

The AMERICAN ASSOCIATION of
IMMUNOLOGISTS



President

Arlene H. Sharpe, M.D., Ph.D.

Vice President

Wayne M. Yokoyama, M.D.

Past President

Dan R. Littman, M.D., Ph.D.

Secretary-Treasurer

Edith M. Lord, Ph.D.

Councillors

JoAnne L. Flynn, Ph.D.

Jeremy M. Boss, Ph.D.

Jenny P. Ting, Ph.D.

Gary A. Koretzky, M.D., Ph.D.

Executive Director

M. Michele Hogan, Ph.D.

May 31, 2017

Francis Collins, M.D., Ph.D.
Director, National Institutes of Health
Building 1, Room 118A
1 Center Drive
Bethesda, MD 20814

by email

Dear Dr. Collins:

We are writing today, on behalf of The American Association of Immunologists (AAI), the nation's largest professional society of research scientists and physicians who are dedicated to elucidating the immune system, to follow up on our letter of April 26, 2017. In that letter, we expressed our deep concern about reports that the National Institutes of Health (NIH) was poised to adopt a new approach to funding science based on the "Research Commitment Index" (RCI). Subsequently, on May 2, NIH announced its intent to implement a renamed RCI, now called the "Grant Support Index" (GSI), as soon as this coming fall.

As we also mentioned to you, we had by then invited NIH Deputy Director for Extramural Research Michael S. Lauer, M.D., to speak to the AAI Council at its May 12 meeting. We were very pleased that Dr. Lauer accepted this invitation and did, in fact, speak with the AAI Council that day. Dr. Lauer's presentation was extremely informative, and we greatly appreciate his willingness to come to our meeting and hear our thoughts and concerns.

Following Dr. Lauer's presentation, AAI held a "town hall meeting" at IMMUNOLOGY 2017™, the 101st annual AAI meeting, which took place in Washington, D.C., from May 12-16. Several hundred people attended this session to learn more about the biomedical research priorities of the new administration and Congress, as well as NIH policy issues. The session featured a presentation on the GSI; some attendees shared their opinions and concerns, while many others learned about the GSI for the first time. To follow up on this session, AAI launched a dedicated email address for member comments on the GSI, so that we can better understand members' questions, thoughts, and concerns.

All of the above-described AAI activities have taken place in the last month, and following the NIH announcement on May 2. We have engaged in these activities because we take seriously our representation of the immunology community and our responsibility to ensure that any comments we make on its behalf reflects its views

and concerns. We cannot, however, offer comprehensive comments on the GSI because NIH has not yet announced many important details, including the final point scale, and because much of the data upon which the GSI is premised was just made available last Friday and has not yet been vetted by the very stakeholders whose lives and careers will be most affected. As a result, AAI respectfully requests that NIH delay the implementation of the GSI, as further described below.

To be clear, AAI supports the stated goals of this policy: to fund a larger number of deserving early stage and mid-career investigators and to maximize grant dollar productivity. As we said in our April letter, we strongly believe that a greater percentage of these scientists should indeed have their grant applications funded, and we have robustly supported – for more than two decades – an active advocacy program focused on increasing the NIH budget.

Because we believe that it is impossible for AAI, or for any other stakeholder, to evaluate fully the proposed GSI until all details have been determined and made available for public review, we urge NIH to thoughtfully consider the input it has received so far, release a final proposed policy and any additional underlying data that supports the GSI, and only then, issue a formal Request for Information (RFI) seeking feedback from stakeholders. In our view, implementing the GSI, with just a few months' notice and limited opportunity for public input, is unwise, and could result in unintended consequences that could irreversibly and irreparably damage both NIH and the biomedical research enterprise.

As you know, the GSI would limit support for individual investigators by assigning point values to their funded grants and capping the number of points an individual could accrue at 21 points, or the equivalent of three R01s. As a result, some currently funded principal investigators (PIs) (6% according to NIH on May 12, or 3% as reported in *Science* on May 26) would be unable to apply for new grants or renew awarded grants unless they are able to adjust their portfolios to stay within the cap (NIH has not indicated how investigators would accomplish this, although AAI appreciates that this portfolio adjustment would take place at the time of grant renewal, rather than immediately). Although we understand that several revisions have been described at some NIH Institute and Center Council meetings since Dr. Lauer's May 12 presentation to the AAI Council, AAI has numerous questions about the GSI, including whether it would:

- accomplish NIH's desired goal of funding more early stage and mid-career investigators (NIH has not released information regarding how it plans to achieve this, or how to help such investigators compete later in the general applicant pool)
- accomplish NIH's desired goal of maximizing grant dollar productivity [the information that NIH has released to date to support its view that there are "diminishing returns" after an investigator reaches a specific support level is largely based on an unproven metric – the "Relative Citation Ratio" (RCR) – of scientific productivity]
- permit exceptions for urgent matters of public health, apparent "breakthroughs," or other mission-critical activities (see <https://www.nih.gov/about-nih/what-we-do/mission-goals>); and if so, how these or other exceptions will be determined
- impact efforts to enhance opportunities for women and underrepresented minority scientists

- create a disincentive for scientists to collaborate due to the high point score assigned to multi-PIs (although NIH has not released the GSI point scale, we understand that NIH may lower the point value assigned to multi-PIs); treating collaborative mechanisms like U19s and P01s so similarly to R01s contradicts a long-held NIH view that such mechanisms are synergistic/more than individual R01s added together, and may undermine efforts to form or continue these projects
- discourage PIs from training the next generation of researchers, hurting postdoctoral fellows and graduate students (the RCI assigns two points to those with T32 grants, even though PIs on training grants receive no direct research support from the grant and devote considerable time and energy to what they consider a responsibility to their field and to the next generation of researchers; we understand that NIH is now considering assigning no points to PIs leading training grants)
- inadvertently discourage other non-NIH agencies from funding capped PIs because NIH has deemed them to be “damaged goods”
- result in a loss of existing jobs and/or a destabilization of the workforce as investigators who reach the cap lose funding (many of the investigators affected have large labs employing – and training – numerous individuals, including postdoctoral fellows and graduate students; jobs lost at one institution may not be replaced at another since the infrastructures are different; e.g., more senior people may lose their jobs in a newly capped lab, whereas newly funded/likely smaller labs may hire more junior people because they are less expensive)
- result in underutilization of existing laboratory space at institutions with affected investigators
- result in a “gaming” of the system by investigators seeking to avoid exceeding the cap
- adversely affect the willingness of investigators to take scientific risks (with a cap of three R01s or two R01s and other small grants, investigators may focus on “safe” projects to ensure the stability of funding for their lab)
- undermine peer review, potentially damaging the longstanding and respected U.S. system of funding the best science (effectively “punishing” those who have the best ideas and best science).

Further, to the best of our knowledge, NIH has not evaluated its 2012 policy that requires NIH Institute and Center Advisory Councils to provide additional scrutiny to applications from investigators who receive \$1 million or more per year in direct costs from active NIH awards (NIH Notice NOT-OD-12-140). NIH has, however, released some data indicating that its 2009 policy to fund applications from new and early stage investigators at success rates comparable to those for new applications submitted by established investigators (NIH Notice NOT-OD-09-013) has stabilized the number of new and early stage investigators who have been funded. Evaluating these existing policies, and determining whether they could be made more effective (if needed), is extremely important, as they were intended to resolve the same concerns that the GSI proposes to address. We also wonder if alternative plans that would better achieve the stated goals of enhancing early and mid-career PI support should be actively solicited and considered.

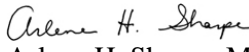
Finally, we note that there has been no independent analysis of the GSI or the metric (the RCR) used to measure productivity. An independent analysis from a respected group such as the National Academy of Sciences (NAS) is urgently needed before NIH moves forward.


AAI Letter to Dr. Francis Collins
May 31, 2017
Page 4 of 4


Because of the above-stated questions, which we believe reflect complex inter-related issues requiring additional discussion and input, **AAI respectfully requests that NIH delay implementation of the GSI until: NIH is able to release all details, after which the public is given fair and adequate time to review and consider the proposal through a formal RFI; an independent body such as the NAS is able to analyze and evaluate the proposal; and NIH has time to – and does in fact – consider all comments received as well as seriously consider alternative plans to support early and mid-career PIs.**


We thank you in advance for your attention to this request. Please contact any of us or AAI Director of Public Policy and Government Affairs Lauren Gross (lgross@aai.org) if you have any questions or if we can be of any assistance.

Sincerely,


Arlene H. Sharpe, M.D., Ph.D.
President


Wayne M. Yokoyama, M.D.
Vice President


Dan R. Littman, M.D., Ph.D.
Immediate Past President


Beth A. Garvy, Ph.D.
Chair, AAI Committee on Public Affairs

cc. Lawrence A. Tabak, D.D.S., Ph.D.
Michael S. Lauer, M.D.
Anthony S. Fauci, M.D.
Gary H. Gibbons, M.D.
Richard J. Hodes, M.D.
Stephen I. Katz, M.D., Ph.D.
Jon R. Lorsch, Ph.D.
Douglas R. Lowy, M.D.
Griffin P. Rodgers, M.D., M.A.C.P.
Carrie D. Wolinetz, Ph.D.