

April 1, 2020

Office of Extramural Research Office of the Director, National Institutes of Health Bethesda, MD

Submitted electronically

Re: NOT-OD-20-064 - Request for Information (RFI): Inviting Comments and Suggestions on a Framework for the NIH-Wide Strategic Plan for FYs 2021-2025.

The Association of American Medical Colleges (AAMC) is grateful for this opportunity to provide our perspectives on the proposed framework for the next NIH-wide strategic plan. The AAMC is a not-for-profit association representing all 155 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic and scientific societies. Through these institutions and organizations, the AAMC represents nearly 173,000 faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Our member institutions collectively perform more than half of all the extramural research funded by NIH.

The NIH RFI requests comments on the following three topics, listed here, with the AAMC's comments under each topic.

Topic 1: Cross-Cutting Themes articulated in the framework, and/or additional crosscutting themes that may be considered.

The framework's proposed cross-cutting themes are:

- Increasing, Enhancing, and Supporting Diversity
- Improving Women's Health and Minority Health, and Reducing Health Disparities
- Optimizing Data Science and the Development of Technologies and Tools
- Promoting Collaborative Science
- Addressing Public Health Challenges Across the Lifespan

AAMC Comment: The Association agrees with the inclusion of these five cross-cutting themes, as they affect all areas of biomedical research and should be included in the final strategic plan. The AAMC has on many occasions endorsed initiatives that embody these themes. For example, the AAMC has previously supported the consideration of sex as a biological variable in human and animal studies, and the incorporation of different ages "across the lifespan" in NIH clinical trials. The Association has expressed continued commitment to women's health and minority health, the promotion of data science, especially around data sharing, and a commitment to team science and collaborations with industry and community partners. (The AAMC would also consider clinical trials and other research directly involving human subjects to qualify as collaborative science.) We point out that inclusion of a particular topic, such as reducing health disparities or optimizing data science, as a cross-cutting theme must not lessen the importance of funding focused research in these same specific areas. The AAMC would hope that any research on the pathology of disease or potential health interventions would consider disparities in the burden of disease, or in access or treatment, as part of its design. At the same time, we strongly

support the work of the National Institute on Minority Health and Health Disparities (NIMHD) on its focused research in those areas. The AAMC also recognizes that the role of directing a research portfolio on a topic that is also "cross-cutting" to all NIH institutes is a special challenge, often shared by such institutes as NIMHD, Child Health, and Aging. The need for targeted funding and trans-NIH coordination is especially true for data science. While all NIH research contributes to the development of data resources and to processing and analyzing data, the NIH should also expand programs that focus on the data science itself, including artificial intelligence, machine learning, and statistical techniques.

We also acknowledge that the several cross-cutting themes proposed in the framework interact with each other: for example, efforts harnessing growing data resources in health care have the potential to exacerbate health disparities and bias—the health system data will not include groups that lack access to care. Future NIH-sponsored research and the final strategic plan should acknowledge these interactions as well.

Although the AAMC does not seek to increase the number of cross-cutting themes identified in the NIH framework as the five clearly high priorities, we note several critical NIH initiatives which are not clearly addressed by this list but should be recognized and supported separately. This includes work in genomics and neuroscience that has demonstrated the importance of concomitant research on ethical, legal and social issues (ELSI), and there may be reason to consider such issues across NIH more broadly (for example, CRISPR). Similarly, evaluation research is important and needed for many programs and projects, and for the strategic plan itself.

Topic 2: NIH's priorities across the three Objectives articulated in the framework, including potential benefits, drawbacks or challenges, and other priority areas for consideration. The NIH's three proposed objectives and subheads are:

Objective 1: Advancing Biomedical and Behavioral Sciences

- Driving Foundational Science
- Preventing Disease and Promoting Health
- Developing Treatments, Interventions, and Cures

Comment: This objective pertains directly to the NIH mission and should be reflected in the agency-wide strategic plan. The importance of the first subheading, driving foundational science, cannot be over-emphasized. In a publicly funded agency, the tension between support for fundamental science and research that is more clearly disease- or health-directed is a persistent challenge. NIH's historic success lies in its ability to balance these priorities. The proposed framework appropriately reflects this balance. Fortunately, there are always examples of basic research outcomes that lead to significant and unpredicted potential for medicine and health; CRISPR is the recent example, past examples include polymerase chain reaction (PCR) or telomerase. The AAMC also considers fundamental or foundational science to include social sciences as well as basic and behavioral research. Despite the enormous advances in basic research over decades, the growth of basic science departments within AAMC member institutions has been relatively much smaller than for other departments (although some clinical departments also often merged or reorganized, in part to reflect changing science and needs and in part to seek greater

efficiency. The next NIH-wide strategic plan, like the previous plans, must continue to reflect an unflagging support for basic science among the NIH's priorities, as a signal to the community and to young scientists that there is a future for this research. The subheadings for "preventing disease and promoting health" and "developing treatments, interventions, and cures" comprehends the broadest stretch from translational science to public health. The AAMC believes the research promoting health and health interventions also engenders implementation science, health effectiveness research, and population health, for which the NIH also partners with other federal agencies. Studies of the Social Determinants of Health are increasingly recognized as essential for proper assessment of health needs and for successful implementation of interventions and health strategies.

Objective 2: Developing, Maintaining, and Renewing Scientific Research Capacity

- Cultivating the Biomedical Research Workforce
- Supporting Research Resources and Infrastructure

Comment: On sustaining "scientific capacity," the AAMC has long supported NIH's broad efforts on strengthening the biomedical research workforce. We support the focus of recent revisions to the T-32 training grants that promote versatility and excellence in research careers, understanding that trainees may successfully contribute to science and health from later employment in different sectors and positions. To assist in training biomedical scientists from a diversity of backgrounds and for a diversity of careers, the AAMC is committed to developing mentors (and mentoring teams) that can better train for such careers. The AAMC also encourages professional development programs that help trainees and early-stage investigations navigate career paths. The AAMC is interested in the concept of "cohort hiring" to promote more diversity in the academic research workforce, although the cohorts would need to be spread across multiple departments or even institutions, as many medical centers have only very limited numbers of tenure-track positions open in a given year.

A central concern for the AAMC is the training and career development of physician scientists. As the NIH's Physician Scientist Workforce Working group confirmed, the population of physician researchers has been held stable largely by the aging of the current investigator pool, and the community must provide more concerted efforts for helping attract new physicians to train as scientists and establish research careers.

In recent comments to the NIH Office of Research Infrastructure Programs, the AAMC noted that NIH maintains important but separate programs for support of shared instrumentation and facilities construction or renovation. Often, the boundary between a sophisticated instrument and the facility that houses it is difficult to define. Also, many institutions are looking to co-locate different types of high-end instrumentation in shared spaces. As the NIH develops its strategic plan, we hope that award programs will allow for better integration of research resources with facilities. We also strongly encourage support for shared regional cores, as supported by many center (P40) grants, and by NIGMS' programs for cryo-electron microscopy (Cryo-EM).

Objective 3: Exemplifying and Promoting the Highest Level of Scientific Integrity, Public Accountability, and Social Responsibility in the Conduct of Science

- Fostering a Culture of Good Scientific Stewardship
- Leveraging Partnerships

- Ensuring Accountability and Confidence in Biomedical and Behavioral Sciences
- Optimizing Operations

Comment: AAMC commends the NIH for placing the objective of ensuring "scientific integrity, public accountability, and social responsibility" on equal footing with the two other objectives, which reflect the traditional "core mission" of the NIH. As the complexity of biomedical research and its importance for society grows, the research community will need to make more concerted efforts to ensure accountability and good stewardship of these resources. We emphasize the importance of leveraging partnerships in this objective.

Future opportunities or emerging trans-NIH needs.

In conclusion, the AAMC notes several elements that should be included in a forthcoming strategic plan:

- Big Data, including from health systems with millions of covered lives, and parallel data generated through personal applications and other data sources. The use of such data sources requires steps to ensure that studies based on "real world evidence" are rigorous and account for and correct for potential biases, such as those arising from inequities in health care.
- Artificial intelligence and machine learning: the recent working group of the NIH Director's Advisory Committee correctly noted that NIH may need different types of grant mechanisms to engage scientists who are expert in these fields.
- Research on the Social Determinants of Health, necessary to more fully understand the burden of disease and the potential for health interventions.
- The development of tools and platform technologies, similar to the BRAIN initiative. Tech transfer and commercialization (noted in Objective 2).
- The integration of instrumentation with specialized facilities, and networks (also noted in Objective 2).
- The development and articulation of more useful and appropriate animal models.

The AAMC would be pleased to provide any additional information or clarification on these comments. Please feel free to contact me directly or Stephen Heinig, AAMC Director for Science Policy, at sheinig@aamc.org

Sincerely,

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Ross McKinney, Jr. MD Chief Scientific Officer