



Advancing Transfusion and  
Cellular Therapies Worldwide

Sent via e-mail to digitaldata@ostp.gov

January 12, 2012

John P. Holdren  
Director, OSTP  
725 17th Street, Room 5228  
Washington, DC 20502

Re: Document #2011-28621

Dear Mr. Holdren,

AABB (formerly the American Association of Blood Banks) is pleased to respond to OSTP's November 3, 2011 *Federal Register* notice requesting comments on "Public Access to Digital Data Resulting from Federally Funded Research." AABB appreciates the opportunity to respond to the issues raised in the notice.

AABB is an international, not-for-profit association representing individuals and institutions involved in the field of transfusion medicine and cellular therapies. The association is committed to improving health by developing and delivering standards, accreditation, and educational programs that focus on optimizing patient and donor care and safety. AABB membership consists of nearly 2,000 institutions and 8,000 individuals, including physicians, nurses, scientists, researchers, administrators, medical technologists, and other health-care providers.

AABB owns *TRANSFUSION*, the foremost peer-reviewed publication in the world for new information regarding transfusion medicine. Written by and for members of AABB and other health-care workers, *TRANSFUSION* reports on the latest technical advances, discusses opposing viewpoints regarding controversial issues, and presents key conference proceedings. In addition to blood banking and transfusion medicine topics, *TRANSFUSION* presents submissions concerning tissue transplantation and hematopoietic, cellular, and gene therapies.

Like many other societies, AABB depends on non-dues revenue such as that generated by data collection, analysis, and dissemination activities to support important work that serves not only a specialized (in this case, medical) community, but also society in general.

AABB offers the following responses to the Request for Information appearing in 76 FR 68517.

- 1. What specific federal policies would encourage public access to, and the preservation of, broadly valuable data resulting from federally funded scientific research, to grow the US economy and improve the productivity of the American scientific enterprise?***

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Through its publisher, John Wiley and Sons, *TRANSFUSION* encourages growth in existing and new markets. The journal has a policy for open access to data from federally funded research. That policy has been in place for some time without controversy or challenge, and appears to meet the needs of the journal's constituency. AABB and Wiley have made investments in digital and online technology, and have actively participated in library consortia worldwide to accelerate and broaden access to research data submitted to the journal. There is more access to more content by more users now than ever before.

However, AABB is unaware of any studies showing that free access to the research data will increase research productivity or economic growth. *Access* to the data does not automatically translate to the ability to *use* that same data. The modern research enterprise is complex and requires huge investments. Limited resources are the constraint, not access to the data.

AABB does not accept the premise that because government funds scientific research, the government is entitled to full access to and control of data reported in this research. Managing, analyzing, disseminating, and archiving data are expensive. The government pays only for the conducting of research; it is unfair for it to lay claim to the fruit of labor by others.

Many research funders require research progress reports on all grants. Expanding this information by requiring the addition of a one-paragraph lay summary, and making both freely available, has more potential to enhance public understanding than does providing free access to data. AABB's strong preference would be that the federal government does *not* mandate deposit of research data in a freely available archive, regardless of format, process, or timing. Rather, the federal government should strive to provide public access to the information that it already controls and has a right to distribute — for example, research summary reports.

Typically, these reports are produced as part of each federally funded project, and they are provided to the government as a contract deliverable. Thus, there is a report for virtually every project. Each project itself undergoes peer review before being selected for funding, and the research results being reported on are solely those that the government funded. In short, these reports are the federally funded research results. Thus, if the policy is to provide public access to federally funded research data, then these reports are the natural vehicle for doing so. The government already has them, so all it has to do is make them publicly available. Several federal science agencies already do this; no new system is required.

***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?***

Input from stakeholders is key. Partnership with publishers will deliver more to taxpayers at lower cost, with minimum economic burden. Publishers maintain an interest in long-term stewardship and improved public access to the data generated by federally funded research. What should *not* be considered is to take

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data that have been collected and analyzed by publishers or learned societies (directly or via a mandate placed on grantees) and make the data freely available.

3. ***How could federal agencies take into account inherent differences between scientific disciplines and different types of digital data when developing policies on the management of data?***
4. ***How could agency policies consider differences in the relative costs and benefits of long-term stewardship and dissemination of different types of data resulting from federally funded research?***

Agencies should collaborate closely with publishers, scholarly associations, universities, and other research entities to achieve the full potential of publicly accessible, interoperable databases. Increasingly, investigators are being asked to share, or provide plans regarding how they will share with other researchers, the primary data and other supporting materials created or gathered in the course of their work. As publishers and societies respond to increasing author demand to making research data available we are focusing on: 1) establishing best practice guidelines to make data available and retrievable in a consistent way, 2) collaboration with publicly endorsed community archives to make data and publications interlinkable, and 3) presenting data in more sophisticated formats to increase reuse.

5. ***How can stakeholders (eg, research communities, universities, research institutions, libraries, scientific publishers) best contribute to the implementation of data management plans?***

Scientific, technical, and medical publishers (including learned societies) make significant amounts of data available as supplementary material to published articles and are already participating in initiatives designed to facilitate the sharing of data. AABB would be willing to work with funders and database/repository operators to develop recommended practices for assigning Digital Object Identifiers (DOIs) to data sets and supplementary material, so that datasets could be linked to primary research articles.

6. ***How could funding mechanisms be improved to better address the real costs of preserving and making digital data accessible?***

Federal agencies are not always aware of existing technologies and solutions in the marketplace, resulting in unnecessary spending and a misallocation of taxpayer dollars—particularly when the Government duplicates and competes with products and services provided by the private sector. For example, the National Institutes of Health (NIH) did not proactively seek collaboration with journal publishers as it developed its procedures and policies for the deposit of NIH-funded researchers' manuscripts into its central repository. Consequently, NIH created an unnecessary separate archive and tagging system at considerable expense and with minimal interoperability with existing data repositories.

It is questionable whether the government could become a credible provider of data management services. Given government budget constraints, the government would be unlikely to use taxpayer dollars to

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duplicate an existing, well-functioning service. PubMed Central, the repository for mandated NIH grantees, is not a simple archive, but a sophisticated platform requiring millions of dollars of investment. Criteria for funding should address and prevent duplication of, or competition with, products and services offered by the private sector.

**7. *What approaches could agencies take to measure, verify, and improve compliance with federal data stewardship and access policies for scientific research? How can the burden of compliance and verification be minimized?***

Again, AABB does not accept the premise of federal data stewardship, especially with the added burden of compliance and verification. Government agencies may fund scientific research, but that does not entitle the government to control of the data reported in the research. Managing, analyzing, disseminating, and archiving data are expensive, value-added activities of publishers and learned societies. The government pays only for the conducting of research; it is unfair for it to lay claim to the fruit of labor by others.

**8. *What additional steps could agencies take to stimulate innovative use of publicly accessible research data in new and existing markets and industries to create jobs and grow the economy?***

As noted earlier, AABB is unaware of any studies showing that free access to the research data will increase research productivity or economic growth. *Access* to the data does not automatically translate to the ability to *use* that same data. The modern research enterprise is complex and requires huge investments. Limited resources are the constraint, not access to the data.

AABB believes that data that have been collected, analyzed, or otherwise managed by publishers should not be made freely accessible without the publisher's permission. AABB believes that publishers — and learned societies — themselves should determine the business models under which they operate. Peer-reviewed papers containing data are the direct result of investment and value added by societies and/or publishers, not the federal government. Thus, material should *not* be made freely available to the public unless the publisher or learned society authorizes the government to do so.

Respectfully,

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