ISSN 2311-3898 Caribbean Library Journal **Volume 5, 2021**

A Look at The U.S. National Institutes of Health's Commitment to Open Access

Ardis Hanson (Dr.)
Assistant Director for Research and Education
USF Health Libraries, Shimberg Health Sciences, University of South Florida, Tampa, USA

Abstract

In 2008, the Consolidated Appropriations Act (Pub. L. 110-161, 2008) codified into law the National Institutes of Health (NIH) voluntary Public Access Policy, which stated that, upon acceptance, electronic copies of final, peer-reviewed manuscripts of federal research must be made publicly available no later than 12 months after the official date of publication. It also requires the NIH to implement the public access policy in a manner consistent with copyright law. How the implementation of required open access came about is the subject of this paper.

***Keywords*:** health policy, libraries, medical research, National Institute of Health, open access.

Introduction

In 2008, the Consolidated Appropriations Act (Pub. L. 110-161, 2008) codified into law the National Institutes of Health (NIH) voluntary NIH Public Access Policy. Division G, Title II, Section 218 of Pub. L. 110-161 requires 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" (Pub. L. 110-161, 2008, p. 345). It also requires the NIH to implement the public access policy in a manner consistent with copyright law.

The importance of this Act is because it guarantees that all published research funded all or in part by an NIH grant will be openly accessible within one year after publication. It is also significant in that compliance with the NIH Policy is 1) a statutory requirement and 2) a term and condition of NIH grant awards and cooperative agreements.

The history of how this public access policy formally became federal law is an interesting exploration of legislative, scientific, and public dialogues surrounding the transparency, accountability, and accessibility of federally funded research. This paper examines these dialogues, starting with the initial policy statement on enhancing public access to archived publications resulting from NIH-funded research, through the multiple Notices of Public Meetings

(as required by US law), to current efforts and technology to track and ensure public access compliance. It also describes how the Fair Copyright in Research Works Act affected the creation of the NIH Open Access Policy. The paper concludes with recommendations on what librarians should know and do to encourage the use of and compliance with the NIH Public Access Policy.

About the National Institutes of Health

A part of the U.S. Department of Health and Human Services, NIH is the largest biomedical research agency globally. Investing annually over $32 billion US in medical research, more than 80% of NIH funding is awarded to more than 300,000 researchers at more than 2,500 universities, medical schools, and research institutions nationally and internationally.

Public access to biomedical literature and information is provided by the National Library of Medicine (NLM) and its division, the National Center for Biotechnology Information (NCBI). In 1964 and 1971, MEDLARS and Medline, respectively, became operational at NLM. Dial-up access to Medline, better known as Grateful Med, allowed medical and health sciences librarians to dial into Medline, run a search, and download results. After establishing NCBI in 1988, it was just nine years before Medline became open access as PubMed (Table 1 provides a brief history of the NIH and its path to public access).

Table 1

NIH Milestones

1887	Marine Hospital
1930	Renamed as the National Institute of Health
1944	Public Health Services Act allows NIH to conduct research
1956	National Library of Medicine established
1960	International Health Research Act expanded NIH reach
1964	Medical Literature Analysis and Retrieval System (MEDLARS) became operational at NLM.
1971	Medline created (internet)
1988	National Center for Biotechnology Information (NCBI) established

1997	Open Access to PubMed established
2000	PubMed Central established
2004	NIH Town Hall meetings
2005	Voluntary Public Access Policy established
2005	NIHMS system established
2007	Europe PMC and PMC Canada established
2009	Omnibus Appropriations Act codifies NIH Public Access Policy

The NIH Public Access Policy differs from open access (OA) in that the NIH Public Access Policy ensures that the public has access to the published results of all NIH-funded research through a government-funded and maintained portal, PubMed Central (PMC). Copyright laws, both US and foreign, protect many of the papers in PMC, through the principles of Fair Use, a common concept in libraries. OA generally uses copyrighted documents under a Creative Commons or similar license agreement see Hanson & Bullers, "The Hard Reality of Open Access" this volume). These agreements are far more liberal in the dissemination, including redistribution, than the principles of Fair Use ("DOAJ News Service," 2019). Only a small subset of papers in PMC fall under OA provisions.

The inception of the NIH Public Access Policy and the process of gaining consensus among the scientific, academic, publishing, and other stakeholder communities is an interesting story, which started almost 20 years ago.

The Initial Policy Statement

In 1999, Dr. Harold Varmus (1999, May 5; June 20), director of the NIH, announced the creation of PMC, a voluntary "web-based repository for barrier-free access" to the biomedical literature indexed in the existing PubMed database. E-BIOMED, as the initiative was originally called, would provide cost-free access to NIH-funded reports and articles.

After three months of candid comments from publishers, researchers, and the larger scientific community nationally and internationally, the work began to establish PMC (Caelleigh, 2000; Delamothe, 1999; Relman, 1999). From a librarian's perspective, this repository addressed concerns such as "universal access, end-user training, techniques of literature retrieval and

evaluation, archival preservation and media migration, retraction for errors and scientific misconduct, and copyright and fair use" (Homan, 1999).

By 2000, PMC was created for the voluntary submission of papers (National Library of Medicine, 2017). In 2004, NIH published the "Enhanced Public Access to National Institutes of Health (NIH) Research Information" notice in the *Federal Register*, the daily newspaper of the Federal government (DHHS, 2004). The *Federal Register* contains federal agency regulations, proposed rules and public notices of scheduled hearings and meetings open to the public, grant applications, administrative orders, executive orders, proclamations, and other presidential documents (Office of the Federal Register, 2018). It is publicly available online or at any Federal Depository Library in the United States.

With the NIH Manuscript Submission System (NIHMS) creation in 2005, authors or publishers now had an online submission platform for manuscripts[1] (National Center for Biotechnology Information, 2006, July 26; 2017, December 4). During the voluntary policy, from May 2005 to December 2007, NIH collected a total of 19% of targeted papers from all sources. With the implementation of Section 218, the collection rate jumped to an estimated 56% of papers per month from April to August 2008 (National Institutes of Health, 2008, September 30).

On March 19, 2009, Division F, Section 217 of Pub. L. 111-8 of the Omnibus Appropriations Act of 2009 made the NIH Public Access Policy permanent. From Financial Year (FY) 2009 forward, all NIH-funded investigators were now officially required to submit an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication to the National Library of Medicine's PubMed Central no later than 12 months post-publication. Since 2005, PMC has been the designated repository for papers submitted in accordance with the NIH Public Access Policy. In 2007, the NLM established two authorized international PMC (PMCI) centers, Europe PMC (formerly UKPMC) and PMC Canada (NCBI, 2017, December 18).

[1] NIHMS converts the deposited manuscript files into archival XML format to ensure that the papers are publicly available in a format that ensures their permanent preservation.

Multiple Notices of Public Meetings

To ensure transparency and participation, the NIH used a variety of communication channels. An open meeting was held on March 20, 2008 to begin delineating stakeholder issues. The feedback from this meeting was used to create a Request for Information (RFI) that was formally published in the *Federal Register* on March 21, 2008. Six hundred and thirteen unduplicated comments were received from the public, including NIH-funded investigators, members of the public, patient advocates, professional organizations, grant awardee institutions, and publishers. Five issues emerged from the public comments: administrative burden, implementation, submission procedures and protocols, accordance with current copyright law and the Administrative Procedures Act, and financial impact on academic/scientific publishers and the NIH. The public comments helped identify operational solutions, such as submission procedures, authority to submit, versioning issues, and managing and protecting copyright. However, the most significant issue dealt with ensuring compliance.

Public Notices: Compliance

A major concern with implementing the NIH public access policy was the potential administrative burden such compliance would place on NIH program directors, principal investigators, and awarding institutions. Reducing administrative burden was a key component of the 1996 Health Insurance Portability and Accessibility Act (HIPAA, 1996). Title II of HIPAA, entitled "Administration Simplification," was intended to reduce healthcare costs and administrative burden by standardizing electronic data interchange (EDI) and ensuring the security and privacy of healthcare information.[2] This was expanded as a federal mandate to reduce paperwork and streamline business processes within agencies of the U.S. Department of Health and Human Services, the umbrella department under which NIH resides, as well as other federal agencies within the U.S. government.

The NIH updated the Public Access website three times during 2008 to clarify procedures and policies brought up from the open comments and review sessions as well as those issues that arose during the implementation of such a far-reaching policy. Although the changes addressed

[2] EDI is the computer-to-computer exchange of business documents in a standard electronic format between business partners. Security and privacy regulations apply to all information that is maintained and transmitted in a digital format and require administrative, physical, and technical safeguards.

submission procedures, reimbursement of costs, publisher support of the policy, and other issues, by far the most significant issue was compliance with the new policy. To help researchers keep up with the changes, formal policy notices (NOT) were published in the NIH Guide for Grants and Contracts (NIH, 2020, October 8), the *Federal Register*, NLM email digests, agency news updates, or searches within the federal grants.gov page.

Procedures were developed to address the administrative burden component of HIPAA. In June 2008, NIH updated the NIH Manuscript Submission System (NIHMS), the online mechanism for submission of manuscripts to PMC. Principal Investigators/Program Directors (PDs/PIs) could now delegate all aspects of the required submission tasks to co-authors. Publishers, who would submit manuscripts to the NIHMS for their authors, had greater control over the length of the embargo before their manuscripts would be available.

In August 2008, the NLM provided a new web tool, the NCBI Batch Citation Matcher, to help the scientific community obtain PubMed Central Identifiers (PMCID) in bulk. PMCIDs provide a unique number to identify a specific manuscript within PMC. By allowing batch matching, the NLM hoped to further reduce administrative burden on researchers and their staff to ensure compliance.

In September 2008, NIH (2008, September 23) issued Guide Notice NOT-OD-08-119 regarding grantee demonstration of compliance, the location of citations for papers in applications, proposals and progress reports; and more details about NIH's monitoring plan for Fiscal Year 2009. Guide Notice NOT-OD-08-119 requires the use of the PMCIDs in new and renewal grant proposals, NIH biosketch, non-competing continuation progress reports, and final progress reports.

Compliance with the public access policy is a term and condition of receipt of NIH awards. When a researcher applies for a federal grant, he is required to submit a biographical sketch (biosketch or SciENcv) to the funding agency. In this biosketch, he lists the relevant publications and grants he has received. Relevant publications would be added to the PMC and indexed in PubMed. Both records would be linked to the grant number (e.g., R25DA031103), indicating the grants the researcher has received or has participated in. The researcher also must certify that all publications linked to a federal grant meet the NIH Public Access Policy compliance requirements. The federal grants submission process matches all research activity and instance of the federal grant number within PubMed and PMC. It also flags any publication that has not been certified

as a publication resulting from a federally funded grant. The researcher must certify compliance or receive an NIHMS number for that non-compliant publication. Otherwise, he will be in non-compliance because the publication does not meet public access requirements.

While compliance with the NIH Public Access Policy would not be a factor in the scientific and technical merit *evaluation* of grant applications, non-compliance would be addressed administratively and may result in delays or awarding of funds. In short, failure to deposit materials in PMC would affect the researcher's ability to be *awarded* a new grant.

Subsequent notices included "Clarification on the Use of an NIHMSID to Indicate Compliance with the NIH Public Access Policy" (NIH, 2009, August), which allows the use of the NIHMSID in lieu of a PMCID before the NIHMSID submission process is fully completed. This notice was issued to address the fact that many researchers did not apply for an NIHMSID within the three-month ("90 days") window of publication of said paper. Since research papers may have an e-publication (ePub) date prior to the establishment in a specific volume/issue of a journal, the ePub date is used as the timeframe compliance mechanism.

In 2012, the NIH issued additional reporting requirements to ensure compliance. NIH announced it would delay the processing of non-competing continuation grant awards if publications arising from that award are not in compliance with the NIH public access policy (NOT-OD-12-160; NIH, 2012, November 16). This change was reinforced with NOT-OD-12-142, which required the use of the Research Performance Progress Report (RPPRs) for all Streamlined Non-competing Award Process (SNAP) and Fellowship awards (NIH, 2012, August 23). The RPPR established a uniform format for interim performance reporting on federally funded research and research-related activities (National Science Foundation, 2010, January 13; 2015, July 23).

Additional Efforts and Technology to Track and Ensure Public Access Compliance

Additional efforts to increase and improve compliance included the development of an institutional review tool, and the Public Access Compliance Monitor (NIH, 2013, January 9). The monitor, designated as an information only tool, does not substitute for official reporting from an institution to NIH. Rather, the compliance monitor provides detailed information about each article (i.e., citation, associated grants, PIs/PDs, PubMed IDs, and status of papers in the NIHMS).

The My Bibliography tool in My NCBI also addresses administrative simplification. It generates a .pdf report of publications required for the PHS 2590 progress report for a multi-year funded award (NIH, 2013, January 10). The report provides the public access compliance status of each publication from each grant awarded. It also ensures that the associations between the grant and its papers are captured in the NIH Research Portfolio Online Reporting Tools (RePORT) and other NIH electronic systems. The NIH RePORT provides open access to reports, data, and analyses of NIH research activities, including information on its expenditures and the results of its supported research. Since users can search a repository of grants projects, publications, and patents, compliance with NIH's public access policy is crucial.

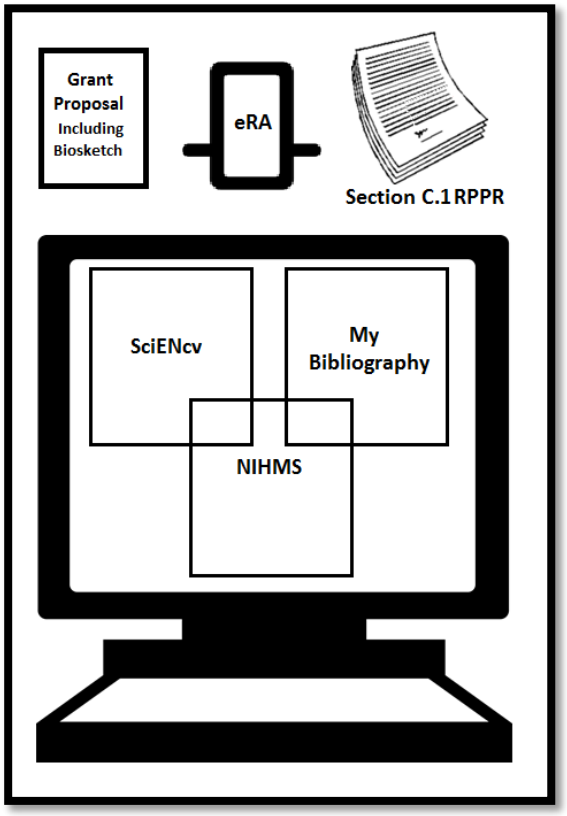
NIH continues to issue additional notices to remind researchers that non-compliance would affect processing of non-competing continuation awards and that researchers needed to use My NCBI to enter papers onto progress reports, either through the RPPR or in the My NCBI generated PHS 2590 report. NIH Notices in 2015 to 2016 have focused on improving reporting RPPR data in eRA Commons (NIH, 2015, April 10), providing guidance in reporting publications from institutional training, career development, and related awards (NIH, 2015, May 25); and how to track data sharing in the RPPR (NIH, 2016, March 24).

NIH Training to Help with Compliance

One of the ways the NIH helps educate researchers about its public access policy is through a variety of public education materials. Its "When and How to Comply" webpage address manuscript preparation, copyright issues, what to do once the paper is accepted for publication and reporting back to the NIH. To accomplish this, the NIH offers video training on the tools, i.e., NIHMS, My NCBI, My Bibliography, and compliance requirements.

Figure 1

Integration with Other Systems



Note. Adapted by the author from open source icons

Figure 1 illustrates the relationships between the grants and reporting process. The top row (grant proposal, eRA, RPPR) show the pre-award (grant proposal) process that is submitted to eRA (the federal agency) and the post-award (reporting) process that follows awarding of a grant. The eRA Commons (eRA) is an online platform where administrative information relating to research grants is stored. Grant applicants, grantees, and federal staff at NIH and grantor agencies can access and share information stored in eRA. Within the computer graphic sits the NIHMS, My Bibliography, and SciENcv (biosketch). These three systems provide the publication information that is fed into the grant proposal and is mapped post-award for all grant reporting requirements.

NIMHS

Figure 2 shows a simplified NIMHS process. Submitted manuscripts are linked by author name and Grants ID number. All manuscripts require submitting authors to assert that the submission of the manuscripts do not violate publishers' copyright and that embargos also comply with publisher requirements. After the manuscript is compiled in the PMC-ready version, final review and corrections are required. After all corrections are made, a confirmation page is generated with the PMCID and when the manuscript will be available in PubMed Central. Tutorials cover submission and post-submission review, using a task management process.

Figure 2

The NIHMS Process

Note. Adapted by the author from open source icons

My NCBI

My NCBI is an online tool that has many research and research support features. The My Bibliography and SciENcv tools are located within MyNCBI. Originally developed to help users save searches and results from multiple NCBI databases and to automate current awareness updates, linked My NCBI and eRA Commons accounts help users manage compliance with the NIH Public Access Policy. This helps to reduce administrative burden with less manual data entry, improved data quality for entered items, increased ease of use across systems, and maintain more accurate, structured and up-to-date bibliographic information.

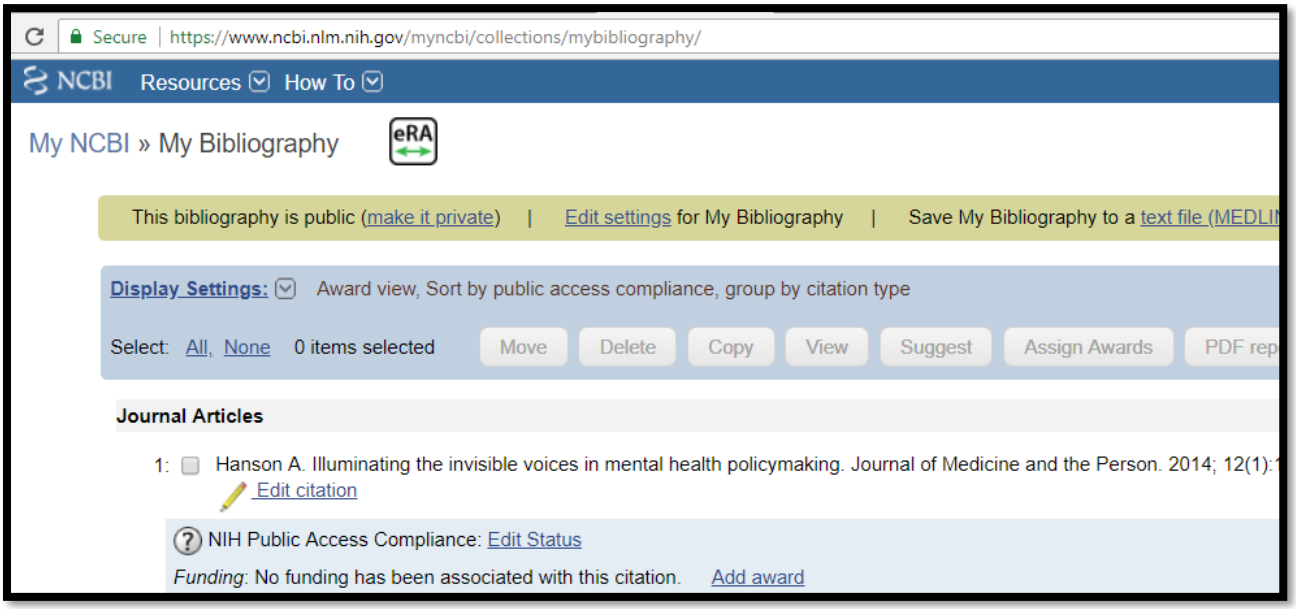
My Bibliography

Located within My NCBI, My Bibliography allows researchers to store, manage, and share citations of their published and presented works. Hence, My Bibliography helps to facilitate the

management of publication compliance with the NIH Public Access Policy. To reduce administrative burden and ensure interoperability of systems, the eRA Commons icon links to the My Bibliography page when the researchers have finished creating and linking their accounts. Each My Bibliography entry also includes a reminder about NIH Public Access compliance to help researchers or their delegates determine which items are not in compliance, there are 5 indicators. These are: three color-coded dots which indicate non-compliance (red), in process (yellow), and compliant (green) and two text messages: one is a reminder that nothing has been associated (not applicable), the other is a question mark that indicates more information is needed. Figure 3. shows the compliance notice associated with a specific publication.

Figure 3

Linked eRA Commons and My Bibliography accounts



Note. Screenshot from: My NCBI, My Bibliography

SciENcv

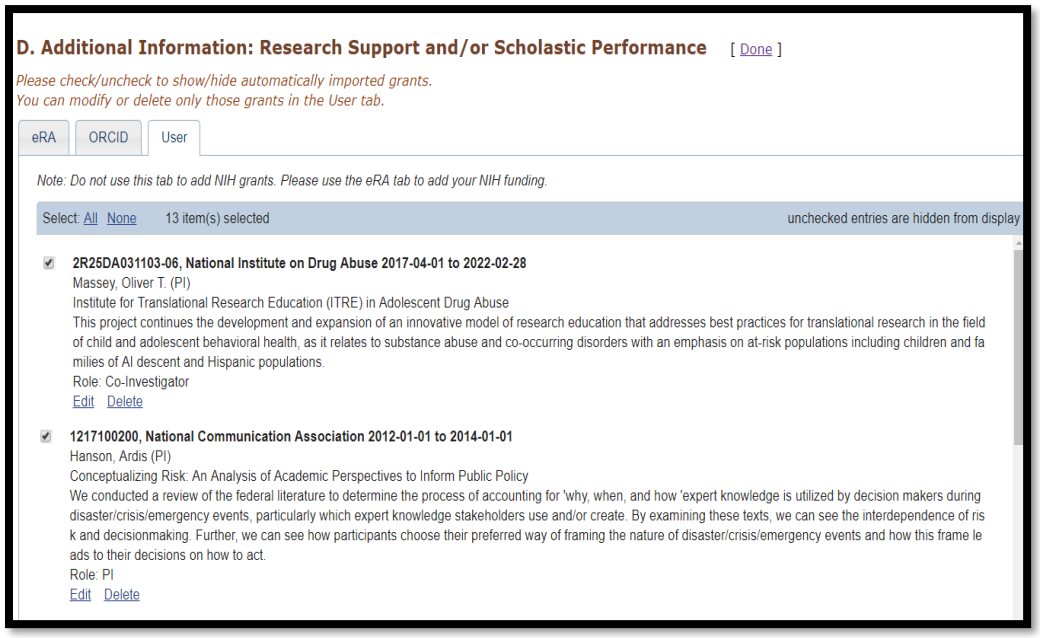
The Science Experts Network Curriculum Vitae (SciENcv) is one of the online tools created by NCBI to help researchers create their research profiles to comply with the required NIH biosketch format. One goal of SciENcv is to reduce the administrative burden researchers often

face when assembling biographical information for grants. To achieve this goal, SciENcv documents a researcher's education, employment, research activities, publications, honors and awards, research grants, and other professional contributions. It also allows researchers to name delegates, i.e., persons who receive permission from the researcher to input data for them into the system.

Both the NIHMS and My Bibliography are tied to SciENcv. The SciENcv integrates information from eRA Commons, My NCBI, NIHMS, My Bibliography, Research.gov, and ORCID into a single NIH Biosketch that is submitted to grants.gov, the U.S. federal grants agency. This ties the grant applications process to the mandatory grant compliance and reporting process as well as the public access compliance to eRA Commons. Figure 4 shows the integration of SciENcv with eRA Commons. The first grant, a federally funded grant, was imported from eRA Commons into the SciENcv; the second grant, an award from a national professional association, was entered manually. Any publications that were written as part of a federal grant must be compliant with the NIH public access policy requirements.

Figure 4

SciENcv Integration with eRA Commons



Note. Screenshot from: SciENcv webpage

Influence of the Fair Copyright in Research Works Act

The Fair Copyright in Research Works Act (FCRW, H.R. 801, 2009-2010) was submitted in direct response to the NIH Public Access Policy, with the intent to reverse the policy and amend Title 17 of the United States Code, prohibiting federal agencies from placing any conditions on copyright transfer that may be associated with federal grants awards. The bill was referred to the House Committee on the Judiciary, which then referred to the Subcommittee on Courts and Competition Policy. Supporters of the bill were publishing houses and professional associations predominantly; opponents of the bill included library associations and educational institutions. Supporters, such as the Association of American Publishers (2008, December 22), for example, felt the NIH Public Access Policy infringed upon their business rights. Opponents, such as the Association of Research Libraries, were concerned that the Act would reduce access to the results of federally funded research. Although H.R. 801 languished in the Subcommittee on Courts and Competition Policy, it was reintroduced as the Research Works Act (H.R. 3699, 2011-2012) in the 112th Congress. However, the publishing company Elsevier, who originally supported the bill, officially withdrew its support in February 2012. Soon after Elsevier's withdrawal, the backers of the bill officially withdrew the bill from further action.

The importance of public access to federally funded research continues. In 2012, the Federal Research Public Access Act (FRPAA; S. 2096, H.R. 4004) was introduced. Its intent was to expand public access to research funded by eleven U.S. federal government agencies. Reintroduced in the Senate in 2013, 2015, and 2017 as the Fair Access to Science and Technology Research Act (FASTR). FASTR would mandate earlier public release of taxpayer-funded research. Although FASTR has been read in the Senate, it is residing in the Committee on Homeland Security and Governmental Affairs.

How Librarians Can Assist with Public Access

As librarians become more involved in the research process as co-investigators, principal investigators, and other key personnel, it is incumbent upon us to educate ourselves as well as new and long-time researchers on the importance of the NIH Public Access Policy and compliance measures. There are four main areas in which there are opportunities for librarians: 1) training, 2) author support, 3) support on publishing agreements, and 4) compliance support. Training efforts

should address NIH Public Policy awareness, the paper/manuscript submission process, and how to accurately prepare citations in grant proposals and the required reporting materials. Training also involves educating faculty on the tools available to them, such as NIMHS, My Bibliography, SciENcv, and My NCBI. Staff presentations and consultations can also address navigating author's rights and the copyright process, understanding the different article deposit methods and approval processes, and how to acquire a PMCID.

Librarians can also provide supports to authors. They can help with manuscript submissions, for example, journal open access versus NIH public access policies, or how to manage the NIHMS submission process more efficiently. Depending upon the level of support the library is willing to provide, librarians should be available to answer questions via any media or be more involved in the compliance process. For example, librarians can send out reminders for the required reports by setting up calendars to notify PIs or the grant administrator that reports are due, and what elements need to be reported in which system. If there are multiple collaborators on a grant, they can work with them to ensure compliance, perhaps by creating a workflow, where each is assigned responsibility for a specific task or during a specific time frame, as to spread around the administrative burden of reporting and compliance.

Information professionals can also provide support to help faculty understand publishing agreements, also known as publishing rights, between the journal publisher and NIH. Each publisher is different, and it pays to be aware of the differences in OA and public access policies to ensure compliance for federally funded manuscripts. Policies change over time, so it never hurts to clarify questions each time a contract is under consideration. Finally, librarians can assist with compliance, checking applications, proposals, and reports. Biosketches, My Bibliography, and required reports can benefit from the detailed review by a librarian to ensure that all research manuscripts have an NIHMSID, a PMID, or a PMCID to demonstrate compliance.

Finally, it important to have an informed citizenry. Public access to government-sponsored research is not a privilege, it is a right. It is incumbent upon all of us, especially librarians, to ensure that patrons know how to find the studies, how to access the studies, and that researchers know how to verify that their research is publicly accessible.

REFERENCES

Association of American Publishers. (2008, December 22). Re: Copyright Protection for Scientific, Technical and Medical Journal Publishing. [Letter]. Retrieved from https://web.archive.org/web/20160314152213/http://www.pspcentral.org/documents/ObamaTransitionTeamLetterandAttachment.pdf

Caelleigh, A. S. (2000). PubMed Central and the new publishing landscape: Shifts and tradeoffs. *Academic Medicine, 75*(1), 4-10. Retrieved from https://insights.ovid.com/pubmed?pmid=10667868

Consolidated Appropriations Act, Pub. L. No. 110-161 (2008). Retrieved from https://www.gpo.gov/fdsys/pkg/PLAW-110publ161/pdf/PLAW-110publ161.pdf

Delamothe, T. (1999). US National Institutes of Health clarifies E-biomed database. *BMJ 319*(7202), 73. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1116226/pdf/73a.pdf

Department of Health and Human Services, & National Institutes of Health. (2004, September 17). Enhanced public access to National Institutes of Health (NIH) research information. *Federal Register, 69*(180), 56074. Retrieved from https://www.gpo.gov/fdsys/pkg/FR-2004-09-17/html/04-21097.htm

DOAJ News Service. (2019, September 1). Large scale publisher survey reveals global trends in open access publishing. Retrieved from https://blog.doaj.org/2019/01/09/large-scale-publisher-survey-reveals-global-trends-in-open-access-publishing/

Fair Access to Science and Technology Research Act of 2017, 115th Congress, H.R.3427 Stat. (2017-2018). Retrieved from https://www.congress.gov/bill/115th-congress/house-bill/3427

Fair Copyright in Research Works Act, H.R. 801, 111th Congress (2009-2010). Retrieved from https://www.congress.gov/bill/111th-congress/house-bill/801

Federal Research Public Access Act of 2012, 112th Congress, H.R.4004 Stat. (2011-2012). Retrieved from https://www.congress.gov/bill/112th-congress/house-bill/4004

Health Insurance Portability and Accountability Act, Pub. L. No. 104-191 (1996). Retrieved from https://www.gpo.gov/fdsys/pkg/PLAW-104publ191/content-detail.html

Homan, J. M. (1999). E-biomed. *Bulletin of the Medical Library Association, 87*(4), 485-486. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC226626/pdf/mlab00089-0117.pdf

National Center for Biotechnology Information. (2006, July 26; 2017, December 4). *NIH Manuscript Submission Help*. Bethesda, MD: U.S. National Library of Medicine. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK3846/

National Center for Biotechnology Information. (2017, December 18). PMC International. [Web page]. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/about/pmci/

National Institutes of Health. (2008, September 23). Reminder concerning grantee compliance with public access policy and related NIH monitoring activities. Retrieved from https://grants.nih.gov/grants/guide/notice-files/not-od-08-119.html

National Institutes of Health. (2008, September 30). *Analysis of comments and implementation of the NIH public access policy*. Bethesda, MD: Author. Retrieved from https://publicaccess.nih.gov/analysis_of_comments_nih_public_access_policy.pdf

National Institutes of Health. (2009, August). Clarification on the use of an NIHMSID to indicate compliance with the NIH public access policy. *NOT-OD-09-136.* Retrieved from https://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-136.html

National Institutes of Health. (2012, August 23). Research performance progress report (RPPR) module and training webinar available to NIH grantees. *NOT-OD-12-142.* Retrieved from https://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-142.html

National Institutes of Health. (2012, November 16). Upcoming changes to public access policy reporting requirements and related NIH efforts to enhance compliance. *NOT-OD-12-160.* [Web page]. Retrieved from https://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-160.html

National Institutes of Health. (2013, January 9). Public access compliance monitor: A new resource for institutions to track public access compliance. *NOT-OD-13-020.* Retrieved from https://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-020.html

National Institutes of Health. (2013, January 10). eRA commons users can now generate a publications report for the PHS 2590 with My NCBI. *NOT-OD-13-017.* Retrieved from https://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-017.html

National Institutes of Health. (2015, April 10). Reporting Publications in the research performance progress report (RPPR). *NOT-OD-15-090.* Retrieved from https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-090.html

National Institutes of Health. (2015, May 25). Clarifying publication reporting instructions for research performance progress reports (RPPR) and renewal applications. *NOT-OD-15-091*. Retrieved from https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-091.html

National Institutes of Health. (2016, March 24). Reporting instructions for publications supported by shared resources in research performance progress reports (RPPR) and Renewal Applications *NOT-OD-16-079.* Retrieved from https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-079.html

National Institutes of Health. (2020, October 8). Notices of NIH policy changes. Retrieved from https://grants.nih.gov/policy/notices.htm

National Library of Medicine. (2017, February 2). Fact sheet: MEDLINE, PubMed, and PMC (PubMed Central): How are they different? Retrieved from https://www.nlm.nih.gov/pubs/factsheets/dif_med_pub.html

National Science Foundation. (2010, January 13). Action: Submission for OMB review; comment request and final notice of a uniform research performance progress report (RPPR) format. *Federal Register*, *75*(8), 1816-1819. Retrieved from https://www.gpo.gov/fdsys/pkg/FR-2010-01-13/html/2010-469.htm

National Science Foundation. (2015, July 23). Request for public comment on an updated standardized research performance progress report format to be used for both interim and final performance progress reporting. *Federal Register*, *80*(141), 43802-43803. Retrieved from https://www.gpo.gov/fdsys/pkg/FR-2015-07-23/pdf/2015-18007.pdf

Office of the Federal Register. (2018). *Federal Register*. Retrieved from https://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR

Omnibus Appropriations Act, Pub. L. No. 111-8 (2009). Retrieved from https://www.gpo.gov/fdsys/pkg/PLAW-111publ8/html/PLAW-111publ8.htm

Relman, A. S. (1999). The NIH "E-biomed" proposal--a potential threat to the evaluation and orderly dissemination of new clinical studies. *New England Journal of Medicine*, *340*(23), 1828-1829. doi:10.1056/nejm199906103402309

Research Works Act, H.R. 3699, 112th Congress (2011-2012). Retrieved from https://www.congress.gov/bill/112th-congress/house-bill/3699

Varmus, H. (1999, May 5; June 20). PubMed Central: A proposal for electronic publication in the biomedical sciences. Retrieved from https://web.archive.org/web/20100211074259/http://www.nih.gov/about/director/ebiomed/ebi.htm