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

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

Date: June 24, 2015.
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 3156, MSC 7770, Bethesda, MD 20892, 301–437–7872, pyonkh2@csr.nih.gov.


Date: June 24, 2015.
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–14–0009–11.

Date: June 24, 2015.
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.
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.


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


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
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
competing 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
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:

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.

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.

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, pintuc@g.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.

Carolyne Baum,
Analyst, Office of Federal Advisory Committee Policy.

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