

August 7, 2015

The White House
Executive Office of the President
1600 Pennsylvania Avenue, NW
Washington, DC 20500

RE: Precision Medicine Initiative: Proposed Privacy and Trust Principles

The Association of American Medical Colleges (“AAMC”) appreciates the opportunity to comment on the draft Precision Medicine Initiative (“PMI”) guiding principles for protecting privacy and building trust, released on July 8, 2015. The AAMC is a not-for-profit association representing all 144 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and 90 academic and scientific societies. Through the AAMC’s member institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and postdoctoral trainees.

The AAMC supports the design of the PMI as “a new model for scientific research that emphasizes engaged participants and open, responsible data sharing with strong privacy and security protections.” We stress that addressing privacy and building trust requires three overarching goals that should guide these efforts:

- 1. Engaging all populations.** Maintaining trust requires the engagement of all populations early in the research process. Ensuring that precision medicine is available to all and beneficial to all in the future will require inclusion of a broad, diverse population to lessen, not accentuate, health and healthcare disparities.
- 2. Setting reasonable expectations.** Researchers and federal agencies need to set appropriate expectations for the outcomes of the PMI. The promise of the PMI is a future in which treatments can be tailored to individuals to better fight disease and improve health. As a community, we can help participants to understand that this involves a long-term commitment by researchers to build an evidence base for future medical care and will not necessarily result in immediate personalized treatments. Further, we need to be

cautious that descriptions of the benefits of the PMI do not suggest that precision medicine is a replacement for effective prevention. Improving the health of all requires the recognition of the effects of both the social determinants of health and the biomedical basis for disease.

- 3. Planning for effective dissemination.** Ensuring that the benefits of the PMI are available to all who could benefit from the outcomes requires a determination of how the findings will be effectively disseminated to providers and implemented in routine practice.

In general, while the principles move in a direction that is fitting of a new research model based on openness, transparency, sharing, and engagement, the implementation will certainly require coordination of individuals and organizations beyond the scope of the initiative. The AAMC acknowledges that the Administration has identified several partners in this effort and encourages additional meaningful partnerships with organizations and groups with proven experience in reaching underserved communities and managing complex healthcare or other personal data. To the extent that the principles can set foundational expectations for broader educational efforts, we are supportive of this document as a starting point for those conversations. If total fulfillment of each of these principles is necessary to commence any research activities, existing systems and regulations may become a barrier to moving forward.

Governance

We applaud the Administration for starting the enumeration of principles of governance with the need to create strong partnerships with participants and others in the planning and conduct of the PMI. As the research cohort develops, organizers should continue to engage broad public and private stakeholders and also rely on the expertise and convening power of the NIH. The AAMC agrees that any research study, particularly one of this size, must provide for “strong oversight, accountability, and consistency.” We note also that governance mechanisms will necessarily have to consider the frameworks of existing cohorts, if those are to be included in the PMI.

With regard to compliance with applicable laws and regulations governing the protection of human subjects, it is critical to consider that we are currently in the midst of changes to these rules, with a revision to the Common Rule expected soon, as well as ongoing Congressional efforts to increase access to and use of health data. As regulatory modernization is one of the objectives of the PMI, the AAMC encourages review of applicable regulations in light of the goals of the PMI.

Transparency; Respecting Patient Preferences

The PMI can only be effective if it recognizes the crucial role of the public as active partners in research and discovery. This must be a national partnership created through collaboration and engagement with patients, researchers, and prospective subjects, and must be in place from the

beginning of the research planning process. The goal should be for information to be conveyed in a format and medium that facilitates learning and understanding.

The AAMC has long supported a model of informed consent designed to give participants relevant information, as well as ample time and opportunity to formulate questions about the research. There should be an intentional effort to provide clear and meaningful information within the appropriate context to enable a person to decide whether to participate in the research cohort. This should include being clear about what data are collected, how the information will be stored, and who will have access to that information. Many prospective participants also seek assurance that results and findings from studies will be applicable to their own communities, and these issues should be addressed by the PMI.

The AAMC agrees that it is important to convey an understanding of the research process, including that a participant may withdraw consent for future studies at any time but data already in use will not be removed from the study. We also encourage the promotion of “participant autonomy and trust through a dynamic information sharing process,” where ongoing interaction between participants and investigators facilitates the continued exchange of information and opportunity for participants to ask questions.

Finally, the AAMC urges the evaluation and assessment of the PMI’s patient engagement to determine the effectiveness of its current efforts and to implement new strategies as needed. Given the interest of the PMI in serving and engaging a broad cohort from a diverse set of communities, particular attention should be paid to communicating with under-engaged populations.

Reciprocity; Data Sharing, Access, and Use; Security; Data Quality and Integrity

Voluntary participation in the research cohort reflects an interest of people to contribute to healthcare innovation, and the PMI as a whole recognizes the fundamental social contract where those who benefit from medical advances are also contributing to the future. The AAMC agrees that the success of the PMI relies on “a minimum data set [to] be defined and required for participation,” and that in turn, the participant should be able to access the health data they contribute—a crucial step in the democratization of the data.

The AAMC agrees that different tiers of data access will be necessary for such an initiative. We note that models for controlled access currently exist within certain clinical trial data sharing initiatives and encourage the consultation of the research community when constructing such a system. The PMI data may be valuable for research on the population-level causes of health and healthcare disparities and should be made accessible to researchers for these purposes.

The AAMC supports the appropriate protection of sensitive personal data, and appreciates the plan to develop a “robust data security framework … to ensure the confidentiality and integrity of all PMI cohort specimens and data.” We suggest that efforts to standardize the approach to addressing informational risks include the flexibility to address instances when the risks associated with the identification of subjects are particularly high. We note that while every effort should be taken to minimize the risks inherent in this type of large-scale data collection, including protection against unauthorized or inappropriate data use, participants should understand that it is not possible to entirely eliminate these risks. Especially given the size of the research cohort and unique commitment to data sharing, there may be privacy issues that have not yet been anticipated, and the structure of the PMI should be able to accommodate and respond to those emerging concerns.

The AAMC is appreciative of the Administration’s commitment to engaging the broader public in the development of privacy and trust principles for the PMI. We would be happy to provide any further assistance as plans for the PMI research cohort continue to develop. Please feel free to contact me or Heather Pierce, Senior Director for Science Policy and Regulatory Counsel at hpierce@aamc.org or (202) 478-9926 with any questions.

Sincerely,



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Chief Scientific Officer