AAMC

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Lida Beninson, Ph.D.
Study Director, Next Generation Researchers Initiative Committee
Board on Higher Education and Workforce
The National Academies of Sciences, Engineering, and Medicine
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Re: Call for Community Input on National Academies of Sciences, Engineering, and Medicine Next Generation Researchers Initiative Committee

Dear Dr. Beninson:

The Association of American Medical Colleges (AAMC) is pleased to have this opportunity to offer comments to the National Academies of Sciences, Engineering, and Medicine's Next Generation Researchers Initiative Committee. Founded in 1876 and based in Washington, D.C., the AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 147 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their nearly 167,000 full-time faculty members, 88,000 medical students, 124,000 resident physicians, and thousands of graduate students and postdoctoral trainees in the biomedical sciences. Our comments reflect input from many of these constituents, primarily our Group on Graduate Research, Education, and Training (GREAT) and Group on Research Advancement and Development (GRAND).[*]

The AAMC is pleased that the National Academies has reached out to the community for input. The following is a summary of AAMC's recommendations, described further below:

- Support institutions in optimizing their research programs, e.g., streamlining regulatory compliance, promoting sharing of research resources across institutions, improving

[*] The GREAT Group is AAMC's professional development group for graduate school deans, MD-PhD program directors, and postdoctoral program directors who have responsibility for biomedical PhD, MD-PhD, and postdoctoral training occurring within medical schools and teaching hospitals. GRAND is a professional development group for research deans and deans of clinical and translational research at these same institutions.

transparency in financing and career outcomes. Accomplishing such reforms depends on the combined efforts of policymakers, institutional leadership, faculty and sponsors.
- Avoid policies that disproportionately shift the costs of research from Federal agencies onto academic institutions or other partners.
- Encourage NIH institutes and centers in efforts to prioritize resources to support early and newly established early-career investigators in the award process.
- Disentangle "workforce" and training, promote support that focuses on the trainee and options for many career paths.
- Include physician- and clinician-investigators in recommendations that support early and mid-career investigators in the NIH portfolio, and for training and career development.

Level, Sources, and Stability of Research Funding

The AAMC advocates for sustained, predictable growth in NIH funding. Our advocacy position is based on an understanding that medical research and training are long-term investments that are intensively demanding of human and physical capital. Thousands of organizations supported by NIH – including medical schools, universities, teaching hospitals and health systems, research institutes, and small businesses –are partners in the US research system. These organizations must daily make decisions with lasting implications for the size and scope of their research activities, including recruiting faculty and hiring personnel, building and renovating facilities, purchasing equipment, accepting new graduate students and post-doctoral trainees, among other decisions. Many if not most of these commitments entail long term obligations and expenditures that typically well exceed the time frames of individual research project grants.

Medical schools and teaching hospitals also invest substantially from their internal resources to sustain the capacity for cutting edge research. Federal grants, even while providing for negotiated facilities and administrative costs, do not reimburse the full costs of maintaining research and training programs. A recent AAMC study of our member institutions' actual financial and operational data found that academic medical centers (AMCs) invest on average 53 cents for every dollar of externally sponsored support.[1] Given this level of internal investment, a stable, reasonably predictable NIH funding environment, which provides for incremental real growth, better allows institutions to plan for and manage their research programs.

In 2015, a group including 18 medical school deans published an analysis of major factors that affect the ability of academic medical centers to support biomedical research and training.[2] The medical school deans agreed with other commentators about the corrosive and destabilizing effects of a hypercompetitive funding environment. They also cited additional factors that threaten the stability of academic institutions as well as scientific careers. Perhaps the most disruptive factor is the evolving US health care system, in which AMCs play crucial roles as hubs of innovation, providers of safety-net care for communities, and venues for treating the most complex caseloads and illnesses. Given trends in the business environment for health care, AMCs are under continual pressure to economize, reducing margins that have traditionally been available for support of research and training programs.

AMCs do offer dynamic environments for experimentation with new programs and policies for improving research and training. But the AAMC is very concerned that policies that disproportionately shift the financial burden of research and training from the federal partner to academic partners or other non-profits would only undermine the stability that we all, including future scientists, seek.

A central goal for academic institutions should be to improve the transparency with which financial and resource decisions are made, so that faculty, trainees, and trustees share the same accurate information about options for growth. Other reforms can be made in concert with Federal partners, some of which are listed here:

- Reduce regulatory burden of research. The Academies has already played a significant and commendable role in catalyzing regulatory reform for science. We see much promise in this approach. At the same time, unfortunately, we see many missed opportunities for making the regulatory environment more effective, including in human subject protections and in regulating conflicts of interest.[3,4]

- Pursue sharing of resources across academic institutions, with effective and transparent systems for partners to share costs. Many institutions already have shared core facilities and are experimenting with other networks.

- Enhance research strategic planning (for individual institutions). Many academic institutions are already considering how and in which directions they wish to expand their research portfolios, to carve out niches for research. A part of this strategy is to develop relationships with academic or other organizations that have complementary skills. Moderately increasing more reliable Federal funding levels would aid such planning.

- Improve understanding of the workforce demands for future laboratories. Many workers engaged in research in universities are not traditional faculty investigators, students or trainees, although policy discussions seem to focus exclusively on these populations with less attention to the growing cadres of technicians and support staff. Policies might aid institutions in thinking how best to employ such scientists and other staff. Many institutions, and several NIH agencies, are looking at staff scientists. The NIH Clinical Center has long employed such positions. It is an open question as to how best to keep staff scientist careers vital and flexible.

- As noted among the Committee's examples for possible recommendations, the AAMC supports giving NIH the flexibility to carry funds across fiscal years (sometimes called zero-year budgeting), to adjust to the needs of research programs and projects.

The Committee's dear colleague letter also invited comments on proposals to increase funding for the NIH Common Fund and to expand awards through the Director's New Innovator Award Program. The AAMC would hope that if such recommendations are made, new funding will be made available to NIH to support the expansion, understanding that otherwise any expansion of one program must come at the expense of others.

Medical research advocates like the AAMC are cognizant of our responsibility to work with the Administration and Congress to address the long term fiscal challenges faced by the nation while balancing the many interests of our constituents, trainees, and communities. But we also recognize that genuine innovations in health and medicine, such as treatment for coronary disease, improved survival rates for many types of cancer, and in preempting emerging infectious disease, have benefitted the nation many-fold in return on the research investment.

The Scope of Grant Award and Review

The AAMC supports the goals of the NIH's Next Generation Researchers Initiative (NGRI) to ensure that the agency's research portfolio maintains support for new investigators and newly established mid-career investigators. The Association approved NIH's efforts to support new investigators, especially with the period of flat funding in the mid- to late 2000s and then the subsequent sequestration and recovery in recent years. We believe that the NIH has been successful in creating career development mechanisms and policies to help young scientists on the path to independence.

The NGRI announced by the NIH Director in June continues with the goals of strengthening early career and newly established career investigators. The NGRI will leave more flexibility to NIH institutes and centers for determining how best to support worthy proposals from early and newly established investigators that fall just short of paylines. More difficult, the institutes and centers must also determine how best to reprioritize resources for this support and how to shift funds across portfolios. These efforts also need to incorporate consideration of the vitality of established investigators, who play a critical role in mentorship and support of new and emerging investigators. Some ICs may end up in effect limiting numbers of awards to individual investigators to accomplish these changes. Clearly, with limitations of the NIH budget means that efforts assisting one cohort puts pressure on the next level, those investigators renewing a first award or seeking a second or third research project grant. The AAMC is pleased with the formation of the Advisory Committee to the Director's NGRI working group with the goal of addressing these challenges.

The AAMC plans to reexamine the use of bridge funding at institutions to support investigators on the cusp of NIH support, which is important for mid-career PIs. We also support the use of the NIH R56 awards that support labs for short duration. AAMC is also following ICs experiences with R35 investigator awards, supporting investigators as opposed to projects. We are encouraged that different ICs are trying different approaches with these awards, as a natural experiment for assessing outcomes.

The Committee's dear-colleague letter asked about recommendations for scope of grant award and review, such as modulating the duration of research project grants or limiting the number of applications permitted to each investigator. We would urge that any changes be based on ample data, and as possible, pilot testing, given the potential for unintended consequences for any system wide changes.

We need to emphasize the complexity of the challenges for NIH and the research community. Not only should the award system provide stability for early stage and early established investigators in the grants portfolio, but NIH must also continue to promote a diverse group of investigators including underrepresented minorities—a commitment that NIH made following the study by Ginther and colleagues[5]—and strengthen support for physician- and clinician-investigators, following on the recommendations of the Physician Scientist Workforce Working Group. The AAMC supports these initiatives. We stress that the aging of physician investigators in the NIH portfolio is far more pronounced than for PIs in general, and there has been no corresponding leveling of awards to first-time physician PI applicants, as there has been for other first-time PIs. The AAMC applauds NIH efforts to improve career development and research support for physician scientists during residency, and to provide support for different "on ramps", as there can be many junctures in medical education where a student/physician decides to become a scientist.

Training, Mentoring, and Transparency

The AAMC has long supported tracking of trainees and agrees that institutions should collect and make available trainee data, including length of training and career outcomes. As we noted in our response to the call for input on the National Academies of Sciences, Engineering, and Medicine Committee on Revitalizing Graduate STEM Education for the 21st Century, AAMC, in collaboration with the GREAT Group, conducted a study to identify how institutions are collecting research trainee information, including career outcomes data, in order to help institutions develop and enhance their own data collection systems.[6] Biomedical workforce data are vital for understanding the careers that trainees are entering, aligning training with those needs, and educating trainees about these career options. Data should be available for doctoral graduates, postdoctoral researchers, and physician scientists.

The AAMC is encouraged by the many ongoing conversations by multiple organizations around career outcomes data collection. Developing and sharing institutional models of data collection and dissemination will help institutions to adopt their own collection efforts. The AAMC acknowledges that the resources available for data collection and dissemination may be limited and would affect schools differently.

The AAMC believes the research community should begin to disentangle "workforce" from "training" and employ multiple approaches to address research demands. One such approach, as noted above, is the use of staff scientists. The AAMC looks forwarded to learning more about the outcomes of the new National Cancer Institute Research Specialist Award to determine if such grant mechanisms help provide a more stable career research options for those scientists who do not serve as independent investigators.

Regardless of funding source, trainees should have a training experience that is rigorous and with institutional oversight. In addition, institutions and funders should also ensure that stipends and benefits are equitable. Training on research project grants should include training plans, allowing for broad scope and diversity in research careers. As noted in previous AAMC comments to the National Institute of General Medical Sciences request for input on strategies for modernizing biomedical graduate education, a number of institutions have mentioned that having trainees be

fully supported on a research grant inhibits ensuring time is allotted for career development activities. It was suggested that a percentage of trainee time (5 to 10%) be supported from other resources, or that specific funds be designated in a research grant for training. Funders should continue to communicate the dual-role of students and postdoctoral researchers to grantees, to ensure that trainees are prepared to enter the workforce after completion of their time in the lab.

Given the importance of biomedical research training for a variety of careers, we see merit to proposals to shift more trainees to support under specific training programs than on research projects, as training programs are more explicitly focused on diverse training and tracking outcomes. Training on research projects is nevertheless extremely important, and continues to be where the majority of young biomedical researchers are trained. This training is also especially important for non-US citizens, who make major contributions to US research, as traditional training programs are limited to US citizens and residents.

Underrepresented Populations

As noted above, AAMC strongly believes that trainee data be collected and disseminated for all trainees regardless of funding source. NIH now requires that any individual with an undergraduate, graduate student, and/or postdoctoral role who participates in a NIH-funded project for at least one month should be registered in eRA Commons and be noted on progress reports (and also required for postdoctoral level on grant submission). This new requirement should enable NIH to analyze demographic data of trainees. The collection of career outcomes data is more complex and includes partnership with training programs and institutions. The AAMC cautions that any demographic and career outcomes data be aggregated to ensure anonymity of individuals.

Increasing the diversity of the biomedical research workforce remains a priority of the research and research training community. The AAMC agrees that efforts should be made to remove any barriers for those populations underrepresented in research from pursuing faculty careers.

The AAMC also supports the committee calling attention to actions that may help prepare physician scientists. Physician scientists play an essential role in our nation's health by linking discoveries and translating research findings to clinical applications and improved care. The AAMC shares the concern of the NIH Director's Advisory Committee Physician Scientist Working Group that the physician-scientist workforce is aging and too few new physician scientists are entering the workforce to replace them. The AAMC is encouraged by multiple NIH efforts, including the NIAID new K99/R00 funding opportunity for physician scientists as well as the new funding opportunity for institutional programs, to provide research opportunities for resident-investigators as well as career transition awards. MD-PhDs combined degree programs provide an important training pathway for those pursuing careers as physician scientists. While it is important to better integrate medical and research postgraduate training for MD-PhDs, these new opportunities are equally important for physicians without PhDs who would like to pursue research.

The AAMC appreciates the opportunity to comment. Please contact me or my colleagues, Stephen Heinig, (sheing@aamc.org) and Jodi Yellin, Ph.D. (jyellin@aamc.org) in the Office of Scientific Affairs with any questions about these comments.

Sincerely,

Chief Scientific Officer
Ross McKinney, M.D.

References:
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4 AAMC Analysis in Brief: Implementing the Regulations on Financial Conflicts of Interest: Results from the AAMC Conflict of Interest Metrics Project. Washington, DC: Association of American Medical Colleges, 2015.
5. Ginther DK, Schaffer WT, Schnell J, et al. Race, Ethnicity, and NIH Research Awards. *Science* 2011;333:1015-9.
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