



February 5, 2007

Attention: Personalized Health Care RFI
U.S. Department of Health and Human Services
Room 434E
200 Independence Ave. SW
Washington, DC 20201

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President

Via e-mail: PHCRFI@hhs.gov

RE: Request for Information (RFI): Improving Health and Accelerating Personalized Health Care Through Health Information Technology, etc.

The Association of American Medical Colleges (AAMC) is pleased to submit the following comments in response to the Department of Health and Human Services' request for information on research and technologies that will accelerate the development of personalized health care. The AAMC is a nonprofit association representing all 125 U.S. and 17 Canadian accredited allopathic medical schools, nearly 400 major teaching hospitals and health systems, 96 academic societies, and the nation's 67,000 medical students and 104,000 residents. The Association seeks to improve the nation's health by enhancing the effectiveness of academic medicine

The AAMC is grateful to the Secretary and the Department for their attention to critically important areas of research and policy, and for seeking information from the health care community, including from academic medicine, to develop effective and coherent policies for development of personalized health care. We have disseminated this request to our members and have vigorously encouraged them to respond.

Advances in genomics, informatics, and population and community health provide critical tools to address physiological variation among patients, and the National Institutes of Health has designated this research among the "3 p's" (health care that is predictive, personalized, preemptive) that are objectives of its strategic planning.^{1,2} In addition to the information that DHHS is receiving from research laboratories and clinics, the AAMC wishes to reiterate at this time several critical observations on policy that we believe must be addressed, primarily in Washington, to create a functional environment for research in genomics and population health to support personalized health care.

First, the American public remains greatly apprehensive of potential misuse of genetic information to discriminate against individuals, and limit eligibility for insurance, education, or employment. AAMC has supported and continues to urge passage of legislation by the Congress

¹ Zerhouni EA. NIH in the post doubling era: realities and strategies. *Science* 2006; 314:188-90.

² Zerhouni EA. US biomedical research; Basic, translational, and clinical sciences, *Journal of the American Medical Association*, 2005; 294: 1352-8.

that would prevent such discrimination, such as the Genetic Information Nondiscrimination Act (S. 358) passed by committee.

Second, we again ask the Department to revise and improve upon the current HIPAA mandated Standards for Privacy of Individually Identifiable Health Information, particularly in areas where the standards unnecessarily impede legitimate medical and health research without substantive benefit to privacy. The rule should be harmonized with the pre-existing and quite stringent protections for research subject privacy in the common rule. The requirements for authorization and waiver of research should be modified (consistent with the findings and recommendations from surveys by the AAMC and the National Cancer Advisory Board).³ The AAMC also recommends relaxing the deidentification standard, eliminating the accounting disclosures for research, and shifting the rule from an organizational focus to a functional focus.⁴ Absent such revisions, medical and health researchers and institutions face severe obstacles in conducting research linking phenotypic expression of disease states (and response to therapy, etc.) with underlying genetic information.

Third, the Department itself should accelerate efforts to harmonize the regulatory and policy requirements of its various offices and agencies, including the Office of Human Research Protections, the NIH, and the Food and Drug Administration, especially, but not limited to, reporting of unanticipated problems and adverse events in clinical research. We welcome the release of OHRP guidance January 15 on reporting of adverse events as an important and long awaited step toward addressing these concerns.⁵ Discordant guidance from different agencies puts institutions in an untenable position and creates confusion and anxiety where none should exist. In the strongest terms, the AAMC endorses trans-agency harmonization to the maximum possible extent, and we urge that the overlapping guidance provided by multiple agencies cross-reference each other and explicitly identify areas that are the unique purview of a particular agency.⁶

Fourth, progress in research relating to personalized health care and other areas of public health require better, more robust partnerships between university-based researchers and community health providers, especially with communities representing large, diverse, and often vulnerable populations. Only through such partnerships can research ensure access to diverse populations that are truly representative and offer the broadest basis for observation. More effective linkages between academic medical centers, their Veterans Administration (VA) affiliates, schools of public health, community physicians, and practice-based networks will require substantial investment in infrastructure, as well as in training programs for faculty, staff, and students in the principles and challenges of community-based research. Such collaborative relationships will

³ AAMC Project to Document the Effects of HIPAA on Research. Presentation slides of Susan Ehringhaus, J.D., to the SACHRP meeting, March 30 2004. <http://www.aamc.org/advocacy/library/research/testimony/2004/033004.pdf>

⁴ Testimony of Ms. Ehringhaus before the National Committee on Vital Health Statistics, Nov. 19, 2003.

<http://www.aamc.org/advocacy/library/research/testimony/2003/111903.pdf>

⁵ <http://www.hhs.gov/ohrp/policy/AdvEvtGuid.htm>

⁶ <http://www.aamc.org/advocacy/library/research/corres/2006/011106.pdf>

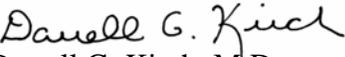
also require institutions to demonstrate their ability to form true partnerships that accommodate the interests of communities and their physicians, as well as those of faculty, such that all participants perceive benefit.

The NIH's ambitious Clinical and Translational Science Awards program to develop integrated infrastructure and "homes" for this research includes components for community partnerships. However, the role for and extent of these components is not explicit, at least not in this first year of implementation. The AAMC sees an opportunity for better guidelines to applicants and more deliberation between awardees and NIH on community involvement in CTSA's. NIH should also coordinate with VA and other PHS agencies on this issue, and the requirements of population researchers related to personalized medicine could be included in such planning.⁷

Fifth, a high priority remains the development of medical information systems that are capable of supporting integrated clinical and translational research. Informatics specialists and investigators can provide better insight on the structures and requirements for such systems in supporting biomedical research. We wish to note that in general research requirements are too frequently considered post hoc and secondary to the priorities of developing electronic medical records and databases for clinical and billing purposes. Consideration of the requirements for personalized health care should re-invigorate discussions about the fundamental role of research in development of electronic medical records and information systems at the national level.

In conclusion, we caution that the nation has become presumptive of its preeminence in biomedical research, built deservedly upon generations of compounded investment in its research institutions through the NIH and other agencies. However many nations already have in place essential national systems, such as comprehensive population health records and universal access to care, that surpass those that exist in the United States. Many nations are also making substantial investments in their medical research infrastructure and are attracting new investigators while the United States has chosen to hold its research spending level and attend to other priorities. While the prospect of personalized health care is a welcome opportunity for the nation, it is an opportunity that is predicated on a robust biomedical research enterprise, but that enterprise is severely constrained and perhaps endangered by the diminishing purchasing power of the NIH budget.

Sincerely,


Darrell G. Kirch, M.D.

⁷ CRTF2 report, www.aamc.org/promotingclinicalscience.