



ASSOCIATION OF AMERICAN UNIVERSITIES

MEMORANDUM

May 17, 2015

TO: Office of Extramural Research
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

FROM: American Association of Universities
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RE: **Request for Information (RFI): Optimizing Funding Policies and Other Strategies to Improve the Impact and Sustainability of Biomedical Research (NOT-OD-15-084)**

To Whom It May Concern:

The Association of American Universities (AAU) represents 60 leading public and private U.S. research universities which collectively receive nearly 60 percent of National Institutes of Health (NIH) extramural funds. As such, we are greatly interested in the sustainability of biomedical research and commend NIH for engaging in a dialogue with stakeholders. AAU's comments below focus on general themes related to sustainability, organized according to the four categories provided in the RFI.

Comment 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.*

We appreciate the opportunity to provide input to NIH on how to optimize funding policies and other strategies to enhance the impact and ensure the sustainability of biomedical research. The Association of American Universities (AAU) represents 60 leading public and private U.S. research universities which collectively receive nearly 60 percent of National Institutes of Health (NIH) extramural funds. As such, we are greatly interested in the sustainability of biomedical research and commend NIH for engaging in a dialogue with stakeholders.

The research community and the NIH, to the extent permitted, should continue to communicate to Congress and the Administration that reliable, predictable, long-term funding is essential for overall progress in biomedical research.

First, as you know, biomedical research has excelled in the U.S. due, in large part to the strong partnership between federal sponsors and universities, but institutions have shouldered an increasing portion of the costs of biomedical research. The university share of research continues to grow faster than any other area. Institution-funded R&D constituted 22.3% (\$15 billion) of total R&D in FY13, rising from 19.5% in FY10. However, the problem lies not only in a decline in funding, but in the instability of funding. A key issue that limits the impact of funding for research has been the inability of Congress to enact annual appropriations before the start of the fiscal year. And this in turn could lead to more strategic and predictable funding of investigators on the part of NIH, for examples in areas such as the use of carryover funds.

Second, AAU believes that it is essential that the federal government – including NIH seek a smarter and balanced approach to the rules and reporting requirements imposed on institutions and researchers. Research funding can be optimized, and investigator burden be reduced through eliminating duplicative or unnecessary guidance, policies, rules and reporting requirements. For example, recent changes to

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Stanford University
Stony Brook University –
State University of New York
Texas A&M University
Tulane University
University at Buffalo –
State University of New York
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University of Minnesota, Twin Cities
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University of Oregon
University of Pennsylvania
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Vanderbilt University
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investigators' biosketch requirements has claimed scores of person hours and eroded productivity for little or no gain in the system. Reducing administrative burden can also be achieved by other measures, such as the use of preliminary grant proposals, greater use of just-in-time submission of ancillary proposal requirements, streamlining and harmonizing research regulations, and using standardized application forms and materials.

Finally, the NIH should continue to work with AAU and other stakeholders to attend to the emerging areas of threat to the ecosystem of the biomedical workforce. The concerns here are many; decreasing opportunities for young investigators to pursue independent research, the structure and duration of graduate training and post-doctoral fellowships, the challenges of supporting high-risk, high-reward research; the need for pathways to non-academic careers. These are urgent challenges, ones that will demand focused attention in the years ahead. Should these impediments discourage the best and the smartest from careers in science, the U.S. will have lost its dominant position in world science.

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

AAU supports the possibility of carrying NIH funding over into the following fiscal year as suggested by Dr. Collins in numerous Congressional hearings and by our colleagues at FASEB.

Like the federal investment in basic research, the federal investment in doctoral education fills a critical gap that neither states nor industry can fill. Universities and the NIH should grow and support programs – such as the Broadening Experience in Scientific Training (BEST) – which enhance training opportunities for graduate students and postdoctoral scholars to prepare them for careers in the biomedical research workforce that might take them outside of conventional academic research. NIH has spent considerable energy brainstorming ways to increase multidisciplinary collaboration that align with current scientific opportunities and spawn innovative thinking. NIH should look to enhance and expand such multidisciplinary collaboration in ways that expand and broaden students' training opportunities when considering new workforce and training mechanisms.

The sustainability of the nation's research effort ultimately depends on our ability to recruit the best students at our colleges and universities to careers in science and provide them with the means to pursue their interests. We applaud NIH's pilot efforts to try to address this issue, such as the New Innovator Award, Early Independence Award, and Pathway to Independence Award. And we commend the NIH to continue to experiment with grant programs to support high-risk, high-reward research and create independent research opportunities earlier in the careers of the next generation of investigators.

AAU has strongly urged Congress to restore the NIH salary cap to Executive Level I, pointing out that our institutions have been forced to divert funds to compensate for the reduction in the salary limit, taking away from critical activities such as providing bridge funding to investigators who may be between grants, and to provide seed grants and start-up packages for young investigators. We have been particularly concerned that the reduction is most likely to impact physician scientists and highly productive investigators.

Additionally, we are concerned about potential limitations that might be imposed to ration grant dollars by awarding partial funding to grants based on their priority score or limiting the amount of funding or number of grants going to a single individual or research group. Awarding excellence in science has long been a hallmark of the success of the NIH. We think it would be a mistake for the NIH to sacrifice this principle in an effort to address existing funding limitations.

Finally, we note that the success of the biomedical enterprise has been built upon a partnership in which both our institutions and the federal government share the costs involved in the conduct of research. With the significant financial pressures facing our universities, we would caution against any proposals that would seek to shift certain essential costs required to support the biomedical enterprise from the federal government onto universities, e.g. the proportion universities pay for research faculty salaries and/or costs for compliance with federal regulations and required for the construction and maintenance of scientific facilities and infrastructure.

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

We support efforts to enhance creativity and research quality by funding scientist or research programs instead of proposals for specific projects and extending the duration of awards. For example, NIGMS' Maximizing Investigator' Research Award (MIRA) program shows promise for an approach which would allow scientists to spend less time on applications and more time on research. Clearly, striking the correct balance between awards aimed at ensuring ongoing support for talented individuals versus the more traditional NIH funding approach of supporting specific research projects would be important to providing a bit more stability and security in the system.

As mentioned earlier, attention must be paid to efforts to simplify regulatory and reporting requirements. AAU and the Council of Government Regulations (COGR) suggest that prime candidates for reform both to reduce institutional cost and investigator burden include: 1) Effort Reporting; 2) Monitoring sub-recipients of university grants; 3) PHS financial conflict of interest (FCOI); 4) Human subjects in research; 5) Animal research; and 6) Financial Reporting Requirements. We would also align ourselves with recommendations made by FASEB in its Sustaining Discovery in Biological and Medical Sciences discussion framework concerning ways to reduce regulatory burden.

Increasing the use of core facilities and shared resources and instrumentation can benefit young researchers (as well as for those who are more established). We urge the NIH to encourage greater resource sharing when funding infrastructure and provide greater flexibility in shared instrumentation and core facility usage.

AAU supports communicating timely and accurate information about career prospects to incoming graduate students and providing information about career paths to current trainees, as well as efforts to create funding opportunities that foster independence. To this end, AAU is currently exploring with its members how they can collect data on and better track the career paths of graduate students after they receive their PhDs.

AAU is encouraged by recent bipartisan efforts in Congress to establish an NIH "Innovation Fund" and re-dedicate federal investment to the biomedical enterprise. The "21st Century Cures" legislative proposal authorizes a five-year, \$10 billion NIH "Innovation Fund" with \$2 billion per year in mandatory appropriations routed through the Office of the NIH Director. While translating the additional dollars provided through such a fund into actual programs will present a challenge, we believe that the creation of such a fund would present an exciting opportunity to explore innovative new approaches to increasing the impact of NIH funding. Among other provisions included in the "21st Century Cures Act" AAU applauds the improvement of loan repayment programs for NIH researchers.

Finally, ensuring workforce diversity - attracting and retaining women and underrepresented minorities to biomedical research, must continue to be a high priority for leaders in all sectors. As long as the research career trajectory involves a long period of uncertain and low-paying employment followed by a long period of intense competition with uncertain outcomes, it will be difficult to attract talented individuals who have an array of other opportunities.

Comment 4: *Any other issues that respondents feel are relevant.*

AAU urges a cautious and serious discussion of proposals shifting graduate students and postdocs from R01 research grants onto training mechanisms, such as training grants, K awards, or NRSA fellowships, as recommended by the NRC Committee to Study the National Needs for Biomedical, Behavioral, and Clinical Research Personnel. We urge NIH to consider the full implications of this concept.

The AAU membership has been engaged in discussion surrounding critical questions about the way we conduct biomedical research. What types of research positions are optimal in the modern biomedical research enterprise? Do we need doctoral-level scientists to conduct the everyday laboratory activity that is necessary to answer every research question? Would we be better served by a cadre of professional scientists at the master's level? How can universities and NIH work together to provide incentives for the creation and design of these graduate programs? Would shifting away from the doctorate as the only standard in research degrees allow for a more permanent technician or research scientist position that would relieve the competitive pressure of our bottom-heavy workforce?

These are complex questions whose answers could result in a radical shift in everyday life in the laboratory. Proposed policy changes are going to need to be carefully evaluated for their impact on the innovative efficacy of

our scientific enterprise as well as their financial impact on the agency and the extramural research community. Therefore, one area of active discussion in the AAU is the creation of new mechanisms for experiments within universities that rigorously test and assess ideas about improving the workforce and the workplace. We look forward to exploring these opportunities with NIH in the coming days.