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October 19, 2006

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President

BY ELECTRONIC MAIL: GWAS@nih.gov

NIH GWAS RFI Comments
National Institutes of Health
Office of Extramural Research
6705 Rockledge Drive, Room 350
Bethesda, MD 20892-7963

RE: Request for Information (RFI): Proposed Policy for Sharing Data obtained in NIH supported or conducted Genome-Wide Association Studies (GWAS)

The Association of American Medical Colleges (AAMC) is a nonprofit association that seeks to improve the nation's health by enhancing the effectiveness of academic medicine. It represents 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 AAMC is pleased to comment on this important issue, and is strongly supportive of the overall goal of the proposed policy, namely to advance science for the benefit of the public through the creation of a centralized NIH GWAS data repository that will facilitate research and enable medical science to better address the health needs of people based on their individual genetic information. AAMC believes that NIH's intent to keep this information in the public domain, unencumbered by proprietary claims, will be particularly valuable in gaining maximum benefit from such studies and broadly advancing scientific knowledge and the public health. However, AAMC does have some specific concerns that we wish to bring to your attention.

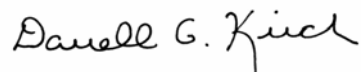
Our first concern relates to the potential risk that GWAS data or genomic information in general could be used to discriminate against both the research subjects (even though the data are to be de-identified) and the general population. Thus, markers that identify and predict susceptibility to disease can be used to limit eligibility for insurance, education, and employment. The solution to this potential risk lies not with the NIH but rather with federal legislation to prevent such discrimination. AAMC has supported and continues to strongly support the passage of such legislation by the Congress. NIH should be aware of this risk as it formulates and implements the details of the proposed policy.

Second, we urge the NIH to formulate the detailed procedures that will allow the investigators conducting GWAS a defined and sufficient period of time to analyze their own data. Considerable intellectual creativity and effort is involved in the creation of successful protocols, questionnaires, and recruitment strategies to gather these data. The investigators who mount such efforts should be allowed an appropriate but not overly long period of time to carry out an initial analysis of their own data, so that they can publish their analyses and receive proper credit for their efforts. The problem of balancing the competing interests of public health and science in rapidly making these kinds of databases available, versus the legitimate desire of the creators of these data sets to be able to study their data and publish their observations, has been discussed in several eminent forums, including the National Academies and the National Research Council.⁽¹⁾ But to our knowledge, the issues have not yet been satisfactorily resolved. In earlier comments on a then-proposed NIH policy for data sharing, the AAMC recommended that, “prior to mandating data-sharing proposals, NIH should convene advisory panels composed of experts in the various scientific disciplines and charge them with devising standards and normative practices for data sharing within their respective fields of research.”⁽²⁾ Similarly, we recommend here that NIH should seek advice from an expert panel. However, to ensure appropriate inclusion of the diverse stakeholders, the panel should include representatives from the patient and public health communities as well as from the contributing scientific disciplines.

Lastly, both investigators and institutions will require resources to comply with this policy. Our best estimate is that individual study investigators will require a partial FTE for entry and transmission of the required data on a regular basis, while institutions may require a full FTE (especially for research intense institutions) or partial FTE to track, process and submit the required certifications and statements. The resources needed to ensure that investigators and their institutions are able to comply with this policy and its requirements should be provided as direct costs that are built into the grant budgets from the beginning.

Please contact Howard B. Dickler, M.D. (hdickler@aamc.org; 202-828-0567) of AAMC staff for questions or clarification of these comments. We thank you again for the opportunity to express our concerns.

Sincerely,



Darrell G. Kirch, M.D.

References

1. See for example, two publications of the NRC’s Commission on Life Sciences, *Finding the Path* and “Priority issues of Access to research resources,” a letter report, National Research Council, 1999. Also,

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Commission on Physical Sciences, Mathematics, and Applications, *A Question of Balance: Private Rights and the Public Interest in Scientific and Technical Databases*, National Research Council, 1999.

2. AAMC comment letter to Dr. Wendy Baldwin, May 10, 2002
<http://www.aamc.org/advocacy/library/research/corres/2002/051102.htm>