

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, (301) 254-9975, helmersk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA-RM-14-030: Nuclear Organization and Function Interdisciplinary Consortium (NOFIC) (U54).

Date: June 24–25, 2015.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 5520

Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Kee Hyang Pyon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7806, Bethesda, MD 20892, pyonkh2@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; SBIR/STTR Informatics.

Date: June 24, 2015.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Melinda Jenkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3156, MSC 7770, Bethesda, MD 20892, 301-437-7872, jenkinsml2@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-14-166: Early Phase Clinical Trials in Imaging and Image-Guided Interventions.

Date: June 24, 2015.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Chiayeng Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Room 5213, MSC 7852, Bethesda, MD 20892, 301-435-2397, chiayeng.wang@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Innovative Therapies and Tools for Screenable Disorders in Newborns.

Date: June 24, 2015.

Time: 12:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Four Seasons Hotel Seattle, 99 Union Street, Seattle, WA 98101.

Contact Person: Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301-435-1779, riverase@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 19, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-12546 Filed 5-22-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Requirements and Registration for: “Harnessing Insights From Other Disciplines To Advance Drug Abuse and Addiction Research” Challenge

Authority: 15 U.S.C. 3719.

SUMMARY: The National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), is seeking from the general public ideas on how to adapt specialized knowledge from other disciplines to inform new directions and discoveries in drug abuse and addiction research. With the “Harnessing insights from other disciplines to advance drug abuse and addiction research” challenge (the “Challenge”), NIDA aims to gain insights into new methods or approaches that could transform discovery in order to significantly expand our basic knowledge about drug abuse and addiction processes, accelerate the development of novel and more effective prevention and treatment strategies, and/or enhance our capacity to implement, monitor, and improve upon evidence-based interventions.

This Challenge is soliciting written proposals that outline novel approaches to addressing research challenges in the drug use and addiction field by leveraging concepts or technologies from other disciplines. This Challenge is being issued as part of NIDA’s strategic planning process for 2016–2020. Winning proposals may be used to guide the development of new research programs within NIDA.

DATES:

- (1) Submission Period begins May 26, 2015, 9:00 a.m., EST
- (2) Submission Period ends June 22, 2015, 11:59 p.m., EST
- (3) Judging Period June 23, 2015 to July 17, 2015
- (4) Winners Announced July 30, 2015

FOR FURTHER INFORMATION CONTACT: Dr. Emily Einstein, Ph.D., Science Policy Branch, Office of Science Policy and Communication, National Institute on Drug Abuse, Phone: 301-443-6071, Email: emily.einstein@nih.gov.

SUPPLEMENTARY INFORMATION:

Subject of the Challenge

For the past four decades, the National Institute on Drug Abuse (NIDA) has led the way in supporting research to prevent and treat drug abuse and addiction and to mitigate the impact of their consequences, which include the spread of HIV/AIDS and other infectious diseases. To confront the most pressing aspects of the complex disease of addiction and to tackle its underlying causes, NIDA’s strategic approach is multipronged and includes research programs in basic, clinical, and translational sciences. These programs support studies in genetics, functional neuroimaging, social neuroscience, medication and behavioral therapies, prevention, and health services, including cost-effectiveness research. NIDA’s evolving portfolio has produced a vast body of knowledge that informs strategic directions for future research, and this Challenge represents a new approach to broaden the pool of testable ideas.

Scientific knowledge about drug addiction and its treatment has increased markedly over the past couple of decades. Today, we have a better understanding of the effects of drugs on the brain, as well as new and more effective treatments than were available in the past. A changing healthcare landscape may provide opportunities to further enhance the quality of addiction prevention and treatment. Still, addiction remains a pressing public health issue, and this Challenge seeks to accelerate progress in the field of drug abuse and addiction research by incentivizing a broader community of stakeholders—including those not formally involved in biomedical or addiction-related disciplines—to propose new ideas or innovations that leverage concepts or technologies from other disciplines to advance drug abuse and addiction research.

While preparing their proposals, applicants should bear in mind NIDA’s traditional priority areas, persistent roadblocks that hamper progress, and evolving and emerging opportunities. Some illustrative examples are discussed below; however, proposals may address any challenge within the drug use and addiction field.

NIDA priority areas. NIDA’s charge, to bring the power of science to bear on drug abuse and addiction, has two critical components. The first is the strategic support and conduct of research across a broad range of disciplines. The second is ensuring the rapid and effective dissemination and implementation of the results of that research to significantly improve

prevention and treatment and to inform policy as it relates to drug use and addiction. These aims are currently met by a broad range of projects in basic, clinical, and translational sciences. For more information on current NIDA research programs please visit www.drugabuse.gov.

Roadblocks to progress in addiction research and its translation. There are many scientific and non-scientific roadblocks that hamper progress on drug use and addiction research. For example, one of the most frequently cited obstacles to clinical advances in the field of drug use disorders is the lack of interest by the pharmaceutical industry in developing new addiction medications. This is largely due to the low success rate of clinical trials for neurotherapeutics and the perceived lack of financial incentives to pursue new pharmacotherapies for substance use disorders. Other key obstacles include the reluctance of some primary care providers to address substance abuse with their patients. On the basic research side, reproducibility, transparency, data sharing, and training a diverse workforce remain areas in need of improvement.

Emerging Opportunities. New discoveries, technologies, paradigms, and ways of thinking play a key role in our efforts to understand addiction, to develop better ways to influence addiction trajectories, and to mitigate its consequences. The examples below are meant to illustrate just a few areas of rapidly evolving technologies and emerging opportunities from which the drug use and addiction field expects to reap significant benefits in the near future.

Genomics and Epigenomics. Recent technological developments have led to important advances in linking genes and their regulation with behavior. We now have an unprecedented capacity to screen for thousands of genetic and epigenetic variations and catalogue how they modulate substance use disorder risk by influencing gene expression, brain maturation, neural architecture, and behavioral patterns. In addition, advances in epigenetics research are enabling increased understanding of how environmental factors (*e.g.*, parenting style, drug exposure) can affect the expression of specific genes to either strengthen or weaken risk for substance use and addiction. Similar approaches could be applied to leverage advances in metabolomics, proteomics, connectomes, transcriptomics and systems biology to better characterize the role of these systems in drug use and addiction.

Big Data. Behavioral disorders including drug use disorders are incredibly complex, with multiple biological, environmental, and developmental factors contributing to risk. Very large data sets (on the scale of tera- or petabytes, typically referred to as “Big Data”) sets are essential platforms for the analysis of such complex systems, overlaying genetic, molecular, cellular, environmental, behavioral, and structural and functional brain imaging data. Big Data also brings analysis opportunities in many other areas, such as social media and socio-economic mapping which, when combined with health information, could lead to an improved understanding of predictors of psychiatric illness risk (including addiction), trajectory, and treatment responses. This area of development presents significant opportunities for innovation for research.

Data Sharing. Data sharing is a critical component that allows the results of NIDA’s research to be distributed to investigators and the public in order to promote new research, encourage further analyses, and disseminate information to the community. Secondary analyses of shared data multiply the scientific contribution of the original research. The development of new strategies to facilitate effective data sharing and analysis is one area in which new ideas could spur significant advancement.

Informatics. NIDA is already pursuing several avenues to realize the research and clinical potential of various informatics tools. Notable examples include:

- Development of a comprehensive clinical decision support systems based on advanced database analysis techniques.
- Research in theoretical and applied areas of medical and clinical informatics, including the study of new methods for acquiring, representing, processing, and managing data within the Intramural Research program (IRP) clinical and research programs.
- Development of transactional electronic recording and telemetry methods for implementation in various research environments such as clinical neuroimaging, pharmacology and therapeutics, and nicotine psychopharmacology research.
- Development of innovative, field-deployable tools to measure exposures to psychosocial stress and addictive substances within geographic contexts in real time.
- Research into technology based delivery of behavioral treatment

interventions including contingency management.

Despite these ongoing efforts there is a significant need for new strategies for leveraging advances in informatics to advance research on drug use and related disorders.

This Challenge welcomes bold new ideas in these fields within the vast scientific, clinical and technological realms. In summary, the overarching goal of the present Challenge is to identify and parlay the untapped power of other (unexpected) technologies, fields, and innovations to inspire transformative advances in the area of addiction research.

Statutory Authority

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 and health services research, research training, and health information dissemination with respect to the prevention of drug abuse and the treatment of drug abusers. Consistent with this authority, one of NIDA’s strategic goals is to support research to improve the quality of addiction treatment. Novel measures, conceptual models or creative, yet feasible ideas, and related research agendas that achieve the goals underlying this Challenge will help set priorities for future research and, accordingly, will support this strategic goal.

Rules for Participating in the Challenge

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 and published in this Notice;
 - b. Shall have complied with all the requirements 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 recognized when the results are announced.
 - d. In the case of an individual, whether participating singly or in a

group, must be at least 18 years old at the time of submission;

e. May not be a Federal entity;

f. May not be a Federal employee acting within the scope of his/her employment, and further, in the case of HHS employees, may not work on their submission(s) during assigned duty hours;

g. May not be an employee of the National Institutes of Health (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.

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 participant 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 individual (whether competing singly or in a group) and entity agrees to assume any and all risks and to 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 their participation in the 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, or property damage, or loss potentially resulting from Challenge participation, no individual (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 individual (whether competing singly or in a group) or 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. Each individual (whether competing singly or in a group) or entity retains title and full ownership in and to their submission and each participant expressly reserves all intellectual property rights (*e.g.*, copyright) in their submission. However, by participating in this Challenge, each participant grants to NIDA, and others acting on behalf of NIDA, an irrevocable, paid-up, royalty-free, non-exclusive, worldwide license to use, copy for use, and display publicly all parts of the submission for the purposes of the Challenge. This license may include posting or linking to the submission on the official NIDA Web site and making it available for use by the public.

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 submissions are deemed worthy.

11. Each individual (whether competing singly or in a group) and entity participating in this Challenge agrees to follow applicable local, State, and Federal laws and regulations.

12. 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.

Submission Requirements

Each submission for this Challenge should consist of a white paper of no more than 6 (double spaced) pages describing a concept for an innovative research initiative to advance drug abuse and addiction research. The white paper must include but not limited to the following:

1. Cover page: indicate title of the proposal and which of the following broadly defined categories would best describe its area of applicability: Prevention, Behavioral treatments, Medications development, Epidemiology, Basic Sciences, Neuroscience, Services and service research, or Other (define).

2. Executive Summary (250 word limit).

3. A description of the innovative concept or technology and how it was effectively applied within another field.

4. A proposal for how the concept can be applied to an outstanding question in drug abuse/addiction research, including a discussion of why that question is important to address.

5. A cogent rationale for why the proposed concept would work in the field of drug use and addiction research.

The white paper must not contain any information directly identifying the participants.

To register for this Challenge, participants must go to www.challenge.gov and search for "Harnessing insights from other disciplines to advance drug abuse and addiction research." Click on the title to go to the Challenge platform Web site, which contains instructions on how to register and submit.

All submissions must be in English. Each submission must consist of a PDF file, containing the white paper document. The PDF documents must be formatted to be no larger than 8.5" by 11.0", with at least 1 inch margins and can include a maximum of two figures. The white paper must be no more than 6 pages long. Font size must be no smaller than 11 point Arial. The participant must not use HHS's logo or official seal or the logo of NIH or NIDA in the submission, and must not claim federal government endorsement.

Amount of the Prize

Up to three monetary prizes may be awarded: \$15,000 for 1st Place, \$7,000 for 2nd Place, \$3,000 for 3rd Place for a total prize award pool of up to \$25,000. 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 will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Basis Upon Which Winner Will Be Selected

The judging panel will make recommendations to the Award Approving Official based upon the following three criteria and point allocation:

1. *Novelty of the concept (5 points):* Concepts shall move the field beyond the existing paradigms commonly used

in addiction research, and focus on novel, underserved, neglected, complex, or intractable aspects of the addiction phenomenon. How novel is the concept? Does it address important basic or clinical features/effects that are not currently or adequately addressed and/or with a fresh perspective?

2. *Feasibility (5 points)*: Ideas, concepts and the approaches, measures and systems derived from them must be rooted on a rational, scientific or otherwise cogent background that would guarantee a modicum of feasibility given the current challenges and state of the art in the field of addiction. How well does the research agenda describe the gaps in the relevant areas of science that need to be addressed by this new approach/concept to be achieved and implemented? Does the agenda describe a logical, feasible plan and timeframe for addressing those gaps?

3. *Importance of the question being addressed/likelihood of impact (5 points)*: How effective would the successful completion of the project be in addressing addiction, enhancing prevention, or improving clinical outcomes? How well does it consider factors relevant to the ultimate success of the concept? How well does it harness innovations from other fields to the existing addiction knowledge base toward advancing drug abuse and addiction research?

Scores from each criterion will be weighted equally. The score for each submission will be the sum of the scores from each of the 5 voting judges, for a maximum of 75 points. NIDA reserves the right to make an award to submissions scoring less than 75 points if NIDA deems any sufficiently meritorious. All submissions will be held until after the deadline is reached for a simultaneous judging process. NIDA reserves the right to disqualify and remove any submission that is deemed, in NIDA's or the judging panel's discretion, inappropriate, offensive, defamatory, or demeaning. NIDA reserves the right not to award any prizes in case none is found to be sufficiently meritorious.

The evaluation process will begin by anonymizing and removing those that are not responsive to this Challenge or not in compliance with all of the rules of eligibility. Submissions that are responsive and in compliance will undergo a preliminary review by the Challenge Judges with expertise in the relevant areas of science. Challenge Judges will examine all responsive and compliant submissions, as well as comments from program staff, if any, and score the submissions in

accordance with the judging criteria outlined above. Judges will meet to discuss the most meritorious submissions. Final recommendations will be determined by electronic (majority) vote of the judges.

Challenge Judges

Dr. Nora Volkow, Director, National Institute on Drug Abuse (NIDA)—Ex Officio

Dr. Roger Little, Deputy Director, Division of Basic Neuroscience and Behavioral Research, NIDA

Dr. David Epstein, Associate Scientist, Intramural Research Program, NIDA

Dr. David Liu, Team Leader, Medical Officer, Center for Clinical Trials Network, NIDA

Dr. Maureen Boyle, Chief, Science Policy Branch, Office of Science Policy and Communication, NIDA

Dr. Meyer D. Glantz, Associate Director for Science, Division of Epidemiology, Services, and Prevention Research

Dr. Ruben Baler, Health Scientist Administrator, Science Policy Branch, Office of Science Policy and Communication, NIDA

Dr. Steve Grant, Chief, Clinical Neuroscience Branch, Division of Clinical Neuroscience and Behavioral Research, NIDA

Dr. Philip Krieter, Pharmacologist, Division of Pharmacotherapies and Medical Consequences of Drug Abuse, NIDA

Dr. Gerald McLaughlin, Chief, Scientific Review Branch, Division of Extramural Research, NIDA

Dated: May 11, 2015.

Nora D. Volkow,

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

[FR Doc. 2015-12632 Filed 5-22-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Transition to Independence Review Committee.

Date: June 11–12, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Giuseppe Pintucci, Ph.D. Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892, 301-435-0287, Pintuccig@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 19, 2015.

Carolyn Baum,

Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-12538 Filed 5-22-15; 8:45 am]

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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 Systemic Injury by Environmental Exposure, June 17, 2015, 08:00 a.m. to June 18, 2015, 05:00 p.m., Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD, 20814 which was published in the **Federal Register** on May 13, 2015, 80 FR Pg. 28630.

The meeting will be held on 06/18/2015–06/19/2015 instead of 06/17/2015–06/18/2015. The meeting time and location remains the same. The meeting is closed to the public.

Dated: May 19, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-12545 Filed 5-22-15; 8:45 am]

BILLING CODE 4140-01-P