



January 12, 2012

Office of Science and Technology Policy (OSTP)
Executive Office of the President
725 17th Street Room 5228
Washington, DC 20502

RE: Request for Information: Public Access to Digital Data Resulting From Federally Funded Research 76 Fed. Reg. 70176, November 10, 2011.

To the Office of Science and Technology Policy:

AVAC welcomes this opportunity to comment on the recent RFI: *Public Access to Digital Data Resulting From Federally Funded Research*. AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical research and development and global delivery of vaccines, male circumcision, microbicides, pre-exposure prophylaxis (PrEP) and other emerging HIV prevention options as part of a comprehensive response to the AIDS pandemic. AVAC believes that the road to safe, efficacious, accessible and affordable HIV prevention options for all who need them will necessitate IP and data sharing for the public good and also effective management of data and materials produced from disparate sources but generated for a potentially common purpose IP collaboration is a critical part of AVAC's mission,¹ and we commend the OSTP for addressing digital data sharing under the America COMPETES Reauthorization Act of 2010 (ACRA).

The public's need to know the complete results of research it pays for is clear and immediate. Immediate access to public or consortia managed access to data that has undergone quality assurance is justified by the benefits which accrue from increasing comparability of results, delivery of information supporting cross disciplinary approaches and promoting cost savings in complex research. Digital data sharing and management are a long over-due means to enhance collaboration in research and speed the translation of scientific advances into quality, affordable health care. Since tax dollars underwrite this work, all Americans should benefit from the broader utilization of digital data and its use in scientific research. Policies also need to be developed to ensure that digital data are collected and stored in formats that are accessible and interpretable by others.

Our responses note the several questions to which they relate.

¹ See *Intellectual Property at the Crossroads in AIDS Vaccines at the Crossroads*, AVAC Report 2005, http://avac.org/pdf/reports/2005_Chapter4.pdf and *Data and Materials: A "to-do" list for the future*, AVAC Report, 2010, <http://www.avac.org/ht/a/GetDocumentAction/i/28317>.

1. What specific Federal policies would encourage public access to and the preservation of broadly valuable digital data resulting from federally funded scientific research, to grow the U.S. economy and improve the productivity of the American scientific enterprise?

AVAC recognizes the potential benefits in productivity to HIV prevention research arising from greater access to digital data generated through Federal funded grants and contracts. Unequal or restricted access to information by researchers creates inefficiencies in scientific research. As a recent article found "the observed differences in access levels between institutions suggest an un-level playing field, in which some researchers have to spend more efforts than others to obtain the same information."² Eliminating this un-level playing field will facilitate increased productivity. Even minor increases in research efficiency can have significant effect on the United States economy. With the United State's investment in gross expenditure on research and development at \$312.5 billion in 2007 and assuming social returns to R&D of 50%, a 5% increase in access and efficiency would have been worth \$16 billion.³

Significant obstacles to digital data sharing exist even if greater access to data is required under ACRA. As noted in the recent National Science Foundation report:

Successful digital research data sharing and management plans depend, in part, on adequate consideration of funding, resources, and structural issues that may either facilitate or impede acceptance and implementation. These plans are especially important for small research institutions and research grants that may not have the resources available to share and manage long-lived data. Thus, just as a single data sharing and management policy will not apply to all research communities, a one-size-fits-all business model will not apply to all institutions and awards.⁴

AVAC recommends that OSTP solicit suggestions on digital data sharing from a variety of stakeholders. We would like to share insights gained from the HIV vaccine research field. The Global HIV Vaccine Enterprise is an international alliance of more than 30 independent research, funding, advocacy and stakeholder organizations and governments, engaged in unprecedented collaboration to speed the development of a safe and effective HIV vaccine.

² Voronin Y, Myrzahmetov A, Bernstein A, *Access to Scientific Publications: The Scientist's Perspective*. *PLoS One*. 2011;6 (11):e27868. Epub 2011 Nov 17.

³ Houghton J.W. and Sheehan, P.J. (2006) *The Economic Impact of Enhanced Access to Scientific Publications*, Centre for Strategic Economic Studies, Working Paper, No 23, Victoria University, Melbourne. (<http://eprints.vu.edu.au/archive/00000472/>).

⁴ National Science Foundation, *Digital Research Data Sharing and Management* December 2011 (Task Force on Data Policies Committee on Strategy and Budget National Science Board)

The Enterprise convened meetings on management of the large data sets including deep sequencing of HIV virus populations, as well as B-cell and T-cell repertoires.

The Enterprise meetings have confirmed first that digital data store requires significant investment of time and resources, in some cases estimated to include storage requirements in the range of petabytes. Vaccine researchers have also identified gaps in the subject matter content of available databases that are critical to the field.⁵ Federal policies that support development of web-based systems and assemble field expert panels to identify priority digital data needs can increase the efficiencies and use of such data. NIH should accommodate expert outside panel recommendations when transitioning previous activities from the now (recently) defunct National Center for Research Resources.

Federal policies must address the significant non-IP related challenges. Obstacles identified by the Enterprise working group include: 1) training to develop human expertise to input, catalogue and design data bases; 2) establishing procedures for depositing and curating data bases; and 3) addressing privacy issues related to patient information.

We also recommend invigorating existing data and resource sharing plan policies to yield substantive results. Currently, NIH grant policy requires submittal of data and resource sharing plans within applications.⁶ In practice, however, application content in many grants is minimal, lacking in detail or extremely modest in promise, if any. NIH may invigorate this element by elevating the importance of data and resource sharing plans within applications during award scoring, requiring content focused on appreciation for field wide benefit of use, and mandating substantive content directed towards identifying those posting and forum opportunities where a grantee's results can have best translational benefit.

2. What specific steps can be taken to protect the intellectual property interests of publishers, scientists, Federal agencies, and other stakeholders, with respect to any existing or proposed policies for encouraging public access to and preservation of digital data resulting from federally funded scientific research?

AVAC does not assume that greater access would, in fact, harm or diminish the IP of those that initially develop digital data. IP discussions, in our view, focus too exclusively on mere ownership without sufficiently discussing responsible IP management or use for public purposes. Useful models of IP management and use for public good are available, for

⁵ [An open-ended plea for the development of a global database of HIV vaccine responses](#) Wilkinson, Peter; Filali-Mouhim, Abdelali; Li, Shuzhao; Ahlers, Jeffrey; Schatzle, John; Pulendran, Bali; Sekaly, Rafick-Pierre; Cameron, Mark J. *Current Opinion in HIV & AIDS*, POST AUTHOR CORRECTIONS, 21 November 2011 doi: 10.1097/COH.0b013e32834e390a

⁶ NIH Data Sharing Policy http://grants.nih.gov/grants/policy/data_sharing

example, such as the regulatory implementation schemes of the California Stem Cell Bond Act program.⁷

3. *What mechanisms could be developed to assure that those who produced the data are given appropriate attribution and credit when secondary results are reported?*

There are strong currents in the present research and product development models which favor unilateral research and which inhibit data sharing. To overcome these barriers, in the HIV field, for example, the AIDS Clinical Trial Group has developed a system for equitable allocation of secondary uses of data in papers.⁸

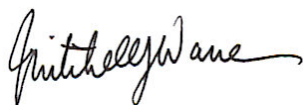
4. *How could Federal agencies promote effective coordination on digital data standards with other nations and international communities?*

AVAC supports continued participation and follow-up to the Board of Research Data and Information, National Academy of Sciences, efforts to develop an internationally supported Microbial Research Commons.⁹ Future efforts should also include participation by public advocacy stakeholders to help design content, public use content and allocations of rights.

Finally, we note that the RFI's description of stakeholders - "e.g., research communities, universities, research institutions, libraries, scientific publishers" – does not include patients, advocacy knowledge users and organizations devoted to promoting research initiatives. AVAC hopes the RFI implementation will place these interests firmly within the outcomes results of this effort.

Thank you again for this opportunity to comment. If you have questions about this letter, please contact me at mitchell@avac.org.

Sincerely yours,



Mitchell Warren
Executive Director

⁷ California Institute for Regenerative Medicine <http://www.cirm.ca.gov/Regulations>

⁸ ACTG *Publication and Disclosure of Study Results SOP 111* available at <https://actgnetwork.org/node/430>

⁹ National Research Council. *Designing the Microbial Research Commons: Proceedings of an International Workshop*. Washington, DC: The National Academies Press, 2011.