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May 31, 2023

Dr. Francis D. Chesley, Jr., M.D. Director, Office of Extramural Research, Education, and Priority Populations 5600 Fishers Lane Rockville, MD 20857

Submitted to grant_queries@ahrq.hhs.gov

Re: Notice Number: NOT-HS-23-011

Dear Director Chesley,

Thank you for the opportunity to provide input on the Agency for Healthcare Research and Quality's (AHRQ) updated Public Access Plan. We are writing on behalf of SPARC, a non-profit advocacy organization that supports systems for research and education that are open by default and equitable by design. Our membership includes over 200 academic and research libraries across the U.S., with institutions ranging from large research intensive universities to community colleges. We believe that sharing knowledge is a human right, and that everyone should be able to access, contribute to, and benefit from the knowledge that shapes our world. Our members are committed to supporting equitable systems of research and education, and we appreciate the opportunity to provide feedback on AHRQ's plan to implement the landmark 2022 OSTP Memorandum on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research.

AHRQ's updated plan puts the agency on strong footing to implement the provisions of the 2022 OSTP Memorandum in pursuit of its mission to make health care safer, higher quality, more accessible, equitable, and affordable. We applaud the agency's approach and offer some specific suggestions below to further strengthen the proposed plan.

Scholarly Publications

We strongly support the continuation of the requirement that authors deposit their final peer-reviewed accepted journal manuscripts into PubMed Central (PMC). This is the most

affordable and equitable compliance mechanism for grantees because it is free for the author. This provision can be further strengthened by adding language that explicitly states there is no charge to the author for depositing a manuscript into PMC. As we described in our <u>comments</u> on NIH's Draft Public Access Plan, we think it is important for the agency to make it clear that any fee that authors may be asked to pay is a publication fee, and not a fee required by AHRQ to comply with its policy. It is critical that authors do not conflate compliance with article processing charges (APCs), which create significant barriers for less-well-resourced researchers and institutions to make their research available. We also encourage AHRQ to engage with the <u>U.S. Repository Network</u> (USRN) to identify additional repositories that meet the agency's criteria for depositing publications.

We appreciate the requirement that final published articles submitted to PMC must carry the rights necessary to make the article available to the public. However, to meet the full requirements of the OSTP Memorandum, articles must also carry the necessary rights to make sure that they can be fully reused as well. We strongly recommend that this section be strengthened to require that publications carry a CC BY 4.0 International License, or its functional equivalent. We also recommend that AHRQ require articles to be made publicly available in standardized, machine-readable formats.

We are encouraged that AHRQ intends to explore with the National Library of Medicine/PMC "the circumstances or prerequisites needed to make the publications freely and publicly available by default, including any use and re-use rights, and which restrictions, including attribution, may apply." Our recommendation is that all agency publications include re-use rights. This would bring the AHRQ plan into conformity with the OSTP Memorandum's expectation that these publications are "findable, accessible, interoperable, and reusable, to the American public and the scientific community in an equitable and secure manner."

To be certain that all agency publications include re-use rights, we suggest that AHRQ require grantees, as a term and condition of funding agreements, to ensure that the agency receives a license to agency publications sufficient for AHRQ to grant the public re-use rights. This is the most straightforward approach that minimizes complexity and burden in compliance by grantee institutions and authors.

To do this, the agency could rely on its existing federal purpose license under <u>2 C.F.R. §</u> <u>200.315(b)</u> or it could require grantees to ensure that AHRQ receives an analogous additional license that specifically provides the right to grant the public re-use rights to agency publications covered by the Public Access Policy.

Requiring that this additional license be granted as a term and condition of funding ensures that the agency receives its additional license at the moment the scholarly publication is created, which is how the longstanding federal purpose license operates. In this way, even if an author from the grantee's institution signs a publication agreement that conflicts with the agency's

license, the agency's license remains intact, as is the case with the agency's federal purpose license.

We also recommend the agency develop template language that can be attached to or included with the publication, either by the author or PMC staff, to indicate the publication is available under an open license.

We have included a more thorough explanation of this recommendation in Appendix A of this submission.

To meet the OSTP Memorandum's requirement for equitable delivery of federally-funded research results, AHRQ should ensure that accessibility accommodations are provided where necessary for any final publisher PDFs that are made available as a result of AHRQ's plan. While publishers of scholarly works are able to add accessible features most effectively and efficiently, PDFs provided by publishers are not always 508 compliant. We recommend that AHRQ include a plan to remediate non-compliant works in accordance with U.S. copyright law, which explicitly grants a broad exception for remediation and distribution of accessible works to people with print disabilities. This exception is bolstered by the Marrakesh Treaty. Copying and distributing works in accessible formats is not constrained by copyright law, and we recommend the agency remove "due to copyright constraints" from this sentence in the plan: "AHRQ will provide an accommodation for final publisher PDF versions that are not 508 compliant but cannot be remediated due to copyright constraints"

Scientific Data

We support the expectation that data underlying publications should be shared no later than the time of publication. However, we also note that the AHRQ plan states that it may not be feasible for authors to share all data and that costs and benefits of data sharing should be weighed in data management planning. To avoid confusion on behalf of authors and to strengthen the data sharing provisions, we recommend AHRQ take the approach that data underlying publications should be made "as open as possible" and "as closed as necessary" to ensure the data meets the accessibility goals of the <u>FAIR Principles</u> outlined in the OSTP Memorandum.

We note that AHRQ's plan currently allows researchers to comply with its public access policy by sharing data on a personal website or mailing a disk to the agency. We are concerned that this approach to data sharing will hamper discoverability and long-term preservation of this data, and therefore encourage the agency to eliminate this as a compliance option.

SPARC applauds AHRQ's commitment to design, implement, and maintain a sustainable network of data management capabilities. A distributed network of capabilities, including repositories, ensures no single point of failure and strengthens the data infrastructure of the research ecosystem so that it best serves the needs of researchers and the broader public. We

strongly encourage AHRQ to ensure these capabilities are dictated by the AHRQ research community and aligned with the characteristics in the National Science and Technology Council's (NSTC) "Desirable Characteristics of Data Repositories for Federally Funded Research."

A sustainable network of repositories is equally important for other research outputs including articles, gray literature, and emerging forms of scholarship. We encourage the agency to consider collaborations with repositories at academic and research libraries. We note that the U.S. Repositories Network (USRN) is working to promote a strategic vision for U.S. repositories built on collaboration, discoverability, interoperability, and preservation, and encourage AHRQ to consider collaboration with USRN and other academic and research community-led networks.

We support the agency's approach to data management costs and commitment to confer with interagency partners on appropriate cost estimates and needed support for future data management. We note again that community-controlled data infrastructure versus systems controlled by commercial entities are key to ensuring data is fully accessible to the public and managed in the most cost-effective manner for the researcher and the agency.

We recognize that AHRQ-funded research may involve data with restrictions to protect privacy, national security, or for other reasons. However, the plan currently states that data that carry agreements that prohibit data sharing will be exempt from submission into a data repository. The agency should clarify that data is exempt if the prohibition is imposed by a third party, not a researcher. In other words, the researcher should not be able to impose a license on their data that prohibits its sharing and be exempt from the Public Access Policy. To this end, we recommend adding "third parties" to this language in the AHRQ plan: "AHRQ-funded research that involves data use agreements or licensing agreements *imposed by third parties* that prohibit data sharing will be exempt from submitting these data to the data repository."

Other Outputs

SPARC welcomes AHRQ's interest in encouraging the sharing of research outputs beyond publications and underlying data. Requiring that code and software associated with research data be openly shared would strengthen the agency's plan. Software, code, and other outputs such as interview protocols, measures, and manuals provide users with the necessary tools to analyze the data, increasing its value to the community and aligning with the FAIR Principles to ensure data is findable, accessible, interoperable, and reusable. The agency should also require researchers to make the software and code available under open licenses that allows for free access, modification, and reuse. We recommend the agency consult the Open Source Initiative which has a number of "approved licenses" that meet these terms. We specifically support the agency's exploration of a research data commons to advance the sharing of a variety of outputs and alignment with the NSTC's guidance on data repositories.

Metadata and PIDS

We strongly support AHRQ's commitment to increase discoverability of agency-funded articles and the associated scientific data. The agency's inclusion of metadata standards when describing what should be in a data management plan is particularly important to facilitate interoperability and alignment with the FAIR Data Principles. The minimum metadata schema already in use by the Federal Government is a helpful starting point to strengthen standards across the federal research agencies.

Sharing metadata about who conducted the research, where it was done, and with what resources can improve scientific integrity and trust in government-funded science. We encourage AHRQ (and other federal agencies) to identify and adopt de facto community standards where they exist. For example, to identify research entities, we recommend that AHRQ leverage the Research Organization Registry (ROR), a registry of more than 100,000 organizations, and require ROR IDs for grantees. We also recommend the agency adopt digital object identifiers (DOIs) for publications, data sets, and data management plans, and ORCIDs for researchers—each of which is a nonproprietary community standard for its identifier type. We support AHRQ's specific commitment to ensure the data repositories it uses have unique identifiers analogous to PMCIDs for publications.

Metrics, Compliance, and Evaluation

Incentivizing compliance will be an important component of AHRQ's plan. We strongly support AHRQ adding a section in applications and proposals that describes "progress to-date" on research output sharing. This sends a clear message to researchers and grantees that public access compliance is an up-front expectation, not an afterthought. Requirements to provide updates in progress reports on research sharing also introduces natural discussion points for program officers and investigators to evaluate compliance methods, especially for data management and sharing. We also recommend that program officers discuss plans for publication with the researcher ahead of grant closeout to ensure the full set of compliance options, especially those that are no or low-cost, are well understood by the researcher. Educating researchers about affordable compliance options can improve equity by removing financial barriers to publishing.

As AHRQ works to evaluate the impact of its Public Access Policy, it should include specific metrics related to equity that are clearly defined and evidence-based. Specifically, it should evaluate any disparate impacts of policy implementation on underrepresented groups including early career researchers and researchers at minority serving institutions. We recommend AHRQ coordinate the evaluation of its Public Access Plan with the work of the NSTC Subcommittee on Equitable Data, the HHS Equity Action Plan, and broader White House recommendations to determine appropriate measures and build evaluation capacity at the agency.

SPARC appreciates the opportunity to provide comments, and we applaud AHRQ for its efforts to ensure equitable, free, immediate access to taxpayer funded research. We look forward to working with the agency to fully accomplish the goals outlined in the OSTP Memorandum and to leverage the full value and utility of AHRQ-funded research.

Sincerely,

Katie Steen-James

Manager of Public Policy & Advocacy

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Executive Director

Appendix A

Compliance Steps to Ensure Public Access with Reuse Rights

Goal: Ensure scholarly publications subject to the 2022 OSTP Memorandum, <u>Ensuring Free</u>, <u>Immediate</u>, <u>and Equitable Access to Federally Funded Research</u>, are openly licensed to maximize global public reuse.

Strategy: Provide agencies, universities, and authors with a menu of compliance steps/options that retain the rights needed to openly license the publications.

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This document was developed by <u>Creative Commons</u>, the <u>Authors Alliance</u>, Michael Carroll at the <u>American University College of Law</u> (PIJIP), Peter Suber of the <u>Harvard Library</u>, and SPARC. It provides recommendations to ensure that public access is provided in a manner that is consistent with copyright law and the obligation under Section 5(j) of the 2022 OSTP Memorandum to make these publications "findable, accessible, interoperable, and re-useable, to the American public and the scientific community in an equitable and secure manner."

This document provides agencies with recommended policy language, contract language, and operational steps to ensure that grantees comply with the obligation to make agency-funded peer-reviewed scholarly publications publicly accessible.

For reference, that obligation in Section 3(a) is that "all peer-reviewed scholarly publications authored or co-authored by individuals or institutions resulting from federally funded research are made freely available and publicly accessible by default in agency-designated repositories without any embargo or delay after publication."

Under longstanding policy, agencies already receive a license to any copyrighted work created with federal funds that authorizes the agency to make broad use of the work for federal purposes and to authorize others to do so. This language likely already provides agencies with sufficient authority to require that publicly accessible copies of scholarly publications are provided to the public with reuse rights.

To avoid any doubt on this issue, the policy language below recommends that the most straightforward means by which a grantee can provide public access is to require that as part of the grant agreement, the grantee provides the agency with an additional copyright license that is analogous to the longstanding federal purpose license. The scope of this additional license directly correlates to the agency's public access obligation under the 2022 OSTP Memorandum.

The recommended policy language is stated generally. We also recommend more specific language that an agency can use in its contracts with its grantees to ensure that copyright is properly managed to provide public access with broad rights of reuse.

The legal effect of this contract language is that the agency receives its additional license at the moment the scholarly publication is created, which is how the longstanding federal purpose license operates. In this way, even if an author from the grantee's institution signs a publication agreement that conflicts with the agency's license, the agency's license remains intact.

Finally, it is important that information about this license is communicated to the public with any copy of the scholarly publication that is made publicly accessible to comply with the agency's public access policy.

The most straightforward method to achieve this is to create a required template that is attached to copies of scholarly publications that are deposited in agency-designated repositories or otherwise in compliance with the agency's public access policy. The contents of this template can include information about the copyright license along with other useful information, such as the funding agreement number, perhaps the author's ORCID ID and any other information that the agency may want to require. The template would ideally be attached by the author, but it also could be attached by the repository manager or a publisher in cases in which the publisher agrees to deposit public access copies in an agency-designated repository.

The following language is limited to the license required to make the work publicly accessible with reuse rights. It does not include language on other areas covered by the 2022 OSTP Memorandum, such as mandatory deposit in agency-designated repositories, mandatory metadata, and so on.

(1) Agency Policy Language

In the event that it is deemed not already provided for by the license reserved by the agency to all copyrighted works subject to the requirements of <u>2 C.F.R. § 200.315(b)</u>, the agency reserves an additional license in any peer-reviewed scholarly publications covered by the 2022 OSTP Memorandum to apply a public license to such publications. The terms of the agency's public license authorize members of the public to exercise all rights under copyright and related or neighboring rights in any covered peer-reviewed scholarly publication subject to the condition that they provide attribution as required by the agency.

(2) Agency Contract Language (Terms & Conditions of an Award)

License Grant

In the event that it is deemed not already provided for by the license reserved by the agency to all copyrighted works subject to the requirements of <u>2 C.F.R. § 200.315(b)</u>, the agency reserves an additional license in any peer-reviewed scholarly publications covered by the 2022 OSTP

Memorandum to apply a public license to such publications. The terms of the agency's public license authorize members of the public to exercise all rights under copyright and related or neighboring rights in any covered peer-reviewed scholarly publication subject to the condition that they provide attribution as required by the agency.

The "additional license" reserved by the agency is a worldwide, royalty-free, non-exclusive, perpetual, irrevocable, standard open copyright license granting the public permission to access, reproduce, publicly perform, publicly display, adapt, distribute, and otherwise use the work and adaptations of the work for any purpose, conditioned only on the requirement that attribution be given to authors and rights holders as designated. The "additional license" must be widely adopted and must contain (i) a symbol that readily communicates to users the permissions granted concerning the use of the copyrightable work; (ii) machine-readable code for digital resources; and (iii) readily accessed legal terms.

Obligation to Communicate

The grantee agrees to take all necessary actions to ensure that the publicly accessible copy of the article will conform to the template for policy-covered works.

"Publicly accessible copy" means any copy of the peer-reviewed scholarly publication that is made freely available and publicly accessible to comply with the 2022 OSTP Memorandum.

(3) Template for Covered Works

Policy-covered works must include the language from one of the two options below when deposited in agency-designated repositories or distributed by any other means in order to meet the grantee's public access obligation.

Template Option 1

"Research reported in this [publication] was supported by [name of the Institute(s), Center, or other agency offices] of the [federal agency] under award number [specific agency grant number(s)]. Pursuant to [cite specific agency policy] and [relevant university policy], this work is made available under the <u>CC BY 4.0 license</u>."

Template Option 2

"Research reported in this [publication] was supported by [name of the Institute(s), Center, or other agency offices] of the [federal agency] under award number [specific agency grant number(s)]. Pursuant to [cite specific agency policy] and [relevant university policy], the authors of this work provide the [federal agency] with a worldwide, royalty-free, non-exclusive, perpetual, irrevocable, standard open copyright license granting the public permission to access, reproduce, publicly perform, publicly display, adapt, distribute, and otherwise use the work and adaptations of the work for any

purpose, conditioned only on the requirement that attribution be given to the authors and rights holders as designated."

(4) Agency-designated Repositories

Agencies should instruct agency-designated repositories to check submissions for compliance with the agency template. When policy-covered submissions do not contain the language specified in the template, repositories should add the language before the works are made public. Agencies may instruct repositories to add template language Option 1 or Option 2, at their discretion.

(5) Universities

Most university IP policies allocate copyright ownership in works of scholarship to individual creators, not the university. However, most university copyright or IP policies also already contain language that will enable compliance with this licensing requirement by modifying that default allocation of rights. This is typically accomplished by university policy ensuring that either the university owns all rights in works created under a grant,¹ or by stating that the university will retain whatever slice of rights is necessary to comply with grant or contract obligations.² Retaining those rights is necessary so the university holds the requisite rights to apply the CC BY 4.0 license of functional equivalent.

Universities also have other options to comply. For example, some universities retain a broad license that allows it to reuse all scholarly works produced by university employees. Others have adopted institutional rights retention policies aimed specifically at public availability and reuse. It is important, particularly for universities with policies that hold that individual creators are the initial owners of rights, to ensure that PIs and other creators under the grants affirm their compliance and agreement with the applicable IP policies.³

¹ See, for example, The University of Texas IP Policy, which provides that "Intellectual property resulting from research supported by a grant or contract with the government (federal and/or state) or an agency thereof is owned by the Board of Regents."

[&]quot;https://www.utsystem.edu/board-of-regents/rules/90101-intellectual-property.

² See, for example, Stanford University's IP policy, which provides that rights are typically held by individual creators but that "Copyrightable works that are subject to sponsored research agreements or other contractual obligations of the University shall be owned by the University, so that the University may satisfy its contractual obligations." See

https://doresearch.stanford.edu/policies/research-policy-handbook/intellectual-property/copyright-policy.

³ For example, the University of Wisconsin requires PIs to attest that they will adhere to the University IP policy and license using this form: https://kb.wisc.edu/images/group156/33081/ipagreement.pdf.