



IDSAs

Infectious Diseases Society of America

2006-2007 BOARD OF DIRECTORS

President
Henry Masur, MD, FIDSA
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD

President-Elect
Donald M. Poretz, MD, FIDSA
INFECTIOUS DISEASES PHYSICIANS
ANNANDALE, VA

Vice President
Anne Gershon, MD, FIDSA
COLUMBIA UNIVERSITY COLLEGE OF PHYSICIANS
NEW YORK, NY

Secretary-Treasurer
Barbara E. Murray, MD, FIDSA
UNIVERSITY OF TEXAS MEDICAL SCHOOL
HOUSTON, TX

Immediate Past President
Martin J. Blaser, MD, FIDSA
NEW YORK UNIVERSITY SCHOOL OF MEDICINE
NEW YORK, NY

Dale N. Gerding, MD, FIDSA
HINES VA HOSPITAL
HINES, IL

Janet R. Gilsdorf, MD, FIDSA
UNIVERSITY OF MICHIGAN
ANN ARBOR, MI

James M. Hughes, MD, FIDSA
EMORY UNIVERSITY
ATLANTA, GA

Jan E. Patterson, MD, FIDSA
UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER
AT SAN ANTONIO
SAN ANTONIO, TX

Michael S. Saag, MD, FIDSA
UNIVERSITY OF ALABAMA AT BIRMINGHAM
BIRMINGHAM, AL

Cynthia L. Sears, MD, FIDSA
JOHNS HOPKINS UNIVERSITY
SCHOOL OF MEDICINE
BALTIMORE, MD

Robert A. Weinstein, MD, FIDSA
JOHN STROGER (COOK COUNTY) HOSPITAL
CHICAGO, IL

Edward J. Septimus, MD, FIDSA
BILLINGS CLINIC
BILLINGS, MT

Executive Director
Mark A. Leasure

IDSAs Headquarters

1300 Wilson Boulevard
Suite 300

Arlington, VA 22209

TEL: (703) 299-0200

FAX: (703) 299-0204

EMAIL ADDRESS:

info@idsociety.org

WEBSITE:

www.idsociety.org

August 20, 2007

Attention: Elias Zerhouni, MD, NIH Director
Office of the Director, NIH
1 Center Drive, Building 1/114
Bethesda, MD 20892-0189
E-mail: PeerReviewRFI@mail.nih.gov

VIA EMAIL

Re: Request for Information (RFI): NIH System to Support Biomedical and Behavioral Research and Peer Review

Dear Dr. Zerhouni:

The Infectious Diseases Society of America (IDSAs) appreciates the opportunity to comment on the National Institutes of Health (NIH) Request for Information (RFI) on the current NIH system to support biomedical and behavioral research and peer review. IDSAs represents more than 8,000 infectious diseases (ID) physicians and scientists devoted to patient care, education, research, and public health.

NIH-funded research and training has led to critical ID discoveries while at the same time supporting economic growth in research incubator sites across the country, fostering innovation and competition, and making the U.S. the leader in global biomedical research. NIH support of biomedical research, including peer review, is critical to the Society as we seek to attract outstanding investigators to ID research. IDSAs views the recruitment and retention of ID researchers, especially clinical investigators, as a key priority. In the ID arena, the apparent shortfall and reported attrition of researchers may relate primarily to low paylines and limited new R01 resources for physician-scientists. The balance between expiring and new grants needs to accommodate the increased need for support of new and existing investigators and should include adjustments for inflation and consideration of total budgets in real terms.

1. *Challenges of NIH System of Research Support*

The biggest hurdle for both new and well-established investigators is the low pay scale for ID research. New investigators have a very hard time getting their first R01. An investigator is projected to have a 20% chance for earning an NIAID extramural award (12% for R01's) in 2007 and 2008 compared with the 43% chance they enjoyed in 1997, because recent surges in the number of applications have far outpaced the number of grants awarded. Increasing competitiveness has led to restricted access to R01 awards, making it more

challenging for new researchers to engage in early research efforts and develop traction in a research career.

The transition from a K-series mentored award to an R-series independent award is critical to developing and sustaining long-term research careers. The short-term R21 has become a surrogate for an R01, but is a poor mechanism to promote stable careers. New investigators also are offered the new Pathway to Independence Award (K99), although there are few data available on the success of this new approach and the numbers of awards are limited (NIH is anticipated to award 171 of over 1,000 new and re-competing submissions in 2007).

Experienced investigators also currently are challenged by very low paylines, making competing renewals difficult for established programs. Thus, throughout the system, investigators are quite discouraged as they weigh decisions about entering or maintaining academic research careers versus those in private practice or industry.

2. Challenges of NIH Peer Review Process

The process of peer review works. Peer review is sometimes viewed as unfair, but this view is not the fault of the process, but, rather, due to variations in the strengths of individual study sections and investigator sensitivities. The main challenge that compromises peer review is the perceived "end-around" programs for specific special interests that drain available funds for investigator-initiated innovation in science. In this context, even excellent grants with excellent scores are often not funded due to low paylines.

3. Solutions to Challenges

NIH System of Research Support

IDSA offers the following suggestions to address some of the challenges associated with competitive research awards and funding opportunities in the area of ID:

- Provide access for both new and established investigators to more unrestricted investigator-initiated funding with long "half-lives" (≥ 5 years) with fewer political mandates.
- Create a New Investigator Award, which should be a 5-year, \$150,000 per year award that encourages new investigators and can be transitioned to an R01 at the time of renewal. These grants would be competitively reviewed by appropriate study sections but would have dedicated funds for which only new investigators compete. The best new investigators will then be funded. This program would directly enhance the aspirations and the success of new investigators. Alternatively, priority for resources could be allocated to existing programs such as the K series.
- Prioritize NIH research on antimicrobial development and approaches to addressing resistance, including new drug development, monitoring the magnitude of the problem, and devising supporting mechanisms to limit the problem. The NIH, the pharmaceutical industry, and other organizations like the Gates Foundation could aid greatly in

supporting research needs in ID, particularly related to antibacterial work involving drug resistance and new drug discovery and development support.

- Integrate biodefense funding with that directed to addressing emerging and reemerging microbial threats, which are interrelated with biodefense agents. Current efforts in these areas do not seem to be keeping pace with medical needs.

Peer Review

IDSA offers the following approaches to studying the strengths and weaknesses of the peer review system in order to enhance the effectiveness and efficiency of the peer review process:

- Conduct a study to examine the pipeline of investigators/fellows being trained in the area of infectious disease, determine a way of capturing who is applying for grants in this area, identify how many applications are being shifted to other mechanisms, and determine if current biases exist against applications that pharmaceutical companies could fund.
- Identify specific obstacles and strategies to accelerate the NIH grant review and approval process, such as a shorter submission, review and funding cycle (e.g. 6 months) for all grants. Such efforts would facilitate the ability to resubmit reviewed but unfunded grant in the next cycle, rather than missing a cycle due to the delay in receiving reviews. The eRA Commons system has been one productive step in this direction. A mechanism to address minor comments without a full re-review may also enhance efficient grant evaluation and funding.
- IDSA will continue to identify and actively recruit qualified physician scientists to apply to the Center for Scientific Review as study section reviewers.

4. Core Values of NIH Peer Review Process

More resolute, effective, and transparent efforts should be made to direct funding in proportion to the magnitude of serious health needs.

5. Peer Review Criteria and Scoring

IDSA believes the peer review criteria and scoring provide a robust and independent analysis of the merits of each proposal. The efforts to include reviewers with specific expertise in this process are appreciated and encouraged.

6. Career Pathways

The NIH website provides specific and useful guidance on the funding mechanisms available to investigators at each sequential level, as well as specific and thoughtful advice for new investigators. The mechanisms for funding are well laid out, but the support for each mechanism from training grants and up the spectrum are currently inadequately funded to engage and sustain individual investigators. The mechanisms for funding are well laid out, but the support for each mechanism from training grants and up the spectrum are currently inadequately funded to engage and sustain individual investigators.

Page Four–IDSA Comments in Response to NIH RFI: NIH Biomedical Research and Peer Review

Should you have any questions, please feel free to contact Beth Rada, MS, IDSA's program officer for science and research at brada@idsociety.org or (703) 299-0200 x1216.

Sincerely,

A handwritten signature in black ink, appearing to read "Martin J. Blaser". The signature is fluid and cursive, with a long horizontal stroke at the end.

Martin J. Blaser, MD, FIDSA
Immediate Past-President
IDSA