DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Health Director's Pioneer Award (NDPA)

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) provides notice of the establishment of the NIH Director's Pioneer Award (NDPA) program. The NIH is establishing the program to identify and fund investigators of exceptionally creative abilities and diligence for a significant term (5 years) to allow them to develop and test far-ranging ideas. Awardees are expected to commit the major portion of their effort to activities supported by the NDPA. The program is not intended to support ongoing research projects or simply expand the funding of persons who are already well supported. The only constraint on the research to be conducted with this award will be that it must be relevant to the NIH mission.

DATES: Nominations must be submitted by 12 midnight, April 1, 2004.

FOR FURTHER INFORMATION CONTACT: To learn more about the award online, please refer to the NIH Director's Pioneer Award Web site at *http://nihroadmap.nih.gov/highrisk/initiatives/pioneer/index.asp,* or e-mail your questions to *pioneer@nih.gov.* The NIH Director's Pioneer Award is among several initiatives being undertaken as a part of the NIH Roadmap Activities, *http://nihroadmap.nih.gov.*

Background

The NIH, in acknowledgment of the changing face of biomedical research,[1] is announcing a new program, the NIH Director's Pioneer Award.

History suggests that leaps in knowledge frequently result from exceptional minds willing and able to explore ideas that were considered risky at their inception, especially in the absence of strong supportive data. Such individuals are more likely to take such risks when they are assured of adequate funds for a sufficient period of time and are free to set their own research agenda. The NIH Director's Pioneer Award (NDPA) program is being established to identify and fund investigators of exceptionally creative abilities and diligence for a sufficient term (five years) to allow them to develop and test far-ranging ideas. Awardees are expected to commit the major portion of their effort to activities supported by the NDPA. The program is not intended to support ongoing research projects or simply expand the funding of persons already well supported.

The only constraint on the research to be done with this award will be that it must be relevant to the NIH mission.

The spectacular advances made in the biological and medical sciences in the last few decades have opened doors to even greater opportunities in the 21st century. The NIH has been, and will continue to be, a major player in the support of this groundbreaking research. Much of the NIH success derives from its reliance on investigator-initiated research proposals (the bedrock R01 award) and its dual system of peer review and advisory council oversight. However, there is evidence that some additional means may be necessary to further accelerate advances in medical science and the resulting gains in the health and well-being of the American people.

The face of biomedical research is changing. Many of the new opportunities for research involve crossing traditional disciplinary lines and bringing forward different conceptual frameworks as well as methodologies. These developments appear to justify support for more aggressive risk-taking and innovation. While the current NIH funding system will continue to support groundbreaking research and innovation within the context of its traditional research grant mechanisms, additional avenues seem necessary to encourage high-risk/high-impact research in this new context.

To address this issue, NIH convened a group of highly distinguished outside consultants with expertise in biomedical, behavioral and social sciences, and in physical sciences and engineering, and representing academia, foundations, business, and industry. This group proposed that NIH implement novel programs targeted specifically to identify, encourage, and support the people and projects that will produce tomorrow's conceptual and technological breakthroughs. These programs would complement the other NIH research grants programs and would provide additional opportunities to those afforded within the Institutes and Centers for research that contests the status quo across the breadth of the NIH mission. A first step in this process is the establishment of a new NIH program to support exceptionally creative individual scientists.

Summary of the Award Process

The award process is summarized briefly below and in detail online at *http://nihroadmap.nih.gov/highrisk/initiatives/pioneer/faq.asp.*

Eligibility

Nominees for the NDPA must be U.S. citizens, non-citizen nationals, or permanent residents who are currently engaged in research. The research need not be related to conventional biomedical or behavioral disciplines; if the individual's experience is in nonbiological areas there must be evidence of interest in exploring topics of biomedical relevance. If selected, individuals must show evidence of infrastructure support. Investigators at early stages of their career, as well as those who are established, will be eligible.

The Nomination Process

In the first phase of the application process, nominations are to be submitted by mentors, colleagues, institutions, or by the individuals themselves. Only a single nomination package may be submitted for each person. The nomination package is to include a letter and the nominee's resume or *curriculum vitae,* each no more than two pages in length.

The letter must explain why the nominee should be considered exceptional and therefore highly likely to pursue original avenues of inquiry directed at very challenging biomedical problems. Although creativity comes in many forms, aspects common to innovative people include an interest in, and the ability to integrate, diverse sources of information, an inclination to challenge paradigms and take intellectual risks, resilience in the face of failure, an ability to attract the right collaborators, and the diligence and concentration necessary to plan and execute effective strategies for accomplishing goals. The letter should also provide evidence of the nominee's interest in the types of biomedical problems that are particularly overdue for fresh approaches.

Nominations should be submitted via the Internet to *http://nihroadmap.nih.gov/highrisk/initiatives/pioneer/index.asp.* The Web site will be open to receive nominations from March 1, 2004, through midnight April 1, 2004, eastern standard time.

The Selection Process

All nominations will be evaluated by NIH staff for eligibility and by outside experts to identify promising candidates who will be invited formally to apply for the NDPA. In the second phase of

[1] While the term biomedical research is used throughout this notice it should be broadly interpreted to include the scientific investigations of biomedical, behavioral, social, physical, chemical, and computer scientists, engineers, and mathematicians.

this process, beginning mid-June, the candidates will be asked to provide an essay of 3–5 pages describing their views on the major challenges in biomedical and behavioral research to which they feel they can make seminal contributions. No detailed scientific plan should be provided since the research plan will be expected to evolve during the tenure of the grant. In addition, each candidate will submit a copy of his/her most significant publication or achievement and arrange for direct submission of letters of support from three individuals who may or may not have been nominators. A subset of the candidates will be interviewed in August-September 2004 by a panel of outside experts. Additional input will be provided by the Advisory Committee to the Director, NIH, and final selections will be completed and announced by the end of September 2004.

Awards

To inaugurate this program, we have set aside sufficient funds in 2004 to provide 5–10 awards. The awards will be up to $500,000 direct costs each year for five years. Although there are no stipulations on the research agenda, the awardee will be required to submit an annual report of activities conducted during the year and to participate in an annual symposium on the NIH Bethesda, Maryland, campus. This symposium will allow awardees to share their ideas, progress, and experience with each other, the research community, and NIH staff.

Dated: February 20, 2004.

Elias A. Zerhouni,

Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute (NHLBI); Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Development of a Novel Endotracheal Tube Cleaning System and Improved Endotracheal Tube Design and Conditions of Use

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The Pulmonary—Critical Care Medicine Branch (P–CCMB) in National Heart, Lung, and Blood Institute (NHLBI) conducts research on lung disease that includes development of new technologies for the prevention of nosocomial pneumonia and ventilator-induced injury.

The great majority of mechanically ventilated patients are intubated with an endotracheal tube (ETT). Millions of endotracheal tubes are used in the United States every year. VAP is the most common nosocomial infection in Intensive Care Unit (ICU) patients, afflicting 8 to 28% of patients receiving mechanical ventilation (MV). VAP is also the leading cause of death from hospital-acquired infection. NHLBI data indicate that improved design of the ETT and conditions of use can significantly reduce the incidence of VAP.

After a few days of MV, the lumen of an ETT is coated with a thick bacterial biofilm, which is a major source for bacterial colonization of the lower respiratory tract, and VAP. Accumulation of mucus/secretions on the interior of the ETT effectively lowers the cross section of the ETT and increases significantly the work of breathing in intubated patients, who then require increased MV support, with prolonged intubation and ICU stay.

In experimental studies, NHLBI showed that it is possible to prevent bacterial colonization of the trachea, bronchi, lungs, ETT, and ventilator circuit over a prolonged time of MV (168 hours), to decrease ETT resistance and therefore the work of breathing, and to avoid tracheal mucosal injury or decrease mucus-clearance following inflation of the cuff, when: (1) The ETT is cleaned with a novel cleaning system to remove all mucus from the lumen of the ETT; (2) the ETT is coated with bactericidal agents (silver-sulfadiazine with or without chlorhexidine in polyurethane); (3) low resistance thin-walled ETT is used; (4) the cuff of the ETT is replaced with gills; and (5) the ETT and trachea are kept horizontal, through a tilting bed that allows lateral body rotation.

This CRADA project is with the Pulmonary and Cardiac Assist Devices Section within P–CCMB in NHLBI. The NHLBI is seeking capability statements from parties interested in entering into a CRADA to further develop, evaluate, and commercialize new design and management of ETTs in patients intubated, and mechanically ventilated, that include a novel ETT cleaning device and a low resistance ultra-thin ETT coated with bactericidal agents, with gills. The goals are to use the respective strengths of both parties to achieve the following:

(1) Preparation of an IDE for FDA approval for the coating of the tube and of the mucus cleaning system;

(2) Assistance in conducting clinical trials to determine the performance of this multi-task strategy in the prevention of Ventilator-associated Pneumonia and improvement of care of patients intubated and mechanically ventilated;

(3) Manufacture of the ultra-thin coated ETT with gills, bactericidal coated tubes, and the cleaning system.

The collaborator may also be expected to contribute financial support under this CRADA for personnel, supplies, travel, and equipment to support these projects.

The tilting bed noted in the experimental studies above will be the subject of a concurrent CRADA announcement issued by NHLBI. Interested parties are encouraged to inquire using the contact information below.

CRADA capability statements should be submitted to Marianne Lynch, JD, Technology Transfer Specialist, National Heart, Lung, and Blood Institute (NHLBI), Office of Technology Transfer and Development, National Institutes of Health, 6705 Rockledge Drive, Suite 6018, MSC 7992, Bethesda, MD 20892–7992; Phone: (301) 594–4094; Fax: (301) 594–3080; e-mail: *Lynchm@nhlbi.nih.gov.* Capability statements must be received on or before May 3, 2004.

The NHLBI has applied for patents claiming the core of the technology. Non-exclusive and/or exclusive licenses for these patents covering core aspects of this project are available to interested parties.

Licensing inquiries regarding this technology should be addressed to Michael Shmilovich, JD, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804, Phone: (301) 435–5019; Fax: (301) 402–0220; e-mail: *shmilovm@mail.nih.gov.* Information about Patent Applications and pertinent information not yet publicly described can be obtained under the terms of a Confidential Disclosure Agreement.

Respondents interested in submitting a CRADA Proposal should be aware that it may be necessary to secure a license to the above-mentioned patent rights in order to commercialize products arising from a CRADA.