

cardiovascular devices. These issues include, but are not limited to:

- Considerations that go into determining if a change is appropriate for an annual report or 30-day notice (e.g., equipment changes, software changes, supplier changes);
- Best practices for submission contents;
- Other issues and questions raised by the public workshop attendees that are relevant to 30-day notices and annual reports for cardiovascular devices.

Dated: August 7, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Announcement of Requirements and Registration for the Challenge To Identify Audacious Goals in Vision Research and Blindness Rehabilitation

**Authority:** 15 U.S.C. 3719.

**SUMMARY:** The National Eye Institute (NEI) is announcing the launch of the *Challenge to Identify Audacious Goals in Vision Research and Blindness Rehabilitation* (Challenge) to stimulate innovation in establishing a national vision research agenda. This Challenge seeks entries from the general public, not just those typically engaged in vision research. The challenge calls for submission of audacious goals in any area relevant to NEI's mission to conduct and support research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the blind (42 U.S.C. 285i).

The NEI will select up to 20 winners to receive a \$3,000 cash prize and will host the winners at the NEI Audacious Goals Development Meeting to present and discuss their winning entries with a broad audience of scientists, NEI staff, and other stakeholders. This challenge will generate valuable contributions from NEI's many and varied stakeholders to inform the Institute's strategic plan, energize the Institute's research efforts, increase public awareness of vision research, and enhance the national effort to reduce the burden of ocular disorders and diseases worldwide.

#### DATES:

- (1) Submission period begins August 13, 2012.
- (2) Submission period ends November 12, 2012, 6:00 p.m. ET.
- (3) Winners notified January 7, 2013.
- (4) Winners present and discuss their winning entry at the NEI Audacious Goals Development Meeting in early 2013 (date will be announced on <http://www.nei.nih.gov/challenge>).

#### FOR FURTHER INFORMATION CONTACT:

Richard S. Fisher, Ph.D., Associate Director for Science Policy and Legislation, National Eye Institute, Phone: 301-496-4308. [NEIPlan@mail.nih.gov.]

#### SUPPLEMENTARY INFORMATION:

##### Subject of Challenge Competition

This *Challenge to Identify Audacious Goals in Vision Research and Blindness Rehabilitation* (Challenge) adds an exciting, unique component to the NEI's current strategic planning effort. In the past, these planning efforts relied primarily on the expertise of NEI-funded scientists to review the state of the science and describe current specific research needs and opportunities. This Challenge seeks input from all eligible individuals (Contestants)—not just vision research scientists—to describe (a) an audacious goal in vision research and blindness rehabilitation, (b) how to achieve the goal within about 10 years, and (c) the impact of reaching the goal.

##### Rules for Participating in the Competition

1. **Eligibility:** To be eligible to win a prize under this Challenge, a Contestant:

- Shall have registered to participate in the competition under the rules promulgated by the NEI and explained in this Notice;
- Shall have complied with all the requirements under this section;
- Shall be an individual at least 18 years of age and shall be a citizen or permanent resident of the United States;
- May not be a Federal entity or Federal employee acting within the scope of their employment. Federal employees seeking to participate in this contest outside the scope of their employment should consult their ethics official prior to developing their submission;
- May not be employees of the NIH or any other company or individual involved with the design, production, execution, judging, or distribution of the Challenge and their immediate family (spouse, parents and step-parents, siblings and step-siblings, and children and step-children) and household members (people who share the same

residence at least three (3) months out of the year);

2. Federal grantees may not use Federal funds to develop America COMPETES Act Challenge applications unless consistent with the purpose of their grant award (Grantees should consult with their cognizant Grants Management Official to make this determination); and

3. Federal contractors may not use Federal funds from a contract to develop a Challenge entry or to fund efforts in support of a Challenge submission.

4. A Contestant shall not be deemed ineligible because the individual used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals participating in the competition on an equitable basis.

5. **Liability:** By participating in this Challenge, Contestants agree to assume any and all risks and waive claims against the Federal Government and its related entities, 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 prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

6. **Indemnification:** By participating in this Challenge, Contestants agree to indemnify the Federal Government against third party claims for damages arising from or related to competition activities.

7. **Insurance:** Based on the subject matter of the contest, 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 contest participation, Contestants are not required to obtain liability insurance or demonstrate financial responsibility in order to participate in this contest.

8. By participating in this Challenge, each individual agrees to abide by all rules set forth in this Notice and the Challenge.gov Terms of Participation (<http://challenge.gov/terms>).

##### 9. Each Entry Must:

- Be limited to a maximum of 4,000 characters, including spaces (roughly a single page). In addition to information requested by <http://www.nei.nih.gov/challenge> to identify the entry, Contestants must complete three statements about the proposed audacious goal. The following statements, which will be the subject of the judging, are:

- It would be fantastic if \* \* \*
- (Explain why the goal is audacious and

how the goal fits within NEI's mission, which is listed in the Challenge summary.)

- To achieve the audacious goal, \* \* \* (Discuss the feasibility of achieving the goal within about a 10 year period, including the technological, scientific, or other advances that are needed to reach the goal.)

- If the audacious goal is achieved, the impact would be \* \* \*

**Note:** Examples of what would have been considered audacious goals in the past can be found at in the "Additional Information" section of this notice.

10. Contestants may submit more than one audacious goal entry, as long as they are unique.

11. The NEI will not select as a winner an individual who is currently on the Excluded Parties List (<https://www.epls.gov/>).

12. Entries must be original works developed solely by the Contestant and not infringe any intellectual property or any other rights of any third party.

#### Process for Registration and Submitting an Entry

For this challenge, registration and submitting an entry are completed in a single step. Participants can register and submit an entry for this challenge by following the instructions at the *Challenge to Identify Audacious Goals in Vision Research and Blindness Rehabilitation* Web site: [www.nei.nih.gov/challenge](http://www.nei.nih.gov/challenge).

#### Amount of the Prize

Up to 20 winners will each be awarded a \$3,000 prize and up to \$2,000 in travel reimbursement to participate in the NEI Audacious Goals Development Meeting in the Washington, DC area in early 2013. Prizes awarded under this competition will be paid by electronic funds transfer and may be subject to Federal income taxes. The NEI, one of the National Institutes of Health, which is a component of the Department of Health and Human Services, will comply with the Internal Revenue Service withholding and reporting requirements, where applicable. Winners will be invited to lead small group discussions on their submitted goal and understand that the submitted ideas may be combined with others during the meeting as part of the process to identify audacious goals. If winners are not present at the meeting, their entries will still be discussed. Travel expenses to and from the meeting location, lodging and meals will be separately reimbursed up to \$2,000 and in accordance with Federal Government travel policy. Winners will need to provide receipts to document travel

expenses for reimbursement purposes in accordance with National Institutes of Health policy and applicable laws and regulations (<http://oma.od.nih.gov/manualchapters/management/1500/>).

#### Basis Upon Which Winners Will Be Selected

The audacious goals entries will be de-identified and then will be judged by a selection board composed of NIH employees in compliance with the requirements of the America COMPETES Act and the Department of Health and Human Services judging guidelines ([http://www.hhs.gov/open/initiatives/challenges/judges\\_guidance.html](http://www.hhs.gov/open/initiatives/challenges/judges_guidance.html)). Judges will be named after commencement of the challenge and will consist of senior scientists and clinicians with knowledge of vision research and ocular disorders as well as allied biomedical disciplines. The judges will consult with technical advisors from biomedical, clinical, or other scientific disciplines if it is necessary to properly evaluate entries. The judges will make selections based upon the following criteria:

1. *Relevance to the NEI Mission:* Each entry will be rated on how the goal would further the NEI mission to conduct and support research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the blind.

2. *Audaciousness:* Each entry will be rated on whether the proposed goal is bold, daring, original or unconventional, exceptionally innovative, creative, novel, or any combination.

3. *Feasibility:* Although it is recommended that contestants consider about a 10 year time period for achieving a proposed goal, NEI recognizes that estimates of the timeframe for an audacious goal could vary considerably depending on the nature of the goal. Thus, audacious goals with shorter or longer time periods may be acceptable. Each entry will be rated on how well it describes the technological, scientific, or other advances that are needed to reach the goal.

4. *Scope:* Each entry will be rated on the extent to which it is broad and/or far-reaching. Goals can include basic, translational, clinical research, or any combination. Goals may also encompass training or health information dissemination as appropriate within the NEI Mission. The goal could have multiple components, for example research requiring multidisciplinary

approaches or involvement of multiple laboratories. Even a goal that addresses a disease affecting a relatively small number of patients may be considered broad and far-reaching if it requires the development of tools and techniques that can be applied to other problems (see the historical example of Lebers Congenital Amaurosis in the additional information section below).

5. *Impact:* Each entry will be rated on its transformative potential; its value in exerting a positive and powerful influence on the NEI mission.

The evaluation process will begin by de-identifying the entries and removing those that are not responsive to this Challenge or not in compliance with all Challenge rules. The judges may consult with technical advisors with relevant expertise if it is necessary to properly evaluate entries. Judges and technical advisors will examine multiple entries in accord with the aforementioned judging criteria. The judges will meet to discuss the most meritorious entries. Final selection of up to 20 winners will be determined by a vote of the judges.

#### Additional Information

NEI is one of 27 institutes and centers of the National Institutes of Health, a component of the Department of Health and Human Services. NEI is the principal U.S. government agency that supports vision research, both in its own labs and in universities and research facilities throughout the U.S. and around the world. NEI has the responsibility of establishing a national agenda for vision research. Since NEI was established over 40 years ago, it has conducted strategic planning activities culminating in a series of national plans and workshop reports that identify needs and opportunities in vision research. These planning efforts have relied primarily on the expertise of NEI-funded investigators to review the state of the science and describe current specific research needs and opportunities.

The current NEI strategic planning effort consists of three phases:

- *Phase I:* (Completed). Reports of six NEI-assembled panels of experts in vision research are compiled in a document entitled, *Vision Research: Needs, Gaps, and Opportunities* (<http://www.nei.nih.gov/strategicplanning/>).

- *Phase II:* This *Challenge to Identify Audacious Goals in Vision Research and Blindness Rehabilitation* invites submissions of audacious goals. Winners of this challenge will present their goals at the NEI Audacious Goals Development Meeting of vision research stakeholders. The NEI and the National

Advisory Eye Council will then select the most compelling audacious goals for the national vision research agenda and to motivate funding agencies in the United States and worldwide to stimulate research efforts to address these goals. The NEI seeks broad and diverse input not only from vision researchers and other biomedical and scientific research communities, but also more widely from all interested individuals. Fresh ideas and approaches are expected to energize research efforts, increase public awareness of vision research, and make important contributions to planning that will enhance our effort to reduce the burden of ocular disorders and diseases worldwide. The creativity arising from a variety of new perspectives is expected to generate new research avenues and approaches.

- *Phase III:* NEI will develop an implementation plan that will outline how the NEI priorities, programs, and operations will address the needs, gaps and opportunities identified in Phase I of the strategic planning process and the newly identified audacious goals.

The following historical examples are presented to provide a sense of what is meant by "audacious goals." These were, or would have been big, bold ideas at that time. Each of these examples required multiple components and advances in a variety of areas. The NEI mission encompasses a variety of areas including basic and clinical research, epidemiology, diagnostics, information dissemination, technology development, training, and education and awareness of the special health problems caused by visual impairment. We invite audacious goals that contribute to NEI's mission.

- An audacious goal in 1997 would have been to develop gene therapy to cure an inherited form of childhood blindness in less than 10 years. The first genetic mutations causing Lebers Congenital Amaurosis, a rare form of inherited childhood blindness, were identified in 1997. Multiple research groups then worked on developing gene therapy to treat this form of LCA, leading to the start of human clinical trials in 2007 and reports of success from three groups in 2008 (<http://www.nei.nih.gov/lca/backgrounder.asp>).

- An audacious goal in 1990 would have been to develop imaging techniques to view the microscopic structures of a living human eye to aid the diagnosis and treatment of disease.

Correcting telescope images for the blurring from turbulent atmosphere was first conceived in 1953 and applied successfully by the late 1980s. The technology was developed because the

Department of Defense needed to view satellites from ground-based telescopes, but atmospheric turbulence distorted the images. Similarly, doctors could not see the microscopic structures in the back of the eye because their view was blurred by the optics of the patient's eye. The technology developed for astronomy was modified to view the back of the eye, and successful use of this approach allowed visualization of the main light-sensing cells in retina, the cone photoreceptors, in 1999 by Roorda and Williams.

- An audacious goal in 1986 was to sequence the entire human genome in 15 years.

The Department of Energy and the National Institutes of Health officially began the Human Genome Initiative in 1990. Important requirements at the time included enhancing sequencing and analytic technologies as well as computational resources to support future research and commercial applications, exploring gene function through mouse-human comparisons, studying human variation, and training future scientists in genomics. This required multiple approaches, labs, and expertise. A draft of the human genome was reported in 2000 and a complete genome was announced in 2003.

#### **Contacting Challenge Winners and Displaying Winners' Information and Entry**

Using information provided in the Audacious Goal Form, winners will be notified by email, telephone, or mail after the judging is completed. Winners' names, hometown, state, and their audacious goal description will also be posted on the Challenge Web site [www.nei.nih.gov/challenge](http://www.nei.nih.gov/challenge).

#### **Intellectual Property Rights**

By participating in this Challenge, each Contestant grants to NEI an irrevocable, paid-up, royalty-free, nonexclusive worldwide license to post, share, and publicly display the Contestant's audacious goal description on the Web, newsletters or pamphlets, and other informational products. Each Contestant understands and agrees that if his/her entry is selected as a winning entry, it will be discussed and refined at the NEI Audacious Goals Development Meeting early in 2013 and may ultimately assist NEI in its prioritization of research goals or funding for research funding.

#### **General Conditions**

NEI reserves the right to cancel, suspend, and/or modify the Competition for any reason, at NEI's sole discretion.

Dated: August 8, 2012.

**Paul A. Sieving,**

*Director, National Eye Institute, National Institutes of Health.*

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**BILLING CODE 4140-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Institute Environmental Health Sciences; Notice of Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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:* National Advisory Environmental Health Sciences Council.

*Date:* September 11, 2012.

*Time:* 8:30 a.m. to 12:00 p.m.

*Agenda:* Discussion of program policies and issues.

*Place:* Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

*Open:* 1:15 p.m. to 2:15 p.m.

*Agenda:* Discussion of program policies and issues.

*Place:* Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

*Closed:* 2:30 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

*Contact Person:* Gwen W. Collman, Ph.D., Director, Division of Extramural Research & Training, National Institute of Environmental Health Sciences, National Institutes of