

Institutions Are Scrambling to Comply With Looming NIH Publications Policy

The simplest and most efficient way to comply with the National Institutes of Health's new policy on mandatory submission of articles to PubMed Central is to give faculty members the tools to negotiate directly with journal editors, a panel of experts agreed.

But once everyone gets over the initial hump of complying with the policy — the "NIH Public Access Policy" — that goes into effect April 7, universities and others should consider institution wide policies, or even employment agreements with federally funded investigators, that codify the obligations and responsibilities connected to the new policy.

That is the consensus of some research compliance officials and a scholarly librarian who have developed strategies for their institutions. They recently participated in a webcast on this issue sponsored by the Association of Research Libraries and the National Association of State and Land Grant Universities. Their statements were also echoed by brief comments that universities have posted on an NIH Web site describing their efforts to implement the policy (see http://publicaccess.nih.gov/comments/comments_web_listing.htm).

ARL supported the policy, which the NIH announced Jan. 11, and has developed resources to help authors and universities comply with the law, which seems straightforward but actually has a number of complicated aspects to it.

Tony Waldrop, vice chancellor for research and economic development at the University of North Carolina at Chapel Hill, has been intimately involved in planning and executing UNC's compliance efforts. He admitted during the webcast that the policy had caught him by surprise.

"We weren't aware of the magnitude of this requirement until recently," Waldrop said.

"In its simplest terms, the policy requires authors of journal articles based on NIH funding to deposit copies of their manuscripts in the PubMed Central depository as soon as they are accepted for publication. Those manuscripts must be made publicly available within 12 months of publication of the articles," explained Karla Hahn, director of ARL's Office of Scholarly Communications, and the moderator of the March 7 webcast.

A New Oversight Area

She noted that there are two main parts to compliance: ensuring that authors retain the right to make or allow a deposit when they negotiate publication copyrights with publishers, and secondly, the actual process of the deposit itself.

A third element comes into play in May. Beginning May 25, anyone submitting an application, proposal, or progress report "or similar documents" to the NIH must include the PubMed Central reference number when citing articles arising from their NIH-funded research. This includes applications submitted to the NIH for the May 25 and subsequent due dates.

But perhaps the first problem to be addressed is that most institutions have not previously been aware of the manuscripts that their faculty have submitted for publication, admitted Jim Siedow, vice provost for research at Duke University, who also participated in the webcast. That will have to change, he said.

"We learn a lot of things from investigators when they submit proposals, when they write reports for renewals and things like that, but actually, historically, we haven't really asked them to tell us what their publications were," Siedow said. "So in trying to ensure compliance, we are entering into an entirely new arena because we just don't know in any formal way what people have published or even submitted for publication. Trying to sort of get a handle on that is really totally new ground for us."

"[T]his is going to require a great deal of education and a great deal of attention to an issue that we have by and large ignored for a long period of time," added Kevin Smith, Duke's scholarly communications officer who has been working with Siedow on this issue and who also participated in the webcast. "Copyright management is something that has frankly been ignored at many of our institutions for too long. Frequently authors are giving away their copyright, which is really a major asset in higher education."

Both Duke and UNC are sending letters to all NIH-funded faculty researchers to let them know about the publications policy, which had formerly been voluntary. While no officials yet know what sort of volume of papers they might be dealing with, the NIH itself said it estimates that about 80,000 papers are annually published that are based on research it funds. The policy affects any paper that is written based on research that had any NIH funding, even if it was just partial funding.

Smith said ensuring that "authors and grantee institutions are able to give the necessary permissions to PubMed Central to make an article publicly available is the most complex problem because it involves the institution, the authors, and the publisher."

"The authors must be very careful that they do not sign agreements that are inconsistent with their obligations, and institutions will need to educate and assist authors in this regard, in order to ensure compliance and to avoid potential problems with future funding," Smith said.

Publishers May Deposit Articles

The easiest way to ensure deposit of an article is to work with a publisher that does this automatically. The NIH has been compiling a list of such publications. "Our understanding is that that list is growing," Smith said. "NIH is also being contacted a great deal from publishers who want to add themselves to that list and make deposit easier. But it is best to ask when in doubt to be sure that the journal that the author wants to publish in is one that will do deposit for them."

The author must determine which version the publisher intends to publish, he warned. The policy calls for "accepted" articles to be published, and some articles may change by the time they are actually published. Even if the journal deposits the article, the author may have to verify with the NIH that the final form of the article as it is marked up for PubMed Central inclusion is correct. If the author's final version is being deposited, the author will have to verify the correctness of the manuscript.

"If the journal is depositing the final published version, the author will not have to do that step. But this is a point in this option where there is some compliance risk," Smith said, if it is not the final version. "There is apparently a significant percentage of authors who fail to take this step. And institutions will need to verify that this last step of confirming the final version of the article gets done."

Give Authors Tools to Comply

If an author wishes to submit a manuscript to a publication that does not offer to deposit the article in PubMed, an institution could decide that it is the researcher's responsibility to ensure that this gets done. Working with faculty to manage the copyright and PubMed deposit themselves "is probably the most common option that people will choose," Smith said.

One way to assist authors is to provide them with a form letter that can be sent, along with the manuscript, to every publisher they submit their manuscript to, so the publisher is immediately aware that the paper must be sent to PubMed.

"This is an opportunity to ask the publisher to comply on the author's behalf, to submit the article themselves, or it is an opportunity to suggest to publishers the appropriate language that should be included in any publication contract that will allow sufficient retention of rights to comply with the mandate," Smith said.

In addition, some universities are giving their researchers sample language that can be added to any publisher's contract stating that the author retains the right to submit the paper to PubMed.

The NIH also produced a paragraph that can be inserted in contracts with publishers. It states: "The journal acknowledges that the author retains the right to provide a copy of the final manuscript to NIH upon acceptance by the journal for publication, for public archiving in PubMed Central as soon as possible but no later than 12 months after publication by the journal."

Using both a submission letter and the sample language is what Smith termed the "belt-and-suspenders" approach to compliance. He said using both items would be a better hedge against the possibility that a paper that should be in PubMed will not be.

Smith said UNC and Duke were pursuing this option, mostly because "it is the one that we can get in place quickly enough."

Faculty Agreements Can Be Useful

Another option shifts the burden to the research institution or university, Smith said. "The grantee institution could take a limited license for deposit from its investigators before any articles are written. That is, it could be part of the agreement between an institution and its researchers that the institution automatically obtains a nonexclusive license sufficient to allow them to oversee deposit in PubMed Central for anything that an author writes in connection with grant-funded research," Smith said.

Reaching such an agreement with faculty may not be easy, and "there is also a risk with this option that authors would sign contradictory publication agreements," he added. "They could forget to inform the publisher that all contracts that they sign will have to be subject to this prior license held by the grantee institution."

But it does have advantages. For example, it is also possible for the license to be structured so that it is flexible enough for the institution to comply with other funder mandates that may occur in the near future, and it could also be written to give the university the right to deposit a manuscript in its own research documents repository, which increasing numbers of universities are creating, Smith said.

"By following this option, institutions could be prepared for those mandates before they arrive and perhaps not have to scramble the way most of us have had to scramble with the NIH mandate," he said. Smith noted that Howard Hughes Medical Center already requires public access to papers based on the research it funds, and it is not inconceivable that other government agencies beyond the NIH would start to do the same.

Both Waldrop and Siedow said this strategy makes good sense in the long run, but they said it will likely have to wait until each institution has more experience complying with the policy.

Ensuring Compliance No Easy Task

Waldrop added that UNC has created a couple of checks and balances within its existing electronics system to remind investigators about the publications policy. A drop-down menu in an electronic submission form asks researchers to certify that they are aware of and have complied with a variety of requirements, such as compliance with animal care standards and human subject protections. The publications policy has been added to that form.

"In addition, when we receive notification of funding for a grant that has been favorably reviewed, the first step is to set up an account," Waldrop said. "When that's done, we inform the investigator that that account has been set up. When that notice goes out, we will also remind them again of this requirement and ask that they comply with it."

Duke uses a similar form. "We will add this NIH mandate to the ever-growing list of compliance issues that are on that form and which faculty need to worry about," Siedow said.

But Waldrop noted that getting the word out is crucial.

"In the end, I think the biggest thing that we are doing to ensure compliance is communication and training," he said. "We are communicating it widely on our campus."