

‘The law is the true embodiment of everything that’s excellent’: mandates – a view from the United States

Based on a presentation given at the UKSG seminar ‘Mandating and the scholarly journal article: attracting interest on deposits?’, London, 29 October 2008

Effective as of 7 April 2008, scientific articles accepted for publication or published that draw upon work done with the financial support of the National Institutes of Health (NIH) in the United States are subject to a sweeping new mandate – the first of its kind – that alters the circumstances under which they are published and read. This paper will review the mandate and the way American institutions are responding to it, after which we will consider mandates on the US scene and their downstream implications.



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*The Law is the true embodiment
Of everything that’s excellent.
It has no kind of fault or flaw,
And I, my Lords, embody the Law.*

*The constitutional guardian I
Of clever young science folks am I,
All very agreeable blokes — and none
Are over the age of ninety-one.
A tedious occupation for
A rather illiterate Chancellor!**

Effective as of 7 April 2008, scientific articles accepted for publication or published that draw upon work done with the financial support of the National Institutes of Health (NIH) in the United States are subject to a sweeping new mandate – the first of its kind – that alters the circumstances under which they are published and read. This paper will review the mandate and the way American institutions are responding to it, after which we will consider mandates on the US scene and their downstream implications.

Let us begin by quoting the mandate itself, which the NIH calls a ‘public access policy.’ What does it actually say?

* The original text of this song seems to depart slightly from the one I give here!

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 electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.

This mandate is effective for articles accepted on or after 7 April 2008, arising from grants and agreements active on or after 1 October 2007. As of 25 May 2008, articles published from new grants must cite the NIH number with the mandated deposit in PubMed Central (PMC). When such a mandate comes from the largest funder of biomedical research worldwide, then scientists and others are bound to pay close attention to the impact on the scientific information food chain that results. The NIH moved to the full mandate after seeing an earlier ‘mandated voluntary deposit’ – that is, offering strong encouragement to grantees to place their resultant articles on deposit with PMC – fail more or less utterly. A 4% submission rate was frustrating to many and led to the decision to move from volunteerism to requirement.

How much funding does the NIH provide to US biomedical research? How does this compare with other large funders? In the UK, the Wellcome Trust has a \$30 billion dollar endowment, and according to its website, it intends to ramp up to \$6–7 billion in grants to biomedical researchers over the next five years. The Howard Hughes Medical Institute has an endowment approaching \$20 billion, and it grants \$700 million a year for research. Between them, they support about 3,000 research institutions annually. By contrast, the NIH has an annual budget of \$30 billion, of which 83% is spent on approximately 50,000 grants a year and approximately 325,000 researchers. (Internally, NIH supports another 6,000 scientists with about 10% of its overall budget.)

At my institution, Yale, that means we received \$372.6 million of NIH funding in the 2008 fiscal year, supporting 600 individual researchers; whereas Howard Hughes funds 16 of our investigators and 14 training fellows. Nothing comes close to NIH for impact.

After a decade of heroic growth in its ability to support research, the NIH budget has now been basically flat for several years – and thus in real terms effectively declining (see Table 1). With an onrushing global economic flash flood and federal deficits reaching historic highs, it's unlikely that funding will grow appreciably and could well decline further.

The relevance of the funding downturn to the hopes and fears of scientists is considerable, but in this context it has another implication. Time and effort at NIH spent on investing in publication

methods is time and effort not spent on funding science. Is the cost of the new initiative truly marginal? Opinions vary, obviously.

Fundamentally, the mandate is an arrangement between authors of articles and the NIH that funds them. There are no other players directly involved, though the impact on publishers could be significant and many players are watching practices and implications with interest. To support authors in complying, the NIH provides numerous training resources, help slides on the PMC submission site, and FAQs. There was an extended public comment period before the mandate was implemented (including online submissions and a large public session held at NIH on 20 March 2008). There are no decisive statistics about the results of the mandate, but early tabulations suggest that compliance has increased dramatically in a short time.

Is this NIH mandate the same as an open access requirement? In this case, not exactly, for the 12-month delay in submission that the mandate allows still gives publication in a subscription-based journal a chance to recoup expenses and publishers of those journals an opportunity to take advantage of the exclusivity thus conferred. (By contrast, the similar mandates from Howard Hughes and Wellcome give grants or allow the author to pay a fee in various cases to obtain immediate release of the article for a general audience.)

In discussions since the mandate was enacted, of course various issues have emerged.

First, what are the impacts of this requirement on copyright ownership and on the contractual terms between authors and publishers? Standard publishing contracts need now to add a clause along the lines of: 'The ____ journal acknowledges that the author retains the right to provide a copy ... [for mandatory deposit].'

Second, just what is the required 'final manuscript'? Is it the final manuscript as submitted, the final manuscript as accepted post-peer review including all the modifications of that process, or is it the 'final published article', that is, the journal's authoritative copy including all modifications from peer review, copy-editing, stylistic edits, formatting changes? There is no authoritative guidance on this point yet.

Third, what will be the effect on players in the information chain? Much debate in the community has focused on the effect this new requirement will have on publishers, libraries and researchers.

Year	Funding (billions USD)	Per centage growth year-to-year
1994	\$10.9	
1995	\$11.2	2.7%
1996	\$11.9	6.25%
1997	\$12.7	6.7%
1998	\$13.6	7.0%
1999	\$15.6	14.7%
2000	\$17.8	14.1%
2001	\$20.4	14.6%
2002	\$23.2	13.7%
2003	\$27.0	16.3%
2004	\$27.8	3.0%
2005	\$28.4	2.1%
2006	\$28.4	0.0%
2007	\$29.0	2.1%

Table 1. NIH funding, 1994–2007

Researchers, for example, should benefit from a single source for their searches. When PMC is flooded with effectively all the NIH-sponsored research in biomedical fields, the tools provided on that site should be very powerful indeed (subject to the proviso that the most recent material may be unavailable for up to 12 months).

Librarians, of course, will watch carefully, the better to think about whether and when to cancel journal subscriptions where enough of the articles those journals contain are free. How institutional customers will react is far from clear, and the consequent impact on the journal publishing industry, the price of journals, and the total costs to libraries will be watched with very close interest. Testimony provided by the Association of Research Libraries (ARL) in March 2008 said that libraries would not cancel subscriptions even if the NIH embargo were as little as six months, though acknowledged that much would depend on just how central a given title is to ongoing research. The most marginal journals, in other words, will be at the greatest risk of loss of revenues. It is hard to know how at this time ARL could speak with confidence on a point that will be very vulnerable to the many pressures on library budgets today. In fact, early studies seem to suggest that as various open access repositories come into play, the length of their OA embargoes are closely correlated to the number of cancellations. The Proceedings of the National Academy of Science (PNAS) apparently found that a two-month embargo generated significant cancellations, while Oxford University Press's research showed that six-month release was correlated with more cancellations than 12-month release.

And, finally, what will publishers do in this new environment if/when they find fewer eyeballs coming to their sites? Some are already depositing articles with PMC and providing open access to their content, while some are doing so for authors (who like the seamlessness) after the embargo period; some publishers are providing author services for free, and others are charging authors a fee. Yet others are reportedly trying to negotiate special arrangements with the NIH. At the other extreme are those who resist the mandate and are supporting a bill in Congress to create the 'Fair Copyright in Research Works Act' (HR6845, submitted 09/11/08), being advanced by John Conyers, Chair of the Judiciary Committee of the House of Representatives. This bill seems to have languished but may be reintroduced in 2009.

HR6845 questions the fundamental need for the mandate. The public, on this argument, can already obtain copies of research articles in numerous ways (via libraries, for example), and so the mandate is unnecessary and unfair. The proposed act would bar any federal agency from requiring 'transfer or license' to the US government of a paper that has been produced in part with non-government funds. (That effectively means every paper produced outside government laboratories, for in the economics of research, the contribution of the host institution, whether commercial or academic, to the costs of doing research is historically high.) To make such a requirement, the bill argues, constitutes an infringement or at least a dilution of copyright.

Passions run high in the debate over the economic future of STM publishing. Sixteen law processors and 33 Nobel laureates have defended the NIH policy in congressional hearings, while it is supported by the American Association of University Presses and the Association of American Publishers. The American Congress has been unaccountably distracted from the business of science publishing by other concerns this fall, but it may yet return to this bill.

One area of particular importance is what universities term 'compliance concerns'. In a highly-regulated society like the US and a sector like higher education, the mechanisms for monitoring and enforcing compliance to a mandate like this are as interesting and as important as the mandate itself. What will this mandate require?

At Yale, the committee working on mandate compliance articulated various concerns. For example, it is difficult (or impossible) for institutions to ensure full compliance, given that the mandate falls directly on authors, even though the institution's ability to win future grants may be at risk if its authors are relatively non-compliant. Furthermore, many articles are jointly authored across institutions, and when the reporting of results depends on colleagues elsewhere (or may even occur after the research award is completed or the authors – particularly postdoctoral fellows – have left the institution), normal grant-monitoring procedures are inadequate. Where sub-awardees have benefited from grant funding, it is even less clear where lines of responsibility run. What we currently have is a policy governing contractual relationships to which institutions as such are not parties, but which can significantly affect

institutional standing and opportunities. Institutions thus find themselves in the middle with investigators who are making decisions about where and how to publish – a position we have happily stayed out of in the past.

Our committee has recommended that NIH should create a safe harbor for institutions that have met the conditions of formulating and enforcing clear policies, of supplying adequate technical support and assistance, and of requiring faculty to certify that they have complied. These steps would represent ‘good faith’ compliance at the maximum level possible from the institution. We have also urged that the consequences of failure to comply be made much clearer than has been the case heretofore. Requirements for monitoring and reporting must be as efficient and streamlined as possible. (And one footnote: NIH should clarify

the idea of the ‘end date’, for as the mandate now stands, awards could be placed in non-compliance years after the award itself has closed, an untenable situation for all concerned.)

At a more strategic level, Yale’s committee has urged that a study be mounted by a reputable third party (e.g. the National Academy of Sciences) to review the impacts of this mandate on scholarly publishing, on incremental costs incurred, and on the effective dissemination of scientific information. We have also urged the NIH to deal directly with publishers in devising the most efficient system of scientific publishing possible.

As part of the preparation for this paper, I queried my peers in the 40 largest US academic research libraries about how they have responded to the mandate, and their replies are summarized in the charts shown here (see Table 2).

Question 1: How were researchers and faculty informed, and by whom?
Iowa: Library notified deans, library liaisons reached out to faculty, and Division of Sponsored Programs referred faculty to the Library.
Berkeley: UC Office of President, supported by senior library planning staff & campus library scholarly communication officers, instructed all 10-campus research administration officers
Michigan: Division of Research Development & Administration (DRDA) and Library notified faculty.
Columbia: Notification came from the EVP for Research.
Minnesota: University Libraries and Sponsored Projects Administration (Office of the Vice President for Research), coordinated this. UL notified departmental newsletters, news feeds, etc.; SPA sent directed emails to PIs.
Cornell: Library and Office of Sponsored Programs notified all researchers with NIH grants in joint letter.
NCSU: Notification from research office, with support from research office and library offered.
Duke: Vice-Provost for Research worked with Vice-Dean at the Medical Center. Multiple workshops (led by Medical Center Librarian) were held and visits to departmental faculty meetings by Scholarly Communications Officer.
Princeton: Notice from the Director of Office of Research and Project Administration (ORPA) to researchers.
Hopkins: No concerted University-level notification.
Yale: VP for Research & Grants/Contracts Office contacted every PI by letter. Memo by Medical library staff was approved by Medical Dean and sent to all medical campus faculty. [YALE STEPS]
Question 2: Did your institution create supporting resources or tools?
Iowa: Library created webpage and offered classes in library and departments and 1-on-1 briefings on request. Webpage one of the most heavily used in the library system.
Berkeley: UCB Library staff met with staff in the Research and created a Web resource. Bibliographers shared with faculty as appropriate.
Michigan: Library created guide and batch upload utility. Library and DRDA provide info sheets, presentations, and ongoing outreach.
Columbia: Library and Office of Research Compliance and Training produced posters, websites, training sessions, and briefings.
Minnesota: Created web site and email address for questions.
Cornell: Library created a website and listserv for questions.
NCSU: Created webpage and a custom guide sent out with e-mail from Research Office.
Duke: Created a web site including letter to be sent with all submissions of articles arising from funded research and an addendum for publication contracts (which uses the NIH suggested language).
Princeton: A suggested addendum to publisher agreements from research office was made available online.
Hopkins: Libraries’ Scholarly Communication Group (members from Main and Medical libraries) added information to Library Web site.
Yale: Library created a LibGuides page with Information about the law, compliance, and general PMC issues: has been viewed 1024 times since creation in May 2008.

Table 2. Responses of some of the largest US academic research libraries to the mandate

(continued over ...)

Question 3: Did you point to another institution's resources?
Iowa: Pointed only to NIH's information on the mandate.
Berkeley: Yes, we point to several UC system and external resources.
Michigan: Just the NIH Public Access Policy website – otherwise in-house materials.
Columbia: No, but the NIH's site was widely publicized.
Minnesota: Referred to NIH and NIHMS FAQs in our Web site, but did not direct users to another institution's site.
Cornell: No, but we looked at a lot of them.
NCSU: No.
Duke: We point only to the NIH site, but have approved requests from other institutions to point to or reproduce materials from our website.
Princeton: Notice to researchers linked to the scholar's copyright addendum.
Hopkins: Pointed to NIH help and submission pages, as well as to other institutions (usually libraries)
Yale: No.
Question 4: Who's responsible for day to day help and support for researchers' needs? How much of this is done in the library and how much do you think is done within labs and departments?
Iowa: The Division of Sponsored Programs directs people to the Library for help with the mandate requirements. The library has received inquiries and taught several classes, but the demand is not overwhelming.
Berkeley: A varying mix of grad students and librarians provide support. Grant recipients in the sciences are more advantaged than the remaining faculty.
Michigan: Voluntary support from Library.
Columbia: Responsibility was shared.
Minnesota: Library has offered assistance, departments are supporting on their own. Low level of activity.
Cornell: Mostly done by administrative assistants to the researchers. Held a workshop for administrative assistants and got a very positive response.
NCSU: The Library handles most of the compliance support and advice.
Duke: Primary source for assistance is the Medical Library, and some University-side reference staff trained to assist. As compliance issues clarify, the task of helping new researchers will be assumed within labs and departments.
Princeton: No central support.
Hopkins: A few practical questions to librarians; otherwise support in departments.
Yale: Library staff have given formal one hour sessions to interested departments. Library liaisons have offered assistance and in-library classes are now being offered.
Question 5: Who's responsible for monitoring your university's participation overall, for compliance and process?
Iowa: Division of Sponsored Programs.
Berkeley: Office of Research.
Michigan: Unknown, though presumably DRDA or the Office of the Vice President for Research will ultimately be responsible.
Columbia: Office of Sponsored Research has primary role; Office of Research Compliance and Training also has a role.
Minnesota: Sponsored Projects will monitor new applications and progress reports to ensure that citations are including PMCIDs when necessary, but there appears to be no way for us to monitor submissions to NIHMS. This is a serious concern
Cornell: VPR and OSP decided that it is the PIs responsibility once they have been notified by the OSP Form they receive when they get a grant. Otherwise not monitored
NCSU: The Research Office.
Duke: Research & assessment staff in the Medical Center Library will try to track compliance; this builds on quarterly research into publication patterns that is already being done.
Princeton: Don't know.
Hopkins: No institutional monitoring. Deans Council approved an author's addendum that Hopkins authors could use.
Yale: Grants & Contracts office; Office of VP for Research Administration; researchers (obviously)
Question 6: Do you know how much time this type of support requires at your University and Library?
Iowa: Very little: anxiety management for first-time submissions and after that essentially none.
Berkeley: Not available.
Michigan: Not overall, no.
Columbia: The Health Sciences Library and the Copyright Advisory Office spent considerable time on this in the early months, e.g. 10 hours per week for the CAO. We now receive few questions
Minnesota: After initial flurry of queries, time commitments approach zero.

Table 2. Continued

Cornell: After the initial flurry it's been quite small- things seem to be going rather smoothly at the moment.
NCSU: After the initial push, we invest a few hours a week total in the Digital Scholarship office. Expect a push some time in the late winter as we do a compliance assessment and conduct outreach to non-compliant researchers.
Duke: Initially a substantial investment of time. Since spring the time involved has diminished, but the research necessary to track compliance will be an added commitment.
Princeton: Not known.
Hopkins: Scholarly Communication Group has spent time updating/adding to Web site. Short presentations made to two medical departments. Fewer library questions than anticipated.
Yale:
Question 7: Have any policy or procedural concerns been expressed at your University about the NIH mandate, that you are aware of?
Iowa: Faculty anxiety at first compliance; nothing on policy.
Berkeley: None thus far. Will meet with the Research Office again in the coming 2 months to see how the strategy above worked.
Michigan: Concerns come up as we work with faculty: One prof. was disturbed to learn that few of her publications could be quickly deposited into PMC because she'd signed away her rights. Others express concern about how to pay for compliance.
Columbia: Because occasional questions arise we know that the news has not reached everyone. We also hear some misinformation that needs correcting.
Minnesota: The institution's role in compliance has been a major concern. Since article records do not appear in PMC until after individual embargoes have expired, we cannot even monitor submission rates and that not until at least April 2009. We simply cannot tell to what extent our faculty are complying with the mandate.
Cornell: The biggest policy concern s the fact that the article posted in PMC is not the publishers authoritative version of the article in most cases.
NCSU: Some scholars want explanation why NIH adds additional layer of work and compliance activity. We acknowledge their legitimate concern and then explain the reasons for the policy.
Duke: The principal concern: final PMC versions should be sent to BOTH the PI listed on the grant AND the lead author. We have asked if an e-mail can be sent by NIH to someone in compliance at Duke when a final PMC version of an article is not approved within a reasonable period of time.
Princeton: The university's Faculty Committee on the Library and Computing has taken open access issues (esp. re NIH) as its main agenda topic for its Fall meeting.
Hopkins: Nothing at an organized level: some grumbling from faculty.
Yale: Numerous technical compliance issues: researchers give incomplete grant numbers to admin staff submitting on their behalf; other confusions about the mail that comes from NIH.

Table 2. Continued

There are, it may be helpful to add, a handful of other mandates for open access or quasi-open access publishing at work in the US today, though the numbers lag behind Europe and other nations. These include:

- The Howard Hughes Medical Institute requires open access after a six months' embargo
- The Harvard University Faculty of Arts and Sciences passed a mandate for its faculty in February 2008, an initiative that remains to be operationalized. The institutional repository in which work would be deposited is under construction, and many have noted that Harvard leaves an 'opt out' clause for its faculty with no requirement of stating a reason why faculty would not want to make their work so available. To monitor and supervise this process, a faculty member has been seconded to the project on a half-time basis

- The Harvard Law School faculty has followed the example of the Arts and Sciences faculty, leaving the 'opt out' option in place
- Stanford University's School of Education has made a similar demand on its faculty.

It has been a pleasure reviewing this material for you in this paper. The presenter will now be represented by Barrister Rumpole in addressing any concerns you may still have on the subject.

References

1. The original text of this song:
The Law is the true embodiment
Of everything that's excellent.
It has no kind of fault or flaw,
And I, my Lords, embody the Law.

The constitutional guardian I
Of pretty young wards in Chancery,
All very agreeable girls – and none
Are over the age of twenty-one.
A pleasant occupation for
A rather susceptible Chancellor!

Iolanthe, Gillbert and Sullivan

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