

Ray English and Heather Joseph

The NIH mandate

An open access landmark

December 26, 2007, was a historic date for the international movement supporting public access to taxpayer-funded research. With the Consolidated Appropriations Act of 2007 (H.R. 2764) being signed into law, the National Institutes of Health (NIH) became the first U.S. federal agency required to make the results of its funded research freely accessible online to the public.

The new law, which Congress passed as part of the FY 2008 appropriations process, directs NIH to require its funded investigators to submit their final peer-reviewed manuscripts to PubMed Central, the National Library of Medicine's online archive of biomedical literature. Manuscripts must be deposited in PubMed Central upon acceptance in peer-reviewed journals and be made publicly available online within 12 months of publication.¹

The NIH mandate, which will have broad implications worldwide, is the result of strong bipartisan support in Congress and years of coordinated advocacy led by the library community in close collaboration with a broad coalition of university, patient advocacy, public interest, and research groups.

A long struggle

Efforts to establish an NIH public access policy through Congressional action date back to 2003, when Rep. Ernest Ishtook (R-OK) secured report language in the House version of the FY 2004 Labor, Health and Human Services (LHHS) appropriations bill commending NIH for developing PubMed

Central and encouraging the agency to work with the library community to further develop the repository. Congressional interest intensified the following year when additional report language expressing concern over the lack of public access to the results of NIH-funded research was added to the FY 2005 appropriations bill. The language specifically recommended that NIH develop a policy, using PubMed Central as its cornerstone, to require its researchers to make the results of their work available within six months of publication in peer-reviewed journals. After months of consultation with stakeholders, NIH enacted in May 2005 its initial *voluntary* policy under which researchers were encouraged to make the results of their funded research publicly accessible within 12 months of publication. NIH pointed to three goals—increased accessibility, acceleration of scientific discovery, and the creation of a permanent archive of research results—as driving factors in implementing the policy.

Public access supporters were concerned that the voluntary policy could not reach its stated goals, and it quickly became apparent that it would never be successful. Only a

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small percentage of investigators (less than 5 percent) complied with the policy. Key advisory bodies, including the NIH Public Access Working Group and the National Library of Medicine Board of Regents, recommended that the policy be made mandatory for researchers and that the optimal embargo period be six months. In testimony before both the Senate and House LHHHS appropriations subcommittees in 2007, NIH Director Elias Zerhouni confirmed that the voluntary policy was not working and that a mandatory policy was indeed needed.

The failure of the voluntary public access policy led Congress to abandon reliance on report language and instead insert language into the text of the appropriations bill itself directing NIH to require its researchers to comply with a public access policy. A provision to that effect cleared the House of Representatives in late 2006, but Congress was unable to pass an appropriations bill at that time and adopted a continuing resolution instead. During the FY 2008 appropriations process, which proved successful, identical language was included in both the House and Senate versions of the LHHHS appropriations bill. That language survived through the entire legislative process, including passage by both the full House and Senate, a veto by President Bush of the bill (due to its overall spending levels), a compromise LHHHS appropriations bill, and finally the signing of the provision into law as part of a consolidated appropriations bill covering several agencies.

Library community involvement

The library community can take great pride in its leadership in advocacy for the NIH requirement. Open Access Working Group (OAWG), which was convened and coordinated by SPARC, began working on NIH-related issues when it was formed in late 2003. OAWG membership consists of all major U.S. library associations and other organizations strongly committed to the principle of open access.² SPARC also coordinated the creation of the Alliance for Taxpayer Access (ATA),

a broader umbrella group that includes numerous patient advocacy, consumer, and public interest organizations as well as many colleges and universities. ATA, organized around a shared commitment to public access to the results of publicly funded research, served a crucial role in developing and implementing a robust campaign to educate stakeholders, policymakers, and the public on the importance of public access to research results.

In addition to coordinating visits to key offices on Capitol Hill and writing joint letters to Congress on specific issues related to the proposed policy, OAWG and ATA organized numerous grassroots communications to Congress, both underscoring the benefits of public access and responding to questions and concerns that surfaced as the legislative process developed. These communications, including those channeled through ACRL's advocacy network, were of critical importance in moving the policy forward.

A notable example involved the initial full Senate consideration of the FY08 appropriations bill last October. Sen. James Inhofe (R-OK), at the urging of public access opponents, planned to offer amendments that would have critically weakened the public access provision or deleted it entirely, but was forced to withdraw them when he failed to muster enough votes in his favor. Congressional supporters of the NIH policy praised the effectiveness of ATA's grassroots communication in quickly and effectively providing information on what was at stake in a manner that neutralized the proposed amendments.

Opposition to public access

The NIH public access provision faced intense and ongoing opposition from segments of the publishing industry, which heavily lobbied Congressional offices as well as numerous executive agencies, including the White House, the Office of Management and Budget, the Department of Health and Human Services, the Commerce Department, and the U.S. Patent and Trademark Office.

As first reported by *Nature* in January 2007, the publishing lobby hired a controversial, high-profile public relations firm to create a messaging campaign that attempted to discredit the concept of public access to taxpayer-funded research. The American Association of Publishers (AAP) also established an equally controversial Web site—the Partnership for Research Integrity in Science and Medicine (PRISM)—designed to educate policy makers and the American people about the risks posed by government intervention in scholarly publishing. Both efforts were notable for their use of similarly themed, misleading allegations about the public access policy, including violations of copyright and international intellectual property agreements, increased opportunity for government censorship, and threats to both the system of peer review and to science itself. Reactions to these tactics were quite negative in many segments of the stakeholder communities, with two members of the executive committee responsible for creating the PRISM site resigning in protest, and several publishing organizations publicly distancing themselves from the AAP-led effort.

The fact that the NIH mandate ultimately cleared numerous House and Senate votes and was eventually signed into law is a testament both to the power of the arguments in favor of public access to government-funded research and also the effectiveness of the broad coalition working to support its passage. Proponents of the measure consistently conveyed key positive messages about both the scientific and societal benefits of public access.

What's next?

The NIH provision effectively became law immediately upon the signing of the consolidated appropriations bill, and NIH is now authorized to begin developing a plan to implement a new public access policy that fulfills the law's requirements. It is expected that the agency will create and make public an implementation plan within the first six months of 2008. Because the voluntary policy

has existed since May 2005, a robust system for submission, verification, and posting of author manuscripts to PubMed Central is already in place. However, because the volume of submissions has been so low, NIH will need to ensure that it can ramp up to meet the coming large increase in volume of submissions.

NIH grant recipients will probably need to ensure that any subsequent agreements they make with publishers allow them to retain the right to make their work publicly accessible via PubMed Central. The length of the embargo period (up to 12 months) for specific articles will depend on individual publishing agreements. Libraries at institutions that have NIH-funded research will need to work closely with their offices of sponsored research to ensure that their institutions are well-positioned to implement the policy and contribute to its success.

Given the opposition to the policy, it seems likely that publishing groups will continue their efforts to weaken or invalidate the NIH mandate. Continued resistance was indicated by Alan R. Adler, AAP vice president for legal and governmental affairs, who was quoted in a December 2006 *Washington Post* article as saying, "The issue isn't finished yet."³ It is possible that publishers will mount a legal challenge, along with a continued legislative campaign, to challenge the new policy.

Implications

The NIH public access mandate is the largest such policy—both in terms of the size of the research budget it covers and the number of articles that result from funded projects⁴—to be implemented by any government agency in the world. As such, it is likely to have important implications both in the United States and abroad. A number of government agencies in foreign countries (six of the seven Research Councils in the United Kingdom, the Canadian Institutes of Health Research, etc.) have now established public access mandates for their funded research. Private funding agencies, including the Wellcome

Trust in Britain and the Howard Hughes Medical Institute in the United States, have also implemented similar requirements.

The NIH mandate should provide a strong impetus for the implementation of similar policies by other U.S. government agencies, by governments and governmental agencies in other countries, and by additional private research funders. It should also encourage further consideration of the Federal Research Public Access Act (FRPAA), which was introduced into the U.S. Senate in May 2006. The mandate is a critical step in the ongoing effort to establish public access to all funded research worldwide.

Notes

1. The following is the specific language of the new law: The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an

("Embedded librarians" cont. from page 74)

ing project. Students made popcorn, greeted attendees, and handed out programs to the local premier of the award-winning Finnish film *Mother of Mine*.

The wishlist feature of Alibris.com was used to list children's books that were needed by the library system. Upon returning home, students wrote to family and friends, suggesting that they consider donating a book.²

The three days in Hancock County were intense and emotional. Even two years after Katrina, a ride along the shore revealed little more than concrete slabs where family homes had once stood. It is difficult for outsiders to understand how little has been accomplished, or to appreciate the small steps that have been taken, given the obstacles of federal, state, and private insurance bureaucracies. Stratification was evident in Hancock County, as the national fast food chains were the quickest to recover and the local casino was humming while other local industries were not. It was clear, however, that the library system was the center of community growth

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2. Current members of OAWG include the American Association of Law Libraries, American Library Association, Association of Research Libraries, ACRL, Association of Academic Health Sciences Libraries, the Creative Commons, Greater Western Library Alliance, Medical Library Association, Open Society Institute, Public Knowledge, Public Library of Science, Special Libraries Association, and SPARC.

3. Measure would require free access to results of NIH-funded research, *Washington Post*, Friday, December 21, 2007, p. A33.

4. The NIH budget of \$29 billion produces an estimated 80,000 peer-reviewed journal articles annually. *W*

Conclusion

Embedding librarians into the fabric of a two week course on the road was a resounding success. Upon our return, we were local celebrities as the course had been highlighted by the ABC news affiliate in Biloxi, Mississippi, it was featured on the main page of the university Web site, and a follow-up story appeared in print and online versions of the *Winston-Salem Journal*. The Z. Smith Reynolds Library achieved heightened visibility as a critical partner in the academic process. We are already planning the next iteration of the trip!

Notes

1. The course site can be viewed at wiki.zsr.wfu.edu/social_stratification/.

2. The wishlist may be viewed at tinyurl.com/2lt5yx. *W*