



May 20, 2013

Association of
American Medical Colleges
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Re: Memorandum Increasing Access to the Results of Federally Funded Scientific Research

The Association of American Medical Colleges (AAMC) noted with interest the Feb. 22 memorandum to heads of executive departments and agencies about improving access to federally sponsored scientific findings and data. The memorandum has already generated positive discussions within the research community about considerations for improving access to findings and data. This letter outlines some observations and recommendations from AAMC on this matter, which we hope contributes to these discussions. The AAMC represents all 141 U.S. allopathic medical schools, nearly 400 teaching hospitals and health systems, and almost 90 academic societies. Our member organizations perform more than half of all extramural research sponsored by the National Institutes of Health, and substantially contribute to the findings and knowledge base that supports improvements to health and other innovation in the United States.

Policy Principles and Objectives for Public Access to Scientific Publications

The AAMC agrees with the observations and major points conveyed in the memorandum regarding the advantages of access to findings and data. As an organization dedicated to improving the health of all, the AAMC also acknowledges the paramount importance of providing complete and precise information to the public on issues pertaining to medicine and health. The quality of data is as important as quantity. Ideally, contextual and other information is provided to help the public guide and interpret health findings. The nation has experienced the difficulties of coping with conflicting and sometimes confusing findings from even the most rigorous studies.

The AAMC therefore believes that it is very important, as the OSTP has proposed, to implement a system consistent with, and as possible emulating the current enhanced public access system of the National Library of Medicine. Key elements of this system focus on findings that are published in the peer reviewed literature. The AAMC supported the NIH enhanced public access system when it was implemented more than eight years ago [*See AAMC letter, Nov. 9, 2004*]

The Association also concurs with the Administration in recognizing that publishers play an exceedingly important role by providing and coordinating peer review and ensuring high quality and integrity of many scholarly publications. In innumerable other ways, both tangible and intangible, publishers build and invest their reputations behind the quality of new articles, which in turn provides the general public some further indication of the quality and importance of federally sponsored findings. The AAMC is encouraged by the variety of different publication and “business” models that have emerged to provide open, or at least less encumbered, access to the medical literature. These organizations include some publishers who opposed—and may still oppose—the public access system, but who are adapting other models to meet increasing expectations. We agree that a system to make results from taxpayer funded studies publicly

available should attempt to minimize perturbations to new markets developing for electronic dissemination and access.

1. Any policies should precisely delineate obligations of the investigators/authors, the institutions, and granting agency. The policy should make clear who bears responsibility to ensure that manuscripts approved for publication are submitted to NIH in a timely way, or otherwise ensure that access to the findings will be available (such as through an open-access journal). The AAMC believes that the authors are accountable to ensure that manuscripts are correctly processed.
2. Meaningful access requires that the results of federally funded research are made accessible within the appropriate context. Access to published manuscripts helps to ensure that such context is provided by the reviewers and the journals. This principle should underpin all data access policies.
3. A federal-wide public access policy should recognize the costs of compliance and provide support in grants to cover such costs (such as for page charges). One issue of course is that grants supporting research projects may reach their end date before all findings from a project are published. Agencies should work out procedures that allow for these publications to be supported.

Objectives for Public Access to Scientific Data in Digital Formats

Efforts to increase public access to information and results should be tailored to keep accessibility requirements from impeding scientific research or leading to the release of misleading or nonvalidated results, and to provide explicit flexibility to ensure that data are collected and reprinted in context. The advantage to providing access to peer-reviewed publications is the ability for the recipient to have some assurance that the methodology and data analysis have been validated through the peer review process. Access to raw data without benefit of analysis or review by a third party in the relevant field could be more harmful than beneficial and could undermine the fundamental reasoning behind the public accessibility efforts.

Any implemented policy should clarify when such scientific data may or must be made publicly available. Unlike access to publications, which can be tied readily to a specific event, a requirement that data in digital formats be available needs additional guidance and boundaries. At what point in the scientific process should such data be made available? Certainly the information should not be made publicly available as soon as it is recorded in a digital format. To do so would be to interfere in the scientific process and would provide access to results prior to the investigators' ability to analyze and publish the findings, potentially inhibiting the ability to protect intellectual property in the work. Access to scientific data requirement could be tied to the publication of results in a peer-reviewed journal to provide access to data already analyzed and reviewed.

If public access to scientific data was required prior to the publication of the results from the project, there is a concern that all such information could be requested by an interested third party at any point in the research process. In addition, human subject research raises concerns

with privacy of identifiable research data. Such individually identifiable information should be explicitly exempt from scientific data access requirements. To have an effective and beneficial program to provide meaningful, reasonable access to scientific data, such access policies must be crafted carefully and thoughtfully.

The AAMC is grateful for the opportunity to provide information toward this implementation, and have encouraged the research community to respond as well. If you have any questions concerning these comments, please feel free to contact me at abonham@aamc.org or 202-828-0509, Heather Pierce, Senior Director for Science Policy and Regulatory Counsel, at hpierce@aamc.org or 202-478-9926, or Stephen Heinig, Director, Science Policy, at sheinig@aamc.org or 202-828-0488.

Sincerely,

A handwritten signature in cursive script that reads "Ann Bonham".

Ann Bonham, Ph.D.
Chief Scientific Officer

cc: Kathy Hudson, Ph.D., NIH Deputy Director for Science, Outreach, and Policy