



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Requirements and Registration for “A Wearable Alcohol Biosensor: A Second Challenge”

Authority: 15 U.S.C. 3719

SUMMARY: Through the “A Wearable Alcohol Biosensor: A Second Challenge” (the “Challenge”), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), a component of the National Institutes of Health (NIH), is building upon the success of the previous challenge and 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 the NIAAA in the arenas of research, treatment, and rehabilitation. 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 further stimulate investment from public and private sectors in the development of functional alcohol biosensors that will be appealing to individuals, treatment providers, and researchers and will continue to further the NIAAA’s mission.

DATES: Submission period begins [INSERT DATE OF PUBLICATION IN THE **FEDERAL REGISTER**], 9:00 a.m. ET.

Submission period ends: **May 15, 2017**

Judging period: **May 16, 2017 – July 26, 2016**

Winners announced: On or after **August 1, 2017**

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

FOR FURTHER INFORMATION CONTACT: M. Katherine Jung, Ph.D., Acting 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. All questions and answers regarding the Challenge will be posted and updated as necessary at <https://stage.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 not be posted on Challenge.gov.

SUPPLEMENTARY INFORMATION:

The NIAAA's Statutory Authority to Conduct the Challenge

The NIAAA is conducting this challenge under the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Reauthorization Act of 2010, 15 U.S.C. 3719. In addition, this Challenge is consistent with and advances the mission of the 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.

Subject of Challenge

The winners of the first Wearable Alcohol Biosensor Challenge achieved significant improvements in detection of alcohol in sweat and sweat vapor, and their products will benefit the mission of the NIAAA in multiple ways. Innovators are challenged to design a wearable monitoring device based on alternate distinct and inventive methods of alcohol detection, specifically using non-invasive technology to detect alcohol directly in blood or interstitial fluid. Innovation is encouraged.

Rules for Participating in the Challenge

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 as Solvers must provide parental consent. By allowing individuals younger than 18 to participate in the Challenge as Solvers, the NIH is not condoning or encouraging underage alcohol

consumption, but is rather encouraging innovation in a manner that is consistent with all applicable laws.

1. To be eligible to win a prize under this Challenge, the Solver—
 - a. Shall have registered to participate in the Challenge under the rules as promulgated by the NIH as published in this Notice and www.challenge.gov;
 - b. Shall have complied with all the requirements set forth in this notice;
 - c. 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;
 - d. May not be a federal entity;
 - e. May not be a federal employee acting within the scope of the employee's employment and further, in the case of the Department of Health and Human Services (HHS) employees, may not work on their submission(s) 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 otherwise excluded who seeks to participate in this Challenge should consult his/her agency's ethics official prior to developing a submission; and
 - f. May not be an employee of the NIH, a judge of the challenge, a member of the technical evaluation panel, or any other party involved with the design, production, execution, or

distribution of the Challenge or the immediate family (specifically, a parent, stepparent, spouse, domestic partner, child, sibling, or step-sibling).

2. Federal grantees may not use federal funds to develop Challenge submissions.
3. Federal contractors may not use federal funds from a contract to develop Challenge submissions or to fund efforts in support of a Challenge submission.
4. Submissions must not infringe upon any copyright or any other rights of any third party.
5. By participating in this Challenge, each individual (whether competing singly or in a group) and entity agrees to assume any and all risks and waive claims against the federal government and its related entities (as defined in the COMPETES Act), 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.
6. 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, property damage, or loss potentially resulting from Challenge participation, individuals (whether competing singly or in a group) or entities participating in the Challenge are not required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.
7. By participating in this Challenge, each individual (whether competing singly or in a group) and entity agrees to indemnify the federal government against third party claims for damages arising from or related to Challenge activities.
8. An individual or entity shall not be deemed ineligible because the individual or entity used federal facilities or consulted with federal employees during the Challenge if the facilities

and employees are made available to all individuals and entities participating in the Challenge on an equitable basis.

9. By submitting the Submission, each Solver warrants that he or she is the sole author and owner of any copyrightable works or patentable inventions 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, where such license need be provided only if the Solver wins the award. This license will be a condition of the award and 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.
10. The NIH reserves the right, in its sole discretion, to (a) cancel, suspend, or modify the Challenge, and/or (b) not award any prizes if no entries are deemed worthy.
11. Each individual (whether participating singly or in a group) or entity agrees to follow all

applicable federal, state, and local laws, regulations, and policies.

12. Except where prohibited, participation in the Challenge constitutes consent by the Solvers to allow NIAAA or its contractors to the use or display the Solvers' names, likenesses, photographs, prototype images, and/or hometowns and states for publications and publicity purposes in any media, worldwide, without further payment or consideration.
13. Each individual (whether participating singly or in a group) and 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.
14. An individual, team, or entity that is currently on the Excluded Parties List (<https://oig.hhs.gov/exclusions/>) will not be selected as a Finalist or prize winner.

Registration and Submission Process for Participants

Solvers must register and submit their Solutions on www.challenge.gov website under the link for "A Wearable Alcohol Biosensor: A Second Challenge."

Amount of the Prize

First Prize: \$200,000

Second Prize: \$100,000

The award approving official for this Challenge is the NIAAA 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. The NIAAA will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Basis upon Which Winners Will Be Evaluated

Solution Desired

Solvers are asked to produce a prototype of an appealing, inconspicuous, low profile, wearable technology capable of monitoring blood alcohol non-invasively. The design can take the form of jewelry, clothing, or any other format located in contact with the human body. Highest priority will be given to devices that use non-invasive technologies to measure alcohol concentration in blood or interstitial fluid, as opposed to the detection of alcohol exuded through the skin in sweat or vapor. Functionally, the solution must:

- Achieve real time-monitoring and quantification of blood alcohol level.
- Collect and interpret data, eliminating as much of the biological and device-related delays as possible through innovative, validated, and verifiable techniques.
- Store or transmit data to a smartphone or other device by wireless transmission. It is desirable that the technology permits subject identification. Data storage and transmission must be completely secure in order to protect the privacy of the individual.
- Verify standardization at regular intervals and indicate loss of functionality. Operate from a dependable and rechargeable power source.
- Be removable.

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

What to Submit

This is a reduction to practice Challenge that requires written documentation and a working prototype of the submitted solution. The submission to the Challenge must be in English and include the following:

1. A working prototype of a wearable alcohol biosensor including all accessories necessary for functionality.
2. Written evidence of successful data storage and retrieval, of consistent function, reliability and robust reproducibility of alcohol quantification. The submitted device and the written documentation must be free of any Personally Identifiable Information (PII) accrued during prototype development. 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. Upon receipt of the written documentation, NIAAA will provide an address for the shipment of the prototypes to NIAAA for evaluation.
3. Image or images of the proposed wearable, to include overall dimensions.
4. A video not to exceed 10 minutes demonstrating the wearable's required capabilities.

Submissions will be judged by a qualified panel of federal employees selected by the NIAAA. The award is primarily contingent upon experimental validation of the submitted Solution by the NIAAA. The panel will evaluate submissions based on the following judging criteria:

- Accuracy, reliability, and frequency of blood alcohol levels as validated by the NIAAA.

- Functionality, accuracy, and integration of data collection, data transmission and data storage.
- Safeguards for data integrity and privacy protection for the wearer.
- Plans for process of manufacture.
- Marketability and likelihood of bringing the product to market.
- Appeal and acceptability to wearers.

During the judging period, the expert panel may request additional information or clarification from the Solver in order to evaluate the entry. The judges will be assisted by a panel of technical experts in the following areas: alcohol pharmacokinetics, chemistry, engineering, information technology and information system security, behavioral and social sciences, development of vehicular alcohol detection systems, and wearables. Depending on the nature of the entries, additional expertise may be sought to advise the judges.

Additional Information

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, 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/hipaa/index.html>

Summary of the HIPAA Privacy Rule:

<http://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html>

Summary of the HIPAA Security Rule:

<http://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html>

Human Subjects—HHS

Office for Human Research Protections: <http://www.hhs.gov/ohrp/>

Protection of Human Subjects Regulations:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.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: <https://www.ftc.gov/tips-advice/business-center/privacy-and-security>

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Lawrence A. Tabak,

Deputy Director

National Institutes of Health

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