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Kathy Hudson, Ph.D.
Deputy Director of Science, Outreach, and Policy
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

RE: Request for Information (RFI): NIH Precision Medicine Cohort - Strategies to Address Community Engagement and Health Disparities (NOT-OD-15-107)

Submitted via <http://grants.nih.gov>

Dear Dr. Hudson,

The Association of American Medical Colleges (AAMC) is pleased to have this opportunity to offer comments and suggestions in service of engaging diverse communities in the National Institutes of Health's (NIH) Precision Medicine Initiative (PMI). The AAMC is a not-for-profit association representing all 141 accredited U.S. allopathic medical schools, 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers, and 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and post-doctoral trainees in the biomedical sciences.

A1. The factors and incentives that would enable participation or make it more likely for people historically underrepresented in research to participate, including examples of successful models of recruiting and retaining participants from communities historically underrepresented in research

The AAMC encourages the NIH to ensure participants from historically underrepresented groups are engaged in all steps of the research cycle, including dissemination of research findings. Community input can be used to identify appropriate methods and measures, to clarify how groups and potential participants understand and perceive difficult scientific concepts, and to identify barriers to research participation and strategies to overcome them. We commend the NIH on the steps taken to increasing research participation among underrepresented groups, and recommend working with minority community organizations, respected leaders, and advocacy groups to continue the education process and report back the results from research studies. As the NIH continues to modify its community engagement strategies, AAMC also suggests comprehensive evaluation of the new engagement strategies to measure their effectiveness.

Precision medicine is inherently complex and can be difficult for the general population to understand. Literature suggests that lack of familiarity with scientific concepts is a barrier to participation among

racial/ethnic minorities¹⁻². The AAMC suggests that the NIH, in collaboration with sub-populations it wishes to reach, prepare project-specific educational modules to help participants better understand the study purpose, time commitment, and logistics of participation. Additionally, we encourage the NIH to develop additional strategies to educate and engage non-English speaking participants and those with low general literacy.

A2. Community engagement strategies and partnerships that can facilitate and integrate multiple perspectives at the community and individual level and account for diverse, social, religious, economic, and geographic settings

Community engagement is important to develop PMI-specific education programs, appropriate measures and methods, and to tailor community-specific communication strategies to report back results. However, just as communities are heterogeneous, so too are the relationships between local community-based organizations (CBO) and the residents they engage. The AAMC encourages the NIH to identify appropriate community partnerships in recruiting participants to the PMI cohort by first understanding the characteristics of and the relationships between individual CBOs and their community members. By understanding the dynamics of how prospective partner CBOs interact with their community, the PMI can create appropriate partnerships and strategies that respectfully leverage and align with community values important to specific CBOs and their members. We commend the NIH for supporting the community engagement function of NCATS' CTSA program and suggest the PMI initiative avail itself of the community engagement expertise at those sites.

Through partnerships with community organizations such as cultural centers, churches, and interest groups, education about the purpose of the PMI can be tailored and presented in a manner that provides deliverables the respective groups see as relevant and beneficial. In service of the mission of the PMI, an active effort must also be dedicated to reaching participants that are not a part of CBOs' membership. The AAMC urges the NIH to invest in sustained dialogue with individuals and community organizations to identify effective recruitment and engagement strategies that could benefit both PMI's enrollment targets as well as CBOs' membership building activities.

A3. The barriers to participation in the precision medicine cohort and strategies to address those barriers

Previous studies have examined potential barriers to participation in genomic research and have found underrepresented minorities are hesitant to participate in research for reasons such as lack of trust, lack of familiarity of scientific concepts, and lack of transparency of the research process. To overcome these barriers, the AAMC recommends NIH researchers utilize the foundational principles of community-engaged research when designing a research program³. The principles can provide guidance on how to

¹ Goodman, M. S., Dias, J. J., & Stafford, J. D. (2010). Increasing Research Literacy in Minority Communities: CARES Fellows Training Program. *Journal of Empirical Research on Human Research Ethics : JERHRE*, 5(4), 33–41. doi:10.1525/jer.2010.5.4.33

² Salman, A., Nguyen, C., Lee, Y. H., & Cooksey-James, T. (2015). A Review of Barriers to Minorities' Participation in Cancer Clinical Trials: Implications for Future Cancer Research. *J Immigr Minor Health*. doi: 10.1007/s10903-015-0198-9

³ Eder MM, Carter-Edwards L, Hurd TC, Rumala BB, Wallerstein N. A logic model for community engagement within the Clinical and Translational Science Awards consortium: can we measure what we model? *Acad Med*. 2013 Oct;88(10) 1430-1436. doi:10.1097/acm.0b013e31829b54ae. PubMed PMID: 23752038; PubMed Central PMCID: PMC3784628

appropriately and bi-directionally engage with communities so barriers such as lack of trust and lack of transparency are mitigated. The AAMC also suggests the NIH work with community-based organizations to develop effective communication and educational programs about Precision Medicine Initiative research studies, their goals, results and relevance for communities' priority local health needs and concerns. Non-profit hospitals as well as public health agencies are required to conduct community health needs assessments, the results of which can help PMI researchers understand the local health needs of community residents and thus tailor their message – and their science – to address those needs.⁴

A4. Ways to avoid potential stigmatization of subpopulations, and to manage unintended adverse consequences of the precision medicine cohort

Underlying assumptions of genetic predisposition to disease may perpetuate social inequalities, and stifle the community engagement process. The literature has shown findings from research studies fuel the perception that disparate health outcomes experienced by communities of color are linked to shared genomes rather than shared environment, social status, or income levels. The AAMC recommends the NIH develop culturally sensitive communication strategies when reporting the findings from the Precision Medicine Initiative. By utilizing race and ethnicity as a proxy in recruitment, analysis, and communication of findings, the NIH runs the risk of implying genetic differences by race, when categories of social experience or ancestry may more accurately characterize differences in health⁵.

A5. Safeguards should be implemented to reassure communities of the net positive potential of the precision medicine cohort to understand health and disease and improve the health of all segments of the US population.

The AAMC commends NIH for developing a more comprehensive and effective policy for sharing genomic information more widely. As noted in a November 20, 2013 comment letter in response to “NIH Genomic Data Sharing Policy”⁶ AAMC recommends a final policy which should restate the NIH’s commitment to community engagement in the research process and complementary efforts to promote health equity in the application of genomic research. Research participants should be reassured that the results and findings from the studies will be relevant and applied appropriately to their communities perhaps by framing PMI research as one response to community health needs assessment-identified priority health needs. Additionally, we urge the NIH to ensure that the research findings are communicated back to the community in the most efficient and effective way.

Providing an in-depth informed consent is crucial to ensuring protections for research participants. The AAMC encourages NIH to utilize innovative practices for consent, such as the dynamic consent model, which allows individuals to indicate an initial interest in participating in a research project and have the opportunity to provide consent on an ongoing basis. This particular consent model promotes autonomy and active participation which provides reassurance to individuals from underrepresented groups about participating in the precision medicine cohort. Providing research participants with new opportunities by which they elect to participate in research studies and give informed consent to share information and

⁴ Reed, J. F., & Fleming, E. (2014). Using community health needs assessments to improve population health. *NC Med J*, 75(6), 403-406.

⁵ Isler, M. R., Sutton, K., Cadigan, R. J., & Corbie-Smith, G. (2013). Community perceptions of genomic research: implications for addressing health disparities. *NC Med J*, 74(6), 470-476.

⁶ AAMC Comment Letter, November 20, 2013, (available at <https://www.aamc.org/download/362234/data/aamccommentsonnihgenomedatasharingpolicy.pdf>)

samples, increases the level of transparency of the research process and adds a level of reassurance to the research participant.

Advances in technology and medicine are not always distributed equitably throughout the US, exacerbating or in some instances creating health and health care inequities. The AAMC urges NIH to ensure the benefits of precision medicine are not only effectively communicated to all communities but that any resulting innovations in treatment are equitably accessible to all populations, regardless of socioeconomic status.

B1. Priority health disparities research questions that can be uniquely addressed within the proposed precision medicine cohort

AAMC defines health disparities as “measureable, systematic, and avoidable differences in health between groups, stemming from differences in levels of social advantage/disadvantage.” In light of that definition, a focus on genetics is insufficient for a comprehensive health equity research agenda. We commend NIH for its inclusion of risk factor and socioeconomic data in addition to genetic information in the PMI dataset. The AAMC recommends the NIH adopt a multi-level, systems approach when analyzing PMI data in order to fully understand the root causes of inequities and the interactions between those causes. Further, PMI data could be aligned with other data sets including public health data, community health needs assessment data, and electronic health record data to create an even fuller picture of the systems that give rise to and perpetuate health inequities.

This data integration will create a powerful tool accessible to existing initiatives such as PCORI’s PCORnet and NIH’s Big Data to Knowledge (BD2K). The accumulation of biospecimen, environmental, and behavioral data generates a body of data that allows for multi-level analysis. The AAMC urges the NIH to encourage and create opportunities for cross-site research collaboration that utilizes the full body of data that the PMI collects.

B2. Opportunities to study the relative influence of health determinants (e.g. personal, social, economic, environmental factors) on disease risk, disease mechanism, and individual response to therapy.

Through the study of multi-level interactions, PMI researchers can investigate the potential causes and protective factors of health inequity which can be identified across the many data streams collected by the PMI, permitting analysis of effect modification between such variables. These findings will greatly advance research that seeks to identify the extent to which lifestyle, environmental, and genetic variability cause population disparities in disease incidence, prevalence, and outcomes. For example, even if one’s genetic dispositions might increase risk of disease, practical interventions targeting an individual’s behavior and environment can potentially lower that risk of disease.

B3. Opportunities to obtain new scientific knowledge regarding individual variability in genes, environment, and lifestyle and their interactions as they affect the incidence of progression of illness where there are significant population disparities in disease incidence, prevalence, and outcomes.

To encourage innovation in patient care, the AAMC recommends the PMI work to fully evaluate how genes and gene-environment interactions contribute to health. We commend the NIH PMI for “intentionally oversampling underrepresented populations” which will allow researchers to analyze genetic material associated with characteristics such as race, environment, or other lifestyle data of individuals who may or may not have a disease. Additionally, epigenetic studies will allow researchers to evaluate environmental influences on the activation of certain disease-causing genes.

Since one of the concepts of precision medicine is “the application of prevention and treatment strategies that take individual variability into account”, exome sequencing is another recommended method for obtaining new scientific knowledge. AAMC member-institutions are at the forefront of studying the clinical applications of exome sequencing. For example, the UNC Chapel Hill School of Medicine, NC Genes program is one of five Clinical Sequencing Exploratory Research projects that will study ways for healthcare professionals to use genome sequencing information in a clinical setting. The UNC research team has also implemented whole exome sequencing (WES) in medically underserved groups and is working to identify barriers to recruitment and retention of patients in the study as well as how WES can be expanded to other medical institutions.

B4. Novel methods to gather data on geographic, environmental, and social determinants of health

Both the Institute of Medicine and the Office of the National Coordinator have proposed the inclusion of social, behavioral, and psychological data in hospital electronic health records (EHRs). Included in the proposed panel are questions about sexual orientation, education, employment status, food and housing security as well as other lifestyle and environment questions. The AAMC recommends the NIH work with health systems in preparation of these data’s availability to align this new information with PMI data in order to gain information on geographic, environmental, and social determinants of health. Health services research efforts can support the understanding of how to validly collect these data.

The AAMC encourages NIH to leverage health information technology in order to gather different types of data about participants. However, the uptake of certain technologies may vary in different populations. PMI’s intention to provide assessment data to participants using mobile devices or wearable sensors requires NIH to understand how subgroups accesses and obtain medical information. In a previous comment letter response to FDA’s report on “Ensuring Access to Adequate Information on Medical Products for All, With a Special Focus on Underrepresented Subpopulations,”⁷ the AAMC provided recommendations to identify communication pathways that will be effective to reach populations who many not benefit from infrastructure and technologies that facilitate communication through electronic means and social media.

Assuring diversity in the PMI cohort is crucial to the initiative’s success and AAMC appreciates the opportunity to submit comments and suggestions. We would be pleased to work with the NIH to advance this initiative. Please contact me or my colleague Philip M. Alberti, Ph.D. (palberti@aamc.org) with any questions about these comments.

Sincerely,



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

⁷ AAMC Comment Letter, September 5, 2013,(available at <https://www.aamc.org/download/353860/data/aamccommentsonfdasreportonensuringaccesstoadequateinformationon.pdf>)