

Robert G. McSwain,

Acting Director, Indian Health Service.

[FR Doc. 2015–04112 Filed 2–27–15; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Requirements and Registration for ''A Wearable Alcohol Biosensor'' Challenge

Authority: 15 U.S.C. 3719.

Award Approving Official: Dr. Lawrence A. Tabak, Principal Deputy Director, National Institutes of Health (NIH).

SUMMARY: Through the ''A Wearable Alcohol Biosensor'' Challenge (the ''Challenge''), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), a component of the National Institutes of Health (NIH), is searching for a wearable or otherwise discreet device capable of measuring blood alcohol level in real time. The advent of alcohol biosensors that can be worn discreetly and used by individuals in the course of their daily lives will advance the mission of NIAAA in the arenas of research, treatment, and rehabilitation. NIAAA has supported academic and small business grants and contracts to advance the development and use of alcohol biosensors in the past. Current technological developments in electronics, miniaturization, wireless technology, and biophysical techniques of alcohol detection in humans increase the likelihood of successful development of a useful alcohol biosensor in the near future. The NIH believes that this challenge will stimulate investment from public and private sectors in the development of functional alcohol biosensors that will be appealing to individuals, treatment providers, and researchers.

DATES:

Submission period begins March 2, 2015, 9:00 a.m. ET.

Submission period ends: December 1, 2015.

Judging period: January 2016.

Winners announced: On or after February 15, 2016.

The NIH will announce any changes to this timeline by amending this **Federal Register** notice.

FOR FURTHER INFORMATION CONTACT: M. Katherine Jung, Ph.D., Program Director, Division of Metabolism and Health Effects, National Institute on Alcohol Abuse and Alcoholism, Phone: 301–443–8744, Email *Kathy.jung@nih.gov.* F.L. Dammann, M.P.A., Management Analyst and Special Assistant to the Executive, National Institute on Alcohol Abuse and Alcoholism, Phone: 301–480–9433, Email: *fl.dammann@nih.gov.*

SUPPLEMENTARY INFORMATION:

Subject of Challenge

Current technologies for real time monitoring of alcohol consumption, used in criminal justice applications, have performed adequately, but have disadvantages for broader use.

NIAAA seeks the design and production of a wearable device to monitor blood alcohol levels in real time. The device should be inconspicuous, low profile, and appealing to the wearer. The design can take the form of jewelry, clothing, or any other format located in contact with the human body. A non-invasive technology is preferred.

Current technology for continuous alcohol monitoring takes a reading every 30 minutes. We are seeking a solution that improves on this interval and most closely approximates real time monitoring and data collection. The device should be able to quantitate blood alcohol level, interpret and store the data, or transmit it to a smartphone or other device by wireless transmission. Data storage and transmission must be completely secure in order to protect the privacy of the individual. The device should have the ability to verify standardization at regular intervals and to indicate loss of functionality. The power source should be dependable and rechargeable. A form of subject identification would be an added benefit. The device can be removable.

This is a *reduction to practice* challenge that requires written documentation and a working prototype of the submitted solution.

NIAAA is open to a range of design forms which can accomplish the above tasks.

Statutory Authority of the Funding Source

This Challenge is consistent with and advances the mission of NIAAA, as described in 42 U.S.C. 285n, to conduct and support biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of alcohol abuse and the treatment of alcoholism, and to conduct a study of alternative approaches for alcoholism and alcohol abuse treatment and rehabilitation.

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, individuals younger than 18 participating in the Challenge must provide parental consent and must abide by the Children's Online Privacy Protection Act.

2. To Win

To be eligible to win a prize under this Challenge, the Solver—

1. Shall have registered to participate in the Challenge at *www.challenge.gov.*

2. Shall have complied with all the requirements under this section on Eligibility.

3. 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: Non-U.S. citizens and nonpermanent residents can 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.

4. In the case of an individual, he/she may not be an employee of the NIH; 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, stepparent, spouse, domestic partner, child, sibling, or step-sibling).

5. An individual, team, or entity that is currently on the Excluded Parties List (*https://www.epls.gov/*) will not be selected as a Finalist or prize winner.

6. 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.

7. 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.

8. Federal grantees may not use federal funds to develop Challenge submissions.

9. Federal contractors may not use federal funds from a contract to develop Challenge submissions or to fund efforts in support of a Challenge submission.

10. 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. Jung or Mr. Dammann, identified above, and answers will be posted and updated as necessary at *http://www.niaaa.nih.gov/research/challenge-prize* under Frequently Asked Questions. Questions from Solvers that may reveal proprietary information related to solutions under development addressed to NIAAA will be held in strictest confidence.

Submission Requirements

The submission to the Challenge should include the following:

(1) The final solution set for challenge award must include *reduction to practice* of a working prototype of a wearable alcohol biosensor.

(2) Solutions should also include written evidence of successful data storage and retrieval, of consistent function, reliability and robust reproducibility of alcohol quantification. A detailed description of the proposed Solution must include an instructive account of the method of alcohol detection, interval of data sampling, the means of subject identification, proposed process of manufacture, verification of data security and integrity, and standardization of measurements.

(3) Image or images of the proposed wearable, to include overall dimensions.

(4) A video demonstrating the wearable's required capabilities.

Registration and Submission Process for Solvers

Solvers must register and submit their Solutions on *www.challenge.gov* Web site under the link for ''A Wearable Alcohol Biosensor''.

Amount of the Prize

First Prize: $200,000
Second Prize: $100,000

The NIH reserves the right to cancel, suspend, and/or modify this Challenge at any time through amendment to this **Federal Register** notice. In addition, the NIH reserves the right to not award any prizes if no solutions are deemed worthy. The award approving official for this Challenge is the NIH Principal Deputy Director.

Payment of the Prize

Prizes awarded under this competition will be paid by electronic funds transfer and may be subject to Federal income taxes. NIAAA will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Basis Upon Which Winners Will Be Evaluated

Submissions will be judged by a qualified panel selected by NIAAA. The panel will evaluate submissions based on the following judging criteria:

1. Accuracy, reliability, and frequency of blood alcohol measurement
2. Functionality, accuracy, and integration of data collection, data transmission and data storage
3. Safeguards for privacy protection and data integrity
4. Plans for process of manufacture
5. Marketability and likelihood of bringing the product to market
6. Appeal and acceptability to wearers
7. Feasibility

The award is contingent upon experimental validation of the submitted Solution by the Seeker. During the judging period, the expert panel may request additional information or clarification in order to evaluate the entry.

Challenge Judges

Director, National Institute on Alcohol Abuse and Alcoholism
A senior staff member from the National Institute of Biomedical Imaging and Bioengineering
One or more members from the National Advisory Council of the National Institute on Alcohol Abuse and Alcoholism
Program Staff from the National Institute on Alcohol Abuse and Alcoholism

The challenge judges will be advised by a technical panel consisting of individuals with expertise in the following areas:

Chemistry
Engineering
Information Technology and Information System Security
Behavioral and Social Sciences
Development of vehicular alcohol detection systems

Additional Information

Intellectual Property: By submitting the Submission, each Solver warrants that he or she is the sole author and owner of any patentable 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 on any copyright, patent 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. Instead, Solvers will 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 will 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 will grant to the federal government and others acting on its behalf, a paid-up, 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. It is the responsibility of the Solver to obtain approvals (*e.g.*, from an Institutional Review Board), if required. The following links are intended as a starting point for addressing 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.*

Dated: February 23, 2015.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2015–04254 Filed 2–27–15; 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; The Genetic Testing Registry

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of 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 November 25, 2014, page 70194 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. The Office of the Director (OD), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

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

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Ms. Sarah Carr, Acting Director, Office of Clinical Research and Bioethics Policy, Office of Science Policy, NIH, 6705 Rockledge Dr., Suite 750, Bethesda, MD 20892, or call non-toll-free number (301) 496–9838, or Email your request, including your address to: *OCRBP-OSP@od.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: The Genetic Testing Registry, 0925–0651, EXTENSION—Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Clinical laboratory tests are available for more than 5,000 genetic conditions. The Genetic Testing Registry (GTR) provides a centralized, online location for test developers, manufacturers, and researchers to voluntarily submit detailed information about the availability and scientific basis of their genetic tests. The GTR is of value to clinicians by providing information about the accuracy, validity, and usefulness of genetic tests. The GTR also highlights evidence gaps where additional research is needed.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 5,536.