## THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS

TION O

May 15, 2015

#### Response of the American Association of Immunologists (AAI) to the NIH Request for Information: Optimizing Funding Policies and Other Strategies to Improve the Impact and Sustainability of Biomedical Research

(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-084.html)

Submitted on behalf of AAI by Lauren G. Gross, J.D., Director of AAI Public Policy and Government Affairs

# **1.** Key issues that currently limit the impact of NIH's funding for biomedical research and challenge the sustainability of the biomedical research enterprise. We welcome responses that explain why these issues are of high importance.

*a)* Large-scale projects, contracts, and centers consume a large proportion of the NIH research *budget*: Although many are important, efficient, and efficacious, it may be that certain large scale projects are not absolutely necessary in these difficult fiscal times. AAI urges NIH to carefully evaluate ongoing - and plans for future - large-scale projects, contracts, and centers for their need, efficacy, redundancy, cost, and likely impact on future research. Further, NIH should increase transparency by making its findings public and by consulting with the scientific community before new programs/projects/centers are created.

*b) Indirect cost rates should be re-examined:* According to the Government Accountability Office (GAO), almost 25% of NIH's extramural grant spending goes to indirect costs (http://www.gao.gov/assets/660/658087.pdf). In addition, between 2003 and 2012,

- indirect cost reimbursements increased at a faster rate than direct cost reimbursements, and
- 10% of institutions awarded grants received 70% of these funds, with indirect reimbursement rates between 46% and 69.5%.

AAI recognizes, however, that many of our members are faculty and students at institutions that receive indirect costs, and is aware that rate caps could result in cost-shifting within institutional budgets that would undermine any benefit from reducing rates. Although AAI is not recommending a specific reduction, AAI 1) supports the GAO recommendation that NIH assess the future impact of increased indirect costs on its ability to fund research grants, and 2) urges NIH to lower indirect cost rates to address perverse incentives or to correct historical or regional discrepancies that may no longer be warranted.

c) An increasing percentage of investigator salary is charged to NIH grants: This practice limits the impact of NIH's funding by 1) increasing the burden on researchers to obtain NIH grants to pay their own salaries, which also increases the number of applications and need for peer review; and 2) reducing the funds available to conduct research. Institutions should also be invested in the success of their researchers, and therefore should be required to provide adequate salary support. AAI encourages NIH to examine this issue in an effort to make more funds available for research, recognizing that any change in the percentage allocated must be phased in over time to avoid job loss or damage to ongoing research.

d) Administrative burden on investigators is high: According to a report by Decker *et al.* (http://www.iscintelligence.com/archivos\_subidos/usfacultyburden\_5.pdf), faculty funded by federal research grants spent 42% of their time on administrative tasks (both pre- and post-award), which takes away from the time that they could be performing valuable research. Some of these administrative activities include progress reports, Institutional Review Board (IRB) protocols, and Institutional Animal Care and Use Committee (IACUC) protocols. In some cases, funded institutions have addressed these issues by hiring more administrative staff, which creates an increased financial burden that may further raise indirect costs. In order to maximize the productivity (and morale) of funded investigators, NIH should consider ways to reduce the administrative burden placed on investigators.

2. Ideas about adjusting current funding policies to ensure both continued impact and sustainability of the biomedical research enterprise. We welcome responses that point to specific strengths or weaknesses in current policies and suggest how we can build or improve them.

*a) NIH should consider reducing RFAs and other earmarked projects:* Many of today's translational successes have been built upon research that produced unexpected results and led the field in new directions. NIH funding makes many of these unforeseeable successes possible through a diverse portfolio of research project grants (RPGs) and investigator-initiated research. Requests for Applications (RFAs) limit the number of potential applicants, and funding for RFAs detracts from the budget available for other RPGs. Therefore, AAI recommends that NIH evaluate and publicly report the number and focus of RFAs, and consider limiting the funds allocated to these types of grants.

*b) NIH should evaluate the efficacy of giving additional scrutiny to applicants who already have multiple NIH grants:* In 2012, NIH implemented a policy that would require additional review of grant applications from investigators who receive more than \$1.0 million in direct costs from NIH (<u>http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-140.html</u>). A similar policy instituted by the National Institute of General Medical Sciences (NIGMS) requires "special analysis and justification" for applications submitted by researchers whose total support exceeds \$750,000 in direct costs

(http://www.nigms.nih.gov/Research/Application/NAGMSCouncilGuidelines.htm).

These policies, which do not necessarily prevent well-funded investigators from receiving additional grants, may facilitate the best use and fair distribution of limited federal funds. NIH should evaluate - and publicly report - whether these policies are achieving their objectives. NIH should not, however

- *i)* limit the amount of money per investigator. Such a limitation would have minimal impact on increasing the funds available for research, but would adversely affect investigators who manage large-scale projects or who are particularly successful and productive, or
- *ii*) limit the total number of grant awards per institution. Such a limitation would have minimal impact on increasing the funds available for research, but might detract from funding the best science.

c) NIH should evaluate and report on newer mechanisms that fund the investigator rather than the project: AAI encourages NIH to publicly release data evaluating the various funding mechanisms, like the NIGMS Maximizing Investigators' Research Award (MIRA), which fund the investigator rather than the project with a larger award for a longer period of time. Such mechanisms, if successful, could result in fewer overall grant applications and more time that investigators could dedicate to research. NIH needs to ensure, however, that this type of funding mechanism, if implemented broadly, would not result in a bias against certain groups (e.g. young or mid-career investigators).

d) NIH should adopt the expedited grant review process used by "AIDS and AIDS-Related Applications" study sections: Using the AIDS grant submission and funding cycle would enable earlier reviews, earlier funding, and the potential for investigators to submit unfunded grant applications in the next review cycle.

*e)* Consider the FASEB analysis: NIH should consider the thoughtful and data-driven recommendations contained in The Federation of American Societies for Experimental Biology (FASEB) discussion document, "Sustaining Discovery in Biological and Medical Sciences" (<u>http://www.faseb.org/Portals/2/PDFs/opa/2015/Sustaining% 20Discovery% 20Report% 20Final.p</u> df). As a founding member of FASEB, AAI contributed to the development of, and supports many of these recommendations.

### **3.** Ideas for new policies, strategies, and other approaches that would increase the impact and sustainability of NIH-funded biomedical research.

a) Increase money available to fund, and encourage full partnership within the scientific community for, staff scientists: The number of academic faculty positions available to biomedical scientists has significantly decreased over time, with fewer than 15% of those with a Ph.D. securing such a position. As a result, many talented researchers have been forced to leave bench science for other careers or remain in postdoctoral positions for an extended period. Many Ph.D. scientists would like to remain in research science, but do not aspire to faculty positions because of the burden of grant writing and lab management. To address this attrition, the National Cancer Institute (NCI) recently introduced a funding mechanism that would support some of these researchers as staff scientists, a position that is currently relatively rare but in increasingly

high demand (http://www.nature.com/news/wanted-staff-scientist-positions-for-postdocs-1.17303). In addition to creating stable, well-paying positions for productive researchers, funding staff scientists would increase lab stability and thereby enhance the impact of NIH funding. In the form presented by NCI, individuals would have to submit competitive grant applications to fund their salaries as staff scientists; this process may put these researchers in the same position as those competing for R01s, decreasing time at the bench. Therefore, NIH should consider including staff scientist funding as part of an R01, or as an addendum to R01 applications (i.e. enabling a principal investigator to request additional funding for such a position).

*b)* Study the use of merit-reviewed pre-proposals: Due to NIH's tight budget and decreasing paylines, investigators have been spending increased amounts of time writing grant applications. By inviting only a select group of applicants to submit full proposals, reviewers will be less burdened and investigators may spend less time writing grant applications, providing more time for conducting research and mentoring graduate students/postdoctoral fellows. AAI recommends that NIH explore the use of merit-reviewed pre-proposals that require the same study section to review and comment on proposals at all levels and specifically to provide feedback to investigators who are not invited to submit full proposals. Any evaluation of pre-proposals should include an outcomes analysis, with a specific focus on the impact on new and early-stage investigators. NIH should also consider whether pre-proposals could lead to increased biases based solely on an investigator's name or institution.

c) NIH must support and encourage the next generation of scientific leaders: NIH must continue to pay attention to recruitment and retention of young scientists, particularly since the current funding situation has deeply discouraged many graduate students and postdoctoral fellows who wish to pursue an academic track. NIH has already taken steps to improve the ability of early stage scientists to receive NIH grant funding, but has not yet explored the merits of extending an advantage to mid-career investigators seeking their first R01 renewal. Therefore, NIH should consider giving these investigators a grace period during which they retain a funding advantage that may enable them to compete with their more senior colleagues.

#### 4. Any other issues that respondents feel are relevant.

### a) Current law and policy impede NIH in "Improv[ing] the Impact and Sustainability of Biomedical Research":

- *i) Insufficient appropriations:* NIH's purchasing power has been dramatically reduced by inadequate budgets that have been further eroded by inflation: in FY 2015, its purchasing power is 22% lower than it was in FY 2003. AAI has submitted testimony to the relevant Senate and House appropriations subcommittees recommending "an appropriation of at least \$32 billion for NIH for FY 2016 to fund important ongoing research, strengthen the biomedical research enterprise, and ensure that the most talented scientists, trainees, and students are able to pursue careers in biomedical research in the United States."
- *ii) Inability to carry over funding from previous year:* NIH forfeits about 1% of its budget each year because it is unable to spend all appropriated funds within the fiscal year. This forfeiture is often caused by uncertainty in the appropriations process, which delays

institute funding decisions and the distribution of grant funds and payments. If NIH funds were "available until spent," or if NIH were permitted to operate on a multi-year appropriations cycle, then returned funds could be used for a larger number of meritorious research projects.

*Removal of the travel restrictions for government scientists:* AAI strongly opposes a federal policy that limits government scientists' ability to attend privately sponsored scientific meetings and conferences
(http://www.hhs.gov/travel/travelpolicy/2012\_policy\_manual.pdf) and believes that "the rules have... made government scientists feel cut off from the rest of the scientific community, wreaked havoc with their ability to fulfill professional commitments, and undermined the morale of some of the government's finest minds." <u>Testimony</u> (Amended) of Lauren G. Gross, J.D., on behalf of The American Association of Immunologists (AAI), Submitted to the Senate Homeland Security and Governmental Affairs Committee for the Hearing Record of January 14, 2014: "Examining Conference and Travel Spending Across the Federal Government"). Removal of these travel restrictions would enhance the information exchange between academia and government, and promote collaborations that may make better use of available funds.

b) Any actions taken by NIH should ensure the following key principles:

- *i) NIH, and the United States, must continue to lead the world in biomedical research and innovation.* NIH is the premier medical research institution in the world, and the world's scientists depend on its leadership and funding. Any changes made must ensure that NIH retains its global position and ability to lead.
- *ii) NIH should continue to recognize that individual investigator-initiated research yields the greatest advances in biomedical research and in improving human and animal health.* The system that NIH has supported for more than 60 years in which research applications are submitted by individual investigators seeking funding is the underpinning of our successful biomedical research enterprise and should be maintained. Although the ways of research are changing, and there is a place for large projects, interdisciplinary "team science," and other funding mechanisms, it is essential that NIH remain committed to investigator-initiated research and preserve the ability of independent investigators to succeed and thrive.