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

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

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on ways to optimize funding policies or strategies to create a more sustainable and effective biomedical research system. The AAMC is a not-for-profit association representing all 141 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and 90 academic and scientific societies. We have encouraged our member institutions to respond, and we encourage the NIH to refer to their comments, which may provide more detail and granularity on various funding policies and their impact. The Association's comments here focus on general themes related to sustainability, organized according to the four categories provided in the RFI and respecting the 500-word limit per category.

RFI Category 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 [NIH] welcome responses that explain why these issues are of high importance.

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 progress in biomedical research.

No government agency or private organization by itself could accomplish the historic advances and productivity of the US biomedical research system; therefore, the NIH supports scientific research and training across thousands of organizations, including academic institutions, independent laboratories, small businesses, state and voluntary health organizations, among others. The medical schools and teaching hospitals represented by the AAMC, which share NIH's mission to advance health, perform approximately half of NIH-funded extramural research and provide most of the research training supported by NIH. We consider this long-established, remarkably successful relationship between the NIH and the extramural community to be a partnership, although the myriad "partners" often must make decisions and take action autonomously based on local circumstances. In the absence of reasonable expectations for a stable, long-term funding and national policy environment, these decisions become far more difficult.

Academic institutions manage commitments across variable time horizons, and many decisions require resources and incur risks over many years and even decades. These include investment in new and renovated facilities or other capital expenditures, and establishing and supporting new faculty positions or graduate programs. Given the rapid pace of change in biomedical science, institutions are challenged to keep current and competitive. A recent AAMC study found that medical schools and teaching hospitals in fact substantially invest their own available resources in research, investing more than one dollar of institutional resources for every two dollars in sponsored research performed.¹

The planning horizon for Federal agencies based on Administration or Congressional priorities can be relatively constrained. The NIH relies on annual appropriations in a process that is at times very difficult to anticipate, making agency planning even more difficult. This is not to say that the NIH cannot accomplish long range objectives—clearly it has often done so—nor that academic or other organizations cannot be flexible or responsive (they have responded very quickly to health emergencies, for example). Given the recent political and fiscal environment, the NIH has been notably successful in its planning. But both the NIH and the extramural community can only effectively manage and sustain the research system when each has expectations for stability and assured funding to support that system.

Finally, we note that at any funding level we must use available resources effectively and productively. **But the determinative question is whether our community must prepare for a research system in which federal funding diminishes steadily over time, or for one that maintains level or growing support, keeping pace with real costs. Effective policies for dealing with these two scenarios will be vastly different.**

RFI Cat. 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.

The AAMC supports efforts to broaden the scope of research training programs, to collect data and identify training outcomes, and further to recognize the diversity of careers that research training can serve. The community should broaden its definition of “success” for research training to include diverse outcomes.

We also support pilot programs for development of extramural staff scientist positions as a means to create a stable workforce for research projects and to become less reliant on trainees for performance of tasks.

Concerns about the sustainability of the biomedical research system largely center on 1) the training and development of the research workforce, and 2) whether the system currently produces more trained scientists than are needed. The research system should ensure some linkage between training opportunities to the eventual positions or careers that new scientists may be trained for. The Association has largely supported the recommendations of the NIH Biomedical Research Working Group and other working groups that have addressed training issues, including groups on diversity, physician scientists, and big data. The AAMC especially

commends establishment of the Broadening Experiences in Scientific Training (BEST) program, which incorporates new ways to prepare students for the breadth of careers in biomedical science, including: commerce, industry, and other business; government, law and policy; journalism and communications; academics and teaching, and other sectors. We see the potential for biomedical science careers to broaden in this century and the students themselves have for many years recognized these opportunities, as more graduates enter these broad careers. As the Biomedical Research Working Group noted, unemployment for biomedical PhDs in these sectors has been relatively low. We recognize that students and post-docs often have expectations of obtaining faculty positions; BEST is designed as an experiment to identify and provide more varied training for broad careers.

We must also provide trainees with better information about career choices and data on prior outcomes. A profound shortfall in the system, underscored by several working groups, has been the lack of data on outcomes of formal training programs and training on research grants. The AAMC encourages renewed efforts by NIH and the community in tracking trainees and their career outcomes. **Data collected on NIH training tables should also reflect the range of careers that trainees are entering.** The AAMC is collecting information on institutions that collect training outcomes data, and is also currently surveying MD-PhD dual-degree program graduates on career outcomes.

The AAMC also commends NIH's efforts to pilot programs (such as at the National Cancer Institute) that provide extramural support for staff scientist positions. Many research projects, centers, and institutional cores make effective use of staff scientists as a means for ensuring quality and stability in their operations. The academic community is interested if such positions can be more broadly implemented, while providing rewarding professional experiences for new scientists. The goal is to provide new opportunities for trainees who wish to pursue academic research without the obligations of faculty investigators, and also to ease demand for trainees as workers on research grants.

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

The AAMC has extensively engaged with constituents on the changing nature of the research system. Change is driven in part by the uncertain federal fiscal climate, and also—perhaps more profoundly—by a dynamic health care environment. For teaching hospitals and academic health systems, there are now enormous competitive pressures across health care delivery for reducing costs and streamlining operations in ways that make it even more difficult to support research and education missions.

Change is also being driven in far more positive ways by the proliferation of research discoveries, new technologies and platforms, and new opportunities for treatment and prevention. From discussions with our constituents, an outline of an evolving research system is emerging, in which:

- Institutions will position themselves more strategically with respect to the research and training initiatives that they pursue. Many schools may further revise or sharpen the

focus of their research and training missions, integrated with their health and community service missions. They are also seeking more transparency on how resources are allocated to achieve these missions.

- Institutions seek opportunities for more strategic collaboration, making use of comparative strengths of peer organizations and for sharing expensive resources. Institutions are also considering development of regional cores or other resources, and shared networks, collaboration on clinical trials, protection of human subjects and other operations.
- Institutions also are looking to diversify sources of research support, including from industry, foundations, other federal and state grants, and international collaborations. These arrangements focus less on transactional relationships and more on longer term partnerships.
- Institutions recognize a much broader spectrum of “medical” research, including health services, quality and outcomes, and patient-centered research. Investigators increasingly identify themselves with efforts to improve the operations of health systems and outcomes, and/or to engage more effectively with and improve the health of communities they serve. This does *not* mean less emphasis on basic research. The full spectrum of research continues to include molecular, cellular, systems biology, and other basic biomedicine. It also includes fundamental behavioral and social science research as well.
- The entire research system is challenged by finding optimal methods to store, utilize, and share data, and to apportion credit accordingly.

The resulting academic research system will be in parts more complementary, seeking and matching comparative advantage over competition (at least to some extent). **NIH can help catalyze this system in many ways, and already has. The CTSA consortia, for example, have built large networks, and NIH can also play more of a role in establishing other regional resources and core facilities. The agency should also create homes for physician-scientist training.** A critical component is development of new metrics to help institutions gauge and evaluate performance across new criteria. A recent study, commissioned by AAMC, may be a useful guide on such metrics.²

Finally, the AAMC also agrees with the proposal endorsed by FASEB, the AAU and others to permit the NIH to carry funds into a following fiscal year if appropriate for budgeting of research projects.

RFI Cat. 4: Any other issues that respondents feel are relevant.

In seeking to establish a more reliable and stable research system, NIH and the research community should oppose any formulation of policies that would seek to maintain or increase certain levels of federal research activity by further shifting the costs of research onto institutions or other partners, such as through caps or arbitrary adjustments. Cost shifting and unfunded mandates do not strengthen the research system, and potentially distort

long-term decision making and strategizing about the optimal allocation of resources. One of the most counterproductive actions has been the imposed cap of 26% on the on the recovery of indirect administrative costs for academic institutions, while the regulatory obligations of those institutions for human subjects and privacy protections, management of financial conflicts of interest, biosecurity, financial reporting, and many other requirements have burgeoned. An AAMC study determined that 71 institutions invested \$23 million in preparations for implementing the revised financial conflict of interest rules; and although the number of significant financial interests disclosed has increased, there has been much smaller proportional increase in the number of financial conflicts of interest identified and needing to be managed.³ This is but one example of the increased regulatory burden for institutions; the AAMC has proposed that federal agencies promulgate “evidence-based regulation” to ensure better linkage between regulations proposed and the commensurate outcomes effected.

Another example is the congressionally mandated cap on recovery of salary on grants, now fixed at executive level II. The AAMC believes that, among other effects, the cap undermines efforts to support new physician scientists. The need to attract highly trained physicians in to research was the central challenge highlighted by the NIH’s own Physician Scientist Working Group (we also commend leadership for not seeking to lower this cap further). **The key to improving the environment for research is to create more resources, to make better use of resources, and to establish a more predictable environment, not to distort, mask, or shift the actual costs of research.**

The AAMC is again grateful for this opportunity to comment, and we look forward to working with the NIH as it considers policies and strategies to improve the impact and sustainability of biomedical research. Please feel free to contact me, or my colleagues Stephen Heinig, Director of Science Policy (sheinig@aamc.org) and Heather Pierce, JD, MPH, Senior Director for Science Policy and Regulatory Counsel (hpierce@aamc.org) with any questions about these comments.

Sincerely,



Ann C. Bonham, Ph.D.
Chief Scientific Officer

References:

- (1) *Academic Medicine Investment in Medical Research*, March 2015.
<https://members.aamc.org/eweb/upload/Academic%20Medicine%20Investment%20in%20Medical%20Research.pdf>
- (2) Susan Guthrie et al. *Measuring Research: A guide to research evaluation frameworks and tools*. RAND Europe, 2013. <http://www.rand.org/pubs/monographs/MG1217.html>
- (3) Implementing the Regulations on Financial Conflicts of Interest: Results from the AAMC Conflict of Interest Metrics Project. AAMC Analysis in Brief, April 2015.
<https://www.aamc.org/download/429214/data/april2015implementingtheregulationsonfinancialconflictsofintere.pdf>