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National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Elsevier is grateful for the opportunity to respond to the National Institutes of Health (NIH) public access policy Request for Information (RFI).

Elsevier is a major Science, Technical and Medical (STM) publisher and has been for well over a century. Our objective is to continue to develop the growth, quality and efficiency of peer review publication and enhance access to published research materials. Elsevier has an unqualified commitment to encouraging wide access to authoritative, peer-reviewed scientific, technical and medical research and continually testing new approaches to access and dissemination of research to meet the evolving needs of the diverse communities we serve.

In this submission:

1. We highlight our efforts to work cooperatively with the NIH.
2. We discuss the leadership of publishers in transforming scientific and medical communication.
3. We detail our concerns with NIH's implementation of the law:
 - A. The NIH's implementation undermines basic principles embodied in copyright and therefore contradicts direction by Congress that "the NIH shall implement the public access policy in a manner consistent with copyright law."
 - B. The NIH's implementation has resulted in practical problems that are burdensome to authors as well as publishers.
4. We respond to the NIH's request for:
 - A. Recommendations for alternative implementation approaches.
 - B. Recommendations for monitoring and ensuring compliance.
 - C. Recommendations on information, training or communications of the Policy.

1. Elsevier's efforts to work cooperatively with the NIH

The NIH voluntary policy, issued in May 2005, stated:

NIH-funded investigators are requested to submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported, in whole or in part, with direct costs from NIH.

Since the voluntary policy was issued, Elsevier has sought to work collaboratively with the NIH in implementation of this policy. Elsevier has proactively identified authors who report NIH-funded research during the manuscript acceptance workflow, deposited accepted author manuscripts to PubMed Central (PMC) and actively monitored policy compliance.

In 2007 Elsevier deposited an average of over 1,000 accepted author manuscripts per month to PubMed Central. Our analysis shows this is over 90% of articles we publish that report NIH-funded research, and approximately one quarter of all articles published by authors reporting NIH research.

2. Publishers' leadership in transforming scientific and medical communication.

During the NIH public meeting on March 20, 2008, Dr. Elias Zerhouni stated that the NIH Policy was necessary to “[apply] 21st century technology to the NIH investment to promote science, health and commerce in the context of a globally wired and networked world of scientific information.”

Elsevier is proud of its technological investments to advance scholarly communications. We find it puzzling that Dr. Zerhouni suggested that the private sector is not applying the latest technology to promote science and health research. Elsevier, like other STM publishers, has a track-record of pioneering advancements in publishing and helping advance scientific discovery:

- Elsevier alone spends several hundred million dollars every year operating and advancing the peer review publishing process. We use the latest technologies to improve peer review (e.g. developing referee tools and anti-plagiarism software), accelerate online production (e.g. developing online author tools to process manuscripts and perform manuscript XML tagging) and enhance our online publishing platforms, such as Elsevier's ScienceDirect.
- As a result of publisher investment, researchers can now perform complex searches of journals, immediately retrieve full text articles, link instantly to cited articles, export text and data to other databases and programs, receive RSS alerts on new articles, and interact with published content in fundamentally new ways compared with even a decade ago.
- Investment in new technologies has dramatically increased researcher productivity. Researchers read more articles from more journals than ever before, and science is the only information sector where researchers have been able to spend a greater proportion of their time analyzing information compared to gathering information, than they were in 2000.
- Investment in online technologies has also dramatically improved access to published research. We estimate that over 90% of scientific and medical researchers globally have access to the STM journals that they need, many through electronic distribution platforms such as ScienceDirect which has approximately 13-14 million individual users each year. Over 75% of researchers globally indicate that access to scientific journals has become easier, with a substantial majority indicating that they have “good to excellent” access.
- Against a backdrop of continuing technological change, publishers have ensured the scientific record is maintained and preserved. For example, on Elsevier's ScienceDirect, we host 9 million articles that appear in over 2,000 trusted, specialized, peer-reviewed journals, with articles dating back to 1823. We continue to add nearly 300,000 new articles each year as well as update articles with the latest technological advancements to better enable researchers to review and interpret published research.

3A. Our concerns with NIH's implementation of the law: The NIH's implementation undermines basic principles embodied in copyright and therefore contradicts direction by Congress that “the NIH shall implement the public access policy in a manner consistent with copyright law.”

The Consolidated Appropriations Act, 2008, containing the following language, clearly intends that the NIH should support the principle of copyright:

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.

The NIH's current implementation of the public access policy deviates sharply from the principles embodied in copyright. Implementing the public access policy in a manner not consistent with copyright law contradicts the direction by Congress and could have serious unintended and undesirable consequences on scientific communication for the following reasons:

1. Copyright provides the copyright holder the right to authorize and define the terms of use and reuse. In contrast the NIH is appropriating published content without publisher authorization, and is reusing copyrighted content, combined with publisher trademarks, with a "one size fits all" implementation.
2. Copyright provides protection against the creation of derivative works without copyright holders' consent. In contrast, the NIH has proceeded to create derivative works of manuscripts. For example, we note that the NIH has advised NIH employees that "PubMed Central may tag or modify the work consistent with its customary practices." Of concern, tagging and modifying published content without the consent of the copyright holder is not consistent with copyright law.
3. Copyright provides certain exclusive rights, that upon transfer of copyright, allow publishers to recoup their investment. The NIH's implementation of the policy undermines these rights, thereby limiting the spectrum of business models available to publishers. By offering a "free" version of publishers' content, the NIH is thereby directly competing with established subscription publishers, and implicitly favoring an author-pays business model. Revenue sources for subscription publishers including subscriptions, transactional sales, commercial redistribution rights, and online advertising or classified display could be compromised, threatening a publisher's ability to recoup costs or make new investments.
4. Specific exclusive rights granted to the copyright holder limit piracy and the exploitation of content by third parties without a publisher's consent. It is unclear that the NIH has taken any substantive steps to limit piracy of copyrighted content that appears on PMC.
5. A benefit of copyright is that upon its transfer to publishers authors are relieved of many of the burdens of the publication process. However, the NIH's implementation of the public access policy has created a dual publishing process that creates additional burdens on researchers, for example, by requiring authors once again to proof-read and correct manuscripts submitted to PMC when they have already proof-read and corrected manuscripts via the peer-review publishing process. At best, this wastes researchers' time, at worst, it confuses and frustrates them.

A legal opinion submitted by the American Association of Publishers also raises serious questions and substantial doubt on the consistency of the policy with U.S. Copyright Law and to the United States' compliance with its obligations under the Berne Convention and the Agreement on Trade Related Aspects of Intellectual Property.

In addition, we note that the NIH's implementation of the public access policy ignores principles of trademark law by using journal names on PubMed Central without publishers' consent, and journal brands may be diluted based on the NIH's implementation of the public access policy. The implementation also departs markedly from the stated objective of the NIH public access policy which is simply to improve on already high levels of access and provide an archive of research that the NIH and awardees could use to manage their research portfolios.

3B. The NIH's implementation of the public access policy has resulted in practical problems that are burdensome to authors as well as publishers.

1. Authors are frequently confused about their freedom to publish with publishers who allow (or in the case of Elsevier, facilitate) compliance with the NIH's Policy. For example, the NIH maintains a list of journals that deposit the XML version of articles, but does not identify journals where manuscripts are deposited to PubMed Central or where authors are allowed to archive their manuscripts. Not surprisingly, authors have been confused about whether they can publish in journals that do not appear on the NIH list, which may discourage authors from submitting to these journals.

2. Thousands of manuscripts appear on PubMed Central in breach of publisher-author agreements. For example, Elsevier has recently requested that nearly 1,500 accepted author manuscripts be removed from PubMed Central as they either appeared on PMC earlier than 12 months after publication or were published prior to the issuance of the NIH Policy. Currently it is publishers, not the NIH, who have to spend time and resources monitoring PMC and requesting take-down of illegally-posted manuscripts.
3. The NIH has chosen to use its own system of article identification (PubMed Central Identifiers) rather than adopt the widely-accepted Digital Object Identifier (DOI) as a means of identifying authoritative material and associating it with the holder of record. This decision to create a separate manuscript identification system could lead to confusion about which document is the definitively published version and creates an additional and unnecessary burden for researchers who have to track two identifiers for their publication.
4. The revised NIH policy has also resulted in further confusion among authors and publishers because:
 - It is unclear whether (or why) review articles are included in the policy, when review articles are often only tangentially related to research awards, if at all. The NIH appears to have changed its policy, dropping review articles from the most recent FAQ (as of May 20, 2008). We note the NIH had previously encouraged publishers to publish review articles to mitigate risks created by the voluntary public access policy.
 - There is little guidance for authors or publishers about when the policy does not apply, for example, when NIH funding of the research is insignificant or significantly supplemented by other public or private sources.
5. The NIH has advised NIH employees that in order to comply with the NIH policy they are required to “not sign any Publisher’s Agreement received from the publisher.” Such direction may prevent authors from submitting to journals that actually enable authors to comply with NIH’s policy. For example, Elsevier’s publishing agreement provides safeguards to Elsevier regarding the originality of research and authorship. It is unclear why the NIH would not allow authors to make prudent decisions in signing agreements in representing their work.

4A. The NIH’s request for recommendations for alternative implementation approaches.

Recommendation 1: The NIH should work with publishers to obtain manuscripts (rather than appropriating them) and have them appear on PubMed Central in a manner consistent with principles embodied in copyright.

- The NIH should work with publishers to obtain manuscripts, rather than shifting the burden to authors to deposit manuscripts of copyrighted content to PubMed Central.
- The NIH should recognize that the copyright holder has the right to define reuse, and the NIH’s implementation must be consistent with this principle.

Recommendation 2: The NIH should display content in the format deposited and discontinue creating derivative works of deposited manuscripts without prior and explicit publisher consent. The NIH should discontinue modifying submitted content or allowing further changes to submitted content upon deposit.

Recommendation 3: The NIH should not compete directly with publishers. The Paperwork Reduction Act of 1995, and OMB Circulars A-76 and A-130 urge agencies not to compete with the private sector. The NIH should:

- Always promote the published definitive version hosted by the publisher over any version that appears on PMC and that is not guaranteed by the publisher
- Use the well-established research community standard Digital Object Identifier and discontinue the parallel PubMed Central Identifier
- Provide usage statistics for any manuscript that appears on PMC so that publishers may assess the harm from PMC and adapt accordingly

- Maintain manuscripts solely for preservation purposes and not for display when the definitive version is publicly available on the publisher website.

In addition, the NIH should focus resources on key undeveloped areas that serve the interest of public access, the stated objective of the NIH policy, while not directly competing with societies or the private sector.

Opportunities the NIH should address include:

- Working with voluntary health organizations and publishers to develop meaningful patient literacy information based on published research.
- Building repositories for raw data storage resulting from experimental research.

Recommendation 4: The NIH should actively work to eliminate unnecessary administrative burdens placed on authors as a result of its revised policy. For example, we encourage the NIH to work with Elsevier, to improve the success of our direct manuscript deposit process and relieve the burden on authors to review manuscripts upon deposit.

Recommendation 5: The NIH should ensure that manuscripts that appear on PMC maintain journal branding in a way that is approved by the publishers, and if applicable, should include corresponding disclaimers and notices so that publishers can preserve their brand assets and manage their liability appropriately.

Recommendation 6: The NIH should work with a publishers committee, appointed by trade organizations, to continue to improve the implementation of the public access policy on an ongoing basis.

4B. The NIH’s request for recommendations for monitoring and ensuring compliance.

Recommendation 1: The NIH should work with publishers to ensure that the correct manuscript is posted to PubMed Central to be publicly available at the correct time, consistent with publisher agreements. The NIH should take proactive steps to discontinue posting manuscripts to PubMed Central that do not comply with publisher agreements.

Recommendation 2: NIH’s policy should explicitly not apply to review articles. Compliance with NIH policy should be required only for authors reporting primary research that has been significantly funded by the NIH. It is unreasonable to require authors to make judgements on whether manuscripts should be deposited to PubMed Central when research may only be tangentially related to NIH funding.

4C. The NIH’s request for recommendations on information, training, or communications of the Policy.

Recommendation 1: The NIH should list all journals on its website that deposit or allow authors to deposit manuscripts to PubMed Central. The NIH should not selectively list some publishers that allow authors to comply with its policy while not listing other publishers who also allow authors to comply with the policy.

Conclusion

As a leading STM publisher we wish to work collaboratively with the NIH to demonstrate leadership in the implementation of the NIH public access policy. To date the NIH implementation of the public access policy has not followed the Congressional directive that: “the NIH shall implement the public access policy in a manner consistent with copyright law.” Our recommendations provide actions that would help the NIH to follow this directive, support the principles embodied in copyright, and not undermine the vital contributions of STM publishers to peer review, innovation and the dissemination of scientific research.



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