Challenge Implementation at the National Institutes of Health (NIH)

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National Institutes of Health Division of Program Coordination, Planning, and Strategic Initiatives

The National Institutes of Health

The Nation's Steward of Medical & Behavioral Research

- <u>Mission</u>: seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
- Composed of 27 Institutes and Centers (ICs) with unique research agendas, often focusing on particular diseases or body systems.
- NIH Office of the Director (OD) is responsible for setting policy for NIH and for planning, managing, and coordinating the programs and activities of the ICs.



Why Does NIH Conduct Challenges?

- Establish an ambitious goal within a relatively short time frame without bearing high levels of risk and paying only for results
- Stimulate creative and unanticipated solutions to a vexing scientific problem
- Reach beyond the "usual suspects" to increase the number and diversity of solvers tackling a problem and bring out-of-discipline perspectives to bear
- Promote solutions for and draw awareness and attention to a public health need
- Encourage the application of NIH research data to address a public health or medical problem
- Increase cost-effectiveness to maximize the return on taxpayer dollars
- Establish clear success metrics and validation protocols that themselves become defining tools and standards for the subject industry or field
- Stimulate private sector investment in a critical need area

Examples of Current NIH Challenges

Clinical Device



Department of Health and Human Services Antimicrobial Resistance Rapid, Point-of-Need Diagnostic Test Challenge

Develop *in vitro* diagnostic test to combat development and spread of antibiotic resistant bacteria or distinguish between bacterial and viral infections.

bacterial and viral infections.					
\$20,000,000 IN PRIZES		\$500,000 IN PR	IZES	\$400,000 IN PRIZES	\$7,000 IN PRIZES
	Open Until : 01/03/2020	Open	Until: 05/31/2019	Open Until: 06/30/2019	Open Until: 05/31/2019
FY11-FY18 Challenges @ NIH	Challenges 45+	Barticipants 3500+	Submissions 1900+	Winning Entries 170+	Cash Prizes \$13 million+

Research Tool

BIOLOGICAL ASSAYS

National Institutes of Health

NCATS ASPIRE Design Challenge 4

Biological Assays for Translational Innovation in Pain, Opioid Use Disorder and Overdose Software App



Department of Health and Human Services

iCare-AD/ADRD Challenge

Can you develop an app to improve care coordination and/or navigation for persons with dementia?

Essay Contest



Department of Health and Human Services

Speaking Up About Mental Health! This Is...

High school students, share YOUR story on how to reduce mental health stigma and overcome cultural barriers.



Updated Interim Policy for NIH Challenges



NIH Interim Policy

The purpose of this interim policy is to provide NIH with initial guidance and procedures for developing, reviewing, approving, and administering NIHsponsored Challenges.

View Details

Challenge Manager Responsibilities

Each IC interested in holding Challenges must designate a Challenge Manager who is trained by NIH to help develop and draft the rationale and rules of participation, assist in determining the appropriate paradigm or funding mechanism, and to manage the judging process and selection of a winner.

View Details

NIH Challenges

NIH Institutes and Centers announce their challenges in the Federal Register and publicize them on challenges.com.

View Details

Key Components of the Policy:

- Statutory authority
- Award approving official
- Expenditure mechanism
- Total prize purse
- Rules for participation and process for participant registration
- Eligibility restrictions
- Intellectual property
- Judging criteria, COI, and review processes
- Advertising and outreach
- Challenge management and resources
- Review, clearance, and approval timelines
- Paying the winners: individuals vs. entities

NIH IC Challenge Managers: Key Roles & Responsibilities



Help draft challenge announcement



Determine expenditure mechanism



Obtain necessary approvals



Arrange Challenge.gov posting



Help announce challenge & engage public



Serve as POC b/w IC and OD personnel



Ensure timelines are adhered to



Manage judging & winner selection process



Disburse awards to winners



File required reports

NIH Challenge Design Process

Example Challenge Team



National Institute of Biomedical Imaging and Bioengineering

Program Officer Challenge Manager

- + Program Director/Branch Chief
- + Budget Officer
- + Executive Officer
- + Policy Analyst
- + Communications Officer

Cash prize or non-cash prize?

- What is necessary to incentivize participation?
- What is the appropriate expenditure mechanism?

Manage internally or contract out?

- What resources (financial and human) are available?
- Which approach is more cost-effective?
- Does the IC possess the IT infrastructure to accept, process, and evaluate submissions?

How will potential participants learn about the challenge?

- What communication products are needed?
- Will there be announcements at key events/conferences, webinars for interested participants, social media postings, etc.?

Who will judge the entries?

- Judges must be Federal employees or SGEs
- Will a technical review panel be necessary/advantageous?

What happens after the challenge?

- Opportunities for follow-on funding or venture capital for further development?
- How will the outcomes and impacts be evaluated?

NIH Challenge Review & Clearance Process



Examples of NIH Challenge Review Considerations

- Does the challenge advance NIH's and the IC's mission?
- Can the desired outcome be achieved more efficiently or effectively with a grant, contract, or cooperative agreement?
- Did the IC "consult widely both within and outside the Federal government" when selecting the topic of the challenge?
- Are the judging criteria sufficiently clear and detailed to enable the judging panel to confidently pick winners?
- Are the eligibility rules and submission directions sufficiently clear and detailed to enable a wide variety of participants to compete?
- □ Is the cash prize purse appropriate to incentivize participation while not risking overpayment for results?
- □ Is the expenditure mechanism for the cash prize appropriate? (appropriated funds, gift funds, contracts, public-private partnerships, intra-agency agreements, etc.)