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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health, National Institute on Drug Abuse (NIDA)

Announcement of Requirements and Registration for “Addiction Research: There’s an App for that” Challenge

Authority: 15 U.S.C. 3719

SUMMARY:

The National Institute on Drug Abuse (NIDA), one of the components of the National Institutes of Health (NIH), announces the Challenge, “Addiction Research: There’s an App for that”. With this Challenge, NIDA aims to develop novel mobile applications (apps) for future addiction research explicitly created on Apple Inc.’s ResearchKit framework. ResearchKit is open-source software which makes it easy for researchers and developers to create apps for specific biomedical research questions by circumventing development of custom code. Contestants will create the solicited app for use by addiction researchers to engage mobile device users in future society-changing research.

DATES:

The Challenge begins [FEDERAL REGISTER PLEASE INSERT THE DATE OF PUBLICATION]

Submission Period: [FEDERAL REGISTER PLEASE INSERT THE DATE OF PUBLICATION] to April 29, 2016, 11:59 p.m., ET.

Judging Period: May 2, 2016 to July 29, 2016

Winners Announced: August 1, 2016

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

The Institute’s Statutory Authority to Conduct the Challenge. NIDA 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. This Challenge is consistent with and advances the mission of NIDA as described in 42 U.S.C. 285o. The general purpose of NIDA is to conduct and support biomedical and behavioral research, health-services research, research training, and health-information dissemination with respect to the prevention of drug abuse and the treatment of drug abusers. App developed as a result of this Challenge will help NIDA to gain strides in behavioral addiction research. After winning apps are selected, NIDA may announce subsequent funding programs for a future research study with real human subjects to engage the widest possible community of participants – “citizen scientists.” These future research studies will help researchers to better understand drug abuse and addiction.

Subject of Challenge

Background: The problem of drug abuse affects almost every community and family and yet it remains an uncomfortable subject for discussion. Each year, substance abuse causes high rates of injuries and mortality among Americans and plays a role in many major social problems, such as drugged driving, violence, child abuse, stress, crime, and problems with employment. It harms unborn babies, destroys families, and contributes to homelessness. The societal burden caused by substance use disorders exceeds half a trillion dollars yearly. This cost to society is greater than other chronic conditions such as diabetes (\$131.7 billion) and cancer (\$171.6 billion). NIDA sponsors the majority of addiction-related scientific research in the world. NIDA-funded researchers seek to answer important scientific questions about the paths people take to avoid or to succumb to drug addiction, about the mechanisms and pathways involved in substance-use disorders, and about new tools and techniques for prevention and treatment.

Because the problems stemming from drug abuse and addiction affect almost every community and family to some degree, NIDA issues this Challenge with the hope that Contestants will actively mobilize around the need to know more about the roots of drug abuse and addiction. Specifically, NIDA is seeking to engage communities to envision and to create an app which will help advance scientific research in areas of nicotine, opioids, cannabinoids (including marijuana), methamphetamines, and prescription drug use. The Institute is also interested in further understanding abstinence and wellness as it relates to drug addiction.

The causes and consequences of addiction are multi-faceted, involving biological, behavioral, social, cultural, economic, and environmental factors. These factors likely

interact, with no single factor exerting substantial independent influence on drug use and addiction risk. Unfortunately, most research addresses these factors separately because it is difficult to collect data on the large numbers of participants needed to understand the multi-factor relationships. However, this is changing. Mobile technology offers the capacity to recruit large numbers of participants, in diverse and distant places and to collect prospective data on a broad range of variables as these study participants go about their daily lives. This approach has already led to advances in addiction research. Mobile assessment has extended to geolocation and physiological monitoring, with promising results for predicting and detecting drug use in the field.

As exciting as these findings have been, however, the scope of studies and the types and number of participants studied have been limited by researchers' access to mobile technology. The problem has been exacerbated by a gap in communication between addiction researchers and software and hardware developers. In addition, NIDA-sponsored mobile tools and technologies are often afflicted by a lack of interoperability and by non-sustainability beyond the grant-funding period.

Fortunately, those concerns can be successfully addressed by the inventive uses of customizable research platforms developed by the established informatics technology companies. The recently unveiled ResearchKit developed by Apple Inc. is the available platform designed specifically for biomedical research (<https://www.apple.com/researchkit/>). NIDA's choice of ResearchKit as the platform does not reflect any endorsement of Apple Inc. and Apple's products in the Challenge; rather, it is a response to Apple's release of a set of tools specifically intended for use in health research.

Challenge Goals: NIDA hopes this Challenge will help to promote the development of innovative research apps created on Apple's ResearchKit framework for future addiction studies. Research questions to be answered could include, but are not limited to: Would tracking lifestyle choices, behaviors, nutrition, stress, social participation, work, school, home, neighborhood, genetics, exposure to technology, etc. help to understand why some people manage to stay away from drug abuse and addiction? What contributes to the choice to abuse prescription drugs? How can we systematically collect the experience of patients recovering from addiction? Are there innovative approaches to recording patients' experiences of impact and burden of drug addiction over time? Can the benefits of reduced drug use be meaningfully detected? Can we reveal and collect the participant-identified disease impacts and the preferences for treatment impacts to identify meaningful, significant, perhaps, novel, and potential measures of benefit?

It is critical to note that the apps developed as a result of this Challenge are to be explicitly created for future scientific research purposes, and not for self-help, education, or self-wellness monitoring like other apps already available on iTunes. The submissions must not contain any data about real people, and the Contestants must not use data from or about real people in the development or testing of the apps. However, the app should be designed such that it could be used in future clinical research studies with real human subjects.

Major ethical and legal issues that have to be addressed at every step of the way should include privacy (especially in terms of the end-user's experience as he or she interacts with the app) and confidentiality (the assurance that end-users' data will be seen

and used only in the ways they want). Contestants are responsible for developing and coding the app so that its future use in a study with real human research subjects would be compliant with all applicable federal, state, local, and institutional laws, regulations, and policies. These include, but are not limited to, Substance Abuse Confidentiality Regulations at 42 CFR Part 2, Health Information Portability and Accountability Act (HIPAA) protections, Department of Health and Human Services (HHS) Protection of Human Subjects regulations at 45 CFR Part 46, and Food and Drug Administration (FDA) regulations.

Rules for Participating in the Challenge. The Challenge is open to any Contestant 13 years of age or older. A Contestant may be (i) an entity or (ii) an individual or group of individuals (i.e., a team assembled with the purpose of participating in this Challenge), each of whom is a U.S. citizen or permanent resident of the United States. Individuals who are younger than 18 must have their parent or legal guardian complete the *Parental Consent Form* found at <http://www.drugabuse.gov/sites/default/files/parentalconsentform.pdf>.

- (1) To be eligible to win a prize under this Challenge, an individual or entity:
 - a. Shall have registered to participate in the Challenge under the rules promulgated by NIDA as published in this Notice;
 - 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. However, non-U.S. citizens and non-permanent residents can participate as a member of a team that otherwise satisfies the eligibility criteria. Non-U.S. citizens and non-permanent residents are not eligible to win a monetary prize (in whole or in part). Their participation as part of a winning team, if applicable, may be otherwise recognized when the 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 HHS employees, may not work on their submission(s) during assigned duty hours;
- f. May not be an employee of the NIH, a judge of the challenge, or any other party involved with the design, production, execution, or distribution of the Challenge or the immediate family of such a party (i.e., spouse, parent, step-parent, child, or step-child).

- (2) Federal grantees may not use Federal funds to develop their Challenge submissions unless use of such funds is consistent with the purpose of their grant award and specifically requested to do so due to the Challenge design, and as announced in the Federal Register.
- (3) Federal contractors may not use Federal funds from a contract to develop their Challenge submissions or to fund efforts in support of their Challenge submission.
- (4) Submissions must not infringe upon any copyright or any other rights of any third party. Each Contestant warrants that he or she is the sole author and owner of the work and that the work is wholly original.

- (5) By participating in this Challenge, each Contestant (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, no Contestant (whether competing singly or in a group) or entity participating in the Challenge is required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.
- (7) By participating in this Challenge, each Contestant (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) A Contestant or entity shall not be deemed ineligible because the Contestant 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 participating in this Challenge, each Contestant (whether participating singly or in a group) and entity grants to the NIH/NIDA an irrevocable, paid-up, royalty-free nonexclusive, sublicensable worldwide license to post, link to, share, use and display

publicly on the Web the submission, including the architectural design of the app and any other information necessary for a third-party to use, adapt, improve or otherwise modify the app. Each Contestant will retain all other intellectual property rights in their submissions, as applicable.

(10) NIDA reserves the right, in its sole discretion, to (a) cancel, suspend, or modify the Challenge, (b) not award any prizes if no entries are deemed worthy, and (c) to disqualify from competition any submission that contains or uses data about real people or is deemed, in the judging panel's discretion, inappropriate, offensive, defamatory, or demeaning.

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

(12) Each Contestant (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 contestant's full and unconditional agreement to abide by these rules. Winning is contingent upon fulfilling all requirements herein.

Registration Process for Contestants. To participate in this Challenge visit <http://nida.ideascale.com>, a NIDA Challenge platform provider. Alternatively, visit www.challenge.gov and search for "Addiction Research: There's an App for that" and follow the instructions. NIDA encourages established addiction researchers to share the ideas via the Forum (<http://nida.ideascale.com>) and seek collaboration(s) with app developers and engineers to create the winning research apps.

Submission Requirements. All submissions must be in English. The Contestants must not use HHS’s logo or official seal or the logo of NIH or NIDA in the submissions, and must not claim federal government endorsement.

Due to sensitivities surrounding addictions information, only fictitious data may be used for app development. The submission must not contain any data from or about real people, and the Contestant must not use data from or about real people in the development or testing of the app. However, the app should be designed such that it could be used in future potential clinical research studies with real human subjects. Entries that include data from or about real people will be disqualified.

Each submission for this Challenge requires a complete “Submission Package.” The Submission Package includes:

- 1) A white paper describing the app built upon the proposed design of future scientific research studies. The white paper must describe a scientific research agenda and study design that could be undertaken using the developed app in future human subject research. Components of the white paper include, but are not limited to:
 - a. Research design or conceptual framework
 - b. Research agenda
 - c. Description of ResearchKit modules and add-apters incorporated and otherwise considered
 - d. Statement about compliance with substance abuse and other applicable

laws and regulations

e. Data collection and management plan

f. Recruitment and retention advantages of the proposed approach

The white paper must consist of a PDF file, not contain any information directly identifying the Contestants. The PDF document must be formatted to be no larger than 8.5” by 11.0”, with at least 1 inch margins. The white paper must be no more than 12 pages long. Font size must be no smaller than 11 point Arial.

- 2) A video of the app prototype. A brief demo video (or its link to YouTube) must be no more than five (5) minutes and clearly demonstrate the app functionality. The Contestant must have permission to use all content in the video, including footage, music and images. The video must not contain any information or images directly identifying the Contestant.
- 3) App software. The working software must operate on a mobile device using Apple’s ResearchKit framework. The Contestants must provide a way for the NIDA to test the app such as a weblink, installation file, or a shared test build. The submission may be disqualified if the software application fails to function as expressed in the prototype description submitted by the Contestant.

Amount of the Prize; Award Approving Official. Up to three monetary prizes will be awarded: \$50,000 for 1st Place, \$30,000 for 2nd Place, and \$20,000 for 3rd Place for a total prize award pool of up to \$100,000. The names of the winners and the titles of their

submissions will be posted on the NIDA web site. The award approving official for this Challenge is the Director of the National Institute on Drug Abuse.

Payment of the Prize. Prizes awarded under this Challenge will be paid by electronic funds transfer and may be subject to Federal income taxes. The NIH/NIDA will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Basis upon Which the Winner Will Be Selected. The judging panel will make recommendations to the award approving official based upon the following 8 criteria. Each criterion will be scored with the maximum of 5 points.

- 1) Quality of the research agenda (0-5 points): How well is the research design or conceptual framework developed? Is it unique and clinically meaningful? Does the research agenda describe a logical, feasible plan and timeframe for addressing addiction knowledge gaps?
- 2) Proposed ResearchKit modules (0-5 points): How many existing features of the ResearchKit does the app use? How are the modules applicable for conducting future addiction research? Does the Contestant consider creating new modules?
- 3) Add-apters (0-5 points): Does the app utilize novel add-apters? How are the proposed add-apters applicable to the future research study?
- 4) Compliance with applicable legal policies. (0-5 points): Although the competition requires that the submission must not contain any research data about real individuals, and the Contestants must not use real data in the development of the

app, the submission will be evaluated on whether the app design and research agenda would be compliant with all applicable federal, state, local, and institutional laws, regulations, and policies. These include, but are not limited to, Substance Abuse Confidentiality Regulations at 42 CFR Part 2, HIPAA protections, HHS Protection of Human Subjects regulations at 45 CFR Part 46, and FDA regulations. Would the app ensure compliance with consent requirements for future potential addiction studies? Would the app clearly explain study participation to the user? Would data management be safe and secure?

5) Study participant's engagement (0-5 points): How well would the app attract and retain human subject engagement? Does it assure the high level of human subject participation?

6) Durability of study participation (0-5 points): How reasonable is the plan for retaining human subjects and data collection over the duration of the future, proposed research study?

7) Clarity of the app context (0-5 points): Will the app provide a transparent, engaging user experience for both addiction researchers and human subjects? Would the future human subjects of research be able to easily track their overall progress during the research study? Would future human subjects of research know what information is being collected, why, and what will happen with their data?

8) Data quality for researchers (0-5 points): Is it easy for addiction researchers to monitor and manage the overall progression of the research study? Is the data management plan appropriate? Are data clearly presented to the researcher?

The evaluation process will begin by anonymizing and removing those that are not responsive to this Challenge or not in compliance with all rules of participation eligibility. Submissions that are responsive and in compliance will next undergo a review by federal employees with expertise in the relevant areas of science and executive scientific advisors. A panel of judges consisting of federal employees will then score responsive and compliant submissions entries in accordance with the judging criteria outlined above. Final recommendations will be determined by a vote of the judges based on score. Scores from each criterion will be weighted equally, but failure to meet a minimum standard for any one criterion might disqualify an application. The score for each submission will be the sum of the scores from each of the 5 voting judges, for a maximum of 200 points.

Additional Information

What is ResearchKit? ResearchKit is an open-source software kit designed specifically for medical and health research; it simplifies the creation of iPhone apps that can help physicians and scientists gather data from willing participants. The framework allows researchers to circumvent the development of custom code for common tasks such as sharing, storage, and syncing of research data. It helps to create apps to recruit human subjects in research, present informed-consent materials, create surveys and tasks, and monitor sensors interoperable with smartphone technology. ResearchKit works seamlessly with Apple HealthKit, a suite of applications that can interact with the iPhone accelerometer, microphone, gyroscope, GPS sensors, and external hardware such as

glucometers, inhalers, and other existing and newly developed sensors. These capabilities could help monitor a participant's gait, motor impairment, physical fitness, speech, and memory, to name just a few. Additional hardware extensions (add-apters) are frequently developed and available.

It is important to note that the ResearchKit framework does not include a data management solution. The framework can be used with a data management solution only after IRB approval of the human health study with consideration of the provider's data privacy and security practices. Apple's ResearchKit debuted in March 2015 with five opt-in health research apps, now available for free public download. For more information about Apple's ResearchKit and the developed apps visit <https://www.apple.com/researchkit/> and <http://nida.ideascale.com>.

Features and modules currently accessible and compatible with Apple's

ResearchKit: Apple's iPhones have a number of built-in sensors, including Touch ID, Barometer, Accelerometer, Gyroscope, Proximity Sensor, and Ambient Light Sensor. The Touch ID is a biometric technology that provides user identification through a finger scanner, the Barometer measures atmospheric pressure, the Accelerometer measure the tilting motion and orientation of the iPhone, and the Three-Axis Gyroscope enables 3-axis angular acceleration around the X, Y and Z axes, enabling precise calculation of yaw, pitch, and roll. The Proximity Sensor deactivates the display and touchscreen when the phone is brought near the face during a call and the Ambient Light Sensor adjusts the display brightness. All sensors are available for the iPhone 6 Plus, iPhone 6, iPhone 5S and iPhone 5. The only exceptions are the Barometer sensor, which is only available for

the iPhone 6 Plus, and iPhone 6, and the Touch ID sensor, which is only available for the iPhone 6 Plus, iPhone 6, and iPhone 5S.

In addition to internal sensors, there are a number of add-apters which work with existing iPhones. The add-apters can measure pulse rate, breathing pattern, blood pressure, blood oxygen saturation, heart rate variability, galvanic skin response, and glucose concentration, and can even help detect ear infections and track inhaler medication use. Some add-adapters can be directly purchased through iTunes or third-party vendors; others must be purchased through a physician. Based on the type of adapter, prices can vary from \$6 to \$249.

Dated: 10/27/2015

Nora D. Volkow, MD

Director, National Institute on Drug Abuse, National Institutes of Health

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