

Health and Medicine Division Board on Health Sciences Policy

Policy and Global Affairs
Board on Research Data and Information

November 30 – December 1, 2023

Hybrid Meeting

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Enhancing Public Access to the Results of Research Supported by the Department of Health and Human Services

A Workshop

November 30 – December 1, 2023 Washington, DC

A planning committee of the National Academies of Sciences, Engineering, and Medicine will organize a public workshop to inform the National Institutes of Health (NIH) and other agencies of the Department of Health and Human Services (HHS) as they develop or update policies to enhance public access to the results of HHS-funded research. The workshop will focus on topics related to scholarly publications and convene interested individuals and communities, including authors, investigators, research institutions, libraries, scholarly publishers, scientific societies, healthcare providers, patients, students, educators, and research participants.

The workshop will feature invited presentations and discussions addressing:

- Additional steps that agencies could consider to ensure that any changes to public access policies
 promote equity in publication opportunities for investigators supported by NIH, Administration
 for Children and Families (ACF), Administration for Community Living (ACL), Food and Drug
 Administration (FDA), and other HHS agencies, and do not create new or reinforce existing
 inequities in publishing opportunities.
- Steps for improving equity in access and accessibility of publications by diverse communities of users, in addition to removal of the currently-allowable 12-month embargo period for federally-supported publications.
- Effective approaches for monitoring trends in publication fees and impacts on affected communities, including perspectives on what constitutes a "reasonable" cost.
- Considerations to increase findability and transparency of research, including efforts to improve use of persistent identifiers (PIDs) (e.g., ORCID IDs, DOIs, RoR ID) and metadata, as well as institutions and researchers' experiences with adoption of different identifiers across publications and research data.

The planning committee will develop the agenda, select and invite speakers and discussants, and moderate or identify moderators for the discussions. A proceedings-in-brief of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.



Enhancing Public Access to the Results of Research Supported by the Department of Health and Human Services A Workshop

November 30, 2023, 9:00 am – 5:00 pm (ET)

December 1, 2023, 9:00 am – 1:30 pm (ET)

National Academy of Sciences Building, Room 120
2101 Constitution Avenue NW Washington, DC 20418

Webcast available at the event webpage: Click Here

PURPOSE

This public workshop is convened by the National Academies to inform the National Institutes of Health (NIH) and other agencies of the Department of Health and Human Services (HHS) as they develop or update policies to enhance public access to the results of HHS-funded research. The workshop will focus on topics related to scholarly publications and convene interested individuals and communities, including authors, investigators, research institutions, libraries, scholarly publishers, scientific societies, healthcare providers, patients, students, educators, and research participants.

The workshop will feature invited presentations and discussions addressing:

- Additional steps that agencies could consider to help ensure that changes to public access policies
 promote equity in publication opportunities for investigators supported by HHS agencies- with a
 particular focus on the NIH, Administration for Children and Families (ACF), Administration for
 Community Living (ACL), and the Food and Drug Administration (FDA)- and do not create new or
 reinforce existing inequities in publishing opportunities.
- Steps for improving equity in access and accessibility of publications by diverse communities of users, in addition to removal of the currently-allowable 12-month embargo period for federally-supported publications.
- Effective approaches for monitoring trends in publication fees and impacts on affected communities, including perspectives on what constitutes a "reasonable" cost.
- Considerations to increase findability and transparency of research, including efforts to improve use
 of persistent identifiers (PIDs) (e.g., ORCID IDs, DOIs, RoR ID) and metadata, as well as institutions
 and researchers' experiences with adoption of different identifiers across publications and research
 data.

DAY 1: THURSDAY, NOVEMBER 30, 2023

9:00 am Welcome and Opening Remarks

Clay Johnston, *Workshop Co-chair* Chief Health Officer, Harbor Health

Adjunct Professor of Neurology, University of California San Francisco

Bonnielin Swenor, Workshop Co-chair

Director, Disability Health Research Center

Associate Professor School of Nursing

Wilmer Eye Institute, School of Medicine

Department of Epidemiology, Bloomberg School of Public Health

Johns Hopkins University

9:15 am KEYNOTE

Adam Politis

Senior Policy Advisor for Disability and Equity

White House Office of Science and Technology Policy

9:15-9:45 am Presentation

9:45-10:20 am Moderated Discussion

Carrie Wolinetz, Moderator

Principal and Chair

Health and Bioscience Innovation Practice Group

Lewis-Burke, LLC

10:20 am COFFEE BREAK (30 minutes)

10:50 am SESSION I - VALUE-COST OF PUBLIC ACCESS: POLICIES, MODELS, OPPORTUNITIES

Session Objectives:

- Discuss equity opportunities and barriers associated with different models that support public access throughout the entirety of the publication process.
- Discuss the impacts of shifted publication costs in response to changes in public access policies, including impacts on affected communities, trends in publication fees, and what constitutes a "reasonable" cost.

10:50 am Panel Discussion

Adriene Lim, Moderator

Dean of Libraries

University of Maryland College Park

Panelists

Stefano Bertuzzi

Chief Executive Officer

American Society for Microbiology

Kimberley Bugg

Associate Library Director

Atlanta University Center Robert W. Woodruff Library

Heather Joseph

Executive Director

Scholarly Publishing and Academic Resources Coalition

Jessica Sebeok

Vice President for Global Government Partnerships and Public Policy Wiley

Günter Waibel

Executive Director, California Digital Library Associate Vice Provost University of California Office of the President

12:30 pm LUNCH BREAK (1 hour)

1:30 pm SESSION II – BEYOND EMBARGOS: ACCESSIBILITY CONSIDERATIONS FOR BUILDING NEW PUBLIC ACCESS POLICIES

Session Objectives:

- Discuss barriers for public access to HHS-funded research results from diverse perspectives, including from communities often excluded from research discussions.
- Discuss how to develop, evolve, and sustain bridges to various communities so that many
 perspectives are included in the process of making and improving public access to research through
 publishing.
- Consider steps for improving equity in access and accessibility of publications by a diverse community of users in addition to removal of the currently allowable 12-month embargo period for federally supported publications.

1:30 pm Panel Discussion

Pamela Padilla, Moderator

Professor & Vice President of Research and Innovation

University of North Texas

E. Yvonne Lewis

Co-Director

Healthy Flint Research Coordinating Center

Lisa McCorkell

Co-Founder

Patient-Led Research Collaborative

Yvette Pearson

Vice President for Diversity, Equity, and Inclusion University of Texas at Dallas

Jenny Peng

Senior Publisher Oxford University Press

John-Ross Rizzo

Ilse Melamid Associate Professor of Rehabilitation Vice Chair of Equity and Innovation New York University Grossman School of Medicine

3:00 pm COFFEE BREAK (25 minutes)

3:25 pm SESSION III – Breakout Discussion: Opportunities Created by New Public Access Policies

Session objectives:

- Identify created by new public access policies to reduce inequities in publishing opportunities and
 increase accessibility to research results, including attributes of the current academic publishing
 ecosystem should be carried forward.
- Discuss short-, medium- and long-term actionable steps that stakeholders, including HHS agencies, can take to ensure that new public access policies enable equity in publication opportunities and accessibility to research results for a diverse community of users (including those historically excluded from research discussions).

3:25 pm Breakout Discussion (50 mins)

Svasti Haricharan Assistant Professor Sanford Burnham Prebys Medical Discover Institute

Iheoma Iruka

Director, Equity Research Action Coalition Research Professor, Department of Public Policy University of North Carolina Frank Porter Graham Child Development Institute

Julie Maués Co-Founder Guiding Researchers and Advocates to Scientific Partnerships

Jessica Polka Executive Director ASAPbio

Additional Moderators Pending

4:15 pm Report Out Discussion (45 mins)

Milagros Nores, Moderator

Associate Research Professor & Co-Director for Research National Institute for Early Education Research Rutgers The State University of New Jersey

5:00 pm ADJOURN WORKSHOP DAY 1

DAY 2: FRIDAY, DECEMBER 1, 2023

9:00 am OPENING AND KEYNOTE

Phillip Sharp

Institute Professor

Professor of Biology Emeritus

Massachusetts Institute of Technology

9:00-9:30 am **Presentation**

9:30-10:00 am Moderated Discussion

Bodo Stern, *Moderator* Chief of Strategic Initiatives Howard Hughes Medical Institute

10:00 am SESSION IV - RESEARCH RESULTS: FINDABILITY, TRANSPARENCY, AND ACCESSIBILITY

Session Objectives:

- Discuss possible benchmarks that could be used to monitor trends for equity in publication opportunities.
- Discuss possible metrics that could be used to assess and evaluate accessibility for HHS-funded research results, including findability.
- Consider ways to improve use of persistent identifiers and metadata, as well as institutions and researchers' experiences with adoption of different identifiers across publications and research data.

10:00 am Panel Discussion

Lori Schultz, *Moderator* Assistant Vice President for Research Intelligence University of Arizona

Roger Schonfeld

Vice President, Organizational Strategy and Libraries, Scholarly Communication, and Museums ITHAKA

Chris Shillum

Executive Director ORCID

Jamie Wittenberg

Assistant Dean of Research & Innovation Strategies University of Colorado Boulder

Joseph Yracheta

Executive Director Native BioData Consortium

11:25 am COFFEE BREAK (20 minutes)

11:45 am SESSION V – Breakout Discussion: Evaluating the Success of Future Public Access Policies

Session Objectives:

- Consider criteria to evaluate successful implementation of the actions identified in Session III
 (Breakout Discussion: Identifying Future Opportunities for Public Access Policies) to ensure that new
 public access polices promote equity and accessibility.
- Discuss benchmarks assess whether new public access policies are successful in promoting equity and accessibility.
- Consider who has responsibility for monitoring the impact of new public access policies.

11:45 am Breakout Discussion (50 mins)

Breakout Group Moderators

12:35 pm Report Out Discussion (50 mins)

Darla Henderson, Moderator

Director, Open Science and Research Integrity

Director, Publications

Federation of American Societies for Experimental Biology

1:25 pm Workshop Closing Remarks

Clay Johnston, Workshop Co-chair

Bonnielin Swenor, Workshop Co-chair

1:30 pm ADJOURN WORKSHOP DAY 2

PREVENTING DISCRIMINATION, HARASSMENT, AND BULLYING EXPECTATIONS FOR PARTICIPANTS IN NASEM ACTIVITIES

The National Academies of Sciences, Engineering, and Medicine (NASEM) are committed to the principles of diversity, integrity, civility, and respect in all of our activities. We look to you to be a partner in this commitment by helping us to maintain a professional and cordial environment. All forms of discrimination, harassment, and bullying are prohibited in any NASEM activity. This commitment applies to all participants in all settings and locations in which NASEM work and activities are conducted, including committee meetings, workshops, conferences, and other work and social functions where employees, volunteers, sponsors, vendors, or guests are present.

Discrimination is prejudicial treatment of individuals or groups of people based on their race, ethnicity, color, national origin, sex, sexual orientation, gender identity, age, religion, disability, veteran status, or any other characteristic protected by applicable laws.

Sexual harassment is unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature that creates an intimidating, hostile, or offensive environment.

Other types of harassment include any verbal or physical conduct directed at individuals or groups of people because of their race, ethnicity, color, national origin, sex, sexual orientation, gender identity, age, religion, disability, veteran status, or any other characteristic protected by applicable laws, that creates an intimidating, hostile, or offensive environment.

Bullying is unwelcome, aggressive behavior involving the use of influence, threat, intimidation, or coercion to dominate others in the professional environment.

REPORTING AND RESOLUTION

Any violation of this policy should be reported. If you experience or witness discrimination, harassment, or bullying, you are encouraged to make your unease or disapproval known to the individual, if you are comfortable doing so. You are also urged to report any incident by:

- Filing a complaint with the Office of Human Resources at 202-334-3400, or
- Reporting the incident to an employee involved in the activity in which the member or volunteer is participating, who will then file a complaint with the Office of Human Resources.

Complaints should be filed as soon as possible after an incident. To ensure the prompt and thorough investigation of the complaint, the complainant should provide as much information as is possible, such as names, dates, locations, and steps taken. The Office of Human Resources will investigate the alleged violation in consultation with the Office of the General Counsel.

If an investigation results in a finding that an individual has committed a violation, NASEM will take the actions necessary to protect those involved in its activities from any future discrimination, harassment, or bullying, including in appropriate circumstances the removal of an individual from current NASEM activities and a ban on participation in future activities.

CONFIDENTIALITY

Information contained in a complaint is kept confidential, and information is revealed only on a need-to-know basis. NASEM will not retaliate or tolerate retaliation against anyone who makes a good faith report of discrimination, harassment, or bullying.

Updated June 7, 2018

Enhancing Public Access to the Results of Research Supported by the Department of Health and Human Services

A Workshop

PLANNING COMMITTEE BIOGRAPHIES

S. CLAIBORNE "CLAY" JOHNSTON, MD, PHD, MPH, (CO-CHAIR) is the Co-Founder Chief Health Officer of Harbor Health, a new health system based in Austin, Texas, and is Adjunct Professor of Neurology at the University of California, San Francisco. He is a neurologist and epidemiologist who studies stroke prevention and treatment, and has led several large, randomized trials. He is a member of the National Academy of Medicine and previously received several research awards from the American Stroke Association and American Academy of Neurology. He was chosen as Austinite of the Year 2016 by its Chamber of Commerce for launching the new Dell Medical School at UT Austin, where he served as inaugural dean from 2014 through 2021. Johnston is a former vice editor for Annals of Neurology. Johnston received his undergraduate degree from Amherst College, MD from the Harvard/MIT Health Sciences and Technology program, and MPH and PhD from the University of California, Berkeley.

BONNIELIN SWENOR, PHD, MPH, (CO-CHAIR) is an associate professor at The Johns Hopkins School of Nursing and holds joint appointments at the Johns Hopkins School of Medicine and the Johns Hopkins Bloomberg School of Public Health. She is the founder and director of the Johns Hopkins Disability Health Research Center, which aims to shift the paradigm from 'living with a disability' to 'thriving with a disability'. Motivated by her personal experience with a visual disability, her work takes a data-driven approach to advancing health equity for people with disabilities and promoting disability inclusion and anti-ableism in higher education, STEMM (science, technology, engineering, mathematics, and medicine), public health, and research. Dr. Swenor has provided advice and expertise on disability data, equity, and inclusion to multiple organizations and agencies. Most recently she was a speaker at the White House Office of Science and Technology Policy (OSTP) Summit on Equity and Excellence in STEMM, served as chair of the National Academy of Science, Engineering, and Medicine (NASEM) planning committee for the Disrupting Ableism and Advancing STEM series, co-chaired the NIH Advisory Committee to the Director (ACD) Subgroup on Individuals with Disabilities, and is a member of the Centers for Disease Control and Prevention (CDC) ACD Health Equity Workgroup. She received her doctoral and Master of Public Health degrees in epidemiology from the Johns Hopkins Bloomberg School of Public Health and completed a postdoctoral research fellowship at the National Institutes on Aging.

IGOR BADO, PHD, is an Assistant Professor in the Department of Oncological Sciences in the Tisch Cancer Institute at Mount Sinai. He works on tumor microenvironment and epigenetic mechanisms involved in breast cancer metastasis and therapeutic resistance. Before his appointment at Mount Sinai, Dr. Bado was subsequently a postdoctoral fellow and an instructor in the Dan L. Duncan Comprehensive Cancer Center at Baylor College of Medicine. He obtained his Ph.D. with Dr. Jan-Ake Gustafsson at the University of Houston, where he studied nuclear receptors in breast cancer. Dr. Bado's innovative research led to multiple publications that have impacted the field of metastasis. He has received several awards and serves as an ad hoc reviewer for multiple journals. Besides serving as an Editorial Board Member of FASEB BioAdvances, Dr. Bado remains an active member of the American Association for Cancer Research (AACR) and the Endocrine Society.

MARGARET R. BURCHINAL, PHD, is a Research Professor in the School of Education and Human Development at the University of Virginia. Her research examines the role early childhood education plays in children's learning and development. She served as the lead statistician for landmark early education studies, including the Abecedarian Project, the National Institute of Child Health and Human Development Study (NICHD) of Early Child and Youth Development, and the Family Life Project and evaluations of major early childhood policy initiatives. She has authored or coauthored over 150 peer-reviewed articles, served on review panels for the Maternal and Child Health Bureau, Institute of Education Sciences, and NICHD, as an associate editor for Child Development and Early Childhood Research Quarterly, and a board member for the William T. Grant Foundation and the American Educational Research Association's Research Board. Previously she served on the National Research Council Committee on Developmental Outcomes and Assessment for Young Children, Early Care and Education Workshop, Leading Educational Indicators Workshop, and committee on Policies and Programs to Reduce Intergenerational Poverty. Dr. Burchinal holds a Ph.D. in Quantitative Psychology from the University of North Carolina.

DARLA HENDERSON, PHD, is Director of Open Science and Research Integrity and Director of Publications at the Federation of American Societies for Experimental Biology (FASEB), the largest coalition of biomedical researchers in the U.S. She is the central business, operational, and thought leader for open science, research integrity, and related partnerships. Henderson has breadth of experience in scholarly communications, first as chemistry books and databases acquisitions editor at John Wiley & Sons, responsible for building the American Chemical Society's (ACS) first Editorial Development team, and later as ACS's inaugural head of open access programs. She developed and launched diamond and gold open access journals, a five-society-led preprint server, and a broad series of open science culture change programs. Works under her remit have been recognized by PROSE, PSP, and ACS-wide awards eleven times. Henderson received a Ph.D. in Biological Chemistry from Duke University. She currently sits on the American Society for Microbiology Publishing Committee.

VÉRONIQUE KIERMER, PHD, is the Chief Scientific Officer at PLOS, the Public Library of Science, where she oversees the editorial department and the development of services, products, and policies to promote open science. Before joining PLOS in 2015, she was Executive Editor and Director of Author and Reviewer Services for Nature Publishing Group where she managed editorial and research integrity policies across the Nature journals. She started her career in

publishing in 2004 as the founding Chief Editor of Nature Methods. Before working in publishing, she trained in molecular biology and worked on gene therapy projects in the biotechnology industry. She currently serves on the Board of Directors of Keystone Symposia and on the National Academies Strategic Council for Research Excellence, Integrity and Trust. Véronique obtained a PhD in molecular biology from the Université Libre de Bruxelles, Belgium in 1998 and was a postdoctoral fellow at the Gladstone Institutes, University of California, San Francisco. She has served on the 2019 National Academies planning committee on Enhancing Scientific Reproducibility in Biomedical Research through Transparent Reporting, and on the 2020 NIH Advisory Committee to the Director Working Group on Enhancing Rigor, Transparency, and Translatability in Animal Research. Véronique is also a former ORCID board member.

ADRIENE LIM, PHD, MLIS, is the Dean of Libraries at the University of Maryland, College Park (UMD) and founder and co-chair of UMD PACT, a cross-campus group convened to advance sustainable, equitable scholarly publishing, facilitate open research, and promote open education. She is also the designated lead for UMD's NASEM Higher Education Leadership Initiative for Open Scholarship (HELIOS) community of practice. Prior to joining the University of Maryland, Lim was Dean of Libraries and Philip H. Knight Chair at the University of Oregon, and served in leadership roles at Oakland University, Portland State University, and Wayne State University. In addition to being active in the Association of Research Libraries (ARL) and serving as Vice Chair for ARL's Advocacy and Public Policy Committee, Lim has served on the boards for ARL, the Center for Research Libraries, and the Academic Preservation Trust. Lim earned her Ph.D. in library and information science (LIS) from Simmons University and her master's degree in LIS from Wayne State University.

MILAGROS NORES, PHD, is the Co-Director for Research and Associate Research Professor at the National Institute for Early Education Research (NIEER). With a profound expertise in early childhood evaluation, informing data-driven policy and programming, cost and benefits of early interventions, evaluation design, equity, and English language learners, she has established herself as a leading researcher in the field of early care and education. Currently, Dr. Nores leads early care and education evaluations in various locations, including Colombia (South America), Philadelphia, and New Jersey. Her extensive work includes studying a high-quality early care and education program in Colombia, examining parental-child educational practices for minority children in the U.S., and evaluating Seattle's preschool program, the West Virginia preschool program, and the Early Care and Education system in Indiana, among others. Recently, she concluded her appointment to a special commission of the National Academy of Sciences, Engineering, and Medicine, which studied the Opportunity Gap for Young Children from Birth to Eight in the United States leading to a high profile national report. Dr. Nores' educational background is in early childhood attainment, the economics of education, and international and comparative education. Prior to her current position, she worked as a Postdoctoral Research Associate at the Taubman Center in Public Policy, Brown University, where she taught Education Policy in a Comparative Perspective and Economics of Public Policy. Dr. Nores serves as a consultant for various organizations on education projects in Latin America and Asia, and is an editor for the journal PLoS One. She is bilingual in Spanish and English.

PAMELA PADILLA, PHD, is vice president of research and innovation at the University of North Texas. She previously served as dean of the college of science, associate dean for research and

graduate studies, and associate vice president for research and innovation. As a professor of biological sciences, she is an active researcher and student mentor, whose research focuses on how environmental and dietary stress affects living organisms at the cellular, genetic, and molecular levels to model human health issues such as ischemia and diabetes. Dedicated to STEM diversity, she has served as president, treasurer, board member, and currently as past president for the Society for Advancement of Chicanos/Hispanics and Native Americans in Science (SACNAS). She has earned numerous awards including an NSF CAREER, the UNT Early Career Award for Research and Creativity, Howard Hughes Medical Institute and SACNAS Advanced Leadership Institute Fellow, Science magazine Prize for Inquiry-Based Instruction in 2012 and was a National Academy of Sciences Kavli Frontiers of Science Fellow. Padilla earned her Ph.D. in biology from the University of New Mexico, conducted her post-doctoral research at the Fred Hutchinson Cancer Research Center in Seattle, Washington. She previously served NASEM as a panelist on workforce development.

LORI SCHULTZ, MACC, is the Assistant Vice President, Research Intelligence at the University of Arizona, and has nearly 30 years of experience in research administration and compliance topics. She has worked with researchers throughout the grant lifecycle, from proposal to award to publication and closeout. Lori's current role is to leverage data on research to serve needs to comply with federal regulations and provide actionable insights to faculty and institutional leadership. Lori works with HSIs and TCUs to build capacity in research administration. She also is passionate in using data to reduce researcher burden around multiple compliance areas including data management, public access, and research security. Lori is a current member of the ORCID board, as well as the Executive Committee of the Federal Demonstration Partnership (FDP), which is convened by the National Academies' Government-University-Industry Research Roundtable. She has also advised National Academies staff on bibliometric and intelligence data.

BODO STERN, PHD, is Chief of Strategic Initiatives for the Howard Hughes Medical Institute (HHMI), where he works directly with HHMI's president and senior executive team to formulate and execute the organization's strategic initiatives and direction, with emphasis on enhancing HHMI's investment in research and science education. Stern joined HHMI in 2015 as a scientific officer. In 2016, he also assumed primary oversight of science operations for the organization, managing field staff who support HHMI investigators around the country. Before joining HHMI, Stern served for eight years as director of research affairs at the Harvard Center for Systems Biology, where he helped to manage the Bauer Fellows Program, a unique initiative that gives young scientists the opportunity to run independent research groups. He is an alternate board member for eLife and previously worked as a senior scientific editor at Cell. Stern earned a PhD in cell biology from University College, London, and an MA in biochemistry from the University of Tübingen, in Germany. His primary research explored how cells correct chromosome errors during cell division. Stern is a member of the National Academies' Roundtable on Aligning Incentives for Open Scholarship and sites on the steering committee for Declaration on Research Assessment (DORA).

CARRIE D. WOLINETZ, PHD, is Principal and Chair, Health & Bioscience Innovation Practice Group at Lewis-Burke Associates, LLC (LBA), a government relations firm specializing in advocating for the public policy interests of higher education and other scientific and research organizations. She came to LBA from having served as the Deputy Director for Health & Life

Sciences for the White House Office of Science and Technology Policy (OSTP), where she helped advance priority presidential efforts including pandemic preparedness, health systems & health equity, and accelerating innovation to patients. Prior to joining OSTP, she served as Acting Chief of Staff to the Director of the National Institutes of Health, as well as the NIH Associate Director for Science Policy, and Director of NIH's Office of Science Policy. During her time at NIH, Carrie led development of significant agency policies, including data management and sharing, clinical trials stewardship reform, and addressing sexual harassment, and stood up the Novel and Exceptional Technology & Research Advisory Council (NExTRAC). Before entering government service, Carrie worked for the Association of American Universities (AAU) as Deputy Vice President for Federal Relations. She also has served as President of United for Medical Research, and at the Federation of American Societies for Experimental Biology (FASEB) as Director of Scientific Affairs and Public Relations. Carrie has a Ph.D. in Animal Science from Penn State University, where her field of study was reproductive physiology, and a BS with Honors in Animal Science from Cornell University.

Enhancing Public Access to the Results of Research Supported by the Department of Health and Human Services: A Workshop

Panelist Bios

DAY 1 KEYNOTE

November 30, 2023, 9:15 – 9:45 AM ET

ADAM POLITIS, M.S., is the Senior Policy Advisor for Disability and Equity at the White House Office of Science and Technology Policy. He is on detail from the National Institutes of Health (NIH), where he is a Health Scientist Administrator in the Office of Behavioral and Social Sciences Research. Previously at NIH, Adam served as Chief of the Speech Language Pathology Section of the NIH Clinical Center, Special Assistant to the Deputy Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, Acting Principal Strategist for People with Disabilities in the NIH Office of Equity, Diversity, and Inclusion, and Program Manager for the NIH Common Fund's Bridge to Artificial Intelligence (Bridge2AI) Program. Before joining NIH, Adam worked extensively with people with disabilities in a variety of clinical, research, and administrative roles in healthcare and academia. As a disabled person who has worked with people with disabilities his entire career, Adam is acutely aware of the discrimination individuals with disabilities face and the urgent need to make the world a more equitable, inclusive, and accessible place for all.

SESSION I: VALUE COST OF PUBLIC ACCESS: POLICIES, MODELS, OPPORTUNITIES

November 30, 2023, 10:50 AM – 12:30 PM ET

STEFANO BERTUZZI, PH.D., M.P.H., is the Chief Executive Officer of the American Society for Microbiology (ASM). Bertuzzi has wide experience in science policy and scholarly publishing. Prior to joining as the CEO of ASM, Bertuzzi was the Executive Director at the American Society for Cell Biology for 3 years and was a senior scientific executive at the National Institutes of Health (NIH), where he served as Director of the Office of Science Policy, Planning, and Communications at the National Institute of Mental Health and as a science policy advisor to the NIH Director, Dr. Elias Zerhouni. He also served as Director of Neurogenetic Laboratory in the Dulbecco Institute Telethon Scientist in Milan, Italy. Throughout his career, Bertuzzi led the U.S. government negotiations with the European Union (EU) to achieve funding reciprocity between the NIH and the EU. He also worked with the Obama White House to develop an information system to capture the benefits of scientific investments during the Great Recession of 2008. He is one of the leaders who spearheaded the Declaration on Research Assessment (DORA) to fight the misuse of journal impact factor metric. He contributed to the NIH revision of the peer

review system and to the development of the key public access policy for NIH funded research, which started the Open Access movement in scholarly publishing. Bertuzzi received his Ph.D. in Molecular Biotechnology from the Università Cattolica del Sacro Cuore of Milan, Italy with a fellowship in the Microbiology Institute, and his Master's in Public Health (MPH) from the Bloomberg School of Public Health at the Johns Hopkins University in Baltimore with a specialization in health policy.

KIMBERLEY BUGG, PH.D., is the Associate Library Director at AUC Woodruff Library. Prior to this position she was Chief of Researcher & Reference Services at the Library of Congress. She holds a PhD in Library Science, Managerial Leadership from Simmons. She chairs the Reference and Information Services Section of IFLA and a member of the ALA Committee on Research and Statistics.

HEATHER JOSEPH., M.A., is the Executive Director of the Scholarly Publishing and Academic Resources Coalition (SPARC), an international coalition of academic and research libraries promoting the open sharing of knowledge. Under her stewardship, SPARC has become the leading advocacy organization for open and equitable global systems of research and education. Based in Washington, D.C., she leads SPARC's strategy and policy work, which has contributed to the establishment of open access and open science policies around the world. She regularly provides input to public research funders through her service on a variety of national boards, ranging from the U.S. Department of Commerce Data Advisory Council to the NIST Research Data Framework Steering Committee, as well as to private foundations and philanthropies through her work with the Open Research Funders Group (ORFG). She is a widely respected expert on national and international open research policies, practices, and implementation strategies and has worked on initiatives and consultations promoting the open sharing of research from the United Nations to the World Bank. Prior to joining SPARC, Heather spent 15 years as a publisher in both commercial and not-for-profit journal publishing organizations. She is deeply engaged in the global knowledge-sharing community and serves on the Board of Directors of organizations ranging from the Arcadia Fund to Public Resource to Our Research. She is a frequent speaker and writer on knowledge sharing and higher education issues and open access to research.

GÜNTER WAIBEL., M.A., is the Associate Vice Provost and Executive Director at the California Digital Library (CDL), University of California Office of the President. As one of the world's largest digital libraries, CDL provides transformative digital library services that amplify the impact of the libraries, scholarship, and resources of the University of California. He co-directs the UC's Office of Scholarly Communications, is a member of UC's publisher negotiation team for open access agreements and was an invited participant to the White House Office of Science and Technology Policy (OSTP) multistakeholder conversations about future paths for scholarly communications (2020). He serves on the boards of UC Press and Dryad, the German Project DEAL+Wiley Advisory Board, and co-chaired the international 15th Berlin Open Access Conference (2021). While Director of the Digitization Program Office at the Smithsonian Institution (2010-2016), Günter was a finalist for the 2014 Samuel J Heyman Service to America Medal.

JESSICA SEBEOK, **J.D.**, became Wiley's Vice President for Global Government Partnerships and Public Policy in March 2022. Jessica came to Wiley from Johns Hopkins University, where she served as Director of Policy and Research in President Ron Daniels' Office. At Johns Hopkins, Jessica successfully helmed numerous projects, including creating the first permanent institution-wide shared governance body, advancing the university's comprehensive policy

initiative, and supporting new DEI and access endeavors. Prior to her time at Johns Hopkins, Jessica worked for seven years as Deputy Vice President for Federal Relations and Counsel for Policy at the Association of American Universities (AAU), a coalition of America's leading research universities, where she led on matters related to intellectual property, information technology, technology transfer, and tax. In addition, as AAU's policy counsel, Jessica worked closely with AAU's General Counsel Committee on complex legal issues facing research universities, including spearheading AAU's efforts on amicus briefs in a wide range of areas, such as immigration, admissions diversity, and intellectual property. She also made significant contributions in other AAU focus areas, ranging from campus speech and academic freedom and open and public access issues to Title IX, antitrust, and labor relations. Before joining AAU in 2014, Jessica served as Counsel for Policy and International Affairs in the U.S. Copyright Office; as Special Assistant to the Assistant Secretary for Educational and Cultural Affairs in the U.S. Department of State; as Assistant General Counsel of Yale University; and as Associate Counsel of Ithaka, a non-profit organization with a mission to make higher education and access to knowledge more affordable, improve outcomes for students and researchers, and to preserve knowledge for future generations. Jessica is a graduate of the Yale Law School and a member of the New York and D.C. bars. She received her master's degree in modern history from Oxford University, where she was a Marshall Scholar. She earned her undergraduate degree in history, with highest honors and as a member of Phi Beta Kappa, from the University of Chicago. Jessica is a member of the board of directors of the Association of Marshall Scholars and volunteers as an election judge in Montgomery County, Maryland. She originally hails from Bloomington, Indiana.

SESSION II: BEYOND EMBARGOS: ACCESSIBILITY CONSIDERATIONS FOR BUILDING NEW PUBLIC ACCESS POLICIES

November 30, 2023, 1:30 PM – 3:00 PM ET

YVONNE LEWIS, B.S., B.B.A., is the Co-Director at Healthy Flint Research Coordinating Center. Yvonne also Chairs the Board of Directors of the Genesee Community Health Center, Federally Qualified Health Center, as well as a member of other community-based organization advisory councils. Yvonne assisted in the development of and moderated the University of Michigan-Flint, Water Crisis Course. The Water Crisis Course focused on the issues of the Flint Water Crisis and provided a platform for the voice of community to be heard. She was responsible for chairing several community-based efforts at both the state and national level that had significant impact on community engagement. These included: the Michigan Multicultural Network, engaging the 5 major ethnic groups (African American, Latino/Hispanic, Arab/Chaldean, Native American and Asian American) in an organized statewide tobacco campaign that focused on prevention programs for youth; the 5 county cancer initiative, Improving Cancer Outcomes of African Americans in Michigan; developing the process for organizing the National Community Committee for the Centers for Disease Control and Prevention, Prevention Research Centers, serving as a founding member and initial chair; she was a founding member of the American Public Health Association, Caucus for Public Health and the Faith Community.

LISA MCCORKELL, M.P.P., is a Long COVID patient who is a cofounder, team lead, and researcher with the Patient-Led Research Collaborative. She is also currently a CalFresh policy analyst at the California Department of Social Services. Her past projects and roles have involved analyzing data and developing policy recommendations in the fields of digital equity, economic justice, housing, and health equity. She is an author of several articles on labor and

employment issues and a study on stable scheduling for hourly retail workers. She received a Masters in Public Policy from University of California, Berkeley, and a Bachelor of Arts in Political Science from University of California, Los Angeles. She is a resident of Oakland, California.

YVETTE PEARSON, PH.D., P.E., F.ASCE., joined The University of Texas at Dallas as Vice President for Diversity, Equity and Inclusion in 2021. A Fellow of the American Society of Civil Engineers (ASCE) and the American Society for Engineering Education (ASEE), Pearson is recognized globally for nearly 30 years in higher education, particularly for her work to advance sustainability, justice, equity, diversity, and inclusion (JEDI) in engineering education and practice. Her most recent work includes research-to-practice on equity in faculty hiring; studying the efficacy of Process-Driven Math, a novel method of teaching and assessing mathematics for students with disabilities; and investigating how multi-team systems converge across disciplinary and cultural boundaries to advance their common goals toward advanced degrees and careers in biotechnology, digital twinning and sustainability and resilience. Her universitybased and consulting efforts have led to over \$40M in funding for initiatives to support JEDI in STEM and changes to policies and practices of global engineering organizations. Pearson is a registered Professional Engineer, an ENVISION® Sustainability Professional and a Commissioner on ABET's Engineering Accreditation Commission. Among her awards and honors are ABET's Claire L. Felbinger Award for Diversity and Inclusion, ASCE's Professional Practice Ethics and Leadership Award, the Society of Women Engineers' Distinguished Engineering Educator Award, and ASCE's President's Medal. Her podcast, Engineering Change, has audiences in over 80 countries. Her book, Making a Difference: How Being Your Best Self Can Influence, Inspire, and Impel Change, chronicles her journey and her work's focus on "making sure other 'Yvettes' don't fall through the cracks."

JENNY PENG, **B.A.**, is a Senior Publisher at Oxford University Press. She is responsible for driving forward OUP's strategy and engagement with open access (OA) and open research in the US, including supporting the expansion of OUP's OA journals program through the acquisition and launch of new titles. Manages and develops a select portfolio of OA journals on behalf of academic society partners. Represents OUP to industry organizations such as CHORUS and C4DISC. She previously worked at CHORUS on the Board of Directors and Wiley as a Senior Editor.

JOHN-ROSS RIZZO, M.D., M.S.C.I., is an American physician-scientist known for his significant contributions to the field of healthcare and rehabilitation. He holds the prestigious Melamid Professorship in Rehabilitation (Disability) Medicine at NYU Langone Medical Center. Dr. Rizzo has made remarkable strides in the areas of disability inclusion, innovation, and equity within the medical community. At NYU Langone Medical Center, Dr. Rizzo serves as the first Health System Director of Disability Inclusion, a role that reflects his commitment to promoting accessibility and inclusivity within healthcare. Additionally, he holds the position of Vice Chair of Innovation and Equity for the Department of Physical Medicine and Rehabilitation at the Rusk Institute of Rehabilitation Medicine, Dr. Rizzo's impact extends beyond traditional medical boundaries, as he holds cross-appointments in multiple departments. His affiliations include the Department of Neurology, where he contributes to the advancement of neurological sciences. as well as the Departments of Biomedical & Mechanical and Aerospace Engineering at New York University Tandon School of Engineering. Within Tandon, he also contributes to the Electrical and Computer Engineering Department and plays a vital role as the Associate Director of Healthcare for the NYU Wireless Center. Dr. Rizzo has published 125 peer-reviewed publications, contributed to 12 textbooks, and co-authored many conference proceedings. Dr. Rizzo is the founding director of the Visuomotor Integration Laboratory (VMIL). n addition to his academic and research pursuits, Dr. Rizzo was appointed in 2023 by Governor Kathy Hochul to

the Board of Directors of the The Metropolitan Transportation Authority (MTA).^[13] This role underscores his commitment to fostering accessibility and inclusivity within the transportation sector, ensuring that individuals with disabilities have equitable access to public transportation systems.

DAY 2 KEYNOTE

December 1, 2023, 9:00 AM - 9:30 AM ET

PHILIP SHARP, PH.D., an Institute Professor emeritus at MIT, is a member of the Department of Biology and the Koch Institute for Integrative Cancer Research. He joined the Center for Cancer Research in 1974, serving as director from 1985 to 1991 before becoming head of the Department of Biology for eight years. He was founding director of the McGovern Institute from 2000 to 2004. Sharp has authored over 500 papers. He is an elected member of the National Academy of Sciences, the National Academy of Medicine, the American Academy of Arts and Sciences, the American Philosophical Society, and the Royal Society, UK. Among his many awards are the Gairdner Foundation International Award, the Lasker Basic Medical Research Award, and the National Medal of Science. His long list of service includes the presidency of the AAAS and Chair of the Scientific Advisory Committee, SU2C Project, AACR. A native of Kentucky, Sharp earned a BA from Union College, Barbourville, KY, and a PhD in chemistry from the University of Illinois, Urbana-Champaign in 1969. His work studying the molecular biology of gene expression relevant to cancer and the mechanisms of RNA splicing earned Sharp the 1993 Nobel Prize in Physiology or Medicine. Sharp is a member of the board of directors of the Whitehead and Broad Institutes, the Gairdner Foundation (Canada), and chairs the advisory boards of Fidelity Biosciences Group, SU2C/AACR Scientific Review Committee, ReMedy/IMol Institute (Poland), the MIT Museum, and the Jameel Clinic at MIT. Sharp is a cofounder of Biogen and of Alnylam Pharmaceuticals Inc. He is chairman of the scientific advisory board and member of the board of directors, Alnylam Pharmaceuticals; advisor and investor, Longwood and Polaris Venture Funds; member of the board of directors, Vir Biotechnology; and member of the scientific advisory board, Danahers, Dewpoint Therapeutics and Skyhawk Therapeutics.

SESSION IV: RESEARCH RESULTS: FINDABILITY, TRANSPARENCY, AND ACCESSIBILITY

December 1, 2023, 10:00 AM - 11:45 AM ET

ROGER C. SCHONFELD., M.S., is the Vice President of organizational strategy for ITHAKA, the not-for-profit organization that operates JSTOR and Portico, and is responsible for Ithaka S+R's libraries, scholarly communication, and museums program. Roger and the team of Ithaka S+R's methodological and subject matter experts that comprise the program conduct research and provide advisory services to drive evidence-based innovation and leadership to foster research, learning, and preservation. This has included extensive survey and qualitative research of faculty members and students, as well as leaders such as senior research officers, presidents and provosts, and the directors of libraries and museums. Additional leadership and policy projects have sought to bolster organizational strategy and leadership, diversity and community engagement, and collections management and preservation. The team provides strategic guidance and advisory services for software companies, publishers and other content providers, and academic libraries on the transformation of scholarly communications and the research workflow. Several additional areas of current emphasis include research data services, student basic needs, and higher education in prisons. Roger currently serves as a board member for the Center for Research Libraries. Previously, he has served on the NSF Blue

Ribbon Task Force for Sustainable Digital Preservation and Access and NISO's Open Discovery Initiative. Roger has testified before the US House of Representatives on government publishing, advocating for strong approaches to digital preservation. In addition to authoring dozens of research reports, articles, and briefing papers, Roger blogs regularly at the Scholarly Kitchen and tweets at @rschon. With Deanna Marcum, he wrote Along Came Google: A History of Library Digitization (Princeton University Press, 2021), examining structural impediments to digital strategy and the role of an outside catalyst in fostering digitization among research libraries. He also wrote JSTOR: A History (Princeton, 2003), focusing on the development of a sustainable not-for-profit initiative for the digitization and preservation of scholarly texts. Roger was previously a research associate at The Andrew W. Mellon Foundation. There, he collaborated on The Game of Life: College Sports and Academic Values with James Shulman and William G. Bowen (Princeton, 2000). He was an Association of Research Libraries Leadership Fellow and received degrees in library and information science from Syracuse University and in English Literature from Yale University.

CHRIS SCHILLUM.,M.ENG., joined ORCID as its second Executive Director in 2021. With more than 25 years of experience in product and platform development in scholarly communications and STM publishing, he brings to ORCID his deep expertise in product and technology strategy in a time of rapidly changing business models, technological advances, and increasing expectations from users and customers. He previously held a number of leadership positions at Elsevier, has served on the boards of Crossref, ORCID, the International DOI Foundation and the National Information Standards Organization, and has lead several industry-wide collaborative projects including SeamlessAccess and GetFTR. Chris holds a Masters in Electronic Systems Engineering from the University of York in the UK, and is based in New York City in the United States.

JAMIE WITTENBERG, ED.D., M.L.I.S., is the primary digital and technology strategist at the University of Colorado Boulder Libraries. Her research includes work on pedagogical models for data services, automating open access policy implementation, publishing digital 3D objects and building infrastructure to support shared big data resources at research libraries.

JOSEPH YRACHETA, M.S, is the Executive Director of Native Biodata Consortium. He places an emphasis an emphasis on American Indian and Latin Indigenous Public Health and Bioethics of research in Indigenous communities to highlight and transform the socio-economic injustice and health disparity in the Amerindigenous of the Western Hemisphere and Polynesia. Yracheta has taught STEM courses at various reservation high schools in South Dakota. He graduated from Loyola University-Chicago in 1993 with a B.S. in Psychology.

BREAKOUT DISCUSSION MODERATORS

SVASTI HARICHARAN, PH.D., is an Assistant Professor at Sanford Burnham Prebys Medical Discovery Institute. Her areas of expertise include cancer research, molecular biology, and genomics. She obtained her Ph.D. from Baylor College of Medicine and completed several years of postdoctoral training at MD Anderson Cancer Center.

IHEOMA IRUKA, PH.D., M.A., is a Research Professor of Public Policy, and the Founding Director of the Equity Research Action Coalition at Frank Porter Graham Child Development Institute at UNC-CH. Prior to rejoining Carolina, she served as Chief Research Innovation Officer and Director of The Center for Early Education Research and Evaluation at HighScope Educational Research Foundation. She was also at the Buffett Early Childhood Institute at the University of Nebraska, and the FPG Child

Development Institute. Dr. Iruka is engaged in projects and initiatives focused on how evidence-informed policies, systems, and practices in early education can support the optimal development and experiences of children from low-income and ethnic minority households, such as through family engagement and support, quality rating and improvement systems, and early care and education systems and programs. Dr. Iruka has been engaged in addressing how best to ensure excellence for young diverse learners, especially black children, such as through development of a classroom observation measure, examination of non-traditional pedagogical approaches, public policies, and publications geared towards early education practitioners and policymakers. Dr. Iruka has served or serves on numerous national boards and committees, including the Brady Education Foundation and the National Academies of Sciences, Engineering, and Medicine committees on Supporting Parents of Young Children, and Applying Neurobiological and Socio-behavioral Sciences from Prenatal through Early Childhood Development: A Health Equity Approach. Dr. Iruka has a B.A. in psychology from Temple University, a M.A. in psychology from Boston University, and earned her Ph.D. in applied developmental psychology from the University of Miami, Florida.

JULIA MAUES, diagnosed with breast cancer while pregnant in 2013, Julia received treatment while still carrying her son. Shortly after delivering a healthy baby boy, she found out that the cancer had already spread outside her breast to other parts of her body. After many treatment setbacks, her cancer began to respond to treatment, and she turned this tragic reality into a drive to improve the lives of people living with this disease. Julia's main focus is working with researchers, clinicians, and other stakeholders to ensure research is patient-centered, innovative, accessible, and inclusive. She is a co-founder of GRASP – Guiding Researchers and Advocates to Scientific Partnerships, – an organization that connects and fosters collaborations between researchers and patient advocates. Julia is also the lead of the Patient-Centered Dosing Initiative, a patient-led movement building a framework to help physicians and patients select the optimal dosage for the patient based upon their unique physical, circumstantial, and psychological factors. Julia is a member of the Metastatic Breast Cancer Alliance, a Komen Advocate in Science, a member of SABCS 2023's conference planning committee, a DoD Congressionally Directed Breast Cancer Research Program reviewer, an ASCO guidelines panelist, and a founding member of the #InclusionPledge to end disparities in breast cancer for Black women.

JESSICA POLKA, PH.D., serves as Executive Director of ASAPbio, a researcher-driven nonprofit organization working to promote innovation and transparency in life sciences publishing in areas such as preprinting and open peer review. Prior to this, she performed postdoctoral research in the department of Systems Biology at Harvard Medical School following a PhD in Biochemistry & Cell Biology from UCSF. Jessica is also a Plan S Ambassador, an affiliate of the Knowledge Futures Group, and a steering committee member of Rescuing Biomedical Research.

August 25, 2022

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: Dr. Alondra Nelson Anda Nelson

Deputy Assistant to the President and Deputy Director for Science and Society

Performing the Duties of Director

Office of Science and Technology Policy (OSTP)

SUBJECT: Ensuring Free, Immediate, and Equitable Access to Federally Funded Research

This memorandum provides policy guidance to federal agencies with research and development expenditures on updating their public access policies. In accordance with this memorandum, OSTP recommends that federal agencies, to the extent consistent with applicable law:

- 1. Update their public access policies as soon as possible, and no later than December 31st, 2025, to make publications and their supporting data resulting from federally funded research publicly accessible without an embargo on their free and public release;
- 2. Establish transparent procedures that ensure scientific and research integrity is maintained in public access policies; and,
- 3. Coordinate with OSTP to ensure equitable delivery of federally funded research results and data.

1. Background and Policy Principles

Since February 2013, federal public access policy has been guided by the *Memorandum on Increasing Access to the Results of Federally Funded Research* (2013 Memorandum). Issued by the White House Office of Science and Technology Policy (OSTP), the 2013 Memorandum directed all federal departments and agencies (agencies) with more than \$100 million in annual research and development expenditures to develop a plan to support increased public access to the results of federally funded research, with specific focus on access to scholarly publications and digital data resulting from such research.

Nearly ten years later, every federal agency subject to the 2013 Memorandum has developed and implemented a public access policy in accordance with its guidance.² As a result, the American public has experienced great benefits: more than 8 million scholarly publications have become accessible to the public. Over 3 million people read these articles for free every day. The 2013 federal public access policy set the stage for a paradigm shift away from research silos and

https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf ² See the 2021 OSTP Public Access Congressional Report: https://www.whitehouse.gov/wp-content/uploads/2022/02/2021-Public-Access-Congressional-Report OSTP.pdf

¹ See the 2013 Memorandum:

toward a scientific culture that values collaboration and data sharing. The 2013 Memorandum helped to reshape the landscape for data and research by sharing results freely and openly with the public and the scientific community.

Building on these important advances, the policy guidance laid out in the 2013 Memorandum can be improved to achieve delivery of federally funded research results and data to *all* of America. Years of public feedback have indicated that the primary limitation of the 2013 Memorandum is the optional 12-month embargo from public access of any publication resulting from federally funded research. This provision has limited immediate access of federally funded research results to only those able to pay for it or who have privileged access through libraries or other institutions. Financial means and privileged access must never be the pre-requisites to realizing the benefits of federally funded research that the American public deserves.

A federal public access policy consistent with our values of equal opportunity must allow for broad and expeditious sharing of federally funded research—and must allow all Americans to benefit from the returns on our research and development investments without delay. Upholding these core U.S. principles in our public access policy also strengthens our ability to be a critical leader and partner on issues of open science around the world. The U.S. is committed to the ideas that openness in science is fundamental, security is essential, and freedom and integrity are crucial.³ Improving public access policies across the U.S. government to promote the rapid sharing of federally funded research data with appropriate protections and accountability measures will allow for greater validity of research results and more equitable access to data resources aligned with these ideals. To promote equity and advance the work of restoring the public's trust in Government science, and to advance American scientific leadership, now is the time to amend federal policy to deliver immediate public access to federally funded research.

2. Learning from the Lessons of COVID-19

When federally funded research is available to the public, it can improve lives, provide policymakers with important evidence with which to make critical decisions, accelerate the rates of discovery and translation, and drive more equitable outcomes across every sector of society.

Americans were offered a window into the great benefits of immediate public access to federally funded research at the outset of the COVID-19 pandemic. In the wake of the public health crisis, government, industry, and scientists voluntarily worked together to adopt an immediate public access policy, which yielded powerful results: research and data flowed effectively, new accessible insights super-charged the rate of discovery, and translation of science soared. The shift in practice during COVID-19 demonstrated how delivering immediate public access to federally funded research publications and data can provide near real-time returns on American taxpayer investments in science and technology.

Immediate public access to COVID-19 research is a powerful case study on the benefits of delivering research results and data rapidly to the people. The insights of new and cutting-edge research stemming from the support of federal agencies should be immediately available—not

³ See: https://www.whitehouse.gov/ostp/news-updates/2022/06/21/readout-of-dr-alondra-nelsons-participation-in-the-g7-science-ministerial-progress-toward-a-more-open-and-equitable-world/

just in moments of crisis, but in every moment. Not only to fight a pandemic, but to advance all areas of study, including urgent issues such as cancer, clean energy, economic disparities, and climate change. American investment in such research is essential to the health, economic prosperity, and well-being of the Nation. There should be no delay between taxpayers and the returns on their investments in research.

3. Updates to Policy Guidance on Increasing Equitable Access to Federally Funded Research Results

To meet these core commitments, OSTP is updating policy guidance to promote improved public access to federally funded research results. In accordance with the provisions listed in Section 3, Federal agencies should develop new, or update existing, public access plans as soon as possible, and submit them to OSTP and the Office of Management and Budget (OMB) no later than:

- (1) 180 days after the date of this memorandum for federal agencies with more than \$100 million in annual research and development (R&D) expenditures; and
- (2) 360 days after the date of this memorandum for federal agencies with \$100 million *or less* in annual R&D expenditures. This extended deadline is designed to accommodate a longer lead time for federal agencies who were not subject to the 2013 Memorandum.

Agencies should complete and publish full policy development for plans implementing provisions in Section 3 by December 31st, 2024, with an effective date no later than one year after the publication of the agency plan. The timeline is designed to accommodate the items identified in Section 5 of this memorandum, including interagency collaboration, public engagement with those impacted by the change in policy, and OSTP feedback on agency drafts.

a) Peer Reviewed Scholarly Publications:

Federal agencies should update or develop new public access plans for ensuring, as appropriate and consistent with applicable law, that all peer-reviewed scholarly publications⁴ 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.

Plans should describe:

- i. How peer-reviewed scholarly publications should be made publicly accessible;
- ii. How to maximize equitable reach of public access to peer-reviewed scholarly publications, including by providing free online access to peer-reviewed scholarly

⁴ Such scholarly publications always include peer-reviewed research articles or final manuscripts published in scholarly journals, and may include peer-reviewed book chapters, editorials, and peer-reviewed conference proceedings published in other scholarly outlets that result from federally funded research.

- publications in formats that allow for machine-readability⁵ and enabling broad accessibility through assistive devices; and,
- iii. 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.

b) Scientific Data

- i. Scientific data⁶ underlying peer-reviewed scholarly publications resulting from federally funded research should be made freely available and publicly accessible by default at the time of publication, unless subject to limitations as described in Section 3(c)(i) and should be subject to federal agency guidelines for researcher responsibilities regarding data management and sharing plans, consistent with Section 3(c) of this memorandum.
- ii. Federal agencies should develop approaches and timelines for sharing other federally funded scientific data that are not associated with peer-reviewed scholarly publications.
- iii. Federal agencies should also provide guidance to researchers that ensures the digital repositories used align, to the extent practicable, with the National Science and Technology Council document entitled "Desirable Characteristics of Data Repositories for Federally Funded Research."
- iv. Federal agency research: Agency public access plans and policies should clarify that federal researchers must follow federal laws and OMB policies that govern federal agencies' information management practices and protect certain types of data, to the extent that the scientific data created by, collected by, under the control or direction of, or maintained by the federal researchers is subject to those laws and policies.

⁵ "Machine readability" refers to a format that can be easily processed by a computer without human intervention while ensuring no semantic meaning is lost (such as the <u>NISO Z39.96-2015 JATS XML</u> standard currently used by PubMed Central).

⁶ For the purposes of this memorandum, "scientific data" include the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings. Such scientific data do not include laboratory notebooks, preliminary analyses, case report forms, drafts of scientific papers, plans for future research, peer-reviews, communications with colleagues, or physical objects and materials, such as laboratory specimens, artifacts, or field notes. The definition of "scientific data" is similar to but broader than the term "research data" defined by 2 CFR 200.315 (e) and 45 CFR 75.322 (e).

⁷ The term "extent practicable" is used to signal that suitable repositories for all types of data may not be available within the timeframe provided.

⁸ See the 2022 NSTC Subcommittee on Open Science guidance: https://doi.org/10.5479/10088/113528

⁹ For instance, the Paperwork Reduction Act, E-Government Act, Freedom of Information Act, Federal Information Security Management Act, Privacy Act, Health Information Technology for Economic and Clinical Health Act, Information Quality Act, Foundations for Evidence-Based Policymaking Act, Confidential Information Protection and Statistical Efficiency Act, Federal Policy for the Protection of Human Subjects, Federal Records Act, and OMB guidance under OMB M-13-13 and subsequent open data policies (e.g., those to be promulgated under the -OPEN Government Data Act and Pub. L. No. 115-435), OMB Circular A-130, and other laws and policies that require federal agencies to protect trade secrets, confidential commercial information, personally identifiable information, and other information which is protected under law or policy. See also, language from OMB M-19-15 with respect to maximizing the amount of data that can be made public using cutting-edge technologies to provide secure access to confidential data while reducing the risk of re-identification.

- c) Public access plans should outline the policies that federal agencies will use to establish researcher responsibilities on how federally funded scientific data will be managed and shared, including:
 - i) Details describing any potential legal, privacy, ethical, technical, intellectual property, or security limitations, ¹⁰ and/or any other potential restrictions or limitations on data access, use, and disclosure, including those defined in terms and conditions of funding agreement or award or that convey from a data use agreement or stipulations of an Institutional Review Board;
 - ii) Plans to maximize appropriate¹¹ sharing of the federally funded scientific data identified in Section 3(a) of this memorandum, such as providing risk-mitigated opportunities for limited data access;¹² and,
 - iii) The specific online digital repository or repositories where the researcher expects to deposit their relevant data, consistent with the federal agency's guidelines.
- d) In consultation with OMB, federal agencies should allow researchers to include reasonable publication costs and costs associated with submission, curation, management of data, and special handling instructions as allowable expenses in all research budgets.
- e) Federal agencies should report to OSTP, when requested, on the status of their public access plans and policy implementation, including the number of all scholarly publications funded by the federal agencies and any other relevant statistics collected by the agency.

4. Ensuring Scientific and Research Integrity in Agency Public Access Policies

Public access policies that deliver transparent, open, secure, and free communication of federally funded research and activities in an expeditious manner are an important tool to uphold scientific ¹³ and research ¹⁴ integrity. Federal agencies should take steps to ensure that public access policies support scientific and research integrity by transparently communicating to the public critical information, including that which is related to the authorship, funding, affiliations, and development status of federally funded research. The public should be able to identify which federal agencies support given investments in science, the scientists who conduct that research, and the extent to which peer-review was conducted. These actions support the value that maintaining and restoring public trust in science requires openness, security, freedom, and integrity. **Federal agencies should take actions to ensure that these elements of scientific and**

¹¹ The term "appropriate" is used to signal that public access to federally funded research results and data should be maximized in a manner that protects confidentiality, privacy, business confidential information, and security, avoids negative impact on intellectual property rights, innovation, program and operational improvements, and U.S. competitiveness, and preserves the balance between the relative value of long-term preservation and access and the associated cost and administrative burden.

¹⁰ Including national security concerns.

¹² For example, secure research data centers, data use agreements, perturbing identifiable information, or excluding sensitive variables.

¹³ See the 2022 NSTC Report "Protecting the Integrity of Government Science": https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting the Integrity of Government Science.pdf

¹⁴ See the 2022 NSTC "Guidance for Implementing National Security Presidential Memorandum 33 (NSPM-33) on National Security Strategy for United States Government-Supported Research and Development" (NSPM-33 Implementation Guidance): https://www.whitehouse.gov/wp-content/uploads/2022/01/010422-NSPM-33-Implementation-Guidance.pdf

research integrity are in place in order to strengthen public trust in federally funded science.

To achieve these goals, the following steps should be taken by federal agencies, as appropriate and consistent with their missions. By December 31st, 2024, federal agencies should submit to OSTP and OMB a second update to their public access plans specifying approaches taken to implement the provisions in this Section 4. Agencies should complete and publish full policy development for plans implementing these provisions by December 31st, 2026, with an effective date no later than one year after the publication of the agency plan. Federal agencies should, consistent with applicable law:

- a) Collect and make publicly available appropriate metadata¹⁵ associated with scholarly publications and data resulting from federally funded research, to the extent possible at the time of deposit in a public access repository. Such metadata should include at minimum:
 - i) all author and co-author names, affiliations, and sources of funding, referencing digital persistent identifiers, ¹⁶ as appropriate;
 - ii) the date of publication; and,
 - iii) a unique digital persistent identifier for the research output;
- b) Instruct federally funded researchers to obtain a digital persistent identifier that meets the common/core standards of a digital persistent identifier service defined in the NSPM-33 Implementation Guidance, ¹⁷ include it in published research outputs when available, and provide federal agencies with the metadata associated with all published research outputs they produce, consistent with the law, privacy, and security considerations.
- c) Assign unique digital persistent identifiers ¹⁸ to all scientific research and development awards ¹⁹ and intramural research protocols that have appropriate metadata linking the funding agency and their awardees through their digital persistent identifiers.

5. Public Access Plan Coordination Among Federal Agencies

Coordination among federal science agencies²⁰ is critical for the success of delivering America's research to the public. The National Science and Technology Council Subcommittee on Open Science was chartered to facilitate such coordination between federal science agencies in conjunction with OSTP. Concurrent with and following the development of agency plans described Section 3 and Section 4 of this memorandum, the Subcommittee on Open Science will:

¹⁵ For the purposes of this memorandum, metadata include information conveyed with the publications and data upon deposit in a public access repository to ensure proper attribution and versioning.

¹⁶ See the NSPM-33 Implementation Guidance for definition: A digital identifier that is globally unique, persistent, machine resolvable and processable, and has an associated metadata schema.

¹⁷ See Point 5 in the Digital Persistent Identifiers section of the NSPM-33 Implementation Guidance

¹⁸ As a complement to implementation of the Federal Funding and Accountability Transparency Act

¹⁹ Consistent with NSPM-33 Implementation Guidance, a research and development award refers to support provided to an individual or entity by a federal research agency to carry out research and development activities, which may include support in the form of a grant, contract, cooperative agreement, or other such transaction.

²⁰ Federal science agencies here are defined as any federal agency with an annual extramural research expenditure of over \$100,000,000 per 42 USC § 6623(f).

- a) coordinate between federal science agencies to enhance efficiency and reduce redundancy in public access plans and policies, including as it relates to digital repository access;
- b) improve awareness of federally funded research results by all potential users and communities;
- c) consider measures to reduce inequities in publishing of, and access to, federally funded research and data, especially among individuals from underserved backgrounds and those who are early in their careers;
- d) develop procedures and practices to reduce the burden on federally funded researchers in complying with public access requirements;
- e) recommend standard consistent benchmarks and metrics to monitor and assess implementation and iterative improvement of public access policies over time;
- f) improve monitoring and encourage compliance with public access policies and plans;
- g) coordinate engagement with stakeholders, including but not limited to publishers, libraries, museums, professional societies, researchers, and other interested non-governmental parties on federal agency public access efforts;
- h) develop guidance on desirable characteristics of, and best practices for sharing in, online digital publication repositories;
- i) identify the key parameters that must be considered in planning how to maximize appropriate sharing of federally funded scientific data that have not been used to support scholarly publications; and,
- j) develop strategies to make federally funded publications, data, and other such research outputs and their metadata are findable, accessible, interoperable, and re-useable, to the American public and the scientific community in an equitable and secure manner.

6. General Provisions

Nothing in this memorandum shall be construed to impair or otherwise affect authority granted by law to an executive department, agency, or the head thereof; or functions of the Director of OMB.

Nothing in this memorandum, or the agency plans developed pursuant to it, shall be construed to authorize or require federal agencies to undermine any right under the provisions of Title 17, 18, or 35 of the United States Code, or to violate the international obligations of the United States.

Provisions of this memorandum should be implemented to the extent feasible and consistent with applicable law, privacy, indigenous rights, foreign policy and international development objectives, and national security considerations. Any provisions of the 2013 Memorandum that are not updated or superseded by this new policy guidance are maintained. Provisions of this memorandum should be implemented consistent with law, OMB Guidance, and the Uniform Guidance 2 CFR 200.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States; its departments, agencies, or entities; its officers, employees, or agents; or any other person.

7. Taking Next Steps Together

The extraordinary progress in open science and public access led by federal agencies has laid the foundation for these critical next steps. As we move forward together in implementing these critical actions, we will do so in partnership and with a shared vision for an ever-stronger and more equitable federal scientific ecosystem.

Immediate public access to America's research publications and data will serve our collective goals of accelerating scientific discovery, strengthening translation and policymaking, and lowering the barriers of access to science for all of America.

As we move forward, OSTP will establish a process for supporting the implementation of these updates. We are grateful to you and your dedicated staff for your valued contributions to strengthening public access and supporting the advancement of health, safety, security, and equity.

Strategic Plan

Published January 2022

STRATEGIC GOAL 1

Advance equity by reducing structural barriers including racism and other forms of discrimination that prevent economic and social well-being

STRATEGIC GOAL 2

Take a preventative and proactive approach to ensuring child, youth, family, and individual well-being

STRATEGIC GOAL 3

Use whole-family, community-based strategies to increase financial stability and economic mobility

STRATEGIC GOAL 4

Support
communities and
families to respond
to acute needs and
facilitate recovery
from a range of
crises and
emergency
situations

STRATEGIC GOAL 5

Enable and promote innovation within ACF to improve the lives of children, youth, families, and individuals

ACF's Strategic Plan includes five strategic goals that together support the agency's mission to promote the economic and social well-being of children, youth, families, individuals, and communities by providing federal leadership, partnership, and resources for the compassionate and effective delivery of human services. Each goal intentionally cuts across ACF programs and populations, rather than being office-specific, to reflect the interrelatedness of our programs and to ensure we are collaborating across our agency in order to move the needle for those we serve. Specific objectives appear in a bulleted list underneath each goal. This plan is envisioned as a living document that will drive action and change. As shown in the graphic above, Strategic Goal 1 is intended to be an explicit part of each of the other four goals, since advancing equity must be central to everything we do and how we do it.

Strategic Goal 1: Advance equity by reducing structural barriers including racism and other forms of discrimination that prevent economic and social well-being

- Center and integrate the perspectives and experiences of program participants in the design, management, evaluation, and decision-making of ACF programs and operations.
- Identify and close gaps in program outcomes for historically underserved and/or marginalized populations across all ACF programs.
- Eliminate systemic barriers to funding access that applicants to grants and contracts face (e.g., limited staff with knowledge of the application process).

Strategic Goal 2: Take a preventative and proactive approach to ensuring child, youth, family, and individual well-being

- Increase access to supportive, upstream prevention resources and services, particularly evidencebased, culturally relevant, and community-based approaches (e.g., effective child-centered parenting strategies, social and economic supports, access to high-quality early childhood programs).
- Improve outreach, engagement, and connections to identify and reach those who may be eligible for ACF services and programs but are not receiving them.
- Empower individuals to determine what supports they need in order to thrive and gain independence.
- Use data and lived experiences to predict and preempt needs.

Strategic Goal 3: Use whole-family, community-based strategies to increase financial stability and economic mobility

- Expand the reach of initiatives that intentionally combine support for parents and caregivers (e.g., financial capability services, workforce training, parent education, social-emotional supports) with services for children and youth, including accessible, high-quality early childhood programs.
- Ensure that programs are focused on the multi-generational linkages between child and caregiver.
- Build capacity and infrastructure at the community level (e.g., through funding, guidance, training, partnerships) to create environments where children, youth, families, and individuals can collectively thrive.

Strategic Goal 4: Support communities and families to respond to acute needs and facilitate recovery from a range of crises and emergency situations

- Ensure that crisis support is trauma-informed, culturally specific, gender-responsive, timely, and tailored to community needs.
- Foster resiliency (e.g., economic, social/emotional) among children, youth, families, individuals, and communities to support them in weathering and recovering from emergencies.
- Encourage and support ACF grantees to exercise authority and discretion during times of crisis to
 use funds strategically, equitably, and efficiently and to share data, information, and resources
 across systems and service sectors.

Strategic Goal 5: Enable and promote innovation within ACF to improve the lives of children, youth, families, and individuals

- Establish structures, processes, and tools that incorporate innovation into the culture and operations of ACF.
- Improve employee job engagement, experience, capacity, and well-being, especially during highpressure periods or emergencies.
- Strengthen evidence-building activities and expand access to and use of data to improve the design and delivery of all ACF programs.
- Bring an equity lens to recruitment, hiring, advancement, and employee satisfaction, recognizing variations in experience across identity groups.

Administration for Community Living (ACL) Public Access Plan

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1. BACKGROUND AND PURPOSE

On February 22, 2013, the White House Office of Science Technology and Policy (OSTP) issued a memorandum to the heads of executive departments and agencies entitled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo or Public Access Memo). In the memorandum, OSTP asks federal agencies with research and development budgets greater than \$100 million per year to develop a plan to ensure free public access to federally-funded, peer-reviewed scientific publications and to maximize public access—to the extent feasible and permitted by law—to digital data resulting from federally funded research.

The Administration for Community Living (ACL) is an Operating Division (OPDIV) within the Department of Health and Human Services (HHS), initially established on April 18, 2012, by bringing together the Administration on Aging, the Office on Disability, and the Administration on Developmental Disabilities. Through budget legislation in subsequent years, Congress moved several programs that serve older adults and people with disabilities from other agencies to ACL, including the State Health Insurance Assistance Program, the Paralysis Resource Center, and the Limb Loss Resource Center. Recently, the 2014 Workforce Innovation and Opportunities Act moved the independent living program, Assistive Technology program, and the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) from the Department of Education to HHS/ACL. The transfer of NIDILRR, which has a current appropriation for research and development of approximately \$104 million, necessitated the development of an ACL public access plan (prior to this transfer, ACL did not administer research programs).

NIDILRR's mission is to generate new knowledge and to promote its effective use to improve the abilities of individuals with disabilities to perform activities of their choice in the community, and to expand society's capacity to provide full opportunities and accommodations for its citizens with disabilities. NIDILRR achieves this mission by providing for research, development, demonstration, training, technical assistance, and related activities to maximize full integration of individuals with disabilities in society; ensuring the widespread distribution of practical scientific and technological information in usable formats; and promoting the transfer, use, and adoption of rehabilitation technology for individuals with disabilities in a timely manner.

ACL will make available to the public ACL/NIDILRR peer-reviewed scientific publications and data arising from research funded in whole or in part by ACL/NIDILRR, to the extent feasible and permitted by law and available resources.

The ACL Public Access Plan is intended to:

- Establish a mechanism for compliance with the OSTP public access policy;
- Make published results of ACL/NIDILRR-funded research more readily accessible to the public;
- Make scientific data collected through ACL/NIDILRR-funded research more readily accessible to the public; and
- Increase the use of research results and scientific data to further advance scientific endeavors and other tangible applications.

ACL plans to implement its public access to publications plan in FY2016. ACL is developing a plan to address public access to scientific data and will begin implementing the data public access plan in FY2017.

2. PUBLIC ACCESS TO PEER-REVIEWED PUBLICATIONS

a. Definitions

Embargo: An embargo is defined as a period between the date of publication and the date the publication is made publicly available for free.

Final peer-reviewed manuscript: A final peer-reviewed manuscript is defined as an author's final manuscript of a peer-reviewed paper accepted for journal publication, including all modifications from the peer-review process.

Final published article: A final published article is defined as a publisher's authoritative copy of the paper, including all modifications from the publishing peer-review process, copy editing, stylistic edits, and formatting changes.

Peer-reviewed publication: A peer-review publication is defined as a publication describing original scientific research findings that has been peer-reviewed prior to being published in a scientific journal.

Peer-reviewed publication's metadata: Peer-reviewed publication's metadata is defined as information that describes a peer-reviewed publication, generally making the publication uniquely identifiable and more easily searchable. Publication metadata often include the publication author(s), publication title, journal title, publication date, publication abstract, and unique identifying numbers or codes.

b. Scope

The ACL requirements for public access to peer-reviewed publications will be applicable to peer-reviewed publications resulting from all research funded by ACL/NIDILRR, regardless of the funding mechanism (e.g., grant, cooperative agreement, contract, other funding mechanism).

The ACL requirements for public access to peer-reviewed publications will also apply to peer-reviewed publications resulting from research jointly supported by ACL/NIDILRR and a partner agency, when the research is administered by ACL/NIDILRR. An exception to these requirements is when the jointly-supported research is administered by a partner agency with a comparable public access policy. In that case, ACL will defer to the partner agency's public access policy for peer-reviewed publications.

ACL employees whose scientific work is published in peer-reviewed journals as part of their assigned duties will be under the scope of this plan.

ACL does not have an intramural research program; therefore, it is not addressed in this plan.

c. Requirements

These public access requirements will be applied prospectively, and not retrospectively.

ACL will use PubMed Central (PMC)—the National Institutes of Health (NIH) digital archive of biomedical and life sciences journal literature, developed and operated by the National Library of Medicine, as its designated peer-reviewed publications repository.

Using PMC service will enable ACL to meet the following objectives:

- Ensure that the public can read, download, and analyze in digital form final peer-reviewed manuscripts or final published articles;
- Facilitate easy public search, analysis of, and access to peer-reviewed publications directly arising from research funded by the Federal Government;
- Ensure full public access to peer-reviewed publications' metadata, without charge upon first publication, in a data format that ensures interoperability with current and future search technology. The metadata will provide a link to the location where the full text and associated supplemental materials will be made available after the embargo period;
- Encourage public-private collaboration to:
 - o maximize the potential for interoperability between public and private platforms and creative reuse to enhance value to all stakeholders,
 - o avoid unnecessary duplication of existing mechanisms,
 - o maximize the impact of the Federal research investment, and
 - o assist with implementation of the ACL Public Access plan;
- Ensure that attribution to authors, journals, and original publishers is maintained; and
- Ensure that publications and metadata are stored in an archive that:
 - o provides for long-term preservation and access to the content without charge,
 - o uses standards, widely available and, to the extent possible, nonproprietary archival formats for text and associated content,
 - provides access for persons with disabilities consistent with Section 508 of the Rehabilitation Act of 1973, and
 - o enables integration and interoperability with other Federal public access archival solutions and other appropriate archives.

The ACL public access plan requires that all peer-reviewed publications generated from ACL/NIDILRR -funded research be publicly available via PubMed Central (PMC) no later than 12 months after the official publication date. The peer-reviewed publications may be made available in either the final published article or final peer-reviewed manuscript format.

ACL/NIDILRR-funded authors may choose one of the following options to achieve compliance:

- When appropriate, publish their work in peer-reviewed journals that currently archive their complete contents in PMC (full participation) with a 12 month or less embargo period. In cases where an author publishes with one of these journals, the publisher will supply the final published article directly to PMC and the author does not need to take any additional action to comply with ACL Public Access Policy.

The complete PMC journal list is available at http://www.ncbi.nlm.nih.gov/pmc/journals/. The "Participation Level" column indicates which journals have a full participation level and the "Free Access" column indicates the journal's embargo period from the date of publication. To exercise this option, only those listed journals with both a full participation level and the embargo period of 12 months or less will meet the requirements of the ACL Public Access Policy.

Submit final peer-reviewed manuscript to PMC through the National Institutes of Health Manuscript Submission System (NIHMS) http://www.nihms.nih.gov/ upon acceptance of the manuscript for publication, with the understanding that these manuscripts will be made publicly available no later than 12 months after the official date of publication. The author should address the requirements for PMC deposit with the publisher at the time of acceptance or earlier to ensure compliance with the ACL Public Access Policy.

ACL employees whose work is published in peer-reviewed journals as part of their assigned duties will also be required to make the peer-reviewed publications publicly available through either one of the mechanisms indicated above.

d. Compliance and Evaluation

ACL will establish compliance terms and conditions for grant, cooperative agreement, contract, and other funding mechanisms, to be included in all Funding Opportunity Announcements and Requests for Proposals issued after October 1, 2016. The compliance terms and conditions will also be communicated to all recipients of new awards for grants, cooperative agreements, contracts, and other applicable funding mechanisms.

ACL/NIDILRR-supported investigators will be required to report any *peer-reviewed manuscripts* that have been accepted for publication in their annual performance reports and final reports, with an indication whether the compliance with the ACL Public Access Policy has been achieved by one of the two methods below:

- The manuscript is being published in a journal with PMC's full-participation status with a 12-month or less embargo period; or
- The final peer-reviewed manuscript has been submitted through the National Institutes of Health Manuscript Submission System (NIHMS) with an embargo period of 12 months or less.

Grantee compliance will be monitored by requiring the ACL/NIDILRR-supported investigators to identify the PubMed Central Identification Number (PMCID) for any *peer-reviewed publications* associated with their grant, cooperative agreement, contract, or other funding mechanism to demonstrate compliance with the ACL Public Access Plan. PMC assigns the PMCID to peer-reviewed publications (final peer-reviewed manuscript and final published article) that are under an embargo period as well as those that are already publicly available through PMC.

The data from the PMC's funding agency administrative portal showing status of submitted final peer-reviewed manuscripts and final published articles associated with ACL/NIDILRR-funded grants, cooperative agreements, contracts, and other funding mechanisms will also be reviewed at a regular interval. This will enable ACL to monitor compliance and take appropriate action such

as prompting investigators who are delayed in completing necessary actions that PMC requires in order to make the peer-review publications available to the public.

Failure to comply with ACL's public access to publications plan could result in withholding, suspension, or termination of funding for non-competing continuation awards. Before awarding new grants or contracts, ACL will inquire whether prospective awardees are in compliance with the ACL Public Access Policy. Prospective awardees' failure to comply with ACL's public access policy could be considered a risk factor in making decisions for new awards.

ACL will rely on the HHS petition process for considering requests to shorten the embargo period for publications in a specific field. This process is described in greater detail in the HHS Guiding Principles and Approach for Enhancing Public Access, Appendix A at http://www.hhs.gov/open/public-access-guiding-principles/index.html#app-a.

Compliance of ACL employees who published in peer-reviewed journals as part of their assigned duties will be monitored through internal clearance and reporting processes.

e. Implementation Timeline

| Implementation Activities | Timeline |
|---|-----------------|
| Begin to communicate ACL requirements for public access to peer-reviewed publications to ACL stakeholders and solicit input and feedback from stakeholders through ACL website and other appropriate venues. | March 1, 2016 |
| Establish an interagency agreement with NIH establishing PMC as the repository for ACL/NIDILRR-funded peer-reviewed publications | March 31, 2016 |
| Publish ACL's requirements for public access to peer-reviewed publications on the HHS Public Access website, ACL website (ACL.gov), and other appropriate venues, and identify point of contact within ACL to respond to questions, comments, or suggestions | October 1, 2016 |
| Incorporate terms and conditions on compliance with ACL's requirements for public access to peer-reviewed publications into ACL-sponsored grant, cooperative agreement, contract, and other funding mechanism notices, such as Funding Opportunity Announcements and Requests for Proposals | October 1, 2016 |
| Communicate terms and conditions on public access to peer-reviewed publications all recipients of new awards for grants, cooperative agreements, contracts, and other applicable funding mechanisms. | October 1, 2016 |

| Implementation Activities | Timeline |
|--|-----------------|
| Review the status of implementation of ACL requirements on public access to peer-reviewed publications and assess compliance | October 1, 2017 |

3. PUBLIC ACCESS TO SCIENTIFIC DATA

a. Definitions

Data embargo: A data embargo is defined as a period between the award's end date and the date the data is made publicly available for free.

Data management plan: A data management plan is defined as a written document describing how researchers will provide for long-term preservation of, and access to, scientific data in digital formats resulting from federally funded research, or explaining why long-term preservation and access cannot be justified.

Dataset metadata: Dataset metadata is defined as information that describes a dataset, generally making the dataset uniquely identifiable and more easily searchable, as well as information that allows a meaningful and appropriate use of the data. Dataset metadata can include, but is not limited to, principal investigator's name, funding sources, project description, sample and sampling procedures, variables, data collection instruments, interview guide and questions, meaning of data codes, and other relevant information about the dataset that would enable meaningful and appropriate use of the data by researchers other than those who originally collect the data.

Scientific data: Scientific data are defined as digitally recorded factual material commonly accepted in the scientific community as necessary to validate research findings including data sets used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as laboratory specimens. For the purpose of this public access plan, the following types of data are excluded from the scope of this plan: personally identifiable data; proprietary trade data; and other data whose release is limited by law, regulation, security requirements, or policy.

b. Scope

The ACL requirements for public access to scientific data will be applicable to all research funded by ACL/NIDILRR, regardless of the funding mechanism (e.g., grant, cooperative agreement, contract, other funding mechanisms). The ACL requirements for public access to scientific data will also apply to research jointly supported by ACL/NIDILRR and a partner agency, when the research is administered by ACL/NIDILRR. An exception to these requirements is when the jointly-supported research is administered by a partner agency with a comparable public access policy. In that case, ACL will defer to the partner agency's public access policy for scientific data.

Scientific data collected by ACL employees as part of their assigned duties will be under the scope of this plan.

ACL does not have an intramural research program; therefore, it is not addressed in this plan.

c. Requirements

These public access requirements will be applied prospectively, not retrospectively. However, in case of ongoing longitudinal data collection, it may be necessary to make the previously collected data available retrospectively if doing so is essential for the prospectively collected data to be meaningful and useful for future analyses.

The ACL public access plan requires that scientific data generated from ACL/NIDILRR-funded research be publicly available no later than 24 months after an award's end date. The scientific data must be packaged and stored in such a way that enables retrieval and meaningful use by interested parties at no cost. When an award funds more than one research project or a research project generates more than one type of scientific data, all datasets must be made publicly available. Each dataset must have a Digital Object Identifier (DOI) for future reference and citation.

ACL designates the Interuniversity Consortium for Political and Social Research (ICPSR), a unit within the Institute for Social Research at the University of Michigan that provides data archiving services, as its preferred data repository for scientific data from all ACL/NIDILRR-funded research. The exception to this designation is the archiving of longitudinal scientific data collected through the ACL/NIDILRR-funded Burn Injury, Spinal Cord Injury, and Traumatic Brain Injury Model Systems. For these three specific funding programs, the longitudinal scientific data have been and will continue to be deposited to and made publicly available by the National Statistical and Data Center of each respective model system. The National Statistical and Data Centers have the capacity to function as a data repository and making those data accessible to the public.

ICPSR operates an internationally recognized repository that meets industry standards and accepts both quantitative and qualitative data. ICPSR also has a provision for an embargo period, where the data can be held but not released for up to 24 months from the date of depositing, at the submitter's request. ICPSR assigns DOIs for datasets that are under an embargo period and those already made publicly available.

ACL/NIDILRR-funded awardees may choose another public repository to deposit their dataset(s), provided that 1) there is a satisfactory justification for why it is not possible to deposit the dataset at ICPSR and 2) the chosen repository is comparable to ICPSR as far as meeting industry standards on data archiving and having an embargo period that will allow the awardee's compliance with this plan.

ACL/NIDILRR-funded awardees may include a justification for using a different repository in the data management plan submitted as part of the original proposal.

ACL requires that applicants for ACL/NIDILRR grants and cooperative agreements, as well as applicable contracts and other types of award as determined by ACL, submit a data management plan. ACL will review the data management plans of potential awardees for completeness and compliance before releasing the awards.

The data management plan (DMP) must include the following components:

- i. Description of the types and format of data to be collected, and how they will be organized, stored, and preserved.
- ii. Description of metadata to be included in the data submission to a repository in order to enable meaningful and useful analysis of the data by users who are not part of the research team.
- iii. Indication of whether the awardee will submit the scientific data to ICPSR or another public data repository. If the data are to be submitted to ICPSR, no further justification is required. If another repository is identified, the awardee must provide a justification of how this repository will provide for a long-term preservation of, and public access to, scientific data in digital formats resulting from ACL/NIDILRR funded research at no cost. This justification should include a description of the way in which shared digital data will be discoverable, retrievable, and analyzable through the chosen data repository.
- iv. If applicable, explain why data sharing, long-term preservation, and access cannot be justified.
- v. Provide a plan to address the study participants' consent process to enable the deidentified data to be shared broadly for future research.
- vi. Indicate an estimated cost to implement the data management plan. This cost is allowable as part of the award's direct costs.

ACL is planning to develop an online training module for ACL/NIDILRR awardees on planning for archiving and preservation of data. Awardees will be required to meet the training requirement within the first 3 months of their award start date. The purpose of this training module is to raise awareness of best practices in data preparation and packaging from the onset of data collection to maximize the data's usability at a later date.

ACL employees who collect scientific data as part of their assigned duties will also be required to deposit the data and make them available through the ICPSR.

ACL may issue additional guidance in specific areas as needed to support the implementation of its public access for scientific data plan.

d. Compliance and Evaluation

ACL will establish compliance terms and conditions for grant, cooperative agreement, contract, and other funding mechanisms, to be included in all Funding Opportunity Announcements and Requests for Proposals issued after October 1, 2017. The compliance terms and conditions will also be communicated to all recipients of new awards for grants, cooperative agreements, contracts, and other applicable funding mechanisms.

ACL will monitor awardees' compliance by requiring ACL/NIDILRR-supported investigators to report their submission of the scientific data to ICPSR or an equivalent repository, the date that the data will be release within 24 months after the award's end date, and the DOIs for all datasets associated with their grant, cooperative agreement, contract, or other types of award. Awardees will be required to report this information in the Final Report for each award.

Failure to comply with ACL's public access to scientific data plan could affect the decision to issue a new award. Before awarding new grants or contracts, ACL will determine whether prospective awardees are in compliance with the ACL plan for public access to scientific data. If an awardee fails to comply with ACL's public access policy, ACL may consider this failure to comply as part of the awardee's history of performance when making decisions about future awards.

Compliance of ACL employees who collect scientific data as part of their assigned duties will be monitored through internal reporting processes.

e. Implementation Timeline

| Implementation Activities | Timeline | |
|--|-----------------|--|
| Begin to communicate ACL requirements for | Ongoing | |
| public access to scientific data to ACL | | |
| stakeholders | | |
| Submit ACL public access plan for scientific data | April 30, 2017 | |
| to HHS Office of Secretary for clearance | | |
| Publish ACL's requirements for public access to | June 30, 2017 | |
| scientific data on the HHS Public Access | | |
| website, ACL website (ACL.gov), and other | | |
| appropriate venues, and identify point of | | |
| contact within ACL to respond to questions, | | |
| comments, or suggestions | | |
| Incorporate terms and conditions on | October 1, 2017 | |
| compliance with ACL's requirements for public | | |
| access to scientific data into applicable ACL- | | |
| sponsored grant, cooperative agreement, | | |
| contract, and other funding mechanism | | |
| notices, such as Funding Opportunity | | |
| Announcements and Requests for Proposals | | |
| Communicate terms and conditions on public | October 1, 2017 | |
| access to scientific data to applicable recipients | | |
| of new awards for grants, cooperative | | |
| agreements, contracts, and other applicable | | |
| funding mechanisms. | | |
| Review the status of implementation of ACL | October 1, 2018 | |
| requirements on public access to scientific data | | |
| and assess compliance | | |

SMG 2126.4

FDA STAFF MANUAL GUIDES, VOLUME III – GENERAL ADMINISTRATION EXTERNAL RELATIONS

ACCESS TO RESULTS OF FDA-FUNDED SCIENTIFIC RESEARCH

Effective Date: July 12, 2017 Changed: October 15, 2019

- 1. Background and Purpose
- 2. Scope
- 3. Policy and Procedures
- 4. Responsibilities
- 5. Definitions
- 6. Legal Authority and References
- 7. Effective Date
- 8. History

1. BACKGROUND AND PURPOSE

On February 22, 2013, the White House Office of Science and Technology Policy (OSTP) issued a memorandum to the heads of executive departments and agencies entitled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo or Public Access Memo). To increase public access to the results of research funded by the Federal Government, OSTP directed federal agencies (such as the FDA) with research and development budgets greater than \$100 million per year to provide free public access to federally funded, peer-reviewed, scientific publications and their associated data. The OSTP Memo also directed agencies to maximize public access, to the extent feasible and permitted by law, to digitally formatted data resulting from federally funded research.

This Staff Manual Guide ("Guide") directly addresses FDA's implementation of this memorandum, as related to FDA-funded research.

2. SCOPE

A. This Guide imposes no requirements on researchers to publish research findings, although this is certainly encouraged, as appropriate. Publication and data access will be triggered if a researcher chooses to publish research findings in a peer-reviewed article. This Guide imposes no requirements to disclose digital data that is the result of FDA-funded research that is excluded from the definition of digital data (see Section 5.B for definition and exclusions).

- B. This Guide establishes the minimum expectations to maximize access to results of FDA-funded scientific research. However, individual Centers/Offices may prescribe additional requirements. Centers/Offices may supplement and expand upon the policy and procedures to meet their specific needs through issuance of written policies, standard operating procedures (SOPs), or template data management plans, so long as those documents support, and are consistent with this Guide.
- C. While FDA embraces the values of openness and transparency in the OSTP Memo, the agency is, in general, restricted by statute, regulation, and policy from disclosing certain categories of information and data, including, but not limited to:
 - information that constitutes trade secret and confidential commercial information, or that otherwise must be protected to preserve intellectual property rights;
 - privileged information, including information related to ongoing product reviews, regulatory decision-making, and enforcement or ongoing criminal or administrative investigations;
 - personal privacy information; and
 - national security and other classified information.

D. Peer-Reviewed Articles: Intramural Research

The policy related to public access to the final published articles described in Section 3.A of this Guide applies to peer-reviewed articles accepted for publication on or after December 29, 2015, and authored, fully or in-part, by an FDA employee as part of their assigned duties.¹

E. Data Management: Intramural Research

The policy related to data management described in Section 3.B of this Guide applies to scientific research to be conducted by an FDA employee who proposes the research to managers for on or after December 29, 2015, including research to be conducted by an FDA employee involving data acquired, collected, or processed by a third party.

¹ This Guide does not apply if the publication is not part of an FDA employee's assigned work. For guidance on non-assigned but FDA-related articles, please see Guide 2126.3: "Review of FDA-Related Articles and Speeches."

Section 3.B does not apply to research that only acquires, collects, or otherwise uses data excluded from the definition of digital data (see Section 5.B for definition and exclusions). Furthermore, Section 3.B does not apply to research required to address immediate threats to public health and safety.

F. Peer-Reviewed Articles: FDA-funded Extramural Research

The policy related to public access to the final published articles described in Section 3.C of this Guide applies to all peer-reviewed articles accepted for publication that result from FDA-funded extramural research.

Program Officials shall ensure that extramural FDA-funded researchers comply with Section 3.C as a term and condition of a contract, grant, or assistance agreement related to scientific research that is initiated, or renewed, on or after December 29, 2015.

G. Data Management: FDA-funded Extramural Research

The policy related to data management described in Section 3.D of this Guide applies to scientific research to be conducted by an FDA-funded extramural researcher.

Program Officials shall ensure that extramural FDA-funded researchers comply with Section 3.D as a term and condition of a contract, grant, or assistance agreement related to scientific research that is initiated or renewed.

Section 3.D does not apply to research that only acquires, collects, or otherwise uses data excluded from the definition of digital data (see Section 5.B for definition and exclusions).

H. Peer-Reviewed Articles and Data Management: FDA Intramural-Extramural Collaborations

When more than one federal public access and data management policy could cover collaborative scientific research proposed to an FDA researcher's manager, compliance with this Guide is only required when an FDA researcher has primary responsibility (e.g., serves as the principal investigator or corresponding author) for the proposed scientific research pursuant to a written collaboration agreement.

3. POLICY AND PROCEDURES

A. Peer Reviewed Articles and Article Metadata: Intramural Research

Peer-Reviewed Articles

The final published articles covered by this policy must appear in the National Library of Medicine's (NLM) PubMed Central (PMC) for free public access to the full-text of the final published article within 12 months of the publication date. In order to ensure that the final published article is available through PMC within 12 months of the publication date, the final published article should be submitted to PMC within 10 business days of the date on which the final published article is available to either the journal's readership in print form or online, if the journal is electronic only.

A final published article can be submitted to PMC by:

- an FDA employee who is an author of the final published article, or their designee, via the <u>NIH Manuscript Submission System</u> (NIHMS), or
- the publisher of a PMC full participation journal carrying the final published article, pursuant to an agreement between the publisher and NLM.

To learn whether the publisher will submit the final published article or whether an FDA employee who is an author of the final published article has the responsibility for submission via NIHMS, please see the list of full participation journals² that submit final published articles directly to PMC.³

For directions on the use of NIHMS and completion of the submission process (including initial submission, processing, and final author review), see the NLM tutorials⁴ regarding use of NIHMS and PMC. FDA-specific tutorials for the submission of final published articles can be found on the website of the Office of the Chief Scientist.

Final published articles authored by agency employees do not carry copyright protections in the United States but may be protectable outside of the United States.⁵ Though not required, to avoid publisher confusion, employees should consider ensuring that any publication agreement or similar copyright transfer agreement with the publisher

² http://www.ncbi.nlm.nih.gov/pmc/journals/

³ Note also that authors using NIHMS to submit an article to PMC will receive a notice if the journal will submit or already has submitted that article to PMC.

⁴ https://nihms.nih.gov/db/sub.cgi?page=stepbystep

⁵ 17 U.S.C. § 105

allows the final published article to be posted to PMC in accordance with this Guide.

Once the PMC process for submitting a final published article is complete, PMC will ensure that the final published article is reviewable and searchable by, and freely available to, the public no later than 12 months after the date of publication.

2. Article Metadata

Article metadata covered by this policy must be made freely available to the public upon publication. Article metadata will be made available via NLM's PubMed index.

For final published articles in journals that are ordinarily indexed by MEDLINE, article metadata will appear automatically within PubMed without action by FDA or the authors.

For final published articles in journals that are not ordinarily indexed by MEDLINE, article metadata will appear within PubMed after the final published article is submitted to PMC via NIHMS.

3. Publication Tracking

To monitor compliance with agency publication access policies and to track agency publications, the FDA Library will maintain the catalog of FDA final published articles (Internal Article Catalog).

4. Compliance

At the conclusion of each calendar year, starting with calendar year 2016, the Office of the Chief Scientist will compare the number of final published articles deposited in the Internal Article Catalog to the number of FDA final published articles deposited into PMC over the same time period—the ratio will serve as a rough compliance rate that the Office of the Chief Scientist will publish on the website of the Office of the Chief Scientist.

At the conclusion of each calendar year, starting with calendar year 2016, the Office of the Chief Scientist will randomly audit 10% of the final published articles listed in the Internal Article Catalog. The Office of the Chief Scientist will determine which of the audited final published articles have been correctly deposited into PMC in accordance with this policy.

For those final published articles not in compliance, the Office of the Chief Scientist will request compliance with this policy, provide assistance in complying, and issue a deadline for compliance. If delinquent final published articles are not deposited by the deadline, the Office of the Chief Scientist will notify the FDA researcher's supervisor. Previous non-compliance may be considered in decisions regarding future research.

B. Digital Data: Intramural Research

1. Data Management Plans

Researchers must submit a proposed Data Management Plan (DMP):

- when submitting a formal research proposal to receive approval from a manager or supervisor to conduct research that acquires, collects, or otherwise uses digital data (see Section 5.B for definition and exclusions);⁶ or
- prior to a decisional funding review for research as part of an intramural grant (for example, the Office of the Chief Scientist Intramural Grant programs).

The Office of Scientific Integrity will work with Centers/Offices to develop a Data Management Plan template⁷. However, Centers/Offices may implement their own Data Management Plan template with the approval of the Office of Scientific Integrity. A researcher's proposed DMP must include the following:

- types of digital data (see Section 5.B for definition and exclusions) to be produced or collected in the study;
- digital data metadata that will be made publicly available and used to describe any publicly stored data;
- the researcher's commitment to make digital data (see Section 5.B for definition and exclusions) supporting a final published article freely available to the public upon publication, if appropriate;

⁶ Refer to Section 2E. This Guide applies to an FDA employee conducting or primarily responsible for proposed research even if the FDA employee proposes to use a third party to acquire, collect, or otherwise process digital data (see Section 5.B for definition and exclusions). The FDA researcher should ensure that the agreement with the third party to acquire, collect, or process data establishes the expectations for data management as described in the approved data management plan.

Form FDA 4070, "Data Management Plan Form and Instructions," https://www.fda.gov/media/131750/download

- digital data structuring (organization) and file formatting that will be used:
- data security measures that will be used and a description of the data that are private, privileged, or otherwise confidential; and
- plans for digital data storage, archiving, and long-term preservation, as feasible, cost-effective, and appropriate (including, as applicable, an explanation why long-term preservation and access to data are not justified), in accordance with applicable records retention requirements.⁸

Researchers seeking research approval from management or seeking research funds via intramural grants should include planned data management costs in their proposals to ensure that they have the resources they believe are necessary to comply with proposed DMPs.

Researchers are expected to acquire digital data pursuant to approved data management plans. All formal status updates, progress reports, or reporting of results to management or the agency office providing intramural grant funding should include a statement of compliance with approved data management plans or a description of and reasons for any departures from approved data management plans.

Agency officials reviewing requests to conduct research or requests for funds will review data management plans on their merits in deciding whether to approve or fund research. In deciding whether to approve or fund research, reviewing officials will approve proposed DMPs as written or require changes to proposed DMPs as a condition of research approval or funding. Reviewing officials should consider the standards and common practices of the relevant scientific community or discipline regarding the value of public access to such data. Reviewing officials will consider the following in evaluating proposed DMPs:

- the value of long-term preservation of research data versus the associated cost and administrative burden—to the agency, Center, and specific agency strategic priorities or research program to which the research proposal relates;
- whether digital data (see Section 5.B for definition and exclusions) should be publicly accessible to search, retrieve, and analyze;

⁸ For questions regarding retention schedules or any other related questions, please contact your Center/Office Assistant Records Liaison Officer (ARLO).

- restrictions regarding the disclosure of research data based upon agency regulations, statute, privacy concerns including HIPAA, proprietary interests, IRB requirements, or otherwise;⁹
- data storage, preservation, or records retention requirements; and
- available Center or agency resources—monetary, physical, human, technological or otherwise.

2. Public Access to Research Data

Researchers will provide public access to research data as provided in the approved data management plan. A researcher will provide access to the digital data (see Section 5.B for definition and exclusions) supporting the published research, consistent with the commitment in the approved data management plan, upon publication of a peer-reviewed article based on those data.

Digital data supporting the published research constitutes digital data and associated key digital data metadata needed to independently evaluate the data presented in the figures, images, charts, and tables in the final published article.

Given the presumption of openness of agency data, the agency will maximize access to digital data (see Section 5.B for definition and exclusions), while

- preserving the integrity of the data;
- adhering to applicable legal or regulatory restrictions on information disclosure; and
- balancing the value of public access to the data and the associated cost and administrative burden such as those related to modifying datasets to allow disclosure. For example, methods of disclosure may include creation of datasets that de-identify human subjects, or redaction or aggregation of datasets prior to sharing.

The Office of the Chief Scientist will support researchers seeking to make datasets freely available to the public by identifying methods and

In evaluating access to digital data, managers may consider the need to keep certain digital data confidential to ensure that research based upon that data can be published in the peer reviewed literature. Such evaluation does not supersede any policies or other considerations regarding access to data important to public health and safety, consistent with applicable statutes, regulations, and policy on information disclosure.

resources for providing public access to datasets. These methods might include:

- depositing data in an existing public data repository (preferred);
- submission of supplemental information to the publishing journal (acceptable for smaller datasets);
- housing data on FDA webservers (acceptable); and
- making data available upon request (acceptable if there are considerations that would make storage in the public domain impractical or inappropriate—e.g., cost and resource limitations).

Information about available resources for making data freely available to the public can be found on the website of the Office of the Chief Scientist.

3. Compliance

FDA researchers are expected to acquire digital data pursuant to approved DMPs. As described in section 3.B.i, above, researchers should certify compliance with approved DMPs or note and explain any deviations from those DMPs whenever reporting results or providing status reports to management or the FDA office providing intramural funding. Managers and funding sources should consider deviations from approved DMPs and address any concerns to researchers. Where concerns with data management practices cannot be resolved, the managers or funding sources may consider whether to continue supporting the research. Managers may also consider whether deviations from approved DMPs should be considered in performance evaluations. Managers may consider prior compliance with this Guide in regards to future research and during performance appraisals.

C. Peer Reviewed Articles and Article Metadata: Extramural Research

Through the Statement of Work, Funding Opportunity Announcement, or similar instrument, Program Officials shall ensure, as a term and condition of a contract, grant, or assistance agreement, that extramural FDA-funded researchers provide, among other things:

- the final published article metadata to PubMed upon publication, and
- the final published article to PMC within 12 months of its publication date.

D. Digital Data: Extramural Research

1. Data Management Plan

Through the Statement of Work, Funding Opportunity Announcement, or similar instrument, Program Officials shall ensure that applicants for FDA funding provide a data management plan to the Program Official prior to commencing any related services or work. Elements of a data management plan should include, without limitation, the following:

- types of digital data (see Section 5.B for definition and exclusions) to be produced or collected in the study;
- digital data metadata that will be made publicly available and used to describe any publicly stored data;
- the researcher's commitment to make digital data (see Section 5.B for definition and exclusions) supporting a final published article freely available to the public upon publication, if appropriate;
- digital data structuring (organization) and file formatting that will be used;
- data security measures that will be used and a description of the data that are private, privileged, or otherwise confidential; and
- plans for digital data storage, archiving, and long-term preservation, as feasible, cost-effective, and appropriate (including, as applicable, an explanation why long-term preservation and access to data are not justified).

2. Public Access to Research Data

Through the Statement of Work, Funding Opportunity Announcement, or similar instrument, Program Officials shall ensure, as a term and condition of a contract, grant, or assistance agreement, that extramural FDA-funded researchers will provide public access to research data as provided in the applicable approved data management plan. In addition, an extramural FDA-funded researcher will provide access to the digital data (see Section 5.B for definition and exclusions) supporting any published research, consistent with the commitment in the approved data management plan, upon publication of a peer-reviewed article based on those data.

4. RESPONSIBILITIES

A. Office of Public Health Strategy and Analysis

The Office of Public Health Strategy and Analysis (OPHSA) provides strategic direction and data-driven analysis for the agency to more effectively and efficiently protect and promote the public health.

OPHSA will collaborate with the Office of Scientific Integrity to implement this Guide. This includes, without limitation, convening and leading steering committee meetings and implementation working groups, delegating tasks, orchestrating work performed by and input received from FDA Centers/Offices and operational components, directing implementation strategy, and developing training materials and additional instruction based on this Guide.

B. Office of Scientific Integrity

The Office of Scientific Integrity (OSI) reports to the Chief Scientist and works with others in the Office of the Commissioner and FDA's Centers/Offices to promote FDA's public health mission by strengthening the credibility of the agency's science and science-based decision-making.

OSI will collaborate with OPHSA to implement this Guide. This includes, without limitation, convening and leading steering committee meetings and implementation working groups, delegating tasks, orchestrating work performed by and input received from FDA Centers/Offices and operational components, directing implementation strategy, and developing training materials and additional instruction based on this Guide.

C. Senior Science Council

The Senior Science Council (SSC) provides advice and guidance to the agency and the Centers'/Offices' leadership on cross-cutting regulatory science planning, reporting, programs, policies, and communication.

SSC will review and provide expert input into agency implementation of the agency's data and publication access policy. Furthermore, OPHSA and OSI will likely recruit members of implementation working groups from the SSC or seek advice from the SSC on appropriate working group participants.

D. Office of Health Informatics

The Office of Health Informatics (OHI), led by the Chief Health Informatics Officer, examines and employs innovative concepts, tools, and informatics solutions to support the agency's mission of promoting and protecting America's public health. OHI also has the primary goal of addressing the informatics and data needs and challenges of the FDA Centers/Offices, and providing the best possible support for their individual missions.

OHI will spearhead efforts related to management of FDA data resources, groups devoted to standardization of data or publication metadata, and otherwise serve as a liaison to HHS and interagency working groups related to development of standards for publication or data access. OHI will investigate various informatics strategies to serve as an agency-wide informatics solutions

E. Program Official (PO)

Contracts: The PO is responsible for ensuring that the requirements of public access are clearly set forth in the Statement of Work or any similar document which describes the requirements that are to be performed by a contractor. The PO is also responsible to ensure that the contractor meets the requirements of public access by the delivery date(s) and/or within the period of performance.

Grants: The PO is responsible for ensuring that the requirements of public access are clearly set forth in the Funding Opportunity Announcement and that the grant recipient meets the requirements of public access by the delivery date(s) and/or within the period of performance. The PO also ensures that the grant applications are in accordance with instructions provided by the DHHS awarding office.

F. FDA Centers/Offices

FDA Centers/Offices promote the public health through the evaluation, surveillance, and review of FDA regulated products and the enforcement of the applicable statutes and regulations. The Centers/Offices are also the agency components primarily responsible for the conduct and funding of agency scientific research.

FDA Centers/Offices may update, or create, policies and procedures required to comply with this Guide.

5. DEFINITIONS

A. Article Metadata

For purposes of this Guide, the phrase "article metadata" is defined as information that describes a peer-reviewed article, generally making the article uniquely identifiable and more easily searchable. Article metadata often include the article author, article title, publication title, publication date, article abstract, and unique identifying numbers or codes. For example, article metadata comprise the records found on PubMed or similar catalog.

B. Digital Data

Pursuant to the OSTP Memo and OMB Circular A-110, the term "digital data" is defined as the digitally recorded factual material that would be commonly accepted in the scientific community as necessary to validate published, peer-reviewed scientific articles. Moreover, the following are expressly excluded from the definition of digital data for the purposes of this Guide:

- preliminary materials underlying the data or factual information, including lab notebooks, preliminary analyses, drafts, plans for future research, peer-review reports, communications with colleagues, or physical objects such as lab specimens;
- data shared with FDA but owned by other organizations (e.g., aggregate electronic healthcare data from other parties used by FDA in product safety monitoring pursuant to FDA's Sentinel program);
- data FDA received as part of an application for market authorization or application for exemption from marketing restrictions for investigational use;
- data obtained under licensing or data use agreements, or cooperative research and development agreements that include terms restricting the release and/or sharing of the data;
- data or information not available for disclosure pursuant to statute or regulation as described in Section 2 above; and
- technical and administrative data.

Nothing in this definition of data imposes requirements on researchers to digitize scientific data in order to comply with agency publication or data access policies.

C. Digital Data Metadata

"Digital data metadata" is defined as information describing the digital data and generally making the information/dataset uniquely identifiable and more easily searchable. Digital data metadata includes, but is not limited to, project title and abstract, collection dates, data format, and contact information.

D. Digital Repository

A digital repository is a focused collection of digital objects that can include text, visual material, audio material, and video material stored in electronic media formats along with means for organizing, storing, and retrieving the files and media contained in the library collection.

E. FDA Center/Office

For purposes of this policy, the terms, "FDA Center/Office" or "Center/Office" refer to one of FDA's core operating components—namely, the Office of Regulatory Affairs, the Center for Food Safety and Applied Nutrition, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Veterinary Medicine, Center for Tobacco Products, and the National Center for Toxicological Research, and other agency components that conduct or fund scientific research, including offices within the Office of the Commissioner.

F. Final Published Article

For purposes of this plan, "final published article" is defined as a publisher's copy of a peer-reviewed article, including all modifications from the publishing peer-review process, copy editing, stylistic edits, and formatting changes.

G. Full Participation Journal

Some journals commit to depositing the complete contents of each issue or volume, starting with a particular volume/issue or publication date, into PMC. PMC has a complete archive for many full participation journals going back to their first volume and issue.

H. Peer-Reviewed Article

For the purposes of this policy, the phrase "peer-reviewed article" is defined as an article published in a scholarly scientific journal that has been peer-reviewed prior to publication.

PubMed Central

PubMed Central (PMC) is a free digital repository of biomedical and life sciences journal literature at the U.S. National Institutes of Health's <u>National Library of Medicine (NIH/NLM)</u> developed and managed by NLM's <u>National Center for Biotechnology Information (NCBI)</u>.

6. LEGAL AUTHORITY AND REFERENCES

Federal statute, regulations, and policy provide the authority, legal framework, and impetus for expanding public access to federally funded publications and digital data, including, but not limited to:

- America COMPETES Reauthorization Act of 2010 (Pub. L. No. 111-358),
 Section 103 sets out the OSTP Director's "responsibility to coordinate
 Federal science agency research and policies related to the dissemination
 and long-term stewardship of the results of unclassified research,
 including [...] peer-reviewed scholarly publications, supported wholly, or in
 part, by funding from the Federal science agencies."
- Food and Drug Administration Modernization Act of 1997 (Pub. L. No. 105-115), Section 113 (requiring establishment of a registry of clinical trials for both federally and privately funded trials of experimental treatments for serious or life-threatening diseases).
- Section 508 of the <u>Rehabilitation Act of 1973 (29 U.S.C. § 794d)</u>, as amended by the <u>Workforce Investment Act of 1998 (Pub. L. No. 105-220)</u>, Aug. 7, 1998.
- Freedom of Information Act, 5 U.S.C. § 552.
- Privacy Act, 5 U.S.C. § 552a.
- Trade Secrets Act, 18 U.S.C. § 1905.
- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. No. 104–191).
- Copyright Act, 17 U.S.C. § 101 et seq.
- Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.
- Public Health Service Act, 42 U.S.C.
- Executive Order, "Making Open and Machine Readable the New Default for Government Information" (May 9, 2013).

- Office of Management and Budget, Memorandum for the Heads of Executive Departments and Agencies, "Open Data Policy—Managing Information as an Asset" (May 9, 2013).
- Office of Science and Technology Policy, Memorandum for the Heads of Executive Departments and Agencies, <u>"Increasing Access to the Results of Federally Funded Scientific Research"</u> (Feb. 22, 2013).
- President Barack Obama, Memorandum for the Heads of Executive Departments and Agencies, <u>"Transparency and Open Government"</u> (Jan. 21, 2009).
- Office of Management and Budget Director, Peter Orszag, Memorandum for the Heads of Executive Departments and Agencies, <u>"Open Government Directive"</u> (Dec. 8, 2009).
- Grants and Agreements, <u>Uniform Administrative Requirements</u>, <u>Cost Principles</u>, and <u>Audit Requirements for HHS Awards</u>, 45 CFR Part 75.
- Federal Acquisition Regulations System, <u>Solicitation Provisions and</u> <u>Contract Clauses</u>, 48 CFR Part 52.
- FDA Regulations, <u>Public Information</u>, <u>21 CFR Part 20</u> (and other regulations cross-referenced therein).
- FDA Regulations, <u>Protection of Privacy</u>, <u>21 CFR Part 21</u>.
- FDA Staff Manual Guide 9001.1, Scientific Integrity at FDA (Feb. 3, 2012).
- FDA <u>Staff Manual Guide 2126.3</u>, <u>Review of FDA-Related Articles and Speeches</u> (Feb. 2, 2011) ("FDA encourages employees to share information that may benefit the public health by giving speeches and publishing articles in scientific or professional journals or other publications.").

7. EFFECTIVE DATE

The effective date of this staff manual guide is July 12, 2017.

8. Document History - SMG 2126.4, Access to Results of FDA-Funded Scientific Research

| STATUS (I, R, C) | DATE APPROVED | LOCATION OF CHANGE HISTORY | CONTACT | APPROVING OFFICIAL |
|---------------------|------------------|----------------------------------|----------------|--|
| Initial | 12/22/2015 | N/a | OC/OCS/ OSI | Walter S. Harris, FDA Chief Operating Officer |
| Revision | 05/21/2017 | N/a | OC/OCS/ OSI | Luciana Borio, Acting Chief Scientist |
| Change | 10/15/2019 | Added footnote 7 | OC/OCS/ OSI | Matthew Warren, Director, Office of Scientific Integrity |

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Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research Notice Number: NOT-OD-23-091

Key Dates

Release Date:

February 21 2023

Response Date: April 24, 2023

Related Announcements

NOT-OD-21-013 – Final NIH Policy for Data Management and Sharing

NOT-OD-08-033 - Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research

Issued by

Office of The Director, National Institutes of Health (OD)

Purpose

NIH seeks public input on the "NIH Plan to Enhance Public Access to the Results of NIH-Supported Research" (NIH Public Access Plan). NIH has a decades-long history of providing public access to scholarly publications and data resulting from the research it supports, including through the 2008 NIH Public Access Policy and the 2023 Data Management and Sharing Policy. In 2022, the White House Office of Science and Technology Policy (OSTP) released a memorandum on "Ensuring Free, Immediate, and Equitable Access to Federally Funded Research" that establishes new guidance for improving public access to scholarly publications and data resulting from Federally supported research. The NIH Public Access Plan outlines the proposed approach NIH will take to implement the new guidance, consistent with its longstanding commitment to public access.

Background

For decades, NIH has pioneered efforts to increase public access to publications and research data resulting from its supported research. The NIH Public Access Policy, in effect since 2008, requires that NIH-supported researchers submit their peer-reviewed manuscripts to the PubMed Central (PMC) digital archive of full-text biomedical literature upon acceptance for publication, making them freely available to the public after an allowable embargo period of not more than 12 months after the publication date. This policy has to-date resulted in more than 1.4 million articles reporting on NIH-supported research being freely available to the public in PMC. NIH has also established a series of policies to improve access to data resulting from its supported research. In 2003, NIH implemented the first NIH Data Sharing Policy, which was replaced by the NIH Policy on Data Management and Sharing (the NIH DMS Policy) that went into effect on January 25, 2023. The NIH DMS Policy requires submission of a Data Management and Sharing Plan for research generating scientific data.

Increasing access to publications and data resulting from federally funded research offers many benefits to the scientific community and the public. Access can accelerate research, generate higher quality scientific results,

encourage greater scientific integrity, and enable future inquiry, discovery, and translation for NIH-supported research. Importantly, these efforts also uphold NIH's commitment to responsible stewardship of the Nation's investment in biomedical research by improving transparency and accessibility of taxpayer-funded research.

NIH efforts align with public access directives, policies, and programs across the U.S. Government. Since 2013, federal public access policy has been guided by the OSTP Memorandum on Increasing Access to the Results of Federally Funded Research, which directed all federal departments and agencies with more than \$100 million in annual research and development expenditures to develop a plan to support increased public access to scholarly publications and digital data resulting from federally funded research. On August 25, 2022, OSTP released updated policy guidance (2022 OSTP Memorandum) that focuses on accelerated access to scholarly publications (most notably, by removing the currently allowable 12-month embargo period for free access), increased access to scientific data, and enhanced tracking of research products through persistent identifiers (PIDs) and metadata.

The NIH Public Access Plan (see Supplemental Information) provides a roadmap for how NIH proposes to accelerate access to scholarly publications and scientific data and will help ensure these research products are findable and equitably accessible to support further scientific discovery. As outlined in the NIH Public Access Plan, the NIH DMS Policy addresses all elements of the 2022 OSTP Memorandum related to scientific data. NIH plans to modify implementation of the NIH Public Access Policy to accommodate novel elements of the 2022 OSTP Memorandum related to scholarly publications. NIH plans to update its Public Access Plan for meeting the provisions of the 2022 OSTP Memorandum related to PIDs and metadata in a future update to OSTP.

NIH looks forward to working across the U.S. Government to support our shared commitment to responsible stewardship of the Nation's investment in biomedical research by improving transparency and accessibility of taxpayer-funded research.

Request for Information

NIH seeks information regarding the NIH Public Access Plan from all interested individuals and communities, including, but not limited to, authors, investigators, research institutions, libraries, scholarly publishers, scientific societies, healthcare providers, patients, students, educators, research participants, and other members of the public. While comments are welcome on all elements of the NIH Public Access Plan, input would be most welcome on Section III related to scholarly publications and on the particular issues identified below.

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators. The NIH Public Access Plan aims to maintain the existing broad discretion for researchers and authors to choose how and where to publish their results. Consistent with current practice, the NIH Public Access Plan allows the submission of final published articles to PMC (in cases where a formal agreement is in place) to minimize the compliance burden on NIH-supported researchers and also maintains the flexibility of NIH-supported researchers to submit the final peer-reviewed manuscript. These submission routes are allowed regardless of whether or not the journal uses an open access model, a subscription model of publishing, or other publication model. This flexibility aims to protect against concerns that have been raised about certain publishing models potentially disadvantaging early career researchers and researchers from limited-resourced institutions or under-represented groups. NIH policy already allows supported researchers to charge reasonable publishing costs against their awards. NIH seeks information on additional steps it might consider taking to ensure that proposed changes to implementation of the NIH Public Access Policy do not create new inequities in publishing opportunities or reinforce existing ones.
- 2. Steps for improving equity in access and accessibility of publications. Removal of the currently allowable 12-month embargo period for NIH-supported publications will improve access to these research products for all. As noted in the NIH Public Access Plan, NIH also plans to continue making articles available in human and machine-readable forms to support automated text processing. NIH will also seek ways to improve the accessibility of publications via assistive devices. NIH welcomes input on other steps

that could be taken to improve equity in access to publications by diverse communities of users, including researchers, clinicians and public health officials, students and educators, and other members of the public.

- 3. **Methods for monitoring evolving costs and impacts on affected communities.** NIH proposes to actively monitor trends in publication fees and policies to ensure that they remain reasonable and equitable. NIH seeks information on effective approaches for monitoring trends in publication fees and equity in publication opportunities.
- 4. Early input on considerations to increase findability and transparency of research. Section IV of the NIH Public Access Plan is a first step in developing the NIH's updated plan for PIDs and metadata, which will be submitted to OSTP by December 31, 2024. NIH seeks suggestions on any specific issues that should be considered in efforts to improve use of PIDs and metadata, including information about experiences institutions and researchers have had with adoption of different identifiers.

How to Submit a Response

Comments must be submitted at https://osp.od.nih.gov/nih-plan-to-enhance-public-access-to-the-results-of-nih-supported-research. Responses will be accepted through April 24, 2023.

Responses to this RFI are voluntary and may be submitted anonymously. You may also voluntarily include your name and contact information with your response. Other than your name and contact information, please do not include in the response any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. After the Office of Science Policy (OSP) has finished reviewing the responses, the responses may be posted to the OSP website without redaction.

Supplemental Information:

NIH Plan to Enhance Public Access to the Results of NIH-Supported Research

I. Introduction

Increasing access to publications and data resulting from federally funded research offers many benefits to the scientific community and the public. Importantly, doing so upholds NIH's commitment to responsible stewardship of the Nation's investment in biomedical research by improving transparency and accessibility of taxpayer-funded research.

NIH has a decades-long record of making the results of the research it supports freely available to the public. Since 2008, NIH's Public Access Policy has required researchers to submit their final, peer-reviewed manuscripts to the digital archive PubMed Central (PMC), making them publicly available no later than 12 months after publication. More recently, NIH implemented a new NIH Data Management and Sharing Policy (NIH DMS Policy) which requires submission of a Data Management and Sharing Plan (DMS Plan) for research generating scientific data.

The U.S. Government as a whole continues to champion policies and practices for leveraging the results of federally funded research to benefit the public. On August 25, 2022, the White House Office of Science and Technology Policy (OSTP) released updated policy guidance for improving public access policies across federal agencies that support research and development to promote the rapid sharing of federally funded research publications and data, to promote equity and advance the work of restoring the public's trust in Government science, and to advance American scientific leadership. Entitled "Ensuring Free, Immediate, and Equitable Access to Federally Funded Research" (2022 OSTP Memorandum), the 2022 OSTP Memorandum sets forth three broad expectations for public access to federally funded research:

- Accelerated access to scholarly publications
- Increased access to scientific data
- Enhanced tracking of research products through persistent identifiers (PIDs)[1] and metadata[2]

This "NIH Plan to Enhance Public Access to the Results of NIH-Supported Research" (NIH's Public Access Plan) provides a roadmap for how NIH will enhance access to research products, namely scholarly publications and scientific data, and will ensure these research products are useful and accessible to the public through mechanisms such as PIDs and metadata. NIH will seek public input on any specific policy proposals to meet these goals. NIH will work closely with OSTP and other Federal agencies to improve consistency of approaches while continuing to meet the specific needs of our research communities. NIH is enthusiastic to move forward on these important efforts to make the results of its research more accessible to scientists and the public.

II. Scientific Data

The NIH DMS Policy, issued on October 29, 2020, aims to ensure scientific data generated from NIH-supported research are made freely available and publicly accessible, as appropriate. With an effective date of January 25, 2023, the NIH DMS Policy was developed via a stepwise process, seeking community feedback at multiple stages, and was designed to reflect the breadth of the NIH research community's data sharing needs. The implementation of the NIH DMS Policy will allow NIH to meet all aspects of the scientific data expectations of the 2022 OSTP Memorandum.

The NIH DMS Policy applies to all research supported in whole or in part by NIH that results in the generation of scientific data. It applies to extramural research supported by grants, contracts, and other funding agreements, as well as to the NIH Intramural Research Program. The NIH DMS Policy requires researchers subject to the NIH DMS Policy to prospectively plan for how scientific data will be preserved and shared, through submission of a DMS Plan. Upon NIH approval of a DMS Plan, researchers and institutions are required to comply with the approved DMS Plan. The NIH DMS Policy also establishes the expectation to maximize the appropriate sharing of scientific data generated from NIH-supported research, with justified limitations or exceptions.

NIH Plan for Scientific Data

NIH's plan to address the individual expectations laid out in the 2022 OSTP Memorandum relevant to scientific data is described below.

II.A. "For the purposes of this Memorandum, "scientific data" include the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings. Such scientific data do not include laboratory notebooks, preliminary analyses, case report forms, drafts of scientific papers, plans for future research, peer-reviews, communications with colleagues, or physical objects and materials, such as laboratory specimens, artifacts, or field notes. The definition of "scientific data" is similar to but broader than the term "research data" defined by 2 CFR 200.315 (e) and 45 CFR 75.322 (e)." (Section 3.b.1., 2022 OSTP Memorandum)

NIH will employ the definition of scientific data 3 used in the NIH DMS Policy. Consistent with the 2022 OSTP Memorandum, the NIH DMS Policy defines scientific data as the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. The definition specifies that scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.

II.B. "Scientific data underlying peer-reviewed scholarly publications resulting from federally funded research should be made freely available and publicly accessible by default at the time of publication, unless subject to limitations as described [in Section II.F.1] below and should be subject to federal agency guidelines for researcher responsibilities regarding data management and sharing plans." (Section 3.b.1, 2022 OSTP Memorandum)

NIH will retain the expectations for data sharing and the timing of data availability contained in the NIH DMS Policy. The NIH DMS Policy requires submission of a DMS Plan outlining how scientific data and any accompanying metadata will be managed and shared, taking into account any potential restrictions

or limitations. NIH expects that in drafting DMS Plans, NIH-supported investigators will maximize the appropriate sharing of scientific data, acknowledging certain factors (i.e., legal, ethical, or technical) may affect the extent to which scientific data are preserved and shared. The NIH Institute, Center, or Office (ICO) will assess whether DMS Plans appropriately consider and describe these factors. NIH has clarified through <u>frequently asked questions</u> that federal, state, local, or Tribal laws, regulations, and policies are examples of justifiable factors that may limit data sharing under the NIH DMS Policy. Importantly, the NIH DMS Policy establishes the expectation that shared scientific data is to be made accessible as soon as possible, and no later than the time of an associated peer-reviewed scholarly publication.

II.C. "Develop approaches and timelines for sharing other federally funded scientific data that are not associated with peer-reviewed scholarly publications." (Section 3.b.ii., 2022 OSTP Memorandum)

NIH will rely on the approaches and timelines for data sharing specified in the NIH DMS Policy. The NIH DMS Policy indicates that scientific data that are *not* associated with peer-reviewed scholarly publications should be made accessible as soon as possible, and no later than the end of the performance period for the research award. NIH has specified through frequently asked questions that these scientific data may underlie unpublished key findings, developments, and conclusions; or findings documented within preprints, conference proceedings, or book chapters. For example, scientific data underlying null and negative findings are identified as important to share even though these key findings are not always published.

The NIH DMS Policy encourages NIH-supported investigators to consider relevant requirements and expectations (e.g., data repository policies, award record retention requirements, journal policies) as guidelines for the minimum time frame that scientific data should be available. The "Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan" also encourages NIH-supported investigators to make scientific data available for as long as they anticipate it being useful for the larger research community, institutions, and/or the broader public.

II.D. "Provide guidance to researchers that ensures the digital repositories used [for sharing scientific data] align, to the extent practicable, with the National Science and Technology Council document, 'Desirable Characteristics of Data Repositories for Federally Funded Research.'" (Section 3.b.iii., 2022 OSTP Memorandum)

NIH plans to rely on supplemental information issued in support of the NIH DMS Policy. The NIH DMS Policy strongly encourages the use of established repositories to the extent possible for preserving and sharing scientific data and encourages NIH-supported investigators to select data repositories that exemplify desired characteristics consistent with the National Science and Technology Council's "Desirable Characteristics of Data Repositories for Federally Funded Research." NIH issued "Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research" to assist NIH-supported investigators in selecting suitable data repositories or cloud-computing platforms for preserving and sharing scientific data. NIH aims to reduce investigator burden by providing information on repositories consistent with other federal agencies and allowing NIH-supported investigators to select any established, suitable repositories to preserve and share scientific data, if no data repository is specified by NIH. NIH-supported investigators' use of repositories exemplifying the desired characteristics promotes data management and sharing in ways that are consistent with FAIR (findable, accessible, interoperable, reusable) data principles.[4]

II.E. "Clarify that federal researchers must follow federal laws and OMB policies that govern federal agencies' information management practices and protect certain types of data, to the extent that the scientific data created by, collected by, under the control or direction of, or maintained by the federal researchers is subject to those laws and policies." (Section 3.b.iv., 2022 OSTP Memorandum)

NIH has provided such clarification in the NIH DMS Policy, which states that federal laws, regulations, statutes, guidance, and policies govern research, specifically research involving human participants, as well as the sharing and use of scientific data generated from research. The NIH DMS Policy

prioritizes the responsible management and sharing of scientific data derived from human participants and emphasizes that NIH-supported investigators should manage and share data in ways consistent with all applicable federal, Tribal, state, and local laws, regulations, statutes, guidance, and institutional policies. The NIH DMS Policy is consistent with federal regulations for the protection of human research participants and other NIH expectations for the use and sharing of scientific data derived from human participants, including the NIH's 2014 Genomic Data Sharing Policy, the NIH 2015 Intramural Research Program Human Data Sharing Policy, and the HHS regulations for the protection of human subjects in research at 45 CFR 46. The NIH DMS Policy expects NIH-supported investigators proposing to generate scientific data derived from human participants to outline in their DMS Plans how privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).

- II.F. "Outline the policies that federal agencies will use to establish researcher responsibilities on how federally funded scientific data will be managed and shared, including:
- II.F.1. "Details describing any potential legal, privacy, ethical, technical, intellectual property, or security limitations, and/or any other potential restrictions or limitations on data access, use, and disclosure, including those defined in terms and conditions of funding agreement or award or that convey from a data use agreement or stipulations of an Institutional Review Board;" (Section 3.c.i., 2022 OSTP Memorandum)

NIH has provided such information in the NIH DMS Policy, which expects that, in drafting DMS Plans, researchers will maximize the appropriate sharing of scientific data, acknowledging that certain factors (i.e., legal, ethical, or technical) may necessitate limiting data sharing to some extent. NIH has issued responses to frequently asked questions that provide the following non-exhaustive list of examples of justifiable limitations on data sharing:

- (1) informed consent does not permit or limits the scope or extent of sharing and future research use
- (2) existing consent (e.g., for previously collected biospecimens) prohibits sharing or limits the scope or extent of sharing and future research use
- (3) privacy or safety of research participants would be compromised or participants would be at greater risk of re-identification or suffering harm, and protective measures such as deidentification and Certificates of Confidentiality would be insufficient
- (4) explicit federal, state, local, or Tribal law, regulation, or policy prohibits disclosure
- (5) existing or anticipated agreements (e.g., with third party funders, with partners, with repositories, with Health Insurance Portability and Accountability Act (HIPAA) covered entities that provide Protected Health Information under a data use agreement, through licensing limitations attached to materials needed to conduct the research) impose restrictions
- (6) datasets cannot practically be digitized with reasonable efforts
- II.F.2. "Plans to maximize appropriate sharing of the federally funded scientific data... such as providing risk-mitigated opportunities for limited data access;" (Section 3.c.ii., 2022 OSTP Memorandum)

NIH will rely on risk mitigation approaches used in the NIH DMS Policy and other NIH data sharing policies. The NIH DMS Policy expects researchers to maximize the appropriate sharing of scientific data, taking into account potential limitations on access and use. It addresses risk-mitigated controls for limited data access to maximize the appropriate sharing of scientific data. The NIH DMS Policy expects researchers to consider whether access to scientific data derived from humans, even if de-identified and lacking explicit limitations on subsequent use, should be controlled.

The "Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research" encourages the use of a repository for human participant data that allows for various features, such as controls on data access. The "Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data" provides points to consider to help NIH-supported investigators decide whether to share scientific data through controlled access. Factors described include whether the scientific data are sensitive and whether the scientific data can be adequately de-identified. This Supplemental Information also identifies factors that may indicate that scientific data can be shared openly, such as when participants have consented to data sharing without restrictions. Additionally, the Supplemental Information outlines best practices for de-identification and highlights institutional review of data sharing to mitigate risks while also maximizing data sharing.

NIH will also continue to develop and promulgate approaches for maximizing access while mitigating risks associated with sharing of specific classes of data. For example, related to its <u>Genomic Data Sharing Policy</u>, NIH has established policies and procedures for data access committees to review requests to access controlled, de-identified, individual-level genomic data contained in repositories such as the NIH Database of Genotypes of Phenotypes (dbGaP) and ensure proposed re-use is consistent with limitations on the data that reflect informed consent. Such approaches help mitigate risks to individuals resulting from access to human participants' data and can be extended to other classes of scientific data.

II.F.3. "The specific online digital repository or repositories where the researcher expects to deposit their relevant data, consistent with the federal agency's guidelines." (Section 3.c.iii., 2022 OSTP Memorandum)

NIH will rely on existing supplemental information developed to support the NIH DMS Policy. The NIH DMS Policy does not expect use of a specific data repository but strongly encourages use of existing data repositories that exemplify the desirable data repository characteristics consistent with the 2022 OSTP Memorandum. The "Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research" helps NIH-supported investigators choose data repositories suitable for the preservation and sharing of data (i.e., scientific data and metadata). The Supplemental Information indicates that, for some programs and types of data, NIH and/or ICO policy(ies) and Notice of Funding Opportunity (NOFOs) may identify particular data repositories (or sets of repositories) to use to preserve and share data and that any designated data repositories should be used. If no data repository is specified by NIH, the Supplemental Information encourages NIH-supported investigators to select a data repository(ies) that is appropriate for the data generated from the research project and provides considerations for selection. If no appropriate discipline or data-type specific repository options, including generalist and institutional data repositories, and cloud-based data repositories for large datasets.

II.G. "Allow researchers to include... costs associated with submission, curation, management of data, and special handling instructions as allowable expenses in all research budgets." (Section 3.d., 2022 OSTP Memorandum)

NIH will rely on existing supplemental information provided as part of the NIH DMS Policy. NIH recognizes that making data accessible and reusable for other users may incur costs. The NIH DMS Policy allows costs associated with data management and data sharing to be included in budget requests for the proposed project. NIH has issued "Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing" that outlines categories of allowable costs associated with data management and sharing, including the costs of curating data and developing supporting documentation costs, local data management considerations, and preserving and sharing data through established repositories.

Conclusion

The NIH DMS Policy accommodates the breadth of NIH-supported research by allowing project-specific consideration of the data that are appropriate to share and the approaches that can maximize data sharing while respecting legal, ethical, and technical factors that may limit the extent of data sharing. Both NIH and the NIH-supported research community will continue to gain experience with data management and sharing as the NIH DMS Policy takes effect, and such experience will inform future implementation and guidance. NIH will also continue to take steps to modernize the data repository ecosystem, as outlined in NIH's Strategic Plan for Data Science, to better support storage, sharing, and use of data generated by NIH-supported research.

III. Scholarly Publications [5]

NIH's approach to accelerating equitable public access to peer-reviewed scholarly publications [6] will build on the success of the long-standing NIH Public Access Policy. In effect since 2008, the NIH Public Access Policy implements Division F, Section 217 of Public Law 111-8, which states that the NIH Director:

"shall require in the current fiscal year and thereafter 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."

Between 2008 and 2022, NIH collected and made approximately 1.4 million articles [7] reporting on its supported research freely and publicly available under the NIH Public Access Policy through PMC, the National Library of Medicine's (NLM's) free full-text archive of biomedical and life sciences journal literature. These articles, along with millions of others submitted to PMC, are accessed by millions of users every day, including researchers, clinicians, entrepreneurs, students and educators, and other members of the public. Making NIH-supported articles publicly available in PMC has enabled the public to have access to research results on some of the most critical public health concerns facing their communities, although access may be delayed for a period of up to 12 months after publication, consistent with the allowable embargo period.

NIH has taken steps to accelerate public access to publications in areas of considerable public interest. Starting in March 2020, NIH launched a new collaboration with scholarly publishers to ensure that all scholarly publications related to COVID-19 and the broader family of coronaviruses were freely available to the public without embargo, including in machine-readable[8] forms that support computational analysis.[9] By the end of 2022, more than 300,000 such publications were available in PMC and had been used to both inform research and public health responses to the COVID-19 pandemic and to engage artificial intelligence researchers in improving search algorithms.[10] In addition, NIH initiatives like the Cancer Moonshot and Helping to End Addiction Long-term (HEAL) Initiative have piloted efforts to make publications accessible without embargo after publication. NIH will build on these efforts to better ensure that publications resulting from NIH-supported research are freely and publicly accessible without embargo to enable use by researchers, clinicians, students, and other members of the public.

Finally, to clarify terminology, the efforts described herein are focused on public access, which is the "free availability of federally funded scholarly materials to the public (including publications, data, and other research outputs)."[11] Open access models, which include publishing models for scholarly communication that make research information available to readers without embargo at no cost, are one of many approaches to meeting the goal of public access.[12] NIH does not anticipate requiring a specific publication model as part of a revised NIH Public Access Policy, recognizing that it will be important to monitor costs and impacts on various communities as the ecosystem evolves to ensure equity.

NIH Plan for Scholarly Publications

NIH's plan to address the individual expectations laid out in the 2022 OSTP Memorandum relevant to scholarly publications is described below:

III.A. "Peer-reviewed scholarly publications... are made freely available and publicly accessible by default in agency-designated repositories without any embargo or delay after publication." (Section 3a, 2022 OSTP Memorandum)

To meet NIH's commitment to enhance accessibility to the public, NIH:

III.A.1. will modify implementation of the NIH Public Access Policy to ensure that scholarly publications resulting from NIH-supported research are made available in PMC without embargo following publication.

NIH plans to modify procedures to remove the allowable embargo period that submitters may select when submitting articles to PMC under the Public Access Policy. Currently, a submitter may request an embargo period of up to 12 months after the official date of publication before NIH will make submitted articles freely accessible to the public through PMC. To meet our commitment to the public to accelerate access to publications, NIH will modify its procedures to make publications available without embargo following the official date of publication. [13],[14]

III.A.2. proposes to clarify the official date of publication to be when the article is first published, either online or in print.

Currently, when calculating embargo periods, NIH bases the date of publication on the issue or "print" publication date, when available. For consistency with expectations under the NIH DMS Policy (see <u>frequently asked questions</u>) and to reflect current practice in scholarly communications, NIH proposes to interpret "official date of publication" as the date on which the publisher first makes an article available, either online or in print. Aligning definitions across the NIH DMS Policy and the NIH Public Access Policy will provide consistency and clarity to those researchers who are subject to both policies.

III.A.3. will maintain other aspects of implementation of the existing Public Access Policy.

NIH plans to keep unchanged other elements of its implementation of the NIH Public Access Policy. NIH will continue to make scholarly publications stemming from NIH-supported research publicly accessible through PMC, NIH's "agency-designated repository," consistent with its legislative mandate. NIH will continue to expect NIH-supported investigators to submit or have submitted on their behalf the peer-reviewed manuscript to PMC via the NIH Manuscript Submission (NIHMS) upon acceptance for publication, as required by legislative mandate. NIH will also continue to consider compliant those NIH-supported investigators who publish in a journal that has a formal agreement with NLM to submit final published articles to PMC at the time of publication. [15] [16] Doing so can be effective in improving compliance while minimizing burden on impacted communities.

This approach will maintain two existing channels for policy compliance:

III.A.3.a. **Manuscript**[17] **submission:** NIH-supported investigators may deposit, or have deposited on their behalf, the final peer-reviewed manuscript to the NIHMS System at the time of acceptance for publication in a journal. NIH will make the manuscript accessible in PMC after the later of the date of publication or the date PMC processing is completed. The investigator will be responsible for completing or for having an author on the paper complete all NIHMS approval steps in a timely manner.

III.A.3.b. **Final published article**[18] **submission:** NIH will continue to consider compliant those NIH-supported investigators who choose to publish in journals that have formal agreements with NLM to submit final published articles to be available in PMC at the time of publication. NIH will make these articles available in PMC once PMC processing is completed. In cases where journals have a formal agreement to submit directly to PMC but with an embargo period that extends beyond

the date of publication, the NIH-supported investigator will be expected to either ensure the final peer-reviewed manuscript is submitted to PMC upon acceptance for publication, to be made publicly available at the time of publication, [19] or arrange with the journal to deposit the individual published article to PMC without a post-publication embargo.

This approach aims to provide free, public availability of articles without embargo after publication, acknowledging there may be some PMC processing period prior to release. While permitting the submission of final published articles to minimize the compliance burden on NIH-supported researchers, it maintains the flexibility of NIH-supported researchers to publish in the journal of their choice and submit the peer-reviewed manuscript, regardless of whether or not the journal uses an open access model, a subscription model of publishing, or other publication model. This flexibility is important in protecting against concerns that have been raised about the potential of some publishing models to disadvantage researchers from limited-resourced institutions and under-represented groups. [20]

III.B. "Maximize equitable reach of public access to peer-reviewed scholarly publications, including by providing free online access to peer-reviewed scholarly publications in formats that allow for machine-readability and enabling broad accessibility through assistive devices." (Section 3.a.ii, 2022 OSTP Memorandum)

To continue to meet our commitment to the public to ensure broad accessibility of scholarly publications, NIH:

III.B.1. will continue current practice and make scholarly publications stemming from NIH-supported research available in accessible and machine-readable[21] formats through PMC and PMC services.

NIH will continue to convert all articles submitted to PMC to the most recent American National Standards Institute (ANSI) NISO Journal Article Tag Suite (JATS) XML format. This format represents the structure and meaning of a document in a simple and human-readable form that can easily be processed by a computer without human intervention. In addition, NIH will continue to render articles in a richly structured HTML format that is responsive to different screen sizes and devices and compatible with assistive technologies to enable broad accessibility. The HTML elements in PMC are in line with the World Wide Web Consortium (W3C) Accessible Rich Internet Applications Recommendation.

To support text mining and other applications of artificial intelligence and machine learning, NIH will continue the current practice of making manuscript files and other article files submitted with permissive licenses available through services that enable easy downloading and automated retrieval.[22] The primary purpose of these services is to enable download of specific subsets of the PMC corpus for analysis.

III.B.2. will continue to make improvements to its procedures to ensure that articles are broadly available through assistive devices.

Accessibility of articles in PMC depends on the completeness of accessibility information provided in the article submissions. NIH will improve guidance for submitters on how they can supply more accessible content. NIH will continue to work with the broader community to develop standards for article accessibility and improve PMC procedures for processing submitted articles. NIH will provide additional educational materials and resources to assist the investigator community in improving the accessibility of articles. Through these improvements and resources, NIH will help ensure clarity for NIH-supported investigators, so as to minimize burden and maximize consistency in approach.

III.C. "Make the publications freely and publicly available by default, including any use and re-use rights, and which restrictions, including attribution, may apply." (Section 3.a.iii., 2022 OSTP Memorandum)

To continue to meet our commitment to the public to ensure use and re-use rights to peer-reviewed publications, NIH:

III.C.1. proposes to clarify how NIH-supported investigators may retain sufficient rights to NIH-supported peer-reviewed manuscripts. NIH will continue to require NIH-supported investigators to retain the rights necessary to comply with the requirements of the NIH Public Access Policy, and NIH proposes to clarify how this may be accomplished. To assist with this process, NIH proposes to develop language that NIH-supported investigators may use for submission with their peer-reviewed manuscripts to journals to retain rights to make the peer-reviewed manuscript available post-publication in PMC as soon as processing is complete, without an embargo period.

III.C.2. will continue to enable metadata reuse and operationalize principles of article reuse. NIH will continue to enable broad reuse of NIH-supported articles through services that allow for automated retrieval and downloading of full text and metadata, consistent with available license terms. NIH-supported peer-reviewed manuscripts, other article files as license terms allow, and article metadata are made available by PMC in formats and through channels that enable text mining, large-scale machine-analysis, and computation. These machine-readable article datasets also include retractions, corrections, and expressions of concern. [23]

NIH will continue to promote the broadest possible reuse of its supported articles, while limiting inappropriate uses, such as redistribution of PMC content for sale. NIH supports these efforts so the results of NIH-supported research become the bases for downstream discovery.

III.D. "Allow researchers to include reasonable publication costs... as allowable expenses in all research budgets." (Section 3.d., 2022 OSTP Memorandum)

To continue to meet the commitment to the public that reasonable costs for publication are part of research budgets, NIH:

III.D.1. will continue to allow reasonable publication costs for all NIH-supported or authored scholarly publications consistent with current policy and guidance.

As noted previously in this Plan, the NIH Public Access Policy does not affect authors' freedom to choose the vehicle or venue for publishing their results. NIH does not propose requiring authors to publish in any particular type of journal or journal with any specific type of business model (e.g., subscription model, open access model). NIH expects that NIH-supported investigators will continue to publish the results of their research consistent with their professional autonomy and judgment to advance science as efficiently and comprehensively as possible. As previously stated through this <u>Guide Notice</u>, NIH encourages authors to publish in reputable journals that follow accepted standards of publishing practices and ethics.

NIH currently allows funding to be used to cover costs of publication, consistent with the <u>NIH Grants Policy Statement, 7.9 Allowability of Costs/Activities</u>. Under the NIH Public Access Policy, NIH has clarified that publication costs, including article processing charges often associated with open access publishing, may be charged to NIH grants and contracts on three conditions:

- 1. such costs incurred are actual, allowable, and reasonable to advance the objectives of the award;
- 2. costs are charged consistently regardless of the source of support; and
- 3. all other applicable rules on allowability of costs are met. Allowable publication costs for electronic and print media include distribution, promotion, and general handling (see <u>Frequently Asked Questions</u> about the NIH Public Access Policy)

NIH intends to develop supplemental information that elaborates on and clarifies allowable costs for publication, consistent with these conditions.

III.D.2. proposes to continue to monitor trends in publication fees and policies to ensure that they remain reasonable.

NIH seeks to ensure that costs associated with the publication of findings from NIH-supported research are reasonable and do not serve as an impediment to publishing by researchers from limited-resourced institutions or under-represented groups. As such, NIH expects that NIH funds be used for costs that are not disproportionately or inequitably charged based on NIH being the source of funding. In addition, NIH reinforces that NIH-supported authors should retain rights to the final peer-reviewed manuscript, regardless of the pathway to publication. NIH proposes to continue to monitor trends in publication fees and policies to ensure that they remain reasonable and do not disproportionally burden one or more segments of the NIH-supported community, and that opportunities to publish are equitable and consistent with NIH's strategic priorities.

Conclusion

Building upon the success of the NIH Public Access Policy, NIH is well-positioned through PMC to ensure that scholarly publications resulting from NIH-supported research are made available without embargo following publication. Additionally, NIH will continue to support machine-readability and broad accessibility so that the results of taxpayer-funded research are available to all. NIH anticipates that the planned modifications and clarifications to the NIH Public Access policy addressed in the NIH Public Access Plan will help ensure that we continue to meet our commitment to the public to make research results broadly accessible. This approach also aims to provide NIH-supported investigators broad discretion to publish in the journal of their choice, regardless of whether those journals use a traditional subscription-based model, an open access model, or other publication model. NIH encourages NIH-supported investigators to select publication venues that will maximize the impact of their work. In addition to seeking public comment on this Plan, NIH will identify opportunities for convenings of relevant affected communities to work through these complex issues. NIH is committed to evaluating the impacts of any future policy changes on impacted communities, and to adapt policies, as needed, accordingly.

IV. Mechanisms to Increase Findability and Transparency of Research

The 2022 OSTP Memorandum instructs Federal agencies to take steps to ensure that public access policies support scientific and research integrity by transparently communicating to the public critical information, including information related to the authorship, funding, affiliations, and development status of federally funded research. Such actions allow members of the public to be able to identify which federal agencies support given investments in science, the scientists who conduct that research, and the extent to which peer review was conducted.

NIH recognizes that public access to the products of research (i.e., data, publications) depend on the findability of these products along with metadata describing the investigators who performed the research, where the research was conducted, and with what funding resources. To facilitate findability, PIDs may be associated with a researcher, their institutions, their funding agency, and their research outputs. Together, PIDs empower researchers, clinicians, students, and the public to rapidly locate, contextualize, and interrogate the outcomes of research. Such transparency increases scientific integrity and bolsters public trust in scientific research.

NIH has considerable experience with PIDs and metadata that will inform its plan. NIH will update the NIH Public Access Plan regarding PIDs and metadata and submit it to OSTP by December 31, 2024. Additionally, NIH will provide opportunities for public comment on any proposed policies related to PIDs and metadata and will publish final policies by December 31, 2026, with an effective date no later than one year later. Below are some considerations that will inform the NIH planning process.

Considerations for the NIH Plan for PIDS and Metadata

To develop its plan for PIDs and metadata, NIH will engage in an iterative process and consult with broad groups of impacted communities. NIH will look to lessons learned through several agency efforts to date that make use of PIDs and metadata, to address the specific elements of the 2022 OSTP Memorandum as described below:

IV.A. "Collect and make publicly available appropriate metadata associated with scholarly publications and data resulting from federally funded research, to the extent possible at the time of deposit in a public access repository. Such metadata should include at minimum: all author and co-author names, affiliations, and sources of funding, referencing digital persistent identifiers, as appropriate; the date of publication; and a unique digital persistent identifier for the research output." (Section 4.a., 2022 OSTP Memorandum)

NIH has considerable experience with metadata and PIDs for research outputs that will inform its approach. NLM, for example, collects metadata and assigns PIDs to each full-text article submitted to PMC (PMCID), each clinical trial registered with ClinicalTrials.gov (NCT number), and each genetic sequence submitted to GenBank (Genbank accession number).

Several recent efforts will also provide near term data points on best practices for utilizing PIDs for different research products and metadata. The NIH DMS Policy directs NIH-supported investigators to deposit data in repositories that meet the National Science and Technology Council's "Desirable Characteristics of Data Repositories for Federally Funded Research." These characteristics include assignment of PIDs to submitted data to ensure that the data are findable. To facilitate repositories meeting these goals, the NIH Office of Data Science and Strategy (ODSS) awarded supplemental funding that will enable data discoverability, interoperability, and reuse by aligning with the FAIR and TRUST principles and using metrics to measure their effectiveness. Furthermore, ODSS established the Generalist Repository Ecosystem Initiative (GREI), which includes seven established generalist repositories that will work together to establish consistent metadata, develop use cases for data sharing, train and educate researchers on FAIR data, and harness the importance of data sharing.

Ultimately, individual PIDs for research outputs are most useful for findability and transparency when they can be unambiguously linked in standardized ways and are therefore searchable. Through engagement with affected communities, the NIH will determine how to address this systematic challenge.

IV.B. "Instruct federally funded researchers to obtain a digital persistent identifier that meets the common/core standards of a digital persistent identifier service defined in the NSPM-33 Implementation Guidance, include it in published research outputs when available, and provide federal agencies with the metadata associated with all published research outputs they produce, consistent with the law, privacy, and security considerations." (Section 4.b., 2022 OSTP Memorandum)

In developing its plan for researcher identifiers, NIH will take into consideration its experience with identifiers for trainees. In 2019, NIH established a requirement for individuals supported by research training, fellowship, research education, and career development awards to have Open Researcher and Contributor Identifiers (ORCID iDs) beginning in FY2020. This requirement was made in response to recommendations from the Advisory Committee to the NIH Director [24] and the National Science and Technology Council's Working Group on Research Business Models that federal agencies adopt tools and approaches to simplify applicant reporting and improve the tracking of career outcomes.

IV.C. "Assign unique digital persistent identifiers to all scientific research and development awards and intramural research protocols that have appropriate metadata linking the funding agency and their awardees through their digital persistent identifiers." (Section 4.c., 2022 OSTP Memorandum)

NIH currently assigns alpha-numeric identifiers to all awards including grants, cooperative agreements, other transactions, and fellowships. Within the NIH system, these award identifiers are persistent, unique, and have meaningful structure that provides information on the type of award, primary funding source, and year of support. Forms of these identifiers are used to identify NIH awards in public sites (e.g., NIH Research Portfolio Online Reporting Tools (RePORT), HHS Tracking Accountability in Government Grants System (TAGGS), and USASpending.gov).

NIH recognizes that although these award identifiers are unique within the NIH database, they have limitations, as they are not registered or indexed to ensure uniqueness beyond NIH and they are not retrievable using a standardized communications protocol that would allow for interoperability. NIH is exploring use of the <u>digital object identifier (DOI) system</u> that would overlay existing NIH grant identifiers to resolve these issues. NIH will coordinate this exploration with efforts of other Federal agencies and relevant external/internal impacted communities to assess how to best develop a robust, connected ecosystem where institutions, researchers, research outputs, and funding sources are linked consistent with FAIR principles.

Conclusion

To increase findability and transparency of research products, NIH plans to build upon our experience with the initiatives described above, consult with other Federal agencies through the National Science and Technology Council Subcommittee on Open Science, and solicit input from broad sets of impacted communities. By integrating lessons learned and best practices through public engagement, NIH will determine an appropriate plan to improve the discoverability of research products, maximize their utility, and support scientific integrity.

V. Summary and Next Steps

NIH has long championed public access to publications and data to enable its mission to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. NIH strongly supports the expectations included in the 2022 OSTP Memorandum, which are consistent with NIH's longstanding commitment to the public to ensure research products are broadly accessible.

As described in this Public Access Plan, NIH has a robust strategy for further enhancing equitable access to the results of its supported research. For expectations related to scientific data, NIH will proceed with implementation of the NIH DMS Policy. For expectations related to scholarly publications, NIH plans to update the NIH Public Access Policy no later than December 31, 2024, with an effective date no later than December 31, 2025. For the elements related to PIDs and metadata, NIH will submit a revised NIH Public Access Plan to OSTP no later than December 31, 2024. A final policy incorporating those additional elements will be issued by December 31, 2026, with an effective date not more than one year later.

NIH will continue to work with OSTP and interagency partners to ensure close coordination across the federal government as we implement this Public Access Plan. NIH will seek public comment on this Public Access Plan upon its release and will provide opportunity for public comment as policy development continues. NIH will iterate on approaches, as needed, to ensure that supported research produces maximal benefits for the scientific community and the public. NIH recognizes that its policy efforts are only one vehicle for achieving the aims of broader public access to research results. We look forward to an ongoing partnership with colleagues in academia, scientific societies, the publishing community, libraries, and the private sector to ensure that efforts to increase public access are equitable and allow all to benefit from NIH-supported scientific results.

Inquiries

Please direct all inquiries to:

IC Name:NIH Office of Science Policy: Email: SciencePolicy@od.nih.gov

References

[1] Per the NSPM-33 Implementation Guidance, a digital persistent identifier is a digital identifier that is globally unique, persistent, machine resolvable and processable, and has an associated metadata schema.

- [2] Per the 2022 OSTP Memorandum, metadata includes information conveyed with the publications and data upon deposit in a public access repository to ensure proper attribution and versioning.
- [3] In the NIH Public Access Plan, "scientific data" are defined as the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications.
- [4] https://www.nature.com/articles/sdata201618 (Accessed February 13, 2023).
- [5] In the "Scholarly Publications" section of the NIH Public Access Plan, there are references to publications and manuscripts at different stages of development and peer review. Where new terms arise for the first time, they have been defined in footnotes for readability.
- [6] The 2022 OSTP Memorandum notes that, "scholarly publications' always include peer-reviewed research articles or final peer-reviewed manuscripts published in scholarly journals, and may include peer-reviewed book chapters, editorials, and peer-reviewed conference proceedings published in other scholarly outlets that result from federally funded research." In the NIH Public Access Plan, "peer-reviewed scholarly publications" will be referred to as "scholarly publications" or "publications" for brevity. NIH clarifies that preprints and book chapters will not be within scope of a revised NIH Public Access Policy.
- [7] In the NIH Public Access Plan, "article" is defined as a complete and public version of a scientific document; for the purposes of this document, the term article encompasses both the accepted peer-reviewed manuscripts and final published articles. A "peer-reviewed manuscript" (sometimes referred to as the "accepted manuscript") is defined as the final version of the author's manuscript that has been accepted for journal publication and includes all revisions resulting from the peer review process, including all associated tables, graphics, and supplemental material. A "final published article" is defined as the journal's authoritative copy of the paper, including all modifications from the publishing peer review process, as well as journal or publisher copyediting and stylistic edits, and formatting changes.
- [8] In the NIH Public Access Plan, "machine readability" is defined as a format that can be easily processed by a computer without human intervention while ensuring no semantic meaning is lost (such as the NISO Z39.96-2015 JATS XML standard currently used by PMC).
- [9] https://www.ncbi.nlm.nih.gov/pmc/about/covid-19/ (Accessed February 13, 2023).
- [10] <u>https://www.kaggle.com/c/covid19-global-forecasting-week-5</u> and <u>https://ir.nist.gov/trec-covid/</u> (Accessed February 13, 2023).
- [11] <u>https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Congressional-Report.pdf</u> (Accessed February 13, 2023).
- [12] https://www.budapestopenaccessinitiative.org/read/ (Accessed February 13, 2023).
- [13] In the NIH Public Access Plan, "official date of publication" or "publication date" are defined as the date on which an article is first made available in final, edited form, either online or in print. Online publication dates generally include the month, day, and year the article was published. Most articles are published online first.
- [14] Approximately one-third of articles deposited under formal agreements with NLM are currently submitted with no embargo beyond the publication date.
- [15] https://publicaccess.nih.gov/submit_process.htm. (Accessed February 13, 2023).
- [16] Currently, some 3,000 journals submit final published articles on behalf of NIH-supported investigators, accounting for approximately 47% of the articles received under the NIH Public Access Policy. The remaining 53% of articles are received as peer-reviewed manuscripts submitted by NIH-supported investigators or submitted on their behalf.

- [17] See definition in footnote 7 above.
- [18] See definition in footnote 7 above.
- [19] In this situation, NIH will make the final published article publicly accessible in PMC after the expiration of the journal's embargo period.
- [20] https://www.aaas.org/sites/default/files/2022-10/OpenAccessSurveyReport_Oct2022_FINAL.pdf?
 https://www.aaas.org/sites/default/files/2022-10/OpenAccessSurveyReport_Oct2022_FINAL.pdf?
 https://www.aaas.org/sites/default/files/2022-10/OpenAccessSurveyReport_Oct2022_FINAL.pdf?
 <a href="https://www.aaas.org/sites/default/files/2022-10/OpenAccessSurveyReport_Oct2022_FINAL.pdf?
- [21] See definition in footnote 8 above.
- [22] These services include the PMC Open Archives Initiative Protocol for Metadata Harvesting (OAI-PMH) Service (https://ncbi.nlm.nih.gov/pmc/tools/oai/), PMC File Transfer Protocol Service (https://mcbi.nlm.nih.gov/pmc/tools/ftp/), PMC Cloud Service (https://www.ncbi.nlm.nih.gov/pmc/tools/ftp/), PMC Cloud Service (https://www.ncbi.nlm.nih.gov/pmc/tools/cloud/), and an application programming interface or API, i.e., E-Utilities (https://www.ncbi.nlm.nih.gov/home/develop/api/) (All Accessed February 13, 2023).
- [23] https://ncbi.nlm.nih.gov/pmc/tools/textmining/ (Accessed February 13, 2023).

[24] This concept has been noted in several NIH Advisory Committee Reports. Please see the recommendations from the; Working Group on Diversity in the Biomedical Research Workforce, the Physician-Scientist Workforce Working Group Report, and the Next Generation Researchers Initiative Working Group Report.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

ACCESS TO SCIENCE AND SCHOLARSHIP: KEY QUESTIONS ABOUT THE FUTURE OF RESEARCH PUBLISHING

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This unpublished report was authored by a self-selected group of MIT faculty and staff, along with an external consultant, who met periodically during the spring of 2023 to explore the scientific and scholarly communications landscape in relation to changes in publishing business models and public access policy. The views expressed in this report are the consensus views of the signed authors, and not an official statement on behalf of MIT.

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EXECUTIVE SUMMARY

The health of the research enterprise is closely tied to the effectiveness of the scientific and scholarly publishing ecosystem. Policy, technology, and market-driven changes in publishing models over the last two decades have triggered a number of disruptions within this ecosystem:

- Ongoing increases in the cost of journal publishing, with dominant open access models shifting costs from subscribers to authors
- Significant consolidation and vertical integration in the publishing industry, and a decline in society-owned subscription journals that have long subsidized scientific and scholarly societies
- ➤ A dramatic increase in what are increasingly termed "predatory journals" by industry analysts, with substandard peer review
- Decline in the purchasing power of academic libraries relative to the quantity and cost of published research

Shifting costs to researchers means less well-funded researchers and institutions may face new hurdles in getting their research published; this is also a concern for researchers in less developed nations. Consolidation and profit objectives in academic publishing have indirectly led to concerns about the quality of peer review in many journals and the selection of publishing options available to researchers. Ecosystemic changes in research publishing are proving especially challenging for smaller non-profit publishers, including university presses and professional societies, even as they embrace the principles of open and equitable access to research. Predatory journals are actively contributing to the growing problems of misinformation and mistrust in science. And the health of academic libraries fundamentally impacts research access for faculty, students, and other scholars.

Many in the research community remain unaware of the drivers of change in academic publishing and the potential consequences for the research enterprise. Although they are often left out of the conversation, researchers are directly affected by these developments. Decisions are being made now that could potentially reduce research budgets, increase researcher workloads, and alter publishing options and the reputational function that publishing has long played.

To illustrate how researcher behavior, funder policies, and publisher business models and incentives interact, part 1 of this report presents an historical overview of open access publishing. Part 2 of the report provides a list of key questions for further investigation to understand, measure, and best prepare for the impact of new policies related to open access in research publishing, categorized into six general areas: access and business models, research data, preprint publishing, peer review, costs to researchers and universities, and infrastructure.

Note, these questions are set out to provide a research agenda, not to recommend particular strategies or practices. Efforts to address these questions will help inform the implementation of open access policies, as well as future policy development.

Introduction

Publishing, broadly defined to include the diverse apparatus of scientific and scholarly communications, is a pillar of the academic and greater research enterprise. Publishing is how knowledge is curated and disseminated (for both research and teaching), and also how the quality and impact of new knowledge are assessed. The health of the research enterprise depends in no small part upon the health of the academic publishing ecosystem.

Digital media have radically transformed the dissemination of all information, impacting news, entertainment, personal and social communications, as well as science and scholarship. Several additional factors are accelerating change in research publishing models, among them:

- The urgency to discover and share potential solutions to global crises that range from climate change and the spread of infectious disease to mental illness and the implications of advanced AI for humanity
- The widespread adoption of preprint publishing models to speed research dissemination in many fields
- Pervasive digital and print piracy of paywalled research publications,
 which incentivizes publishers to adopt alternative business models
- Consolidation in the publishing industry, with fewer companies owning an increasing share of the journal publishing market
- An academic peer review system under strain (due to lack of appropriate incentives and credit for peer reviewers, inconsistent quality in peer review, and the absence of mechanisms for ensuring fairness in the selection of peer reviewers, among other factors)
- The imperative of equity and inclusivity in access to knowledge, and the resulting growth of diverse open access publishing models

Although the report does not address the impact of generative Al technologies, this too will accelerate change in science and scientific publishing.

Public access policies now being adopted by governments around the world (most notably in the U.S., the U.K., and the E.U.) are intended to remove paywalls from the outputs of publicly funded research, with the undisputed imperative of enabling globally equitable access to knowledge. The new public access directive from the U.S. Office of Science and Technology Policy (OSTP) takes effect in January of 2026 and, in the interim, requires each federal funding agency to develop its own plan for policy-compliant research awards. More specifically, the new policy requires that research publications be "made freely available and publicly accessible by default in agency-designated repositories without any embargo or delay after publication."

This period prior to full implementation of the policy is an opportunity for the academic community to consider the practical implications of the policy and to raise questions that can inform the implementation of current public access policies as well as future policy development. Is open access changing who is conducting, publishing, or consuming research results? How will open access impact the availability of funds for research, the amount and kind of research being published, publishing models and strategies, researcher workflows, and how science is communicated to the general public? Most importantly, how can we ensure that the academic community's response to changes in policy ultimately serves to strengthen the research ecosystem?

We note that there are a range of perspectives on open publishing across academia, among them differing perspectives on how to balance the desirability for openness in the research enterprise with security, privacy,

and needs for authors and their institutions to sometimes delay release of research products. There are also important differences across disciplines (and sub-disciplines) in how "open" they already are. For example, in some disciplines, sharing preprints is a long-accepted norm, and in others, open sharing of data is common.

One voice that needs to be better represented in the future-of-publishing conversation is that of the researcher. Decisions are being made now that will potentially reduce researchers' budgets, due to new publication costs, and increase their workloads, and also potentially alter the reputational function that publishing has long played in academic career advancement. There is as yet little practical understanding of how much time, effort, and funding open science will require of the average researcher.

Furthermore, there has been limited discussion of the technological, cultural, and business model innovations necessary to reduce costs and burden to researchers and improve the communication of scholarly works. To protect the health of the research enterprise, the impacts and trade-offs associated with open access publishing and open science practices need to be better analyzed and clearly understood. Ideally, changes in policy that promote increased access to research outputs should be evidence-driven and designed to strengthen the research ecosystem.

To illustrate how researcher behavior, funder policies, and publisher business models and incentives interact, a history of open access publishing is presented below, along with a list of critical questions that should be explored further. Several key observations emerge:

 Open access has been one factor driving consolidation in the publishing sector, and has created financial incentives for many publishers to increase the number of articles published. This trend towards "quantity over quality" risks reducing high-quality publishing options for researchers (meaning, journals that adhere to established norms of peer review, curation, and editing). The future sustainability of research quality is now an issue, as is preserving a diversity of publishing options. The future of non-profit publishers, including scientific society and university presses, and the development and maintenance of new publishing pathways (e.g., preprint servers), will likely require research funders and universities to make (or increase) direct investments in the scholarly communications ecosystem.

- 2. Open access has been implemented in ways that have advantaged commercial publishers to the detriment of most scientific society and university publishers — although this has clearly not been the intention of policy makers. Non-profit publishers lack the financial resources to pivot quickly and to compete at scale. Without intervention by key stakeholders, open access will lead to more money flowing from universities, governments, and other research funders to commercial publishers. Money flows in the form of both "pay to play" (Gold) open access and purchased academic information technologies, thus tying academic reputation to the ability to pay publishers. A publishing ecosystem dominated by — or consisting only of — a few major commercial publishers would reduce the variety of publishing options and leave universities and researchers without choices on pricing and publishing approaches. It would also leave poorly-funded or unfunded researchers from the U.S. and abroad increasingly disadvantaged compared to well-funded researchers.
- 3. There is no one-size-fits-all model in academic publishing. Different fields of study have different cultures, communication norms, funding

models, and publishing prerogatives. Hence, the future of research publishing and open access should involve a variety of models (Green OA, Gold OA, Diamond OA, preprint publishing, etc.).

4. The fast-changing landscape is causing confusion among researchers. Many in the community remain unaware of the drivers of change in academic publishing and the potential consequences for the research ecosystem, underscoring the need for an in-depth, evidence-driven examination of key questions concerning the future of research publishing. Several guiding questions are provided in the last section of this report.

We acknowledge that this effort is limited by the absence of readily accessible, comprehensive data about the current state of scientific publication. We likewise acknowledge that there are a range of perspectives on open science and open publishing across academia, including on how to balance the desirability for openness in the research enterprise with security, privacy, and cost.

PART 1 - Business Models in Journal Publishing: Looking Back and Ahead

Scholarly communication is undergoing rapid change in which business models, platforms, and services are co-evolving. In journal publishing, quality has traditionally stemmed from serving readers and institutions well. In recent years, with the shift to open access and author-paid models, providing competitive services to authors as a primary customer base takes increasing precedence. This also impacts publishing practices in peer review, editing, and marketing.

Until the mid-1990s, journals were largely sold as print subscriptions to individuals, institutions, and other research entities. In the mid-1990s, journals started moving online, and access to content was typically provided through individual usernames and passwords at institutions. Over time, institutional sales shifted to site licenses, in which an institution's library purchases a subscription for the whole campus, and access is granted through IP address identification.

GROWTH IN ARTICLE OUTPUT

The last several decades have seen significant growth in the number of journals and articles published. There was a nearly fivefold increase in the number of articles produced annually from 1995 and 2022 (Figure 1), placing strain on library budgets. Contributing factors include increased global research funding (with huge growth in China for example, see Figure 2 below) combined with the continued emphasis on "publish or perish" in academia — with hiring, promotion, and funding decisions dependent on publication output. The growth in scholarly literature produced every year is also causing the number of peer review requests to skyrocket, raising concerns that the scientific community cannot sustain the pressure of increased requests to

peer review publications and that continued increases in peer review requests could potentially erode the overall quality of peer review.

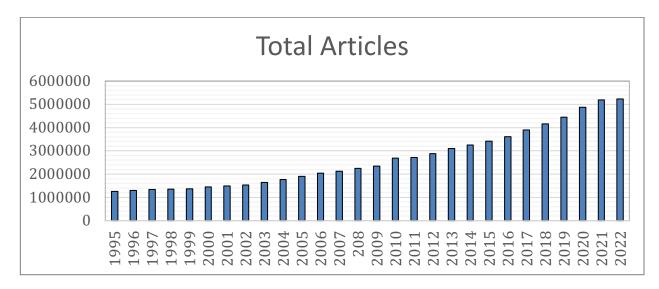


Figure 1. Source: Dimensions (Digital Science). Search limited to "articles".

| All fields | 1998 — 2000 (PY) (Average) The number of papers | | All fields | All fields 2008 — 2010(PY) (Average) The number of papers | | | All lielus | | - 2020 (PY) (Average) number of papers | | |
|----------------|---|-------|------------|--|---------------------|-------|------------|----------------|---|-------|------------|
| Country/Region | Fractional counting | | | Country/Region | Fractional counting | | | Country/Region | Fractional counting | | |
| | Papers | Share | World rank | Country/Region | Papers | Share | World rank | Country/Region | Papers | Share | World rank |
| U.S. | 203,669 | 27.9 | 1 | U.S. | 246,188 | 22.7 | 1 | China | 407,181 | 23.4 | 1 |
| Japan | 64,752 | 8.9 | 2 | China | 107,955 | 10.0 | 2 | U.S. | 293,434 | 16.8 | 2 |
| Germany | 51,597 | 7.1 | 3 | Japan | 64,783 | 6.0 | 3 | Germany | 69,766 | 4.0 | 3 |
| U.K. | 51,053 | 7.0 | 4 | Germany | 58,095 | 5.4 | 4 | India | 69,067 | 4.0 | 4 |
| France | 37,657 | 5.2 | 5 | U.K. | 54,116 | 5.0 | 5 | Japan | 67,688 | 3.9 | 5 |
| Italy | 24,707 | 3.4 | 6 | France | 42,811 | 4.0 | 6 | U.K. | 65,464 | 3.8 | 6 |
| Canada | 24,320 | 3.3 | 7 | Italy | 36,858 | 3.4 | 7 | Korea | 53,310 | 3.1 | 7 |
| China | 22,549 | 3.1 | 8 | India | 35,150 | 3.2 | 8 | Italy | 52,110 | 3.0 | 8 |
| Russia | 22,351 | 3.1 | 9 | Canada | 34,913 | 3.2 | 9 | France | 45,364 | 2.6 | 9 |
| Spain | 17,140 | 2.3 | 10 | Korea | 31,650 | 2.9 | 10 | Canada | 43,560 | 2.5 | 10 |

Figure 2. Average papers per year per country. Digest of Japanese Science and Technology Indicators 2022, Chart 15¹

Although comprehensive data is not available, libraries anecdotally report that their budgets have remained relatively flat or declined relative to inflation over the last few decades. One study notes the decline of library spending as a percentage of university expenditures (Figure 3). (Note: This

¹ https://www.nistep.go.jp/en/wp-content/uploads/NISTEP-RM318-SummaryE_R.pdf

data covers 1982 to 2017, and more recent data on this metric does not appear to be publicly available.). Regardless of their budgets in absolute terms or how universities prioritize library spending, libraries whose budgets have remained flat effectively have less purchasing power in the face of continued growth in research publications.

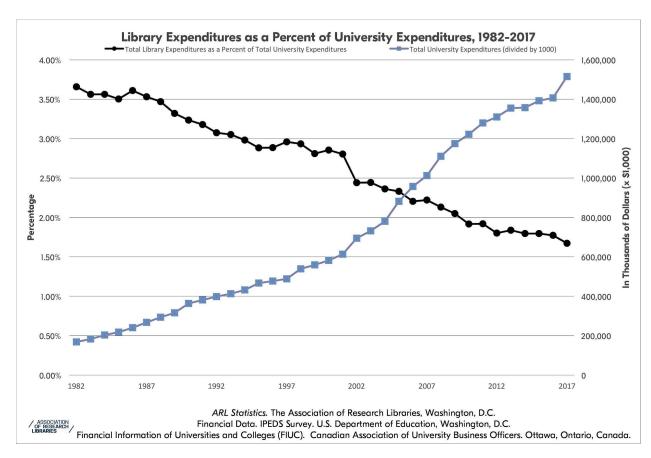


Figure 3. Library expenditures as a percent of university expenditures, 1982-2017, Association of Research Libraries²

This growth contributed to the rise in bulk pricing, and what has become known colloquially as "The Big Deal". Rather than purchasing individual journals from a publisher at list price, libraries were offered annual access to a package of journals at a discounted price — often the entire catalog of journals from a given publisher.

² https://www.arl.org/wp-content/uploads/2020/03/ARL-Library-Expenditures.pdf

The Big Deal made more research content available on participating campuses, and resulted in declining cost per article download. (Figure 4).

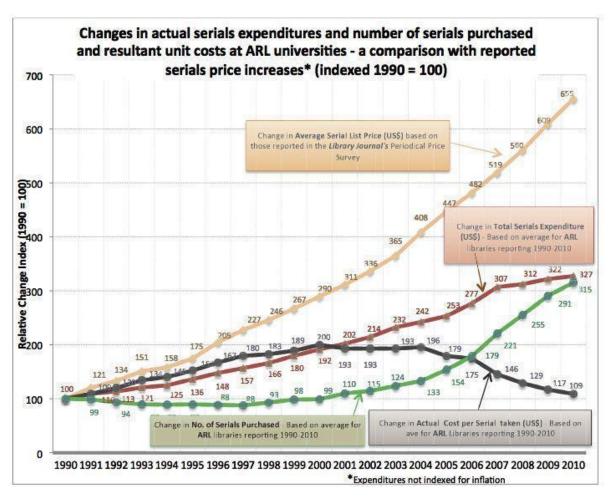


Figure 4. Changes in Expenditures, Gantz, P. (2013) Journal print subscription price increases no longer reflect actual costs. *Learned Publishing* **26**, p. 155-231³

Journal packages from larger publishers are expensive, and prices rise every year. Over time, an increasing proportion of library collections budgets have had to be allocated to purchasing journal access from large commercial publishers, leaving decreasing funds for books and subscriptions to journals from smaller publishers, including scientific societies and university presses.

³ https://doi.org/10.1087/20130309

Before the Big Deal, a library could cancel individual journals that didn't see much use on campus, and redirect the savings elsewhere. Under the Big Deal, library budgets effectively became locked in, since canceling an individual journal in a package is typically not an option. When it is possible, cancellation of one journal has little to no effect on the price of the overall package. As a result, journals from publishers outside of Big Deal packages have been the most vulnerable to cancellation, driving market consolidation. Many libraries are now canceling their Big Deal subscriptions, although the rate and scope of these cancellations have not been studied.

A WAVE OF CONSOLIDATION

The consolidation that resulted has been pronounced. Individual journals, or entire publishing houses, were sold to the larger publishers, and many research societies with independent journals chose to sign Publishing Services Agreements in which they outsource their publishing operations to a larger publisher and become part of their sales packages (Figure 5).

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⁴ https://ospolicyobservatory.uvic.ca/2023/03/17/market-consolidation-and-scholarly-communications/

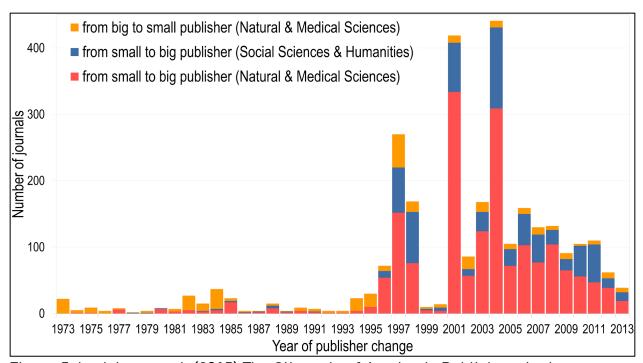


Figure 5. Lariviere, et al. (2015) The Oligopoly of Academic Publishers in the Digital Era, *PLOS ONE*⁵

Scale became an essential component to success in the journals market⁶. Being part of the largest Big Deal packages extended a journal's reach and offered financial security. Further, by partnering with the largest publishers, smaller organizations received the benefits of scale through improved services and technologies that they couldn't afford on their own. For example, a small publisher might have one marketing person, but an international commercial publisher can offer access to a global network of hundreds of sales and marketing professionals. Furthermore, because the larger publishers purchase supplies and services in bulk, costs to produce a journal typically decrease for a society engaged in such a service partnership.

A study published in *PLOS ONE* in 2015 which analyzed papers published in 2013 describes an oligopoly — the top five publishers published more than

⁵ https://doi.org/10.1371/journal.pone.0127502

 $^{^{6}\,\}underline{\text{https://scholarlykitchen.sspnet.org/2015/06/25/the-changing-nature-of-scale-in-stm-and-scholarly-publishing/}$

50% of papers (more than 70% in the social sciences)⁷. Those publishers were Elsevier, Wiley, Springer Nature, Taylor and Francis, and the American Chemical Society (ACS) in the sciences, and the same top four but with Sage Publications instead of ACS in the social sciences and humanities (Figure 6).

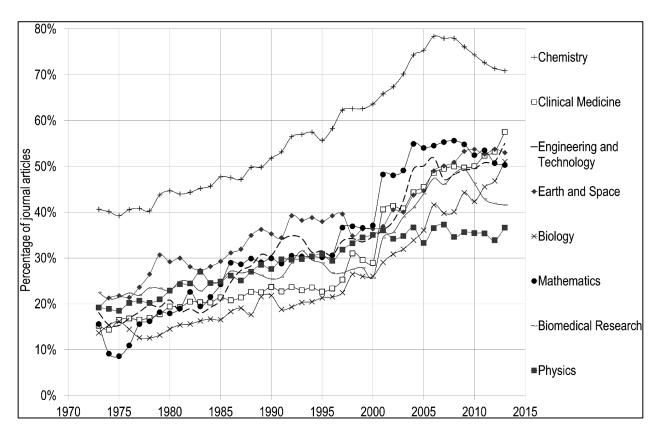


Figure 6. Percentage of papers published by the five major publishers, by discipline in the Natural and Medical Sciences, 1973–2013. Lariviere, et al. (2015) The Oligopoly of Academic Publishers in the Digital Era, *PLOS ONE*⁸

OPEN ACCESS

In parallel with the other ongoing shifts in the subscription journal market, the advent of open access (OA) to science and scholarship has been a major force driving change in academic publishing.

⁷ https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0127502

⁸ https://doi.org/10.1371/journal.pone.0127502

Open access (OA) is a set of principles and practices intended to result in the free and unencumbered distribution online of research publications. OA has a compelling rationale: to drive research progress by ensuring that everyone has access to published science and scholarship. But implementing OA in sustainable and equitable ways has long proved challenging.

In the U.S., the two dominant models for achieving open access in journal publishing are referred to as "Green" and "Gold". In the Green OA model, the author deposits a version of the article on an institutional repository, preprint server, or funder platform such as PubMed Central (PMC), at no cost to author or reader. In compliance with publisher policies, the deposited work is typically the author's final accepted manuscript (AAM) rather than the published version of record (VOR). This model functions in parallel with journal subscriptions, and hence does not necessarily relieve the financial pressure on institutional customers. However, to prevent the erosion of subscriptions, many publishers implemented embargoes that delay access to deposited versions for some period of time (typically 12 months). In addition, the Green OA model has raised concerns about "version confusion" in citation, although it is unlikely that this is a significant problem and the question has yet to be studied.

Gold OA publishing, on the other hand, results in the final version of the article being made freely available upon publication in the journal itself, typically after payment of an article processing charge (APC) by the author or their home institution. This eliminates most issues surrounding version control, but creates new challenges. BioMed Central, an independent organization before being sold to Springer Nature, introduced APCs in 2002. With the subsequent launch of *PLOS Biology* in 2003, the APC was cemented as the preferred business model for OA in many regions of the world for

certain disciplines including the biomedical sciences. In the intervening years, several unintended consequences have become apparent.

Under Gold OA, the business model shifts from reader-centric to authorcentric. Publishers are paid an APC for each article published, rather than relying solely on traditional subscription revenue. Thus, for-profit publishers adopting the APC-based Gold OA model have two basic ways to increase profits: publish more articles, or cut costs. As a result, the Gold OA model has created a perverse economic incentive for these publishers to increase the quantity of articles published within a given journal, potentially at the expense of quality. To reduce expenses, some OA journals do away with copyediting, for example, or minimize plagiarism and integrity checks. For a subscription journal, by contrast, the emphasis is on the subscriber's (institution and reader) perception of quality, hence the focus is on publishing only those articles that are likely to attract readers and increase the reputational value of the journal.

Until recently, OA was viewed by many publishers as an additive engine of growth rather than as a model to replace subscription revenues (Figure 7). Most subscription journals became "hybrid" journals that created a new revenue stream by offering an option for authors to pay for their papers to be published OA. But at the same time, fully Gold OA journals became increasingly attractive for both libraries and publishers because of the pressure on library budgets.

Gold OA journals could be funded through sources other than a library's collections budget, such as a university OA subvention fund or research grants. From the publisher perspective, OA journals could also become sustainable or profitable more quickly (assuming an adequate flow of article submissions) than a traditional subscription journal, which might take years

to reach profitability through reputation building and the associated subscription growth.

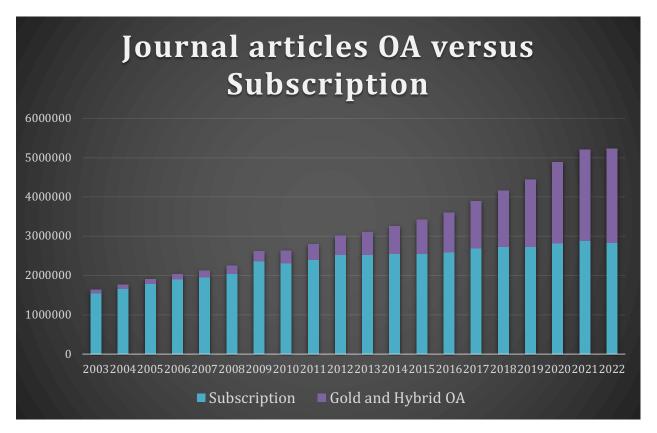


Figure 7. OA was largely additive until policies came into effect circa 2013. Data source: Dimensions (Digital Science). Search limited to "articles" AND "Gold OA" AND "Hybrid OA", OR excluding "Gold OA" AND "Hybrid OA".

Gold OA renders publishers' revenues dependent upon a relatively small number of authors, rather than on a large number of readers. This creates an incentive not only to publish more articles but also to make APCs as high as possible. Journals with high APCs create equity issues, since not all authors can afford them, which is at odds with the OA goal of increasing equity. Further study of the impact of APCs on journal publishing choice is needed to determine if the shift to Gold OA is creating unintended equity challenges. If authors who are well funded or at wealthier institutions have better publishing options than researchers with less, or no, funding, then this

publishing model fails to align with the principles of democratized access and participation.

Gold OA originally took hold in scientific fields in which research is generally well funded, but it has grown to encompass the humanities and social sciences where funding levels are typically much lower. This disparity puts entire fields at a disadvantage. Gold OA further drives inequity by privileging researchers in wealthier countries and at wealthier institutions over those for whom paying an APC is impossible. Publishers' APC waiver programs do not satisfactorily address this fundamental inequity.

It is worth acknowledging that this exacerbates disparities that already exist in the research system. Virtually all research benefits from better grant funding, more and better equipment such as high-quality microscopes and powerful computers, more staff, and more experts hired to collect and analyze the data. In effect, wealthier countries and researchers with grants have always had a significant research advantage.

Gold OA can also be problematic at the institutional level. It is sometimes argued that there is currently enough money in the research system to support flipping a traditional subscription journal to Gold OA9. However, that money is not readily transferable. If the literature is made openly available, then costs for institutions that publish less but still access the literature go down, as costs are shifted to institutions that publish more papers. For example, Dimensions data show some 8,337 articles in 2022 listing an author affiliated with the Massachusetts Institute of Technology (MIT). If MIT was responsible for paying a \$3,000 APC for every paper with an MIT author in 2022, the cost would be over \$25 million (Figure 8). For Harvard, with 32,714

9 https://pure.mpg.de/pubman/faces/ViewItemOverviewPage.jsp?itemId=item_2148961

affiliated papers in 2022, the cost would be nearly \$97 million. Even if only a subset of these affiliated authors are responsible for paying the article's APC (which typically falls to the corresponding author), it would still represent a significant cost increase for the institution. Further study of how much individual universities would pay annually for APCs and how that compares to current subscription spending is needed.

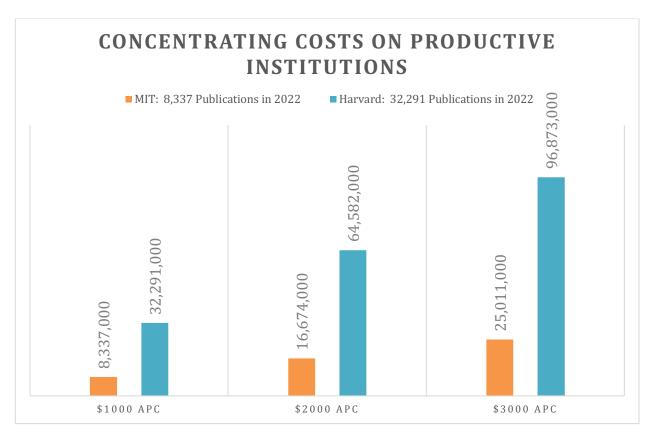


Figure 8. Productive institutions pay more under Gold OA. Data source: Dimensions (Digital Science). Search limited to "articles".

As Gold OA has grown over the past two decades, it has increased the incentives for profit-oriented publishers to consolidate and to publish as many articles as possible, regardless of quality. Under Gold OA, the more articles a journal publishes, the more money it makes.

This has led to three new market trends. The first is the megajournal — first seen in *PLOS ONE*, but now surpassed by Springer Nature's *Scientific*

Reports. Scientific Reports is now the largest journal in the world, publishing more than 22,000 papers last year (Figure 9). These "sound science" journals review papers solely on the basis of accuracy — i.e., did the authors do what they said they did and are their conclusions supported by the data presented? No judgment is made concerning the significance or novelty of the work. One positive impact of megajournals is that they surface a huge amount of incremental work that might otherwise not be made public. The resulting journals are, however, largely undifferentiated containers of content without any notable signals of the relative contribution papers make to a field.

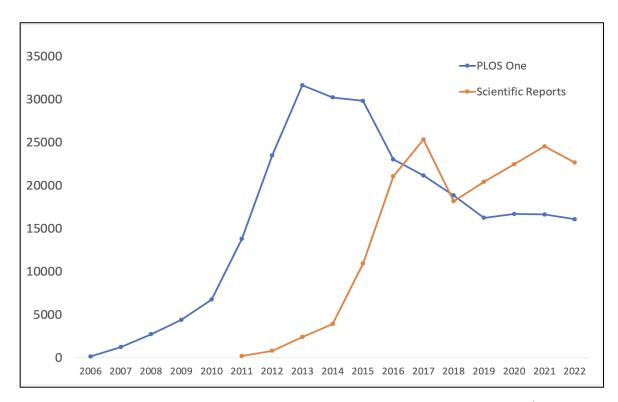


Figure 9. Megajournal publication volumes. Data source: Dimensions (Digital Science). Search limited to "articles".

A second trend is the cascade or transfer model. Publishers incur costs for every paper that is submitted to their journal, but under the Gold OA model they are only paid APCs for the papers that are accepted and published. If the top journal in a given field rejects 95% of submissions, then authors of the accepted 5% of papers effectively have to bear the processing and review

costs of those rejections, as well as the costs that their own papers incur. This fundamentally changes the economic position of flagship journals like *Nature* or *Cell*. Under a pure subscription model, flagship journals are high earners because so many people want to read the small number of high-quality articles they publish. Under a Gold OA model they are far less valuable, even if the publisher charges a high APC, because they are expensive to run but publish relatively few articles.

This has led to the transfer strategy, in which the goal is to ensure that once a manuscript is submitted to one journal in a publisher's portfolio, it stays in that portfolio. This makes it more likely that the publisher will get paid an APC to recoup some of the costs of reviewing the article. The paper can be published in one of the portfolio's other titles after being rejected from the author's (more selective) target journal. In other words, the manuscript "stays in the family" of journals rather than leaving it to go to another publisher. This also provides some convenience to authors, who benefit from not having to resubmit their publication to a new journal; if the paper was reviewed, those reviews typically transfer with the paper, so that authors of rejected papers don't have to start over with a completely new set of reviewers. This, in turn, can reduce the time to publication.

In the Nature Publishing Group, for example, *Nature* sits at the top of the cascade, and rejected papers work their way down through Nature's subject-specific titles such as *Nature Medicine*, *Nature Genetics*, etc., until they reach *Nature Communications*, which serves as a catch-all for high-level research that does not make it into their other flagship publications. If it is not a good fit there, then the paper moves down to *Scientific Reports*, which collects all the rest that pass sound science review. Springer Nature is by no means alone in this strategy. It is being used by nearly every major journal portfolio (e.g., *Cell*, *The Lancet*, *JAMA*, etc.).

In response, some societies have followed the same strategy and launched additional journals to capture articles rejected from their flagship publications. This has allowed them to increase the quantity of articles they publish without compromising the rigor and selectivity of their top journals. Anecdotally, however, many societies and smaller publishers report seeing significant submission declines at their subject-specific journals. Papers they may have received in the past following rejection from top-tier journals like *Nature* are now staying in the Springer Nature family of journals. There is no quantitative data on the scale of the cascade trend or its impacts on publishers that cannot take advantage of the model, because most journals consider submission data to be proprietary. How these shifts are impacting publishing trends, particularly the revenues of societies and other small presses, merits further investigation.

A third key trend is the creation of new publishers that are entirely OA. Without legacy publications to transition, it is easier for these publishers to optimize their practices to meet new market conditions. The two fastest growing OA publishers of this kind are MDPI and Frontiers. MDPI is now the third largest scientific journal publisher and Frontiers the sixth largest (Figure 10).

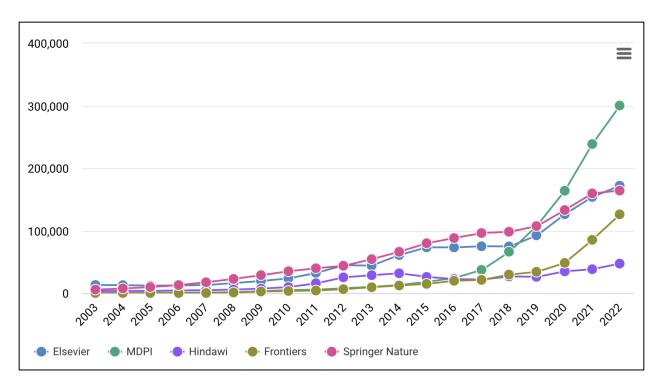


Figure 10. MDPI and Frontiers are the fastest growing OA publishers. Data source: Dimensions (Digital Science). Search limited to "articles" and "Gold OA" or "Hybrid OA".

MDPI and Frontiers are highly efficient organizations that are optimized for article quantity. They employ large in-house staff to handle many of the tasks traditionally managed by academics serving as journal editors. This results in faster and more consistent turnaround times, which can help attract authors. Both publishers put enormous effort into recruiting authors, to the point that their "spamming" practices have damaged their reputations among researchers. Both have seen their share of controversy over editorial decision-making processes. A recent article noted the use of the term "MDPI Professors" (El Pais) to describe researchers whose CVs were populated with large quantities of such articles¹⁰.

¹⁰ https://english.elpais.com/science-tech/2023-06-04/a-researcher-who-publishes-a-study-every-two-days-reveals-the-darker-side-of-science.html

MDPI and Frontiers drive growth of articles and revenue by putting out subject-focused "special issues." (Figure 11). Huge numbers of individual researchers are recruited to guest-edit special issues. These guest editors are expected to recruit other authors to contribute to the special issue (each paying an APC for publication of their article). The numbers of special issues are staggering. MDPI is on track to produce 56,000 special issues in 2023, with some journals publishing 10 special issues per day, every day of the year.

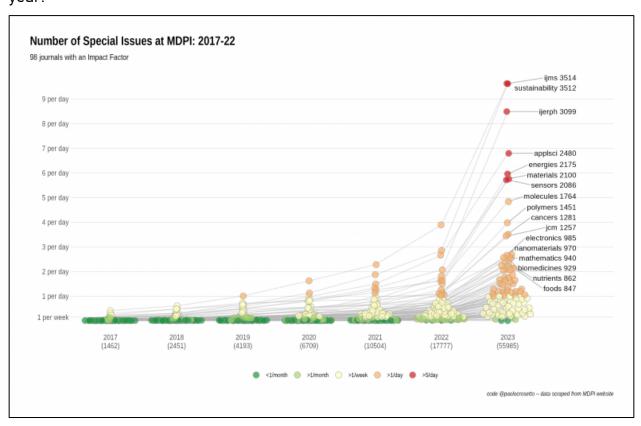


Figure 11. MDPI Special Issues. Source: Paolo Crosetti¹¹

A recent cautionary tale involves Hindawi, a fully OA publisher purchased by Wiley in 2021. According to Retraction Watch, much of what Hindawi was publishing was "fraudulent" — essentially, fake papers being sold to authors

¹¹ <u>https://www.timeshighereducation.com/news/quality-questions-publishers-growth-challenges-big-players</u>

by "paper mills" for publication in special issues that had very little quality control^{12,13}. Wiley is in the process of retracting at least 1,700 articles and shutting down the corresponding journals¹⁴. Web of Science delisted 19 Hindawi journals from having Impact Factors, representing 50% of Hindawi's published articles in 2022¹⁵.

The strategy employed by MDPI and Frontiers has been incredibly successful from a financial perspective. A comparison of the top 10 publishers by volume of articles published in 2012 versus 2022 (Figure 12) shows MDPI and Frontiers becoming two of the largest scholarly publishers (numbers 3 and 6, respectively).

| Publisher | Publication Volume 2012 | Publisher | Publication Volume 2022 |
|-------------------------|-------------------------|-------------------------|-------------------------|
| Elsevier | 514,157 | Elsevier | 782,636 |
| Springer Nature | 269,367 | Springer Nature | 448,643 |
| Wiley | 214,201 | MDPI | 300,366 |
| Taylor & Francis | 130,474 | Wiley | 243,955 |
| Wolters Kluwer | 81,276 | Taylor & Francis | 147,043 |
| SAGE Publications | 64,674 | Frontiers | 126,407 |
| Oxford University Press | 58,719 | Wolters Kluwer | 98,842 |
| Trans Tech Publications | 55,506 | Oxford University Press | 91,756 |
| ACS | 41,860 | CABI Publishing | 83,804 |
| IEEE | 37,499 | SAGE Publications | 79,310 |

Figure 12. Largest scholarly publishers by volume, 2012 and 2022. Data source: Dimensions (Digital Science; search limited to "articles").

 $^{^{12}\,\}underline{\text{https://retractionwatch.com/2022/09/28/exclusive-hindawi-and-wiley-to-retract-over-500-papers-linked-to-peer-review-rings/}$

¹³ https://en.wikipedia.org/wiki/Research paper mill

¹⁴ https://scholarlykitchen.sspnet.org/2023/04/04/guest-post-addressing-paper-mills-and-a-way-forward-for-journal-security/

 $^{^{15}\,\}underline{\text{https://www.science.org/content/article/fast-growing-open-access-journals-stripped-coveted-impact-factors}$

RESEARCH FUNDER POLICIES

In 2008, the US National Institutes of Health (NIH) started requiring the deposit of articles resulting from funded research in PMC, to be made available within 12 months of publication. At the time, publisher groups raised concerns about version control, pirating of papers, and undermining the sanctity of the editorial process, but they nonetheless began to deposit articles in PMC on behalf of funded authors as a service. There was little to no measurable impact on journal subscriptions as a result of the 2008 NIH policy, although it is difficult to measure, and the free availability of articles, even with delayed availability, may play a role in enabling the aforementioned Big Deal cancellations.

2013 saw two landmark policies: the Research Councils UK (RCUK) 0A policy and the US White House Office of Science and Technology Policy (OSTP)

Holdren Memo. RCUK was, at the time, the UK's main research funder (now subsumed by the UKRI). The RCUK policy required all articles supported by their funding to be published 0A, with a strong preference for Gold 0A routes to compliance. If the journal of choice did not offer Gold 0A, or if the researcher had no funds for it, Green 0A routes with a delay were acceptable. Rather than using research grant money to pay APCs, the RCUK made block grants to universities to cover these costs. The policy was largely successful in driving strong growth in 0A in the UK, but it was also far more expensive than expected, particularly on the administrative side (e.g., managing payments and monitoring compliance)¹⁶. Because the UK took this action in isolation, UK universities had to continue to pay for subscription content from around the world. There was no offsetting of the additional costs.

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 $^{^{16}\,\}underline{\text{http://www.research-consulting.com/new-report-highlights-9m-compliance-cost-of-uk-open-access-requirements/}$

In the US, the 2013 Holdren Memo extended the earlier NIH public access policy across all US federal science funders that spent more than \$100 million per year on research funding. The policy called for the same 12-month embargo on access with no reuse rights required. (This is a public access policy as defined in the glossary in Appendix B, not an open access policy.) As with the initial NIH policy, publisher groups pushed back but ultimately cooperated with the federal agencies. Many offered automatic deposit on behalf of authors, increasing compliance. The Holdren Memo policy does not appear to have impacted journal publisher revenues, while public access to research content was significantly enhanced.

PLAN S

In 2018, an international consortium of research funding and performing organizations called "cOAlition S" launched Plan S. Plan S only covers about 5% of the scholarly literature, and yet it has had an outsized effect on the market as a major tipping point in the shift to OA^{17} . Although it has been revised over time, Plan S essentially requires all research funded by coalition members to be published OA, and only in fully-OA journals. Research funding cannot be used to pay for OA in hybrid journals. Exceptions to this rule were added over time, largely in response to concerns that researchers would be shut out from publishing in the venue of their choice. Hybrid journals are now permissible, at least through 2024, but only within the "Transformative Agreement" framework described below.

Transformative Agreements (TAs) marked a significant shift in open publishing business models and the journals market (Figure 13). Under a TA — a "bigger Big Deal" — institutions pay not only for access to a publisher's full portfolio of journals, but also pay to cover all the costs for authors at the

¹⁷ https://deltathink.com/news-views-plan-s-effects-2021-part-1-article-volumes/

institution to publish OA in that publisher's journals. For this reason, TAs are sometimes referred to as "Read and Publish" or "Publish and Read" agreements.

It requires a great deal of data collection and analysis to put together a TA. The deal parameters are time consuming to negotiate, meaning only publishers with sufficient resources can pursue them. TAs are also generally limited to larger publishers because they only make economic sense for the publisher and the institution if there will be a large number of readers and authors. If researchers from an institution publish only a handful of papers annually in a publisher's journals, it is hard to justify the work involved in negotiating a TA.

The rise of TAs led to a further wave of market consolidation. Many scientific societies entered into new partnerships with larger publishers to avoid being left out. This wave of market consolidation has not been thoroughly studied; data is needed to understand the impact on smaller, independent, and scientific society publishers. cOAlition S is now retrenching, and seeking alternatives to pay-to-publish models in achieving the broader goals of open access¹⁸.

It is also worth noting that TAs likely create an incentive for researchers to choose to publish in paid open access journals that their libraries subsidize over those their libraries do not subsidize. These non-subsidized outlets include most journals independently published by scholarly societies and university presses. Data on the scale of this phenomenon is not publicly available, but would elucidate the impact that TAs have had on publishing choice.

¹⁸ https://www.researchprofessionalnews.com/rr-news-europe-infrastructure-2023-6-alternatives-to-dysfunctional-open-access-model-sought/

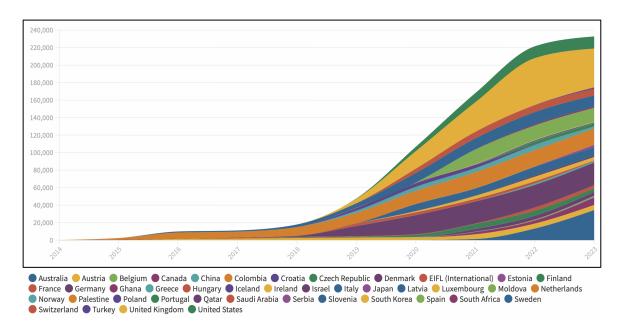


Figure 13. Articles published via Transformative Agreement per year 2014 – 2023. Source: ESAC Transformative Agreement Registry (Data current as of 21 April 2023)¹⁹.

THE NELSON MEMO

The "Nelson Memo", named for then-Acting OSTP Director Alondra Nelson, was released in August 2022 with the aim of enabling free, immediate, and equitable access to federally funded research²⁰. The Memo directs federal agencies to remove the 12-month embargo for public access to federally funded research papers and, further, mandates immediate public release of data collected using federal funding. The Nelson Memo requires federal agencies to have new policies in effect by January of 2026. It also extends the Holdren Memo public access requirements to all federal agencies, not just science agencies that spend more than \$100 million on funding annually.

¹⁹ https://esac-initiative.org/about/transformative-agreements/agreement-registry/

 $^{{}^{20}\,\}underline{https://www.whitehouse.gov/wp\text{-}content/uploads/2022/08/08-2022-OSTP\text{-}Public\text{-}access-}\underline{Memo.pdf}$

Specifically, the Nelson Memo requires that the author's accepted manuscript (AAM) version or, if possible, the published version of record (VOR) of any paper listing federal funding be deposited in an agency-designated repository and made publicly available immediately upon publication. Again, this is "public access," and no specific licensing requirements, such as the use of a Creative Commons license, are required. As with the Holdren Memo, no additional funding has been provided to support the policy, and federal agencies have not been provided with formal guidance on how to cover the costs of Gold OA publishing from their research budgets.

As a result, Gold OA publication costs for researchers are presumably going to be paid by their universities or come directly out of their research grants. Without additional publishing subsidies, a laboratory that publishes 10-20 papers per year under this model could lose the equivalent of a postdoc's salary, or a significant amount of equipment or reagents; whereas an alternative to such subsidies could be lower-priced publication. With funding diverted from performing experiments to paying for publication, it is possible that less research will be done in exchange for more access to the results of federally funded research. It remains an open question whether that reduction will be balanced out by research progress enabled by immediate public access to papers or other benefits of open access. (The same tradeoff would exist if agencies fund Gold OA costs without having their budgets increased accordingly.)

Independent analyst Christos Petrou estimates that the Nelson Memo will cover around 200,000 papers per year, about a third of total output from US researchers²¹. However, those 200,000 articles are not evenly distributed.

 $^{^{21}\,\}underline{\text{https://scholarlykitchen.sspnet.org/2022/09/13/guest-post-quantifying-the-impact-of-the-ostp-policy/}$

Some journals and fields will see little impact (e.g., a mathematics journal where federal funding is scarce, versus an oncology journal where the majority of papers carry some level of NIH funding). Because grant funding is increasingly competitive and tends to fund high-quality research from top laboratories, the Nelson Memo could impact researchers publishing in highend, selective journals more strongly.

While the Nelson Memo allows compliance through Green OA, it is not yet clear how significant a role that model will play in researchers' and publishers' response to the Nelson Memo. Compliant Green OA articles would be made available simultaneously in subscription journals and for free online in agency (or other) repositories. Publishers that do not trust subscriptions to hold up under such circumstances will likely attempt to promote Gold OA instead. Springer Nature, for example, has stated that all federally funded authors will be required to pay an APC to publish in their journals.²² Only a few journals, particularly those that publish significant amounts of nonresearch paper content (e.g., Science) or those more reliant on licensing rights and advertising for revenues (e.g., Journal of Clinical Oncology), have stated that they prefer the Green OA model.

For now, we exist in a liminal space²². While the research community in principle embraces a future of increasing open access to articles, data, code, and other research products, how current policies will be implemented remains to be seen. Without further policy guidance, or interventions to support future diversity in the publishing ecosystem, we are likely to see continued rapid growth of publishing models that emphasize quantity and efficiency over quality control. This may be good for some publishers, but it is likely not what's best for science or the broader research community.

²² https://scholarlykitchen.sspnet.org/2022/01/13/life-in-a-liminal-space-or-the-journey-shapesthe-destination/

For the moment, journal publishing is fragmented. OA is growing, but does not represent the whole market; there are still entire fields and parts of the world that are likely to stay with the subscription model for the time being. China, given that country's large and growing research output, would have to increase spending enormously if their authors were required to publish under Gold OA²³. Subscriptions are not going away on January 1, 2026 when the Nelson Memo goes into effect. Over time, it will be important to track what proportion of a journal's articles has to be OA, on average, before subscription sales decline, particularly from libraries, which make up the majority of subscription revenue.

The largest commercial publishers are committed to APC-based Gold OA models and are now facing competition from large born-OA publishers in terms of submissions. Mid-sized publishers such as Wolters Kluwer and Oxford University Press (the world's largest university press) are in growth mode, launching new journals and signing partnerships with scientific society journals in an effort to achieve the scale necessary to survive an OA market. Smaller and independent publishers are in crisis, with many signing agreements to outsource their publishing operations to larger commercial publishers or facing an uncertain future. The volatile market has made larger publishers more risk-averse, making the terms offered to society journals less favorable (for example, with respect to revenue sharing). Some societies and researcher editors are abandoning commercially-owned journals and moving to smaller non-profit publishers due to the high APCs put in place by large publishing houses and the requirement to publish more papers. For

²³ https://www.ce-strategy.com/2023/06/an-interview-with-china-stm-publishing-expert-nickogoncharoff/

example, the entire editorial board of a top neuroscience journal published by Elsevier resigned in April of 2023 to start a new journal with the MIT Press²⁴.

There is indeed growing researcher awareness of, and unhappiness with, the unintended consequences of the author-pays APC model for OA. An earlier example of this trend is the journal *Quantitative Science Studies*, which launched at the MIT Press in 2019 after the editorial board of *Journal of Informetrics* (Elsevier) resigned to protest high APCs and restrictive policies related to the free distribution of abstracts and reference lists²⁵. Despite this upheaval and the absence of an impact factor at the outset, the new non-profit journal's submissions and reputation grew quickly, and it is now ranked #1 out of 77 journals in the 2022 Emerging Sources Citation Index (ESCI) Information & Library Science category with an impact factor of 6.4.

RESEARCH DATA

The new OSTP policy also requires federal funding agencies to develop policies obligating researchers to make the data underlying their published findings "freely available and publicly accessible by default at the time of publication." The widespread availability of open, reusable data democratizes research by decoupling the ability to access and analyze research data from having the resources to collect that data. It also promotes trust and transparency in research.

This shift in policy will require universities and individual researchers to share the data related to research publications on or before publication. How, where, and at what cost are not yet clear. There are also situations in which the sharing of data publicly is not possible, for example, for federal security and due to patient privacy concerns. Hence, the policy leaves open questions

²⁴ https://www.nature.com/articles/d41586-023-01391-5

²⁵ https://direct.mit.edu/gss

 $^{{}^{26}\,\}underline{\text{https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-access-Memo.pdf}}$

about how federally funded researchers will comply, and how universities should plan and budget accordingly.

Note: we acknowledge that research data is a huge and multifaceted topic. This section of the report is short because the group did not bring in outside expertise on the topic of research data during the course of our discussions. However, the group did raise several questions related to data sharing that are included below.

VERTICAL INTEGRATION IN THE INFRASTRUCTURE OF RESEARCH COMMUNICATION

Scholarly and scientific communication relies on tools, standards, and platforms for hosting, editorial management, analytics, and more. Some of this infrastructure is open-source or community owned, but more of the highly utilized technology is proprietary. Mergers and acquisitions over the last several years have resulted in a handful of large publishers owning much of the relevant infrastructure.

As open access publishing grows, major commercial publishers have expanded into associated areas, largely by acquiring scholarly infrastructure, services, and data analytics. Many of the core tools used to publish and access research results have, consequently, gone from being independently owned to being part of commercial publishing houses and technology companies. In their 2019 book chapter *Vertical Integration in Academic Publishing: Implications for Knowledge Inequality,* Chen, Posada and Chan report on a detailed analysis of the mergers and acquisitions of three of the five major academic publishing companies.

Elsevier, Wiley, and Taylor and Francis each have a long history of acquiring other publishers and established journals. More recently, these companies have made significant acquisitions of tools and services that function across the knowledge production lifecycle. For example, Aries, and their Editorial Manager submission and peer review system, is now owned by Elsevier.

Wiley now owns the Atypon platform, host to over 100,000 publications, along with J&J editorial services and most recently, the eJournal Press submission and peer review system. Wiley has stated that nearly half of the world's peer-reviewed research at some point goes through Wiley-owned platforms²⁷.

Figure 14 depicts the results of Chen et al.'s analysis of the various Elsevier academic services and how they influence institutions and individuals' decision making.

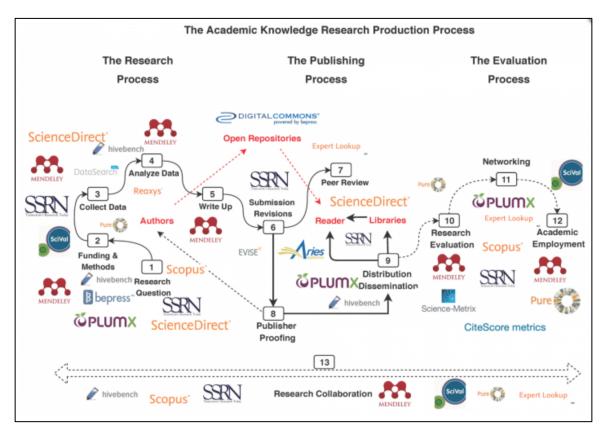


Figure 14. Elsevier presence throughout the research lifecycle. Source: Figure 5 in CHEN, George; POSADA, Alejandro; et CHAN, Leslie. Vertical Integration in Academic Publishing: Implications for Knowledge Inequality. In: Connecting the Knowledge Commons — From Projects to

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²⁷ https://edscoop.com/wiley-jay-flynn-open-access-research/

Sustainable Infrastructure : The 22nd International Conference on Electronic Publishing – Revised Selected Papers Marseille : OpenEdition Press, 2019.²⁸

In 2022, Elsevier acquired Interfolio, a system that enables academics to collect and manage critical data for academic hiring, review, promotion and tenure. As Aspesi and Brand argued, the growing ownership of data analytics, hosting, and portal services by large scholarly publishers may enhance publishers' ability to lock in institutional customers through combined offerings that condition (or discount) one product or service upon purchase of another²⁹.

THE IMPERATIVE FOR EXPERIMENTATION

Some smaller not-for-profit publishers are in a state of rapid experimentation, developing new models. These are works in progress, looking for solutions to compensate for the negative consequences of the APC model. Small non-profits are well placed to take on this experimentation because they are at risk in the market, are eligible for grant funding to pursue innovative ideas, and because they do not have the pressure of constantly needing to meet shareholder expectations.

Many of these new models are risky because they rely on the goodwill of, and voluntary spending from, the library community. For example, Subscribe to Open is a model wherein the publisher sets a threshold of subscription levels for a journal (or a collection of journals) and, if enough libraries subscribe, the journal (or collection) is made OA for that year.³⁰

Other models rely on community approaches, like the Open Library of the Humanities, which solicits donations from supporter libraries each year. One

38

²⁸ https://books.openedition.org/oep/9068

²⁹ https://www.science.org/doi/10.1126/science.aba3763

³⁰ https://subscribetoopencommunity.org/

concern about these types of models is that there is no penalty imposed on free riders. If you stop paying, it's likely that you will still have full access to the journal as long as it endures, so why pay for something that is otherwise free? If a library has to make a budget cut, it is easier to stop spending on something that they will retain access to anyway. It remains to be seen whether this will happen in practice, and many of these models hedge against the free rider problem by providing additional benefits to participating libraries.

Other models include the University of California's "multi-payer" model, in which the university pays a portion of the APC and requires researchers to cover the rest out of grants, if they have them. Right now, participation is voluntary — a funded researcher can choose not to contribute³¹. It is unclear how well the model will be accepted if authors are required to pay part of the fee.

PLOS has introduced a Community Action Publishing model that has been described as "subscribe-to-publish." It spreads the costs of publication out over all authors on a paper, rather than asking for one (large) fee from the corresponding or lead author. In addition, the number of papers published at an institution in the preceding three years is averaged, and an annual charge to the institution is determined based on a given institution's publishing rate. The downsides of this model include the enormous amount of ongoing data crunching, and the year-to-year variance. So too, the model does not support authors who are not affiliated with institutions under one of these deals (or not affiliated with any institution at all). Hence, this model may not be viable

 $[\]frac{31}{https://osc.universityof california.edu/uc-publisher-relationships/negotiating-with-scholarly-journal-publishers-a-toolkit/an-introductory-guide-to-the-uc-model-transformative-agreement/$

³² https://plos.org/resources/community-action-publishing/

for a publisher with few journals or a low article volume, as it could prove difficult to engage libraries in the effort required.

DIAMOND OPEN ACCESS

Under Diamond OA, access is free for readers *and* publishing remains free for authors. Diamond OA relies on a combination of subsidy (e.g., through an endowment, direct university or society support, or grant funding), and unpaid volunteer time. This model can work, up to a certain volume. If a journal has a small number of submissions, an academic editor can reasonably be expected to manage the review process as well as publication. But as a journal grows, the workload may become too significant to be handled by volunteers alone.

A few society journals have adopted Diamond OA, notably among them *Cultural Anthropology*, the prestige journal of the Society for Cultural Anthropology (SCA), a section of the American Anthropological Association.³³ Diamond OA since 2014, *Cultural Anthropology* is currently published on an instance of Open Journal Systems, a low-cost journal hosting platform.³⁴ The journal's modest budget includes salary and benefits for two half-time editorial positions, with costs shared by the SCA and in-kind contributions from the individuals' home institutions. To support its share of the budget, the SCA recently ran a successful campaign to secure funding from LYRASIS's Open Access Community Investment Program³⁵, for an initial five-year commitment. The journal's financial future remains uncertain but nonetheless demonstrates a viable non-profit alternative to the Gold APC model.

³³ https://journal.culanth.org/index.php/ca

³⁴ https://openjournalsystems.com/

³⁵ https://www.lyrasis.org/content/Pages/oacip.aspx

Diamond OA has worked on a larger scale in some regions, including South and Central America where national funders have built cooperative models such as SciELO.³⁶ These large-scale, multimillion-dollar models have promise, but may be easier to build in areas that do not have established publishing infrastructure and expectations already in place. One question about this model concerns innovation: in a cooperative model with no competing journal publishers, there may be less incentive to invest in improvements. Many of the new tools valued by research funders and researchers (e.g. persistent identifiers, and paper mill and image manipulation detection tools) have been instigated by large publishers. If competition is removed or reduced, how will that impact the drive towards ongoing improvements in publishing infrastructure, in service to the research ecosystem, and how will those technological advances be funded?

As the transition to open access continues, more experimentation and study is needed, particularly to monitor the impact of different models on researchers and the research enterprise. There is no one-size-fits-all model in academic publishing. Different fields of study have different cultures, publishing norms, and funding models. Hence, the future of research publishing and open access will continue to involve a variety of models.

A publishing ecosystem dominated by a few major commercial publishers would reduce the diversity of publishing options and leave universities and researchers without choices on pricing and publishing approaches. It would also leave less well-funded or unfunded researchers from the U.S. and abroad increasingly disadvantaged compared to well-funded researchers.

³⁶ https://scielo.org/

Many in the research community remain unaware of the drivers of change in academic publishing and the potential consequences for the research ecosystem, as well as for society publishers (many of whom have relied on journal subscription revenue to subsidize other society activities) and university budgets. There is now a need for an in-depth, evidence-based examination of key questions concerning the future of quality research and its availability.

PART 2 – OPEN QUESTIONS ON THE FUTURE OF ACADEMIC PUBLISHING IN SIX KEY AREAS, WHERE MORE RESEARCH AND DATA ARE NEEDED

The health of the research enterprise is closely tied to academic publishing practices and systems. As detailed above, policy-driven changes in publishing business models over the last two decades have triggered a number of disruptions in this ecosystem that raise concerns about their impact on the research enterprise. Because different research fields have differing publishing practices and funding mechanisms, it is critical to the health of the overall research enterprise that stakeholders help construct and sustain a publishing ecosystem that encompasses a variety of access and business models (Green OA, Gold OA, Diamond OA, pre-print publishing, etc.) and a diversity of publishers and knowledge infrastructures (by which we mean, systems and technologies that support researchers in the generation, sharing, and maintenance of scientific knowledge).

In the discussions that led to the drafting of this report, we focused on defining key questions for investigation to understand, measure, and best prepare for the impact of open access in research publishing, as well as broader open science practices such preprint publishing, open peer review, open software, and open protocols. These questions are intended to spur research that will help inform future policies and their implementation. We raise questions in six areas:

- Access and business models
- Research data
- Preprint publishing
- Peer review
- Costs to researchers and universities
- Infrastructure

Below we include the five key questions in each area that the group considered to be high priority. Appendix A contains additional questions that our conversations generated.

ACCESS AND BUSINESS MODELS

- 1. How do we assess whether open access policies are measurably improving equitable access and the overall research enterprise? The Nelson memo is designed to increase equity of access. How will equitable access be defined and measured over time, to determine if the policy change has had the desired impact in terms of access to scholarship? Is open access changing who is conducting, publishing, or responding to research? Is there any indication of different research questions/directions or any other change in research because of open access? Does access equate to impact and beneficial use by society, and how can that be quantified? Does "equitable access" apply to authors as well as readers of the literature?
- 2. What new metrics or indicators should be developed to assess academic reputation? Gold OA may have the unintended consequence of tying academic reputation (conveyed by the prestige of a journal and associated citation metrics) to publisher APC payments, since more prestigious journals tend to have higher APC charges. Is cost per citation a valuable metric for assessing the value of publishing in a particular journal? What new indicators of the value of one's research should be developed to assess academic reputation?
- 3. How is paid open access impacting the publishing output of less well funded researchers, fields, institutions, and countries? Is the shift to Gold OA creating unintended equity issues and, if so, how can that be quantified? How will open access models, in particular APCs, impact research disciplines that attract fewer and smaller grants (especially in the humanities and social sciences)? What does an OA system that does

- not mostly benefit well-funded labs, and institutions that can afford to publish their results in their journals of choice, look like? Is it possible to measure the extent to which authors from places and disciplines that typically receive less funding are excluded from publishing in journals with high author fees (controlling for quality of submitted work)?
- 4. How is open access policy impacting scientific and scholarly societies? How will new open access policies impact scientific and scholarly societies that have relied on subscription revenue to subsidize other activities? What challenges and opportunities are there for these societies in developing and adapting to new business models, and how would such transitions be funded? How is publishing's transfer strategy to keep submissions within a single company's family of journals impacting the revenues of scientific societies and other small publishers? More generally, what is the role of for-profit publishers in research dissemination? Do they benefit the current ecosystem beyond what can be provided by society and non-profit publishers? If they are generally causing harm to academic publishing, what steps might be taken to make non-profit alternatives successful, and to help disciplines that currently depend on for-profit publishers to cut free from that dependence?"
- 5. How is the Gold open access model impacting industry consolidation? The journal publishing industry has been consolidating, with larger publishers acquiring established journals and related academic infrastructure, as well as launching new open access journals. Reduced competition may lead to increased costs for researchers and universities. How will new federal policies impact industry consolidation and what metrics should be used to measure industry trends? Could current trends have been predicted? How should the rate of industry consolidation and its impact on publication quantity, quality, and cost be tracked and made publicly available?

RESEARCH DATA

- 1. How can we estimate the overall cost of research data sharing over time? How much data is the research enterprise generating, how can this be measured, and how is this output changing over time? How will the overall cost of implementing research data sharing be estimated and how much will it cost stakeholders to implement broad data sharing policies?
- 2. What metrics should be used to measure the broad impacts of research data sharing over time? How do we measure the impacts of open science policies on intellectual property protection and management, innovation, and technology licensing at universities? What measures could be developed to assess the impact of open data sharing on scientific progress and commercialization? How will new data sharing policies impact intellectual property and the commercial impact of research discoveries, and how should those be measured over time?
- 3. How should universities and researchers prepare for required research data sharing? How can federal agencies work with universities to ensure the longevity of data, especially when grants run out or researchers change institutional affiliation or retire? How can stakeholders assess if researchers have the expertise in data management needed to make the data they deposit truly useful to the community? What data management and curation training should be developed and required of researchers and how will that training differ by field? How can universities help their researchers acquire this expertise?
- 4. What standards for exemptions to sharing research data should be developed? What exemptions are acceptable for delaying the sharing of data that underlies a submitted/published paper? Can these exemptions be standardized across federal agencies? Across fields? Is there value in developing a cross-agency standard for data sharing?
- 5. What tools and technologies should be developed to make the most of broad research data sharing practices? Should technologies that enable

research data to be re-used without exposing or publishing the underlying data be part of open data sharing practices? This is particularly important for health data that potentially includes identifying patient/subject information. It is also important when considering the impact of generative AI.

PREPRINT PUBLISHING

- 1. How have preprint sharing practices impacted different fields? How are preprints being read in different fields, and by whom? How has growth in preprint publishing impacted peer review, speed of publication, and rates of journal publishing in different fields? What percentage of preprints go on to be formally published in peer reviewed journals?
- 2. How has preprint sharing impacted scientific outcomes and public communication of science? What measures should the community develop to assess how increasing access to preprints is impacting scientific outcomes (e.g., accuracy, reproducibility, etc.)? How does public access to preprints that have not been peer reviewed impact public understanding and media coverage of scientific research?
- 3. What standards should be developed for preprint sharing? There are, thus far, no common standards in preprint archiving for vetting papers prior to posting, linking preprints to journal versions of papers that may result, removing preprints when final papers are retracted, or when preprints themselves are retracted, verifying that a preprint has the same content (modulo formatting) at the reviewed journal version, etc. What are the desirable standards for preprint publishing and how should they be developed, deployed, and enforced? What does the community need by way of improved discovery tools to make searching across disparate preprint archives most efficient in the research process?
- 4. What are the measurable impacts from sharing preprints and author manuscripts on citation practices? Have preprints and the availability of

- author manuscripts through Green OA models created significant citation confusion associated with multiple versions being available? How much do preprints and Author's Accepted Manuscript (AAM) versions of papers differ from Versions of Record (VOR) of papers (wherever they may be posted)? Does this vary among fields, and what impact has this had on the scientific enterprise?
- 5. How can we assess differences in scientific or public impact between preprint sharing and OA article publishing (within a journal)? Are there measurable differences in scientific impact between articles published immediately on preprint servers and articles that are made available through open access after full peer-review (and not first deposited in a preprint archive)?

PEER REVIEW

- 1. How can we make the type of peer review a journal article has undergone more transparent, and will this help promote trust in science? What standards and tracking capabilities should be developed to signal the quality and type of peer review a journal has used, and what metrics could be used to assess the quality of research peer review? Would these measures help identify predatory publishers and journals (where "predatory" describes publishers that exploit authors by charging APCs but don't provide the editorial and publishing services, such as peer review, that are associated with legitimate publishers)?
- 2. What experiments and technologies should be developed to improve the quality and efficiency of peer review? With respect to research integrity, among other concerns, what experiments in peer review could help inform the deployment of new and better peer review models? What AI tools could be developed to accelerate and improve the peer review process? What new technologies could help reviewers become more efficient and increase the quality of their reviews?

- 3. What steps can be taken to ensure the long-term viability of quality peer review in academic publishing? With the dramatic increase in article publication rates over the last two decades, peer review burnout is a problem for the entire scholarly communications ecosystem. How much time are researchers dedicating to peer review? How can we ensure that reviewers are representative of their fields? What could universities and funders do to encourage high engagement and appropriate credit for peer reviewing, especially for early career scholars?
- 4. What models of publisher-independent, cost-effective *closed* peer review could be developed? Many journals are piloting or using forms of open peer review, but "closed" peer review remains more common. Indeed, one of the major functions of journals is to manage closed peer review, to hide the identities of the reviewers in order to avoid social pressures that can bias review results. What models of publisher-independent, cost-effective closed peer review could or should be developed?
- 5. What standards should be established for ensuring the quality and veracity of research data submitted to journals for publication? Now that researchers will be required to share the data underlying the conclusions in their publications, should that underlying data also be subject to peer review? If so, how would standards for peer review of data be developed and implemented? How will this impact publication cost? As the quantity of data explodes, how will peer review scale? With the existing peer review system already under stress, how would it cope with such increased volume of material for review?

COSTS TO RESEARCHERS AND UNIVERSITIES

1. What models should the research community adopt to track how much funding is going toward publication costs over time? Should the flow of university and federal funds to publishers according to business model and publisher size/type be monitored? If so, how? Is open access

expenditure reducing the availability of funds for research? Who is paying APCs and other charges? Is the total cost of publication to research entities changing, or just being redistributed? Should standards for reporting publication spending be developed for both grant recipients and for university allocations of grant overheads? How much will it cost researchers and universities over time to pay to publish their research under different open access models, including APC-based and Read-and-Publish models? How is this best estimated, and how do costs compare to current expenditures?

- 2. How should the research community monitor shifts in the amount and type of research publishing costs over time? As more journals shift to APC models, the cost to read journals is moving from libraries paying for subscriptions to authors who pay APC charges to make their papers freely available at the time of publication. At the same time, libraries that engage in Read-and-Publish agreements are now carrying publication costs. How do the costs of subscriptions currently compare with the future total costs in APC charges for libraries? For authors? For universities? How much does the APC model concentrate costs on research-intensive universities?
- 3. What are the most effective ways for universities and researchers to manage changing publication costs? Historically, publishing was mostly free to authors, and accessing literature was paid for by library collections budgets. Most major research libraries have now converted at least some of their collections budget to cover some publication costs, whether via an APC fund available to institutional authors, via Read-and-Publish contracts that cover APCs in bulk, or via direct subsidies to support open access ventures. How will/should stakeholders determine the most effective ways to fund the costs of publication? What are the implications of different models for university stakeholders (budget offices, provosts, departments, scholars, libraries, etc.)?

- 4. How should universities track the costs of open access over time and what are possible mechanisms for public sharing of such data? How can the manner in which universities are paying for "supply side" open access be tracked over time? Will it mostly come from grant funds, other university sources, or from dollars saved in library budgets if and when subscriptions are canceled? How will federal agencies track changes in APCs over time to keep track of the cost of publishing? How are savings/cost increases at institutions reflective of research productivity?
- 5. How should researchers and universities budget for compounding costs associated with data deposition and storage over time? The cost of storing data, along with the creation and maintenance of metadata over time, will increase with the amount of data shared and archived. How should researchers budget for long-term data storage and metadata maintenance in grant proposals? Is it possible to match the requirement for indefinite/long-term data storage to the short-term nature of grant proposals?

INFRASTRUCTURE

- 1. What data management and storage infrastructures are necessary to ensure long term access, discoverability, and integrity of research data over time? Is current data storage and management infrastructure in the U.S. sufficient for the purpose of managing and storing data into the foreseeable future? Data sharing infrastructure is siloed and often field specific. For example, there are ~1,300 biomedical research databases alone. How does the potential cost of maintaining a fragmented system compare with the cost and benefit of creating and supporting a federated/distributed infrastructure system?
- 2. What open or community-owned research publishing infrastructure is needed to help support the research ecosystem? How can we measure investments in essential infrastructure for scholarly communication on

the part of different stakeholder groups (funders, publishers, universities, etc.)? How has vertical integration of publishing companies — meaning, the growing ownership of data analytics, hosting, and portal services by large scholarly publishers — impacted researchers and research communication?³⁷ Once built, how can infrastructure be maintained and improved over the long term?

- 3. What infrastructure should be developed to support compliance with new public access requirements? How well-prepared are researchers, in terms of knowledge and skills, to comply with new requirements? What new technology and human services should be developed to ensure that researchers can easily comply with public access requirements? What are the appropriate infrastructure and support services that universities should be putting in place to aid researchers in complying with new policy requirements?
- 4. How can we track and learn from successful examples of academyowned publishing infrastructure? What are the leading examples of widely
 used open or community-owned infrastructure, developed through grant
 funding, by nonprofits, or through university consortia? What can we learn
 from these examples to inform the future development of academyowned publishing infrastructure?
- 5. How can we ensure the longevity and stability of code sharing infrastructure? What are the current infrastructures available to researchers for sharing code, and how well do they meet the needs of ease of use, longevity, and stability? How can we create a federated infrastructure for software and code that ensures longevity and stability? How can this infrastructure account for evolving code and updated contributions? How should the costs and benefits of this effort be assessed?

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³⁷ https://www.science.org/doi/10.1126/science.aba3763

APPENDIX A: Other Questions Generated By The Group

ACCESS AND BUSINESS MODELS

- 1. What are the key opportunities going forward for scholarly societies and university presses to serve the research enterprise, given the changing publishing landscape?
- 2. Lariviere et al., studied market consolidation up to 2013, before many of the major publication policies from governments and funders went into effect. What has happened since then and how much has the market consolidated? How many smaller/independent society journals remain in the market? How much are different publishers of different sizes (and approaches) growing? How much of that growth is through partnering with existing journals, including society journals, and how much is through launching proprietary competitor journals to those societies? How has the impact of publishing in various sectors of the market changed over the past ten years?
- 3. What impact will the changes in scholar's behavior/choices have on the evolving landscape? For example, what are the broader and longer-term impacts of editorial boards resigning from for-profit journals and starting new journals with non-profit publishers? What about scholars electing to publish their work with non-profit publishers, who typically charge lower APCs (or provide Diamond OA journals), thus reducing the overall cost of publishing to the university and keeping the funds "in the system"? If authors choose to publish their papers in commercial journals because they feel the journals offer higher quality services, should universities try to incentivize them to change their behavior?
- 4. How will scholarly book publishing be impacted by open access policies? Will such policies create disincentives to apply for federal

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³⁸ https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0127502

- funding if the product will be a book that must be made available through open access?
- 5. There has been a steady increase in the rate of research papers being published over time, including a dramatic increase in publications overall. This growth has been driven in part by the volume incentive to journals of author-funded open access, and in part by the incentive system for scientists to publish more often, along with the opportunity to publish smaller contributions. How do we balance the contribution of more substantial publications with the contribution of publishing less well-developed research results faster, and how do we measure these changes? Has the Gold open access model affected the publication quality of research papers given the incentive to publish more articles?
- 6. How do journal offerings of services such as highly selective peer review, professional editors, copyediting, integrity checks, etc. compare between subscription and OA journals? How have some commercial and highly selective nonprofit journals managed to keep their citation rates so high? Are there lessons to be learned by journals with lower impact factors? Are there correlations in the amounts of services offered and the price level of the APC charged?

RESEARCH DATA

- 1. How can standards best be developed and maintained for common data types? Common standards (file types, metadata, etc.) for data types greatly increase efficiency of reuse, allowing for cross comparison between experiments and different research groups. How can community-driven standards be developed and supported as they evolve?
- 2. Should the funding agencies require in data management plans that grant applicants explain how the data will be stored forever? Will it be necessary to create some form of "storage annuity" that will allow

- researchers to pay up front for indefinite storage? What are best practices for federally funded researchers in budgeting for research data storage and access over time?
- 3. How will established intellectual property be impacted if data are reused in a new publication? In generative AI systems?
- 4. What is the role, present and future, for libraries as data repositories?
- 5. What are best practices for teaching researchers -- especially early career researchers -- good data (and code) sharing and stewardship practices?
- 6. Will agencies specify Creative Commons or Open Source licenses for data and code publications?

PREPRINT PUBLISHING

1. How can we assess the financial impacts to journal publishers from expanded preprint publishing access?

PEER REVIEW

- 1. How can the scientific community better communicate to its own broad membership, and to the wider world, which journals are reliable or of particularly high quality? What role do networks of trust and endorsement play?
- 2. There are different types of open peer review. For example, some open peer review involves the reviews being shared openly while the identity of reviewers remains protected. Other open peer review practice opens the identity of reviewers as well. What measures can we use to assess the pros and cons of different types of open peer review and recommend best practices?

COSTS TO RESEARCHERS AND UNIVERSITIES

1. How will university costs for patenting be impacted, if data sharing compliance requires researchers to seek patents before commercial partnerships (with patent sponsorship) are solidified?

APPENDIX B: GLOSSARY OF TERMS

- Article processing charge (APC). A fee charged to authors to allow for immediate, unrestricted access to the full version of a publication. APCs are paid by the author, the author's funding body, or their institution.
- **Big Deal**. Bundled online subscriptions to academic journals are sold under a Big Deal at prices lower than the sum of their individual prices.
- coAlition S. coAlition S is a group of private funding agencies and national research funding organizations, with the support of the European Commission and the European Research Council (ERC), whose goal is to ensure all the research they fund is made open access immediately on publication.
- Creative Commons (CC By) licenses. CC licenses include six different Creative Commons licenses that allow users to distribute, remix, adapt, and/or build upon the author's work depending on the specific license, so long as the user gives credit to the original author.³⁹
- **Diamond open access journals**. Diamond open access journals typically receive financial support from one or more institutions and organizations and thus do not have article processing charges (APCs) or other fees for publication.
- **Embargo Period.** An embargo period is the time between the formal publication of an article and when it becomes freely available online.
- **Gold open access**. Gold open access papers are immediately and freely accessible via the journal on the publisher's website as the version of record, often (but not always) via a fee paid by or on behalf of an author. They are published under a Creative Commons license.

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³⁹ https://creativecommons.org/about/cclicenses/

- **Green open access**. Green open access papers are freely accessible outside of the formal journal, often via an open access repository.
- **Hybrid journals**. Hybrid journals are subscription-based journals that provide authors with an option to publish their papers as Gold open access, accompanied with a Creative Commons license.
- **Mega journal.** Mega journals publish a broad variety of research without judging the perceived importance of it. Instead, they look purely at the soundness of the research. Well-known mega journals include PLOS ONE and Scientific Reports.
- **Open access**. Open access (or OA) is the practice of providing free and unrestricted online access to research publications. Open access research is made available for free in perpetuity with limited restrictions on how readers can share and re-use the content.
- Open Access Journal. An open access journal is a peer-reviewed publication that makes all of its articles freely available online without the need for subscriptions. It includes Gold open access journals, which charge APCs, and Diamond open-access journals, which usually do not include additional charges and rely on institutional funding.
- **Plan S initiative.** Initiated in 2018 by cOAlition S, a global consortium of research funding bodies, Plan S requires all scholarly publications that are funded by its member organizations to be made immediately open access.
- **Predatory publishing.** Predatory publishing is an exploitative publishing model to intentionally take advantage of the academic need to publish by charging authors while not conforming to the normal peer review process for individual articles.
- **Preprint**. Preprint papers are posted by authors to a preprint server where they can be viewed freely prior to peer review and formal publication.

While preprints have been shared for decades in the physics, math, and computer science communities, the practice of posting preprints in other scientific disciplines is relatively new. Typically (but not always), preprinted publications are published twice: first in an open repository for the purposes of establishing intellectual priority and communicating with colleagues, and, secondly, in a journal for the purposes of peer review, broader dissemination of the work, and reputational advancement, among other traditional functions of journals.

Public access. Public access refers to the requirement placed on recipients of federal funds to make research results freely available. It does not address copyright or choice of open access business model.

Read and Publish agreement. (See Transformative Agreements below) In Read and Publish agreements the publisher receives payment, typically from an institution or consortium, for reading and publishing by authors from that institution or consortium in that publisher's journals.

Transformative Agreements. Transformative Agreements (Sometimes called Read and Publish agreements) are made between publishers and research institutions or consortia. They include provisions to cover the costs of Gold OA content published by researchers based at the institution, negating the need for APCs when those researchers publish their work Gold OA. They allow affiliated authors to make the final version of their article Gold open access as well as providing access to subscription content for the library users.

Version of record. The full-text HTML and formatted PDF of the final edited publication posted to a journal website.

AFTER THE "NELSON MEMO": KEY CONSIDERATIONS FOR DELIVERING ON THE PROMISE OF OPEN & EQUITABLE SCHOLARSHIP

A BRIEFING TO THE NATIONAL ACADEMY OF SCIENCES, ENGINEERING, AND MEDICINE'S ROUNDTABLE ON ALIGNING INCENTIVES FOR OPEN SCHOLARSHIP

ABOUT THE ROUNDTABLE

The National Academy of Sciences, Engineering, and Medicine's Roundtable on Aligning Incentives for Open Scholarship convenes critical voices to discuss the effectiveness of incentives for adopting open science practices and ways to align incentives that support common missions. To learn more about the Roundtable's activities, or to join the hundreds of universities, departments, foundations, government agencies, and professional societies that are collaborating to align research practices, values, and incentives, contact the Roundtable secretariat.

ABOUT THIS RESOURCE

WHAT IS THE IMPETUS FOR THIS BRIEFING?

In June 2023, the National Academies of Sciences, Engineering, and Medicine's Roundtable on Aligning Incentives for Open Scholarship hosted a public workshop to hear from key members of the research ecosystem whose work will be directly impacted by the 2022 White House Office of Science and Technology Policy (OSTP) memorandum titled "Ensuring Free, Immediate, and Equitable Access to Federally Funded Research". By the end of 2025, all articles and data resulting from the U.S.'s \$90 billion annual investment in research will be required to be made immediately publicly available. By the end of 2027, additional requirements for enhanced metadata and Persistent Digital Identifiers (PIDs) will present new opportunities for diverse research outputs to be made more discoverable and more easily assigned credit. Given these imminent inflection points, it was timely to convene a diverse panel of speakers to provide perspectives on what the Roundtable, its members, and the broader research community can do to proactively align reward systems to take advantage of the OSTP directive. In the aftermath of the June 2023 public workshop, the Roundtable convened an ad hoc working group to draft this brief. It enumerates important considerations pertaining to the "post-Nelson" world that require careful, coordinated attention.

HOW CAN THIS BRIEFING BE USED?

This resource details practical steps that individuals and organizations can take to ensure that the emerging open-centric research ecosystem is optimized for equity, inclusivity, efficiency, replicability, transparency, trust, and engagement. It provides guidance to colleges and universities, public and private funders, professional societies, and others for aligning their processes and their incentive structures with open scholarship values. Additionally, it highlights a range of organizations that are exhibiting good practices in the field.

CONTRIBUTORS

The following Roundtable members and/or designates contributed to the authorship of this resource: Chris Bourg, Massachusetts Institute of Technology; Maryrose Franko, Health Research Alliance; Athena Jackson, University of Houston; Shelley Stall, American Geophysical Union; and Greg Tananbaum, Open Research Funders Group.

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ALTERNATIVE JOURNAL BUSINESS MODELS

WHY IS THIS CRITICAL TO AN OPEN & EQUITABLE ECOSYSTEM?

- Non-APC open access journals remove financial barriers, allowing authors from diverse backgrounds and institutions to publish their research without the burden of high costs while simultaneously ensuring readership access for anyone anywhere in the world.
- Equity in scholarly publishing means that all researchers should have an equal opportunity to disseminate their work and have it recognized within the academic community. Non-APC open access journals ensure that publication decisions are based on the quality of research rather than the ability to pay, promoting a level playing field for authors.
- Many researchers (including but not limited to those early in their careers) often lack the
 financial support needed to cover APCs, making it difficult for them to publish in certain
 journals. Non-APC open access journals empower all researchers to contribute to the
 scientific discourse without being held back by financial constraints.
- By removing the financial barriers, non-APC open access journals encourage a broader range of researchers to participate in publishing. This leads to diverse perspectives and a richer academic discourse that expands canonical structures and benefits the global research community.
- APC waivers don't address the root issue of socioeconomic disparities in academia. Instead
 of rectifying the financial barriers that hinder researchers' ability to publish, fee waivers can
 further entrench these disparities by not challenging the underlying financial model of
 scholarly publishing.
- Waivers might not be a sustainable long-term solution for researchers who cannot afford APCs. They might provide temporary relief but do not address the larger issue of establishing a publishing system that is equitable and accessible for all researchers, regardless of their financial situation.
- APC models may create perverse incentives for journal publishers to focus on volume of articles published at the possible cost of quality.
- APC models create conditions for predatory publishers to exploit the publish-or-perish culture of academia for profit.

WHAT DO WE MEAN BY "ALTERNATIVE JOURNAL BUSINESS MODELS"?

Traditionally, the dominant journal business model has been subscriptions, primarily via academic libraries. As open access has grown in prominence, some publishers have increasingly relied on article processing charges (APCs). This is a fee paid by or on behalf of authors before publication. These articles are then typically free to read, but not necessarily reuse. Alternatives journal business models eschew both subscriptions and APCs, typically in a manner that centers equity.

PRACTICAL WAYS TO ADVANCE ALTERNATIVE JOURNAL BUSINESS MODELS

- Colleges and universities, funders, agencies, and inter- and intra-sector coalitions can allocate institutional funds to directly support non-APC open access journals. This could include grants, subsidies, or direct funding to cover the operational costs of these journals, helping them maintain quality and sustainability without relying on APCs or subscriptions.
- Colleges and universities, funders, and agencies can provide training and resources for faculty to understand the benefits of non-APC open access journals, encompassing the perspectives of authoring, reviewing, and editing. This can involve workshops on open access publishing, copyright, and licensing issues.
- Funders and agencies can build or provide supportive publishing and repository infrastructure that will scale and reduce operational costs across the board.
- Funders, agencies, and libraries can nurture partnerships with scholarly societies that are working towards sustainability operations that are fair and equitable.

"OPEN SCIENCE SHOULD PLAY A SIGNIFICANT ROLE IN ENSURING EQUITY AMONG RESEARCHERS FROM DEVELOPED AND DEVELOPING COUNTRIES, ENABLING FAIR AND RECIPROCAL SHARING OF SCIENTIFIC INPUTS AND OUTPUTS AND EQUAL ACCESS TO SCIENTIFIC KNOWLEDGE TO BOTH PRODUCERS AND CONSUMERS OF KNOWLEDGE REGARDLESS OF LOCATION, NATIONALITY, RACE, AGE, GENDER, INCOME, SOCIO-ECONOMIC CIRCUMSTANCES, CAREER STAGE, DISCIPLINE, LANGUAGE, RELIGION, DISABILITY, ETHNICITY OR MIGRATORY STATUS, OR ANY OTHER GROUNDS."

UNESCO RECOMMENDATION ON OPEN SCIENCE

GOOD PRACTICES IN THE FIELD

There are a number of models for disseminating scholarly content that do not rely on either subscription or APC fees, including:

- Science Europe's Diamond Open Access Collaborative
- Subscribe to Open Community of Practice
- Open Library of the Humanities

AUTHOR RIGHTS RETENTION

WHY IS THIS CRITICAL TO AN OPEN & EQUITABLE ECOSYSTEM?

- Rights retention empowers authors to maintain control over their scholarly works and make informed
 decisions about how and when their research is disseminated, shared, and reused. This includes
 empowering authors to determine how their research can be reused for educational purposes,
 derivative works, and collaborations, and ensures proper attribution.
- Clear licensing terms makes it easier for users to know the circumstances under which they are allowed to reuse research.
- Rights retention gives authors and their institutions greater control over how their research is used by generative AI and other emerging technologies.

PRACTICAL WAYS TO ADVANCE AUTHOR RIGHTS RETENTION

- Institutions and research funders can enact policies that encourage or require authors to retain their copyright and all rights therein when publishing. This could be integrated into institutional open access policies or grant agreements.
- Institutions and funders can develop resources and templates that provide researchers with clear explanations of copyright terms, Creative Commons license options, and how they can retain their rights.
- Institutions and funders can implement rights retention policies that explicitly enumerate how the copyrights associated with the work they support can be assigned. This reduces the burden on individual authors to understand the nuances and complexities of copyright law.
- Institutions and research funders can engage with publishers to amend their Basic Copyright Transfer Agreement to ensure the author maintains a basic set of reuse and sharing rights.
- Libraries can include rights retention in the required terms for contracts they sign with publishers (including, but not limited to journal subscription and transformation agreements), so that authors are required to grant only "limited" or "non-exclusive" licenses to publishers.
- Libraries can negotiate with publishers to change the terms of the license-to-publish contracts authors have to sign when publishing, ensuring these agreements only restrict what end users may do under the license and not what the licensor (rights holder) can do.

GOOD PRACTICES IN THE FIELD

Among the community-driven initiatives to support author rights retention are the following:

- Authors Alliance
- cOAlition S Rights Retention Campaign
- University of Californiia Statement on Retention of Author Rights in License to Publish Agreements

ENGAGING THE PUBLIC IN RESEARCH RESULTS

WHY IS THIS CRITICAL TO AN OPEN & EQUITABLE ECOSYSTEM?

- Being able to communicate complex scientific findings in a manner that the general public understands can promote transparency, engagement, and informed decision-making.
- Clear and accessible communication helps the public comprehend the significance of research and its implications for society. It fosters trust, encourages public participation, and promotes a sense of engagement with scientific advancements.
- When the public is well-informed about scientific research, they can make informed decisions on matters that impact their lives, such as health, environment, and policy issues.
- Increased engagement with and understanding of scientific developments can combat both misinformation and disinformation.

PRACTICAL WAYS TO IMPROVE COMMUNICATION WITH THE PUBLIC

- Universities and professional societies can offer funding, workshops, and training sessions for researchers on effective science communication techniques, emphasizing the importance of clear language, storytelling, and engagement.
- Universities, professional societies, funders, and research institutions can recognize and reward researchers who excel in science communication. This can be considered in promotion, tenure, awards, and grant funding decisions.
- Research funders can require grant recipients to include a science communication plan as part of their grant proposals.
- Explore and support research dissemination through diverse modalities (videos, podcasts, social media, etc.) and a range of outlets (in-person events, livestreams, makerspaces, etc.).
- Support and fund repositories that provide research data and information in formats that local and regional communities and decision makers can access and use.

GOOD PRACTICES IN THE FIELD

There are a host of emerging initiatives focusing on stimulating and rewarding public engagement, such as:

- <u>University of Arizona's Inclusive View of Scholarship</u>
- Civic Science Fellows Network

TRANSPARENCY OF PROCESSES AND DATA AS REMEDIES AGAINST MISINFORMATION

WHY IS THIS CRITICAL TO AN OPEN & EQUITABLE ECOSYSTEM?

- How research is designed, executed, and disseminated can be critical in ensuring that impacted communities and populations have a sense of equity in both processes and outcomes.
- Sharing not just research findings but also the code, protocols, data, and other building blocks on which these findings are based allows others to verify the work, detect errors, and build upon the research, improving accuracy and reducing the potential for misinformation.

PRACTICAL WAYS TO IMPROVE TRANSPARENCY OF PROCESSES AND DATA

- Institutions and funders can recognize and reward transparent research and reporting practices, such as study preregistration, protocol sharing, data sharing, etc.
- Institutions, societies, publishers, and funders can implement data ethics and reproducibility review practices.
- Institutions, societies, and funders can recognize and promote those publishers that are aligned to these characteristics through policy and practice such as requiring datasets supporting research to be preserved in a community-accepted trusted repository, described, and cited in the paper.
- Publishers should review not just the submitted manuscript, but also apply dedicated expertise to reviewing the underlying data.
- Funders, institutions, and societies can encourage researchers to select digital preservation repositories that provide services to researchers to improve documentation, interoperability, and other elements of the FAIR Principles.

GOOD PRACTICES IN THE FIELD

Examples of organizations working to improve and incentivize the transparency of research processes and data include the following:

- Data Curation Network
- FASEB/NIH DataWorks! Prize
- American Heart Association Open Science Policy

CONFERRAL OF CREDIT TO REFLECT FULL RANGE OF CONTRIBUTIONS

WHY IS THIS CRITICAL TO AN OPEN & EQUITABLE ECOSYSTEM?

- Full and accurate credit conferral recognizes the diverse roles individuals play in research projects, promotes collaboration, and prevents the marginalization of certain contributors.
- It promotes equity by valuing the input of all team members, regardless of their titles or seniority.
- It recognizes alternative career tracks that are increasingly common and central to the research endeavor (e.g., data stewards, research software engineers).
- Full and accurate credit facilitates research transparency by clearly denoting the roles of each contributor.

PRACTICAL WAYS TO IMPROVE CONFERRAL OF CREDIT

- Develop guidance and training for researchers and project leaders on acknowledging various contributions. This could include authorship guidelines, data contributor acknowledgments, and more.
- Establish clear guidelines for authorship that reflect specific contributions. Encourage the use of contributor roles (e.g., "data analysis," "experimental design") to acknowledge different aspects of research work.
- Support the implementation and recognition of the CRediT taxonomy, which can be used to granularly detail the roles played by contributors to research outputs.
- Funders can require research teams to articulate each member's contributions in grant proposals and progress reports.
- Redefine metrics of success beyond publication count. Recognize other contributions, such as software development, data management, and public engagement.
- Create visible platforms for more diverse research team members to present their findings, not just summary results presented by principal investigators.

GOOD PRACTICES IN THE FIELD

Projects in this area include the following:

- <u>CRediT Contributor Role Taxonomy</u>
- <u>University of North Carolina Tips for Highlighting Team-Based Research and Scholarship in Appointment, Promotion and Tenure Packages</u>
- Royal Society's Résumé for Researchers

INCLUSION OF DIVERSE COMMUNITIES AND VOICES IN DESIGNING AN OPEN RESEARCH ECOSYSTEM

WHY IS THIS CRITICAL TO AN OPEN & EQUITABLE ECOSYSTEM?

- Diverse participation brings in a variety of viewpoints, enhancing the depth and breadth of research discussions and outcomes.
- Research outcomes are more likely to address real-world challenges and conditions when diverse voices contribute, making the research relevant and impactful.
- Engaging with impacted communities and populations during a project's early stages, rather than just communicating the end results, can foster a spirit of co-creation and co-ownership that ultimately benefits all parties.
- "Nothing about us without us" remaking the research ecosystem to be more equitable without the active engagement of traditionally marginalized voices is self-defeating.
- By incorporating historically marginalized communities, we not only rectify past exclusions but also ensure that the benefits of open knowledge dissemination extend to all.

PRACTICAL WAYS TO INCLUDE DIVERSE COMMUNITIES IN DESIGNING AN OPEN RESEARCH ECOSYSTEM

- Ensure diverse representation in grant review panels to prevent biases and increase sensitivity to projects involving marginalized voices.
- Include statements on public websites, application/review material, annual reports, etc., that highlight the value of including diverse experiences and perspectives.
- Provide implicit bias training for researchers, program officers, graduate students, and other contributors to the research ecosystem.
- Collaborate with marginalized communities to co-design research projects, ensuring local expertise and priorities are integrated.
- Fund and empower research among a broader set of principal investigators across geographies, institution types, and backgrounds.

GOOD PRACTICES IN THE FIELD

The array of activity in this space includes the following:

- Collaboratory for Indigenous Data Governance
- Project Pathways
- Wellcome Trust's Equitable Funding Practices Library



Towards responsible publishing: a proposal from cOAlition S

31 October 2023

www.coalition-s.org

DOI: 10.5281/zenodo.8398480

Towards responsible publishing:

seeking input from the research community to a draft proposal from cOAlition S

cOAlition S – an international consortium of research funding and performing organisations, committed to making full and immediate Open Access a reality – is seeking input from the global research community on a proposal to establish a community-based scholarly communication system, fit for open science in the 21st century.

1

INTRODUCTION

"New research builds on established results from previous research. The chain, whereby new scientific discoveries are built on previously established results, can only work optimally if all research results are made openly available to the scientific community."

Marc Schiltz, "Why Plan S", cOAlition S (2018), www.coalition-s.org/why-plan-s

In the five years that have elapsed since the publication of the Plan S principles, the move toward full and immediate Open Access (OA) has become global and irreversible. However, academic publishing practices are not keeping up with rapid advances in the way science is performed, openly disseminated, and used. This disconnect increasingly threatens the goal of universal OA for research outputs.

The COVID pandemic has illustrated the need for faster and more efficient publishing models. The traditional publishing system was simply too slow to disseminate critical and urgently needed scientific information on SARS-CoV2. In response, scholars all over the world are adopting new publishing practices to improve dissemination and peer review of new research findings. Researchers are increasingly sharing articles ahead of peer review and are starting to participate in open peer review of such author-shared articles. In addition, research institutions and researchers, such as in Latin America, have championed innovative models, referred to as "diamond" publishing, that offer scholar-led publishing services free to authors and readers.

These developments are forcing funders and other stakeholders – especially university libraries who procure publishing services on behalf of their researchers – to re-think how best to support the dissemination of research in a responsible, equitable, and sustainable way.

In this document, we propose a **vision** and set of **principles** that a future scholarly communication system should aspire to, along with a **mission** that enables research funders – in collaboration with other key stakeholders – to deliver on this.

For such a scholar-led system to be successful, however, it will need broad support from the research community. To understand if the proposal outlined here resonates with the community of researchers, cOAlition S with support from Research Consulting Limited in partnership with the Centre for Science and Technology Studies (CWTS) will embark on a consultative process that offers researchers the opportunity to voice their opinions and contribute to the development of a proposal that serves their needs. Further details of this consultation are provided in **Section 8**.

Based on the feedback we receive through this consultative process, a revised proposal will be developed for the cOAlition S funders to consider in June 2024.

WHY SCHOLARLY COMMUNICATION NEEDS TO CHANGE

Much has been written about the problems with the current scholarly communication ecosystem, and we consider that these can be distilled into four key challenges.

2.1

THE DOMINANT PUBLISHING MODELS ARE HIGHLY INEQUITABLE.

The overwhelming majority of academic journals cover their costs through subscriptions, article processing charges (APCs), or both. As a result, researchers can find themselves unable to access relevant research findings (because of subscription paywalls) or unable to publish (because of APC barriers). We fully recognise that publishing incurs costs, but we believe that all researchers should be able to publish their work as Open Access, without author-facing charges.

2.2

THE SHARING OF RESEARCH OUTPUTS IS NEEDLESSLY DELAYED.

Research can only progress as quickly as it is shared. The current pre-publication peer review model contributes to publication delays because it requires that improvements are implemented before a "publish" decision is reached. As a result, online publication in some journals can now take longer than when articles and journals were printed and shipped through the postal service. In an era of the internet and digital technologies, a 12-month delay in releasing new knowledge into the public domain – a not <u>uncommon</u> timeframe whilst pre-publication peer review is undertaken – is just as detrimental to science and society as the 12-month open access publication embargo that Plan S has eliminated.

2.3

THE FULL POTENTIAL OF PEER REVIEW IS NOT REALISED.

Peer review is currently the main method to ensure quality control and context for new scientific knowledge. Unfortunately, its confidential nature often hides the efforts and insights of peer reviewers. When articles are rejected, this information is lost, and the entire process must be repeated at a different journal. At best, such repetitive and confidential reviewing processes waste the insights from earlier peer review reports; at worst, they undermine quality control and accountability of authors, peer reviewers, and editors.

Moreover, when peer review reports and editorial evaluations remain inaccessible, they cannot contribute to a better understanding of the scholarly discourse or support responsible research assessment based on intrinsic merit rather than proxies like journal names or impact factors.

2.4

THE COUPLING OF EDITORIAL GATEKEEPING WITH ACADEMIC CAREER INCENTIVES IS DAMAGING SCIENCE.

The rejection-resubmission cycle and the coupling of editorial gatekeeping with academic career incentives have led to idealising journal selectivity. High rejection rates and requests for substantial revisions unnecessarily burden scientists, particularly early career researchers, who spend a significant fraction of their effort on article publication. The current state of publishing thus threatens the well-being and persistence of the next generation of scientists in academic research.

We believe the solution to these problems is a scholar-led communication ecosystem, as described below.

SCOPE

In this document, we focus on scholarly communications that disseminate research articles (including the underlying research data) and associated content-related elements (such as peer review reports, author responses, editorial decisions/assessments, etc.). Other research outputs, such as monographs, are important, but they are out of the current scope. In this context, the concept of Open Science covers all disciplines, as defined by the UNESCO Recommendation on Open Science.

4

VISION



Our vision is a community-based scholarly communication system fit for open science in the 21st century. This system empowers scholars to share the full range of their research outputs and to participate in new quality control mechanisms and evaluation standards for these outputs. This approach will ensure rapid, transparent dissemination of high-quality scientific knowledge.

Research is a social endeavour that produces and scrutinises research results to create trusted knowledge for the benefit of society. Because this social process of dissemination and discourse thrives on the largest possible participation and knowledge exchange, research funding and performing organisations promote the concept of "open science": research and society are best served if research results are shared openly and as early as possible.

However, these "open science" aspirations are constrained by prevailing business models and incentive structures that value just a static snapshot of the research process, the final peer-reviewed publication.

Scholars should be able to choose when and where they communicate their work, driven by the desire to accelerate research and to expose their work to feedback and re-use. Such a scholar-led approach to communicating new findings better reflects the research process and opens opportunities for feedback and assessment along the way.

Scholar-led communication is defined here as those publishing initiatives where all content-related elements (e.g. primary research articles, peer reviews, editorial decisions, scientific correspondence, etc.) are controlled by, and responsive to, the scholarly community.

Under this approach, researchers face no charges for reading or publishing, keep ownership of their outputs, and have the right to share them freely.

PRINCIPLES

The following principles support the vision outlined above:

Principle 1

AUTHORS ARE RESPONSIBLE FOR THE DISSEMINATION OF THEIR FINDINGS.

Authors – and not third-party suppliers, such as publishers - should decide when and where to publish, including versions before and after peer review and the associated peer review reports.

Service-related elements (copyediting, typesetting, submission systems, hosting, formal quality checks) can be outsourced.

Principle 3

QUALITY CONTROL PROCESSES ARE COMMUNITY-BASED AND OPEN, TO ENSURE TRUSTWORTHINESS OF RESEARCH FINDINGS.

Academic communities set quality standards and monitor them through acknowledged quality control processes. Third-party service providers may supply tools that facilitate quality controls by the academic community, including technical checks, peer review, and editorial assessments, if appropriate, but do not set the rules for the process. The outcomes of these processes, including peer review reports, are published to enable open quality control, signal trust, and allow further scrutiny.

Principle 5

STAKEHOLDERS COMMIT TO SUPPORTING THE SUSTAINABILITY AND DIVERSITY OF THE SCHOLAR-LED PUBLISHING ECOSYSTEM.

Stakeholders, including research funders, researchers, and service providers, agree to use their resources – money, expertise, and services – to drive development and adoption of community-based publishing. Moreover, in supporting and refining scholar-led initiatives in an open dialogue with all scholarly communities, funders and other stakeholders commit to respecting bibliodiversity, disciplinary differences, and the specificity of epistemic traditions.

Principle 2

ALL SCHOLARLY OUTPUTS ARE SHARED IMMEDIATELY AND OPENLY.

Researchers share scholarly outputs openly, allowing others to adapt, reuse, and build upon these results, at no cost to themselves.

This principle supports the overarching ambition of Plan S to provide full and immediate OA but is extended to include all scholarly outputs, such as preprints and peer review reports.

Principle 4

ALL SCHOLARLY OUTPUTS ARE ELIGIBLE FOR CONSIDERATION IN RESEARCH ASSESSMENT.

All scholarly contributions are considered in research assessment. Their value is determined by the relevant research communities. This approach will form the basis of a more complete assessment of the qualitative contribution of individual articles than that afforded by derivative proxies such as journal names and impact factors.



MISSION



In line with the vision and principles above, our mission is to facilitate the transition to an open, scholar-led communication ecosystem. We seek to do this in partnership with the research community, and through our funding requirements and research assessment processes.

7

OPPORTUNITIES TO ENGAGE

A scholar-led communication system is not a new idea. We simply seek to expand and build on existing good practices. The **Annex** describes a concrete working example, referred to as Publish – Review – Curate (PRC).

For a community-based communication system to thrive and grow, it needs support. We recognise that we cannot change the current publishing system overnight, nor can one stakeholder change it on their own. We need researchers, service providers, funders, and institutions to work together if we want to put scholarship at the centre of scholarly communication.

Researchers will need to take a more active role in the dissemination of their research outputs. They will gain the freedom to share their research findings at various stages of maturity – before, during, and after peer review. But they will also take on the responsibility to contribute more openly to peer review such that this scholarly dialogue can benefit the whole community and not just an editorial decision.

Service providers will need to tailor their services to support and augment scholarly contributions rather than control or withhold them from view.

Finally, research funders and institutions will need to encourage and reward practices that are aligned with the principles in this proposal, and they can do this in several ways. First, they can incentivise researchers to participate in a scholar-led communication system through their research funding and assessment policies and practices. Second, they can provide financial support for infrastructure and services that align with scholar-led systems. And third, they can use their convening power to bring together other key stakeholders, namely researchers, institutions, scholarly societies, and service providers.

The potential future adoption of the proposed strategy by members of cOAlition S is subject to the decision process of the cOAlition and its individual members, which will take place after the consultation. Even if cOAlition S funders adopted the proposed strategy and refined it through public consultation, existing (and emerging) OA business models - such as APCbased fully OA publishing, Subscribe to Open (S2O), etc. - will continue to be supported by cOAlition S for some time. However, we expect that funders supporting this strategy will, over time, increase their spend with service providers that offer services that align with these principles and reduce their spend with those that do not. Similarly, supportive funders would replace the use of journal metrics in the assessment of researchers with assessment practices that take advantage of the complete scholarly record the new communication system would make available.

Table 1, below, provides a menu of options for actions that funders and institutions could take to support participation of researchers and service providers in the proposed system. We have arranged these actions into three different levels of stringency (Levels 1 – 3) to illustrate that implementation of this strategy enjoys considerable flexibility.

For example, cOAlition S or individual funders could adopt Level 1 actions early on and adopt next level actions later, if appropriate, in a phased approach. Funders could also engage in these actions collaboratively with other stakeholders. It may, for example, make sense to follow the lead of initiatives like **COARA** that are already focusing on reforming research assessment.

| Activity | Level 1 | Level 2 | Level 3 |
|--|---|--|---|
| Research funding and assessment policies and practices | Encourage scholar-led communication; specifically, support scholars to retain sufficient copyright to their work, promote publication of research outputs before peer review and participation in open, postpublication peer review. | Reward applicants for posting preprints, open peer review reports, and open data by explicitly including those practices in the assessment of researchers; instruct assessors that journal names, impact factors, and number of journal articles will play no role in researcher assessment. | Remove journal metrics and journal names from application materials. |
| Financial support | Pay transparent fees and/or award grants to platforms that perform services aligned with the principles of a scholar-led communication system (e.g. preprint servers and peer review and curation services); financially support diamond publishing models and infrastructure for a scholar-led communication system. | Commit to <i>increasing</i> funding to scholar-led services by <i>decreasing</i> , over time, funding to traditional publishing models, for example, by phasing out agreements that include hybrid or subscription journals. | Make payments contingent on the public availability of relevant scholarly or service products such as peer review reports and curation reports. |
| Convening power | Bring together other key stakeholders to discuss their role in this new strategy and determine the optimum way of implementing a scholarled communications ecosystem. | Form coalitions with other stakeholders – institutions, scientific societies – to develop and support a scholar-led communication ecosystem. | Together with other stakeholders, form a global community of scholar-led communication supporters/infrastructure providers/advocates; move from an open access community to a global scholar-led communication community. |

Table 1: Activities funders and institutions could take to support the establishment of a scholar-led communications ecosystem

CONSULTATION

The overarching aims of this consultation are to:

- determine to what extent the vision, mission and principles set out in the draft proposal serve the needs of the research community including researchers who are funded by cOAlition S funders and those who are not
- understand how the "Towards Responsible Publishing" proposal might be modified or refined to ensure it resonates with the needs and aspirations of the research community and consequently garners broader support and adoption
- identify any showstoppers or unintended consequences in the draft proposal and propose proactive measures to mitigate them, ensuring successful implementation
- ascertain whether (and, if so, to what extent) the existing scholarly communication infrastructure can support this proposal; if it cannot, identify areas where research funders and others should best direct their funding to strengthen the infrastructure

The consultation will run from November 2023 until April 2024. Details of how the research community can contribute to this can be found at: www.coalition-s.org/towards-responsible-publishing



CONCLUSION

The Plan S initiative has enabled more research to be made available as Open Access than ever before. However, in the main, this has been delivered through business models – such as Read and Publish agreements and APCs – which are highly inequitable. Moreover, the current practice of pre-publication peer review needlessly delays the sharing of research outputs, and as long as peer review reports and editorial evaluations remain inaccessible, they cannot support responsible research assessment.

The proposal presented here seeks to rectify these issues, through the development and support of a scholar-led communications ecosystem. This approach builds on and expands good practices that already exist and is fully aligned with the recent conclusions from both the **Council of the European Union** and **UNESCO**.



A scholar-driven ecosystem already exists

a working example

To illustrate how a scholar-led communication system can (and already does) work in practice and supports the principles of Open Science, we highlight the Publish, Review, Curate (PRC) model, which we find particularly promising. This model distinguishes three core functions of scholarly communication – publication, peer review, and curation – to ensure full and immediate sharing of scholarly outputs. We focus here on the characteristics of an editor-based PRC model. But cOAlition S is mindful of the plurality of existing community-based efforts, including disciplinary differences, and is open to supporting a scholar-led ecosystem broadly with the expectation that gradual convergence may happen over time.

STEP 1: AUTHORS DECIDE WHEN TO PUBLISH THEIR UNREVIEWED PUBLICATIONS.

Unreviewed publications (a.k.a. preprints) are hosted on dedicated platforms (such as institutional and subject-based repositories and preprint servers) after formal guideline checks (such as authorship criteria, plagiarism, data availability, language, ethical approval, guidelines, etc.) have been undertaken. No costs for providing this service are passed to authors. Preprints are made available under an open licence, such as CC BY. Readers are given the opportunity to comment on these unreviewed publications informally and openly.

STEP 2: AUTHORS DECIDE WHEN TO EXPOSE THEIR WORK FOR FORMAL REVIEW.

At some point, potentially after receiving (and responding to) some informal feedback, the authors will expose their work for a full review by submitting it to a high-quality reviewing process managed by practising scholars. The costs of providing this service will not fall on the author.

The purpose of the reviewing process is to help the author improve the paper and to enable readers to put the work into context of the published literature.

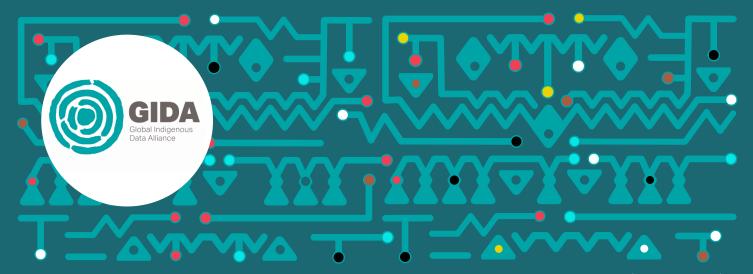
Peer Review Editors then provide an editor's evaluation or summary of the reviewing process, but do **not** make any recommendation as to whether the article is suitable for publication.

Reviews (signed or not), author responses, revised articles, and evaluations resulting from this process are openly shared.

STEP 3: CURATION EDITORS SELECT ARTICLES FOR PUBLICATION.

Among other roles, curation editors decide which peer-reviewed papers to include in the (overlay) journals or platforms they edit. Selection criteria may include, for example, perceived quality, originality, or thematic cohesion of sets of papers. The roles of peer review editors and curation editors are incompatible.





GLOBAL INDIGENOUS DATA ALLIANCE (GIDA) Indigenous Data Governance & Universities

GIDA INDIGENOUS DATA SOVEREIGNTY SUMMIT 28TH JUNE 2023
NAARM (MELBOURNE), AUSTRALIA

COMMUNIQUÉ

TO:

All Universities¹ and funders involved in creating, collecting, accessing, analysing, interpreting, managing, disseminating, and reusing data and data infrastructure

FROM:

Participants in the 2023
Global Indigenous Data
Alliance (GIDA) Summit
in Naarm (Melbourne):
Indigenous Peoples from
Australia, Aotearoa (New
Zealand), the United States,
Canada, Norway, Sweden,
Finland, and Tonga and
Samoa (diaspora Aotearoa)

Universities create, use, and hold enormous amounts of Indigenous data. These data range from old historical records to contemporary large datasets, including Open Data² and the data underpinning emerging Artificial Intelligence (AI) Technologies. Indigenous Peoples' data include information about individuals, families, and communities, and environments as well as knowledges, cultures, languages and specimens.

All Universities are responsible for managing research data ethically, effectively, and transparently. The issue for Indigenous Peoples is that Universities are failing to affirm and uphold Indigenous Data Sovereignty (IDSov) and operationalise Indigenous Data Governance (IDGov), leaving these academic institutions open to claims of complicity in the ongoing structure of colonisation.

The 2023 Summit progressed a shared understanding amongst GIDA members that Universities must work in collaboration with affected Indigenous Peoples to:

- Uphold IDSov and IDGov principles as defined by their respective Indigenous Peoples.
- Recognise that any data concerning Indigenous Peoples is Indigenous Data.
- Identify Indigenous Peoples' data currently held by the institution or its research partners.
- Introduce and strengthen University policies to align with IDSov and IDGov and ensure Indigenous Peoples' governance of, access to, and future use of their data now and into the future.
- Support and grow Indigenous leadership to assess digital research infrastructure needs and enact control over all IDGov processes.
- Train University administration, faculty, staff, and students to implement IDSov & IDGov principles and policies.
- Operationalise Data Management Strategies and Plans with specific IDGov principles and mechanisms embedded throughout.
- Allocate adequate resources for Indigenous Peoples to govern their data on their terms.











DEFINITIONS:

The United Nations

Declaration on the Rights
of Indigenous Peoples
(UNDRIP) supports

Indigenous rights over data.3

Indigenous Data Sovereignty (IDSov) asserts Indigenous Peoples' rights to govern the creation, collection, ownership, and application of the data about, from, or connected to Intellectual Property (IP).4

Indigenous Data Governance (**IDGov**) is the mechanism for realising IDSov principles.

Indigenous Peoples reserve the right to determine which data held by Universities require IDGov and to abstain from data governance arrangements not adhering to this Communiqué.

- 1 While our focus is universities, this extends to any tertiary education provider or research institute.
- 2 | Walter, M. et al., Indigenous data sovereignty in the era of big data and open data, Australian Journal of Social Issues 56, no. 2 (2021): 143-156.
- 3 | For further information please see UNDRIP Articles 3, 4, 5, 15(i), 18, 19, 20(i), 23,31, 32, 33, 38, & 42.
- 4 | Kukutai, T. and Taylor, J. eds. 2016. Indigenous Data Sovereignty: Towards an Agenda (Vol. 38) ANU Press.
- 5 I Wilkinson, Mark D., et al. "The FAIR Guiding Principles for scientific data management and stewardship." Scientific data 3.1 (2016): 1-9.
- 6 | A tangible or intangible item or matter of special cultural significance.

Resources to Assist in Operationalising Indigenous Data Governance (IDGov)

The CARE Principles for IDGov

The CARE Principles are people and purpose-oriented, reflecting the crucial role of data in advancing Indigenous innovation and self-determination. These principles⁵ complement the FAIR principles, encouraging open and other data movements to consider people and purpose in their advocacy and pursuits.

gida-global.org/care

Indigenous Peoples' Rights in Data

Establishing Indigenous Peoples' Rights in Data provides a concrete step toward operationalising IDSov and Indigenous Research Sovereignty by articulating a range of specific rights that can be recognised to support Indigenous Peoples' aspirations for control of data and self-determined research activities.

gida-global.org/data-rights

Indigenous Metadata Bundle

Indigenous metadata provides critical organisation and structure for Indigenous Peoples' data to be findable, accessible, interoperable, and with proper attribution, which enables governance, decision-making, and cultural authority by Indigenous Peoples. Indigenous metadata guides the inclusion of cultural context, data protection, and ownership for Indigenous rights holders. This helps recognise, refine, and define Indigenous Peoples' relationships with their data.

indigenousdatalab.org/3006-2

First Nations Information Governance Committee (FNIGC)

Developer of Ownership, Control, Access, and Possession (OCAP®) Principles and the First Nations Data Governance Strategy (FNDGS). The FNDGS calls for embedding First Nations knowledges and competencies into leading-edge information management and information technology at national and regional levels to support First Nations as rights holders through improved data stewardship across the data lifecycle.

A First Nations Data Governance Strategy

Māori Data Governance Model

The Māori Data Governance Model is designed by Māori data experts for use across the Aotearoa (New Zealand) public service. Māori data is a taonga⁶ that requires culturally grounded models of protection and care. The Model provides guidance for the system-wide governance of Māori data, consistent with the Government's responsibilities under te Tiriti o Waitangi.

kahuiraraunga.io/tawhitinuku

Maiam nayri Wingara

In Australia, Aboriginal and Torres Strait Islander people expect enactment of their IDSov and IDGov principles. Universities can assist this process by providing adequate resourcing and support for Indigenous leadership and control of Indigenous data at each stage of the data lifecycle.

Indigenous Data Governance Communique

Citation

Jacob Prehn, Riley Taitingfong, Robyn K. Rowe, Ibrahim Garba, Cassandra Price, Maui Hudson, Tahu Kukutai, Stephanie Russo Carroll. (2023). "Indigenous Data Governance and Universities Communiqué." Global Indigenous Data Alliance. DOI: 10.6084/m9.figshare.24201585.

Economic Landscape of Federal Public Access Policy



A Report by the Office of Science and Technology Policy

Pursuant to the Consolidated Appropriations Act, 2022

August 2022

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About the Office of Science and Technology Policy

The Office of Science and Technology Policy (OSTP) was established by the National Science and Technology Policy, Organization, and Priorities Act of 1976 to provide the President and others within the Executive Office of the President with advice on the scientific, engineering, and technological aspects of the economy, national security, homeland security, health, foreign relations, the environment, and the technological recovery and use of resources, among other topics. OSTP leads interagency science and technology policy coordination efforts, assists the Office of Management and Budget with an annual review and analysis of federal research and development in budgets, and serves as a source of scientific and technological analysis and judgment for the President with respect to major policies, plans, and programs of the federal government. More information is available at http://www.whitehouse.gov/ostp.

About this Document

This document was prepared voluntarily by OSTP in response to a request made in report language accompanying H.R.2471, the FY 2022 omnibus appropriations legislation signed into law in March 2022. In that request, OSTP was asked to provide a report to Congress on the potential economic impacts of anticipated federal public access policy changes.

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Summary

The White House Office of Science and Technology Policy (OSTP) submits this report to the Appropriations Committees of the Senate and House of Representatives pursuant to the Consolidated Appropriations Act, 2022. This report draws on current research and data available and information received through extensive engagement and consultation with diverse stakeholders, including publishers, federal agencies, and other organizations. Building on the status report on federal public access policies submitted by OSTP to Congress in November 2021, this report elaborates on the potential economic impact of a change to federal agencies' public access policies to remove the current 12-month embargo period on making federally funded research publications publicly accessible. OSTP estimates that the total cost of public access to the American taxpayer through investments in research accrues annually on average to between roughly \$390 million on the low-end and \$789 million on the high-end. This range of costs is relatively small in comparison to the billions of dollars invested each year in research by American taxpayers at less than half a percent, on average.

Background

Broad and expeditious sharing of federally funded research is fundamental for accelerating discovery on critical science and policy questions. New insights into pandemic preparedness response, national security, climate change, energy, cancer, economic justice, and other research and development priorities of the federal government depend on reliable access to the latest state-of-the-art advances in these fields. Moreover, American taxpayers make investments in science for the benefit of all of society and public access policies help ensure that the returns on those investments are open, equitable, and available to all for general and specialized uses alike.

Since the Reagan Administration, it has been the policy of the federal government to provide unrestricted access to the products of basic and applied research funded by the United States to foster the free exchange of ideas.³ The Obama Administration reaffirmed this position for research publication products by issuing the policy guidance *OSTP Memorandum on Increasing Access to the Results of Federally Funded Research* (2013 Memorandum).⁴ The 2013 Memorandum directed each federal department and agency with more than \$100 million in

https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp public access memo 2013.pdf

¹ H.Rept. 117-97 (Committee Report to accompany H.R. 4505, Commerce, Justice, Science, and Related Agencies Appropriations Bill, 2022) adopted by reference in the Joint Explanatory Statement for Division B—Commerce, Justice, Science, and Related Agencies Appropriations Act, 2022 accompanying Consolidated Appropriations Act, 2022 (Pub. L. 117-103), p. 121.

² https://www.whitehouse.gov/wp-content/uploads/2022/02/2021-Public-Access-Congressional-Report OSTP.pdf

³ National Security Council. (1985, September 21). NSDD 189 National Policy on Transfer of Scientific, Technical and Engineering Information. National Archives Catalog. Retrieved from https://catalog.archives.gov/id/6879779

⁴ Holdren, J. P. (2013, February 22). Memorandum for the Heads of Executive Departments and Agencies: Increasing Access to the Results of Federally Funded Scientific Research. Obama White House Archives. Retrieved from

annual research and development expenditures to develop a plan to support increased public access to the results of federally funded research, specifically providing access to scholarly publications and digital data resulting from such research. As of 2022, every federal agency subject to the 2013 Memorandum has developed and implemented public access policies, and additional agencies that were not originally subject to the 2013 Memorandum have also issued and implemented public access policies.^{5,6}

The 2013 Memorandum provided a 12-month grace period for academic publishers to embargo any publication resulting from federally funded research from public access. As a result, all federal agency public access policies have allowed for this provision, collectively known as the 12-month publication embargo.

Between 2013 and 2022, the technological and social landscapes of federally funded research have changed dramatically. The shift from print to digital, the sharp decline in costs of hosting data online, the rise of widespread availability of cloud storage services, advancements in digital persistent identifiers, and the founding of both generalist and domain-specific digital repositories have lowered barriers to sharing, storing, finding, and accessing research data and publications. Market conditions have also evolved toward greater favorability of research sharing: an increasing number of fields, including computer science and physics, now depend on the availability of online publication pre-print and data repository services.

Building on these important advances, the policy guidance laid out in the 2013 Memorandum can be improved to achieve more equitable delivery of federally funded research results and data to all of America. Years of public feedback have indicated that the primary limitation of the 2013 Memorandum is the optional 12-month embargo from public access any publication resulting from federally funded research. This provision has limited immediate equitable access of federally funded research results to only those able to pay for it or who have privileged access through libraries or other institutions. Financial means and privileged access must never be the pre-requisites to realizing the benefits of federally funded research that all Americans deserve.

OSTP and federal agencies draw distinctions between the terms *public access* and *open access*. *Public access* refers to the free availability of federally funded scholarly materials to the public (including publications, data, and other research outputs) and is a policy term; whereas, *open access* refers to a broad set of publication sharing principles and practices, including those required by public access, as adopted by the scientific and publishing communities. According

⁵ Implementation of Public Access Programs in Federal Agencies. Science.gov. (2022). Retrieved from https://www.science.gov/publicAccess.html

⁶ Lander, E. S. (2021, November 5). Public Access Congressional Report, 2021. The Executive Office of the President, Office of Science and Technology Policy . Retrieved from https://www.whitehouse.gov/wp-content/uploads/2022/02/2021-Public-Access-Congressional-Report OSTP.pdf

⁷ Measuring the Digital Transformation: A Roadmap for the Future. (2019). OECD. https://doi.org/10.1787/9789264311992-en

to the UNESCO definition: "Open Access (OA) is the provision of free access to peer-reviewed, scholarly and research information to all. It requires that the rights holder grants worldwide irrevocable right of access to copy, use, distribute, transmit, and make derivative works in any format for any lawful activities with proper attribution to the original author." This distinction is important in the context of the ongoing transformation towards greater openness and transparency in science, as open access models have become more diverse in practice than required by public access policies of the federal government. OSTP provides policy guidance to federal agencies on public access to federally funded research.

Modernizing Public Access Policy Guidance to Federal Agencies

Since the 2013 Memorandum was issued by OSTP, there has been a seismic shift in the cultural and technological contexts in which science is conducted and communicated. Federal agency public access policies must be updated to reflect and support the more open and accessible landscape in which federally funded research now exists. There are at least four ways in which academic and scientific publishing has changed since federal agencies issued their public access policies that warrant elaboration.

First, in response to federal, institutional, local, and international public access policies and demands from scientists, researchers, students, and other producers and consumers of science for greater open access, there has been a slowly emerging move away from subscription-based models of academic journal use by research libraries and towards various "transformative agreement" models whereby institutions pay academic publishers for open accessⁱ publishing of their scientists' scholarship.¹⁰

Second, publishers have introduced other novel business models through a tiered system of open access publishing referred to as the *color system*. In this system, different open access colors—Diamond, ¹¹ Gold, ¹² and Green ¹³—each represent a different copyright, payer, and access combination, allowing authors flexibility in choice of how their research becomes openly accessible. ¹⁴ These models provide for open access research articles through a variety of

⁸ Swan, A. (2012). Policy Guidelines for the Development and Promotion of Open Access. UNESCO Digital Library. The United Nations Educational, Scientific and Cultural Organization. Retrieved from https://unesdoc.unesco.org/ark:/48223/pf0000215863

 $^{^{9} \, \}underline{\text{https://www.govinfo.gov/content/pkg/USCODE-2020-title42/pdf/USCODE-2020-title42-chap79-subchapII-sec6623.pdf}$

¹⁰ Borrego, Á., Anglada, L., & Abadal, E. (2020). Transformative agreements: Do they pave the way to open access? Learned Publishing, 34(2), 216–232. https://doi.org/10.1002/leap.1347

¹¹ Diamond OA: the publisher provides, without fees, immediate public access to the final published version, made freely available for anyone

¹² Gold OA: the publisher provides immediate public access to the final published version, made freely available for anyone, with the fee paid by either the author, their institution, or their funder as a publication charge

¹³ Green OA: free access to a version of the manuscript (not the final published version), self-archived by the author in a repository, with no author fee

¹⁴ Gadd, E., Fry, J., & Creaser, C. (2018). The Influence of Journal Publisher Characteristics on Open Access Policy Trends. Scientometrics, 115(3), 1371–1393. https://doi.org/10.1007/s11192-018-2716-8

mechanisms either through publisher systems paid for by the author (or the author's institution) or uploaded by the author to a freely accessible online digital repository. The scholarly publishing industry has also introduced alternative models such as article processing charges (APC) whereby authors and institutions pay publishers a fee to make research articles available in open access, peer-reviewed journals. Publishers prefer "Gold" open access models with their associated APCs, as they represent revenue growth opportunities. However, at least one study concluded that a transition towards open access involving a mixture of traditional subscription models along with a "Green" open access model would represent optimal economic benefits to the American public. Federal agencies, and their public access policies, do not make preferential recommendations for specific business models to provide public access to the scholarly publications that they fund and their researchers produce. OSTP proposes that remaining agnostic on these models would allow opportunities for business model innovation in this space while supporting zero-embargo public access to federally funded research publications and results.

Third, online platforms that share and disseminate scholarly knowledge have grown in capacity and scope, with an increasing use of "pre-print" repository services to share pre-peer reviewed and final "post-print" peer-reviewed manuscripts alike.¹⁷ While a pre-print is typically considered to be a version of a scholarly manuscript that is early in the development process ahead of formal peer-review, many pre-print repositories have capacity for sharing peer-reviewed manuscripts and the full record of manuscript versions throughout the review and revision process as well.^{18, 19}

Finally, publishers across disciplines have demonstrated the ability to pivot quickly towards immediate open access models, particularly in response to several public health crises. This includes during times of rapid investment in research and development and greater demand for rapid publishing of findings and data. In the wake of the COVID-19 crisis, academic publishers voluntarily removed the 12-month publication embargo²⁰ and used various open access models to make research immediately available to the public just as they had done in years past to

¹⁵ Pollock, D. P. and A., & Michael, A. (2020, October 19). Open Access Market Sizing Update 2020. Delta Think. Retrieved from https://deltathink.com/news-views-open-access-market-sizing-update-2020/

¹⁶ Bernius, S., Hanauske, M., Dugall, B., & König, W. (2013). Exploring the Effects of a Transition to Open Access: Insights from a Simulation Study. Journal of the American Society for Information Science and Technology, 64(4), 701–726. https://doi.org/10.1002/asi.22772

¹⁷ Flanagin, A., Fontanarosa, P. B., & Bauchner, H. (2020). Preprints Involving Medical Research—Do the Benefits Outweigh the Challenges? JAMA, 324(18), 1840. https://doi.org/10.1001/jama.2020.20674

¹⁸ https://www.nsf.gov/pubs/2016/nsf16009/nsf16009.jsp

¹⁹ https://web.archive.org/web/20110830003949/http://www.crossref.org/02publishers/glossary.html

²⁰ https://trumpwhitehouse.archives.gov/wp-content/uploads/2020/03/COVID19-Open-Access-Letter-from-CSAs.Equivalents-Final.pdf

respond to other emerging infectious diseases, such as Ebola virus disease and Zika fever. ^{21,22} As a result, research and data flowed effectively, new accessible insights super-charged the research environment and the rate of discovery, and translation of science soared. The pandemic exception to the research embargo demonstrated how lives can be improved and saved as the result of immediately-available scientific results. As OSTP reported to Congress in November 2021, this last case—the public access changes compelled by wide-ranging crises—illustrates the critical need for an updated federal public access policy that makes federally funded research articles and data immediately available upon publication. As the report stated, "the COVID-19 pandemic highlighted the importance of open science to society and urgent national priorities and demonstrated new paths for innovation." ²³ The global and interconnected emergencies beginning in 2020 were a window into the power of immediate public access to federally funded research, and the ways it can accelerate scientific discovery and translation of science into practice and policy. The approach publishers voluntarily took to COVID-19 must not be an exception possible only in times of crisis; it must instead be the new norm for all federally funded scientific research.

Most importantly, the scholarly publishing industry has undergone a comprehensive shift toward digital content, with nearly 90 percent of all science, technology, and medicine publications now produced in digital format.²⁴ As costs associated with printing have decreased, remaining publisher costs are now primarily associated with staffing and services related to moving the article from submission to publication, such as editing or proofreading. Evidence reported in a cost-benefit analysis of moving to a zero-embargo policy for research publications funded by United Kingdom Research and Innovation finds that "marginal costs of publishing have fallen to close to zero" as a result of the digital transformation to online publishing.²⁵ In part, this shift has resulted from improvements in commercial cost and efficiency of hard digital data storage, which has fallen from roughly \$0.05 (five cents) per gigabyte in 2013 to roughly \$0.01 (one cent) today. Additionally, distributed storage systems (i.e., 'the cloud') that have recently come to market in the last decade make throughput,

²¹ Global Scientific Community Commits to Sharing Data on Zika. Wellcome. (2016, February 10). Retrieved from https://wellcome.org/press-release/global-scientific-community-commits-sharing-data-zika

²² Arrizabalaga, O., Otaegui, D., Vergara, I., Arrizabalaga, J., & Méndez, E. (2020). Open Access of COVID-19-Related Publications in the First Quarter of 2020: A Preliminary Study Based in Pubmed. F1000Res, 9, 649. https://doi.org/10.12688/f1000research.24136.2

²³ Lander, E. S. (2021, November 5). Public Access Congressional Report, 2021. The Executive Office of the President, Office of Science and Technology Policy. Retrieved from https://www.whitehouse.gov/wp-content/uploads/2022/02/2021-Public-Access-Congressional-Report OSTP.pdf

²⁴ International Association of Scientific, Technical, and Medical Publishers. (2021). STM Global Brief 2021 – Economics & Market Size. Retrieved from https://www.stm-assoc.org/2021 10 19 STM Global Brief 2021 Economics and Market Size.pdf

²⁵ United Kingdom Research and Innovation. (2021, August 6). Economic Implications and Benefits of Updated UKRI Open Access Policy. UKRI. Retrieved from https://www.ukri.org/publications/economic-implications-and-benefits-of-updated-ukri-open-access-policy/

storage, and access simpler and affordable and improve the equitability stakes for institutions and individuals that do not have access to in-house storage.

Other technological and policy advances in the last decade that support public access include the advent of data translators for improved interoperability between repositories, a more robust data and information science federal workforce, development and adoption of linking structures like digital persistent identifiers that enable open research systems, the development of application programming interfaces between data repositories, and improved interagency coordination and cooperation to share digital resources through policy alignment.

Restrictions on public access to federally funded research results and publications, such as the 12-month publication embargo, create inequities between the taxpayers funding the research, the public at large, academic institutions, and the scientific community. Those with greater financial means or specialized access can benefit sooner from research publications and results than those without such resources. The benefits which researchers provide to taxpayers through their publications—and which taxpayers fund with their tax dollars—are delayed in delivery through such restrictions. Moreover, the embargo creates a perverse incentive for individuals without means to access federally funded publications behind paywalls to undertake circumvention strategies that violate copyright. ²⁶ Lifting the embargo will likely have immediate benefits by reducing these inequities at a relatively small cost.

While there are budgetary implications of implementation that federal agencies must consider—including some which would require Congressional appropriations—federal agencies are largely in a place of technological readiness for improved public access to the research they fund on behalf of the American public. A recent study published in Nature suggests that around 5 percent of research expenditures would be appropriate to fund long-term management of public access to research results and data. Specific appropriations would be contingent upon individual federal agency missions and their existing resources.²⁷

Modernizing public access policies to remove the 12-month publication embargo would deliver research results to all Americans quickly, equitably, and accessibly by leveraging the cultural, economic, and technological advances described above. In the balance of this report, OSTP provides Congress an analysis of the economic landscape of the public access policy for federally funded research. Using the most current and available data, OSTP describes the ways American taxpayers subsidize publication costs of federally funded research publications under the current policy, the underlying financial implications of these costs, and the likely results of a change to an immediate public access policy by removing the 12-month publication embargo. The following sections describe the state of knowledge about, and OSTP estimations of, the costs and benefits of such a change

²⁶ McCallum, J. C. (2022, May 15). Disk Drive Prices 1955+. JCMIT. Retrieved from https://jcmit.net/diskprice.htm

²⁷ Mons, B. (2020, February 25). Invest 5% of Research Funds in Ensuring Data are Reusable. Nature News. Retrieved from https://www.nature.com/articles/d41586-020-00505-7

Economic Analysis

American taxpayers support academic publishing costs in at least five direct and indirect ways:

Agencies fund the research. Taxpayers directly support research and development funding agencies, which in turn, provide financial awards to researchers, who produce research results in scholarly publications.

Researchers pay to publish their articles. A researcher can generally use their award "allowable costs" to fund the per-article costs of publication in subscription-based or open access journals.

Libraries pay for journal subscriptions. Taxpayers indirectly fund libraries to pay for access to journal content through journal subscriptions. These funds are included as "indirect costs" charged against federal awards.

Researchers dedicate unpaid time to review the research articles. Taxpayers indirectly provide financial support to researchers, whose salaries often come, in part, from federal research awards, who regularly serve as uncompensated peer reviewers and editorial board members on academic journals.

Americans pay direct costs to access content behind paywalls. Additionally, individuals who do not have specialized access to scholarly publications, such as through institutional support of research libraries, must pay out-of-pocket for access to federally funded research publications subject to the 12-month embargo.²⁸

For their part, publishers provide a range of services to taxpayers through their intellectual property and financial agreements with individuals, researchers, and institutions. These services include management of peer-review; editorial, and copyright processes; public access curation of the final peer-reviewed version of scholarly publications, including some that interface directly with federally funded repositories such as PubMed, housed at the NIH and made publicly available after the 12-month publication embargo has ended; print material; tracking metrics; advertising and press coverage for research; support for scholarly conflict resolution, support for professional associations; and, in some cases, prestige.

Additional research, and more extensive and detailed data from the publishing industry, scholarly societies, and large and small research institutions alike, is needed to determine the full scope of the economic impact of a zero-embargo public access model. These data limitations are described in the next section, which is subsequently followed by OSTP's analysis.

Limitations on Data

There is limited public information available on the exact per-article publication costs and revenues incurred by the publishing industry because most publishers consider this type of data

²⁸ Publons Global State of Peer Review Report. Publons. (2018). Retrieved from https://publons.com/community/gspr#open-elq-form-slider-DLGSPR

to be proprietary information.²⁹ Few publishers are publicly traded companies with SEC filing requirements. Additionally, many publishers hold non-disclosure agreements with their subscribing libraries that limit those institutions from releasing details on contracts with specific publishers. However, data from United States federal agencies, indirect market indicators, reports from institutions and organizations, and cost comparisons with peer agencies in other countries facilitate prudently conservative estimates of the economic landscape. Additional data on the impact on other stakeholders and the general public is also limited. These data limitations have been previously noted in reports by the Government Accountability Office and the Scholarly Publishing and Academic Resources Coalition (SPARC).^{30,31} The basis for the evaluation provided in the balance of the report reflects these data limitations which may affect generalizability.

Publication Expenditures for Federally Funded Research

Just six federal agencies—the National Institutes of Health (NIH), National Science Foundation (NSF), Department of Defense (DOD), Department of Energy (DOE), Department of Agriculture (USDA), and NASA—account for more than 94 percent of the approximately \$150 billion in funds obligated to federal research and development. Around \$85 billion of these obligations were committed in 2020 to research, representing a significant source of funding in research and development that results in scientific publications. Between 2013 and 2020, universities were awarded on average about 42 percent of the federal government's research obligations. Federal intramural research—defined as science conducted by the federal scientific workforce—constituted about 30 percent of total research obligations. The balance (28 percent) was made up by other entities, including private companies, individuals, and research institutes. While only a few federal agencies support the total federal research and development funding, virtually all federal agencies have either some such obligations or otherwise use federally funded science in their policy, regulatory, and decision-making capacities. Collectively, NSF estimates all federal expenditures on basic research to equate to roughly 40 percent of the total spending on all basic research in the United States, inclusive of all sources of support including non-governmental sources. 32,33

²⁹ Aspesi, C. (2022). Setting the Default to Open in Research and Education. SPARC. Retrieved July 18, 2022, from https://sparcopen.org/wp-content/uploads/2022/04/Public-Research-and-Publisher-Profits.docx.pdf

³⁰ Aspesi, C. 2022. Public Research Benefits and Publisher Profits. SPARC. Retrieved from: https://sparcopen.org/wp-content/uploads/2022/04/Public-Research-and-Publisher-Profits.docx.pdf

³¹ Campbell , S., & Shirley, C. (2018, June 21). Estimating the long-term effects of federal R&D spending: CBO's current approach and research needs. Congressional Budget Office. Retrieved from https://www.cbo.gov/publication/54089

³² National Center for Science and Engineering Statistics (NCSES). 2022. Federal Funds for Research and Development: Fiscal Years 2020–21. NSF 22-323. Alexandria, VA: National Science Foundation. Available at https://ncses.nsf.gov/pubs/nsf22323/.

³³ Robbins, C., Khan, B., & Okrent, A. (2020, January 15). The State of U.S. Science and Engineering 2020, Science & Engineering Indicators. National Science Foundation. Retrieved from https://ncses.nsf.gov/pubs/nsb20201/u-s-r-d-performance-and-funding#:~:text=Although%20the%20levels%20of%20federal,from%2025%25%20to%2022%25

According to NSF data, the United States accounted for only about 16 percent of the global output of science and engineering journal articles in 2020, with American investigators contributing roughly 464,000 of the 2.9 million total peer reviewed articles published worldwide. The Organisation for Economic Co-operation and Development (OECD) additionally estimates that United States scientists contributed 626,295 science and technology publications in 2020.³⁴ While there are limited data on how many of these publications were supported by federal funds, taking the 42 percent of research that the United States government funds as a proportional basis, OSTP estimates that between 195,000 and 263,000 articles were federally funded in 2020.

A recently published report by the Scholarly Publishing and Academic Resources Coalition (SPARC) showed the average cost to publish a research article from all funding sources falls between \$2,000 and \$3,000 dollars.³⁵ In their report, SPARC estimates that this range captures the preponderance of the variance around publication costs for American science and engineering research. These figures most likely represent *revenue per article* and not the production cost per se as the totals include sunk costs of marketing, investments in infrastructure, and other costs not typically attributed solely as costs of sale or production. However, revenue estimates based on available data on prices of journal content from Wiley and Elsevier are concurrent with this figure, at roughly \$2,300 and \$3,000 respectively.³⁶ Because publishers seek revenue parity between publication models, together with the consistency in estimates from available data, the relationship between the two likely represents relatively stable values.

Data are limited on the costs of production of an article to a publisher. Recent estimates from the literature on the cost of producing an article range from \$200 to \$1,000, with the high end representing a selective, prestigious journal with a 90 percent rejection rate.³⁷ Over the last decade, publishers have seen total revenues grow well in excess of the rate of inflation (sometimes as high as 110 percent of inflation).³⁸ A recent article estimates that the average total profit expectation for a representative article by a publisher of scholarly articles to be about \$1,200, although that is conservative relative to estimates made by SPARC, which estimates profits between \$1,500 and \$2,000 per article for publishers. Comparatively, the "production" cost of depositing a federally funded research article into a free public access

³⁴ https://www.oecd.org/sti/scoreboard.htm#publications

³⁵ Aspesi, C. (2022). Setting the Default to Open in Research and Education. SPARC. Retrieved July 18, 2022, from https://sparcopen.org/wp-content/uploads/2022/04/Public-Research-and-Publisher-Profits.docx.pdf

³⁶ Elsevier. (2022, July 12). Article Publishing Charge (APC) Price List. Wiley Journal Price List. Wiley Online Library. (2022). Retrieved from https://onlinelibrary.wiley.com/pb-assets/ PriceLists/Wiley journals price list-1646045161317.xls

³⁷ Grossmann, A., & Brembs, B. (2021). Current Market Rates for Scholarly Publishing Services. F1000Research, 10, 20. https://doi.org/10.12688/f1000research.27468.2

³⁸ Shu, F., Mongeon, P., Haustein, S., Siler, K., Alperin, J., & Larivière, V. (2018). Is it Such a Big Deal? On the Cost of Journal Use in the Digital Era. College & Research Libraries, 79(6), 785–798. https://doi.org/10.5860/crl.79.6.785

repository can be, conservatively, as low as \$15 and even lower under a federally owned and managed repository such as PubMed.³⁹

Notably, costs associated with publishing an article can be charged against contracts, grants, and research budgets associated with federally funded research awards. Several federal agencies, including NSF and NIH, currently permit including publication costs in allowable expenses. An expansion of this allowance by all federal agencies with research and development budgets that support scholarly publications would improve public access policy implementation and help to control costs by offsetting any new financial burdens on authors. Most federal agencies that fund scientific research currently do not explicitly set aside dedicated funding for these costs and do not track such expenditures. One example is NIH, which allows for researchers to include funds as allowable expenses although they do not track such expenditures post-award. However, using data from the NIH, OSTP estimates that perarticle publication charges (for subscription and open access journals) accrue to approximately \$150-200 million per year for NIH-funded research (representing on average about 0.5 percent of the total annual NIH research and development budget).

Assuming proportionality with the research and development budgets of the other major federal funders, together with the estimated annual federally funded publications (195,000 to 263,000), and the range of estimates for per-publication costs (\$2,000 to \$3,000), OSTP estimates that the total cost to the American taxpayer through these investments accrues annually on average to between roughly \$390 million on the low end and \$789 million on the high-end. This range of costs is relatively small in comparison to the billions of dollars invested each year in research by American taxpayers, at less than half a percent, on average.

Library Expenditures for Public Access

The vast majority of expenditures on public access publications for federally funded research are absorbed by research libraries. Average individual research library expenditures on public access resources range greatly, from around \$65,000 to over \$2.5 million depending on the size, mission, and budget of the institution (which also vary widely from \$10 million to \$100 million). These investments include transitional agreements, article processing charges, membership fees with open access journals, institutional repositories, and open access monograph subscriptions or funding. The Association of Research Libraries estimates research library expenses in Fiscal Year 2021-2022 dedicated to open access range between 0.2 and 11 percent with a median of 1.45 percent of their budgets. It is predominantly through contracts with research libraries that publishers monetize the products of federally funded research either through multi-year subscription or through transformative agreements with these

³⁹ Schopfel, J. and Boukacem-Zegmouri, C. (2017) Assessing the Return on Investments in Grey Literature for Institutional Repositories. https://doi.org/10.1515/9783598441493.2.227

⁴⁰ Ruttenberg, J. & Vitale, C.R.H. ARL United States Academic Member OA Publishing Expenditures FY 2021-2022. Washington, DC, Association of Research Libraries, 2022

institutions—some offering immediate access for library members to all journal content regardless of funding mechanism of individual scholarly work through these contracts.

Several studies have estimated the cost implications of switching from subscription-based models to various transformative, hybrid, or other open access models. 41 In general, the literature reflects broad consensus that large research-intensive universities would pay more on an annual basis under a fully open access model because such models generate large numbers of articles that would accrue article processing charges, whereas universities conducting a lower rate of research would pay less. However, the University of California (UC) system reports that it reached a landmark multi-publisher agreement for a net-zero year-over-year cost of switching from a subscription to an open access model, demonstrating that the published model assumptions may not accurately reflect real-world market responses to increased public access. 42 Many research libraries are already engaged in adopting their own open access policies to better support their constituents and expand the global reach of their institutions' research findings. 43 As recently as March 2021, the University of California system, whose researchers produce nearly 10 percent of United States academic publications, and with more than a dozen public research libraries, negotiated a single contract worth around \$12 million with Elsevier for providing open access publications under a transformative agreement.⁴⁴ This contract resulted directly from the UC's adoption of an open access policy that required immediate access to published research by their researchers. 45 This shift set an important

⁴¹ Borrego, Á., Anglada, L., & Abadal, E. (2020). Transformative agreements: Do they pave the way to open access? Learned Publishing, 34(2), 216–232. https://doi.org/10.1002/leap.1347; Shu, F., Mongeon, P., Haustein, S., Siler, K., Alperin, J., & Larivière, V. (2018). Is it Such a Big Deal? On the Cost of Journal Use in the Digital Era. College & Research Libraries, 79(6), 785–798. https://doi.org/10.5860/crl.79.6.785; Robinson-Garcia, N., Costas, R., & van Leeuwen, T. N. (2020). Open Access Uptake by Universities Worldwide. PeerJ, 8. https://doi.org/10.7717/peerj.9410; Campbell, C., Dér, Á., Geschuhn, K., & Valente, A. (2022, July 5). How are Transformative Agreements Transforming Libraries? IFLA Repository. Retrieved from https://repository.ifla.org/handle/123456789/1973; Schlak, T., & Macklin, A. (2022). Open Access Overtaking Academic Library Leadership: Staying Ahead of the Organisational Dynamics an Increasingly Open Future May Bring. New Review of Academic Librarianship, 28(2), 117–124. https://doi.org/10.1080/13614533.2022.2079539

⁴² University of California. (2022, June 7). UC Publisher Relationships, Press room. Office of Scholarly Communication. Retrieved from https://osc.universityofcalifornia.edu/uc-publisher-relationships/press-room/
⁴³ AIP Publishing. (2022, June 10). Open Access Advocacy is High, Despite Pressures on Librarians. Research Information. Retrieved from https://www.researchinformation.info/premium-access/7/open-access-advocacy-high-despite-pressures-librarians

⁴⁴ University of California. (2021). 2021 University of California Accountability Report. Accountability Report: Research. Retrieved from https://accountability.universityofcalifornia.edu/2021/chapters/chapter-9.html; Elsevier. (2021, March 16). University of California and Elsevier Sign Ground-Breaking Transformative Agreement. Elsevier Press Releases. Retrieved from https://www.elsevier.com/about/press-releases/corporate/university-of-california-and-elsevier-sign-ground-breaking-transformative-agreement; University of California. (2021, March 16). UC Secures Landmark Open Access Deal with World's Largest Scientific Publisher. California Digital Library. Retrieved from https://cdlib.org/cdlinfo/2021/03/16/uc-secures-landmark-open-access-deal-with-worlds-largest-scientific-publisher/

⁴⁵ University of California. (2022, March 16). UC and Elsevier. Office of Scholarly Communication. Retrieved from https://osc.universityofcalifornia.edu/uc-publisher-relationships/uc-and-elsevier/

precedent, demonstrating the industry's capacity to absorb major shifts in public access policies and negotiate agreements that are agreeable to both parties. In fact, many large, well-resourced research libraries have negotiated transformative agreements with publishers, including Cambridge University Press, Wiley, Elsevier, and the American Chemical Society, among others. 46 Smaller institutions which may not be as well-resourced as their larger counterparts benefit from open access as it delivers research publications to their members.

Another important precedent comes from the 2020 agreement between Wiley Publishing and universities in the United Kingdom (UK). The agreement allows for a four-year read-and-publish deal, which permits UK institutions to access Wiley's journal portfolio for an undisclosed fee and grants researchers at UK universities the ability to publish their research as open access articles in all Wiley journals at no direct cost to them.⁴⁷ It is expected that this deal will increase the number of articles UK researchers produce as open access publications from 27 percent to 85 percent within the first year, with the potential to reach 100 percent by the end of 2022. Wiley is negotiating or has negotiated other comprehensive agreements with consortia in Austria, Finland, Germany, Hungary, Netherlands, Norway, and Sweden. Wiley's 2021 annual report to investors cites such agreements as a potential source of future growth in revenue.⁴⁸

Impact of Change to Zero-Embargo Public Access

Updating federal agency policies to require immediate public access to federally funded research results would be a critical step in ensuring the continued economic, social, and scientific advantage of American investment in research and development today and into the future. Immediate access to federally funded research would lower barriers to accessing science, accelerate discovery and translation, and strengthen scientific integrity through greater transparency.

The potential economic costs of a change in federal public access policy toward immediate public access are fewer and less varied than the economic benefits. These potential costs include increased fees to publish (i.e., through the use of article processing charges) should publishers adopt greater fidelity to such business models, increased need for federal expenditure on public access policy compliance, and direct effects of lower revenues for some scholarly publishers and societies. The societal and economic benefits of a change in federal policy toward immediate public access to federally funded research results greatly exceed costs.

⁴⁶ Borrego, Á., Anglada, L., & Abadal, E. (2020). Transformative agreements: Do they pave the way to open access? Learned Publishing, 34(2), 216–232. https://doi.org/10.1002/leap.1347

⁴⁷ Wiley. (2020). Open Access Agreement for Authors at Eligible UK Institutions. Open Access for Authors in the UK. Retrieved from https://authorservices.wiley.com/author-resources/Journal-Authors/open-access/affiliation-policies-payments/jisc-agreement.html

⁴⁸ Wiley Financials Annual Reports. Annual Reports. (2021). Retrieved from https://investors.wiley.com/financials/annual-reports/default.aspx

Effects on Scholarly Publishing

An update to federal public access policy would likely affect the scholarly publishing industry and its practice. At present, more than half of the 8.2 million articles deposited into NIH PubMed to comply with the NIH Public Access Policy are available immediately at the time of publication, despite the policy allowing an embargo period of up to 12 months. ⁴⁹ Recognizing that the global scholarly publishing industry is already in this active transition toward greater public access through the open access movement, any change in federal policy is likely to result in some downward pressure on publishers to adapt business models.

Consistent with these trends, the International Association of Scientific, Technical, and Medical Publishers (STM) estimates that by 2024 open access journal revenue will represent between 7 and 9 percent of the market and constitute around \$1.1 billion of all scholarly publication outputs. The growth in open access publishing has also outpaced the underlying market, with a revenue compound annual growth rate estimated to be in the range of 12.5 percent between 2019 and 2021. OSTP anticipates that this growth would further accelerate under a zero-embargo public access policy as publishers already anticipate growth in their open access journal portfolios.

A shift in federal policy would also likely impact smaller not-for-profit publishers and those supporting scholarly and professional societies. Professional and scholarly societies often use surplus revenues (i.e., profit equivalent) from scholarly journal publishing to support other activities, including hosting conferences and seminars, public education and lobbying, and providing travel and research grants. Using data from the United Kingdom, the Research Information Network estimated the average profits in 2008 at 18 percent of revenues per publication, equivalent to £600 for for-profit publishers and £315 in surpluses for not-for-profit publishers. It is difficult to estimate how a shift in federal public access policy would affect these figures, given that most data available is on for-profit publishers. Assuming market conditions slightly disadvantage not-for-profit publishers because they are smaller and hold less

⁴⁹ U.S. National Library of Medicine. (2022). PubMed Central National Library of Medicine. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/

⁵⁰ Albee, B., & Bosch, S. (2021, April 27). The New Abnormal: Periodicals Price Survey 2021. Library Journal. Retrieved from https://www.libraryjournal.com/story/The-New-Abnormal-Periodicals-Price-Survey-2021; Pollock, D. P. and A., & Michael, A. (2020, October 19). Open Access Market Sizing Update 2020. Delta Think. Retrieved from https://deltathink.com/news-views-open-access-market-sizing-update-2020/

⁵¹ International Association of Scientific, Technical, and Medical Publishers. (2021). STM Global Brief 2021 – Economics & Market Size. Retrieved from https://www.stm-assoc.org/2021 10 19 STM Global Brief 2021 Economics and Market Size.pdf

⁵² Thorn, S., Morris, S., & Fraser, R. (2009). Learned Societies and Open Access: Key Results from Surveys of Bioscience Societies and Researchers. Serials: The Journal for the Serials Community, 22(1), 39–48. https://doi.org/10.1629/2239

⁵³ Activities, costs and funding flows in the scholarly communications system in the UK Report. Research Information Network. (2008, May). Retrieved from https://docplayer.net/15594627-Activities-costs-and-funding-flows-in-the-scholarly-communications-system-in-the-uk-report-commissioned-by-the-research-information-network-rin.html

market leverage, it is possible that any loss in revenue resulting from a zero-embargo policy would disproportionately affect their surpluses relative to those of their for-profit counterparts. However, the same downward pressure to adapt to new business models would apply to not-for-profit publishers and similar innovation in business models in response to policy change would be expected. Additionally, since 2008, publishers have experienced increased profit margins. Moreover, according to SAGE Publications, there is no evidence that a zero-embargo policy would negatively affect subscriptions, which is the primary mode of funding for society publishers.⁵⁴

Likewise, while OSTP estimates that federal funds currently only support between 16 and 18 percent of research resulting in scholarly publications, a shift toward immediate public access would likely increase the use of open access and related models by publishers, resulting in a rise in the market share of global scholarly publishing output produced through such mechanisms. Federally funded investigators who publish their research results would likely also be impacted by a shift toward a zero-embargo publication policy. In addition to additional administrative processes related to new compliance mandates that agencies may issue, any economic burden falling on individual researchers resulting from a zero-embargo publication policy would likely be offset by the greater benefits of increased visibility, consumption, and potential impact that their research would realize. Many studies show that articles published under an open access model would offer greater impact through better readership and generate more citations than subscription-based articles. 55,56,57

In assessing these benefits to researchers and the public, the Congressional Budget Office (CBO) used a bibliometric approach to estimate the return-on-investment of federally funded research publications through the lens of a direct link between federal funding and research outputs. That study concluded there was insufficient data to make inferences on such links and that more research would be needed on the matter. It is likely that the lack of data referenced by CBO was in part due to poor funding disclosure compliance in research

⁵⁴ Grove, J., Pells, R., & Ross, J. (2019, April 23). Open Access: 'no evidence' that Zero Embargo Periods Harm Publishers. Times Higher Education . Retrieved July 18, 2022, from https://www.timeshighereducation.com/news/open-access-no-evidence-zero-embargo-periods-harm-publishers

⁵⁵ Langham-Putrow, A., Bakker, C., & Riegelman, A. (2021). Is the open access citation advantage real? A systematic review of the citation of open access and subscription-based articles. PloS one, 16(6), e0253129. https://doi.org/10.1371/journal.pone.0253129

⁵⁶ Sotudeh, H., Estakhr, Z. (2018) Sustainability of open access citation advantage: the case of Elsevier's authorpays hybrid open access journals. Scientometrics 115, 563–576. https://doi.org/10.1007/s11192-018-2663-4
⁵⁷ OACA List. SPARC Europe. (2017, March 4). Retrieved from https://sparceurope.org/what-we-do/open-access/sparc-europe-open-access-resources/open-access-citation-advantage-service-oaca/oaca-list/; Piwowar, H., Priem, J., Larivière, V., Alperin, J. P., Matthias, L., Norlander, B., Farley, A., West, J., & Haustein, S. (2018). The state of OA: A large-scale analysis of the prevalence and impact of open access articles. PeerJ, 6. https://doi.org/10.7717/peerj.4375

⁵⁸ Campbell , S., & Shirley, C. (2018, June 21). Estimating the long-term effects of Federal R&D spending: CBO's current approach and research needs. Congressional Budget Office. Retrieved from https://www.cbo.gov/publication/54089

publications and the lack of immediate access to federally funded publications. A change in federal policy to remove the embargo would improve tracking and reporting of the research outputs that Federal agencies fund by making publications more findable and accessible. While a direct link between publications and return on investment is difficult to ascertain, the annual rate of financial return on investment of federally funded research and development estimated in a working paper at the National Bureau of Economic Research (NBER) to be between 25 percent and 100 percent.⁵⁹

Effect on Society

Equally important to the economic impact is the rate of social returns on research and development investments. ⁶⁰ Social returns involve the societal goods and improvements to quality of life that result from direct financial investment in research. These research benefits can be traced across society, and include outcomes such as improved longevity, greater diversity and representative participation in innovation, improved air and water quality, improved health outcomes, reduced economic inequality, and greater food security, among many other benefits. ⁶¹ The NBER study has also studied the social returns on federal research investments and concludes that these returns are likely comparably as high as—or even higher than—the direct financial returns. ⁶² The NBER study concludes: "Even under very conservative assumptions, it is difficult to find an average return below \$4 per \$1 spent. Accounting for health benefits, inflation bias, or international spillovers can bring the social returns to over \$20 per \$1 spent, with internal rates of return approaching 100%." These figures represent substantial social benefits and are more quickly and equitably realized when the barriers to accessing research, such as publication embargos, are removed.

Importantly, the NBER study assessed several models to measure social returns of delaying translation from research to practice, concluding that longer the delay in translation of basic research led to lower return on investment and an immediate translation of results in the highest benefit with an estimated average of 67 percent annual social return on investment. Research publications and data are essential to the translational process; by removing the delay of the embargo and providing results more quickly, the translational process happens more efficiently and individuals, communities, and industry can sooner realize important societal benefits.

⁵⁹ Hall, B.H., Mairesse, J. & Mohnen, P. (2009). Measuring the Returns to R&D. NBER Working Paper. DOI: https://www.doi.org/10.3386/w15622

⁶⁰ Tennant, J. P., Waldner, F., Jacques, D. C., Masuzzo, P., Collister, L. B., & Hartgerink, C. H. (2016). The Academic, Economic and Societal Impacts of Open Access: An Evidence-Based Review. F1000Research, 5, 632. https://doi.org/10.12688/f1000research.8460.3

⁶¹ Jones, B. (2022). The Social Value of Science and Innovation Investments and Sources of Breakthroughs. The Reporter. No. 1, March, Retrieved from: https://www.nber.org/reporter/2022number1/social-value-science-and-innovation-investments-and-sources-breakthroughs

⁶²Jones, B.F. & Summers, L.H. A Calculation of the Social Returns to Innovation. (2020). NBER Working Paper. Retrieved from: https://www.nber.org/papers/w27863

OSTP also notes that a shift to zero-embargo for federally funded research would effectively lower the cost of access to scientific research and lead to faster knowledge diffusion across society. ⁶³ The rapid delivery of research to the public under a zero-embargo policy also benefits educators and ensures that students have access to the latest state of the science in course curricula. ⁶⁴ In addition to these research and development gains, other benefits include improved capabilities of plagiarism detection systems to identify academic dishonesty and improve scientific integrity; removing a perverse incentive to pirate embargoed publications by individuals without the ability to pay for access during the current 12-month embargo, and facilitating greater reproducibility. ⁶⁵

Some social costs would likely be associated with a change in public access policy. These may include complications for early-stage investigators, who are less likely to have funding available than their more senior counterparts, but under greater pressure to publish their research more frequently. Academic faculty have expressed concerns that open access publications pose a barrier to their tenure and promotion packages. There are also concerns that funds available to pay rising APCs create a two-tiered system between funded and unfunded researchers where only funded researchers can publish their research in open access journals. Similarly, academic institutions with fewer resources, including minority serving institutions, may find it difficult to negotiate similar contracts with publishers to support open access publishing as their larger counterparts. While the impact on minority serving institutions of a shift to zeroembargo is difficult to assess given the limited data available, a recent study indicates that

⁶³ Tennant, J. P., Waldner, F., Jacques, D. C., Masuzzo, P., Collister, L. B., & Hartgerink, C. H. (2016). The Academic, Economic and Societal Impacts of Open Access: An Evidence-Based Review. F1000Research, 5, 632. https://doi.org/10.12688/f1000research.8460.3

⁶⁴ Strand, J. F., & Brown, V. A. (2019). Publishing Open, Reproducible Research with Undergraduates. Frontiers in Psychology, 10. https://doi.org/10.3389/fpsyg.2019.00564

⁶⁵ Turnitin partners with core, the world's leading aggregator of Open Access Research Articles. Turnitin. (2019, May 19). Retrieved from https://www.turnitin.com/press/turnitin-partners-with-core; Björk, B.-C. (2017). Gold, Green, and Black Open Access. Learned Publishing, 30(2), 173–175, https://doi.org/10.1002/leap.1096; Green, T. (2017). We've failed: Pirate black open access is trumping green and gold and we must change our approach. Learned Publishing, 30(4), 325–329. https://doi.org/10.1002/leap.1116; Bohannon, J. (2016). Who's downloading pirated papers? Everyone. Science, 352(6285), 508–512. https://doi.org/10.1126/science.352.6285.508; https://doi.org/10.1126/science.352.6285.508; https://doi.org/10.1126/science.352.6285.508; https://doi.org/10.1126/science.352.6285.508; https://doi.org/10.1126/science.352.6285.508; https://doi.org/10.1126/science.352.6285.508; https://doi.org/10.1126/science.352.6285.508;

⁶⁶ Flaherty , C. (2017, June 6). Analysis suggests age bias at play in reduction of Federal funding to early-career researchers. Retrieved from https://www.insidehighered.com/news/2017/06/06/analysis-suggests-age-bias-play-reduction-federal-funding-early-career-researchers

⁶⁷ Odell, J., Coates, H., & Palmer, K. (2016). Rewarding open access scholarship in promotion and tenure: Driving Institutional Change. College & Research Libraries News, 77(7), 322–325. https://doi.org/10.5860/crln.77.7.9518
⁶⁸ Ross-Hellauer, T., Reichmann, S., Cole, N. L., Fessl, A., Klebel, T., & Pontika, N. (2022). Dynamics of cumulative advantage and threats to equity in open science: a scoping review. Royal Society open science, 9(1), 211032. https://doi.org/10.1098/rsos.211032

⁶⁹ https://doi.org/10.1038/d41586-022-00724-0

⁷⁰ HBCU Library Alliance. (2015). Expanding Library Support for Faculty Research in Historically Black Colleges and Universities. Retrieved from: http://hbculibraries.org/images/FinalLibrarySurveyResults8-2015.pdf

HBCU librarians have a favorable position on open access policies overall.^{71,72} Open access publications increase equitable and inclusive reach of science for all members of the scholarly community, including people from underrepresented groups, early stage investigators, and students and academic faculty at under-resourced institutions.

However, the concerns that such inequities would expand under a zero-embargo policy are important to consider and federal agencies' public access policies should be accompanied with support for protecting against any inequalities that might arise from a change toward a zero-embargo public access model. Some of these protections are already in place and more are in development. For instance, many federal agencies, including DOE, NIH, and NSF have launched programs aimed at awarding grants to support early-stage researchers as well as increasing the racial and gender diversity of award applicants and the scientific workforce. Other federal agencies have focused grantmaking efforts on leveling the playing field for minority serving institutions, including at colleges, museums, and libraries. Additionally, incentive structures to reward institutions for supporting open access publications and open science products produced by their faculty are increasing in number and have the support of many stakeholders across government, industry, and education, as recently reported by the National Academies of Science, Engineering, and Medicine.

While OSTP anticipates that such social costs might expand under a zero-embargo policy, considerable offsets—including the availability of more research available through public access at no cost, a greater number of grant and workforce development programs aimed at reducing inequalities in research, and the ability to charge publication costs to grants, awards, and contracts—would counteract their effect. OSTP expects that a change toward a zero-embargo public access policy would accelerate these incentives and further alleviate the concerns about social costs of such a change. On balance, OSTP estimates that the potential financial and social gains realized from increased access to federally funded research— by removing the 12-month publication embargo— greatly outweigh the potential costs.

https://www.nationalacademies.org/our-work/roundtable-on-aligning-incentives-for-open-science

⁷¹ Ross-Hellauer, T. (2022). Open science done wrong, will compound inequities. Nature 603, 363. https://doi.org/10.1038/d41586-022-00724-0

⁷² Crawford II, J. (2022). How HBCU libraries can help with ACEJMC standard 5. Journalism at Historically Black Colleges and Universities, 133–159. https://doi.org/10.1007/978-3-030-97501-2 9

⁷³ https://beta.nsf.gov/funding/initiatives/broadening-participation

⁷⁴ https://extramural-diversity.nih.gov/guidedata/data

⁷⁵ https://www.energy.gov/articles/doe-awards-36-million-promote-equity-and-diversity-clean-energy-innovation

⁷⁶ https://ies.ed.gov/aboutus/diversity.asp

⁷⁷ https://imls.gov/grants/grant-programs

https://www.nationalacademies.org/our-work/roundtable-on-aligning-incentives-for-open-science

⁷⁹ Advancing open science practices: Stakeholder perspectives on incentives and disincentives. (2020). National Academies Press. https://doi.org/10.17226/25725; Roundtable on Aligning Incentives for Open Science. National Academies of Sciences, Engineering, and Medicine. (2022). Retrieved from

Conclusion

This report has described the current state of federal access policies and laid out the potential economic impact and feasibility of updating policies to remove the 12-month embargo on federally funded research publications. The landscape of the scientific research enterprise has changed significantly in recent years, with a worldwide cultural and technological shift towards a more open, collaborative, and equitable model of conducting scientific activities. Scholarly publishing has moved with this shift, with nearly 90 percent of articles available in digital format and many available as open access publications. However, the 12-month publication embargo period represents a significant delay in the ability for scientists to share their research, industry to translate science into practice, and the American public to access the returns on their investments in science and technology. This sentiment was articulated by Senators Ron Wyden and Senator Ed Markey in their February 2022 letter to Dr. Alondra Nelson in her capacity as performing the duties of director of OSTP. The Senators noted: "To truly meet the magnitude of the research and innovation needs of today's fast-paced, globalized world, including meeting the goals of the Cancer Moonshot, our nation needs a bold, comprehensive, and government-wide public-access policy guaranteeing rapid access for all federally funded research articles with broad re-use rights."80 Updating federal public access policies to provide immediate access to the research results they conduct and fund would answer this call.

The public access policy of the United States Government should benefit all sectors of society. Evidence demonstrates that many constituents are ready, willing, and able to remove the 12-month publication embargo on federally funded research: from the publication industry's shifts to an open access model and other rapid changes to longstanding institutional policies during the COVID-19 response, to federal funding agencies' incorporation of publication costs into grant and contract budgets, the new technological capabilities for online research sharing, and many new innovative models that the publishing industry has introduced to adapt to existing open access policies. Ultimately, a change in federal policy is unlikely to cause significant market disturbance as evidenced by the recent precedents mentioned in this report. Instead, our analysis indicates it could deliver extraordinary benefits for the American people and beyond.

⁸⁰ Wyden, R., & Markey, E. J. (2022, February 23). Letter to Deputy Director Nelson from United States Senators Wyden and Markey. United States Senate. Retrieved from https://www.wyden.senate.gov/imo/media/doc/OSTP%2002232022.pdf

Collaborative transition to open access publishing by scholarly societies

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ABSTRACT For decades, universities, researchers, and libraries have sought a systemwide transition of scholarly publishing to open access (OA), but progress has been slow. There is now a potential for more rapid and impactful change, as new collaborative OA publishing models have taken shape. Cooperative publishing arrangements represent a viable path forward for society publishers to transition to OA as the default standard for disseminating research. The traditional article processing charge OA model has introduced sometimes unnavigable financial roadblocks, but cooperative arrangements premised on collective action principles can help to secure long-term stability and prevent the risk of free riding. Investment in cooperative arrangements does not require that cash-strapped libraries discover a new influx of money as their collection budgets continue to shrink, but rather that they purposefully redirect traditional subscription funds toward publishing support. These cooperative arrangements will require a two-way demonstration of trust: On one hand, libraries working together to provide assurances of sustained financial support, and on the other, societies' willingness to experiment with discarding subscriptions. Organizations such as Society Publishers Coalition and Transitioning Society Publications to Open Access are committed to education about and further development of scalable and cooperative OA publishing models.

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On June 11, 2020, evidence of the new front in the conflict over scientific communication's future came into view. One of the world's most prominent research institutions, the Massachusetts Institute of Technology (MIT), announced that it would be ending negotiations with one of the world's largest publishers of scientific journals, the Dutch commercial publisher Elsevier. According to MIT, Elsevier was unable to present a proposal that aligned with the principles outlined in the MIT Framework for Publisher Contracts, which is premised on the values "that openly sharing research and educational materials is key to the Institute's mission of advancing knowledge and bringing that knowledge to bear on the world's greatest challenges." (MIT, 2020). With the cancellation of their Elsevier deal,

MIT joined an increasingly vocal chorus of universities, researchers, and libraries (such as the University of California, which similarly terminated journal negotiations with Elsevier in 2019) that—recognizing the alignment of open access (OA) with the fundamental values of scholarship—are calling for a systemwide transition of scholarly publishing to OA and are prepared to walk away from publishing agreements that fail to make progress toward it (Barber, 2020; University of California, Office of Scholarly Communication, 2020).

This movement seeking to regain control of scholarly publishing, particularly from commercial—in some cases, oligopolistic (Larivière et al., 2015)—forces, is not new. Libraries, scholars, and activists have been calling for this shift since academic journals were wholly transitioned to online, questioning the validity of the centuries-old subscription model for the digital age, in which scientific research could be more rapidly produced and broadly disseminated. Although formalized with a series of declarations in 2002/2003 (such as the Budapest Open Access Initiative, https://www.budapestopenaccessinitiative.org/read, and the Bethesda Statement on Open Access Publishing, http://dx.doi.org/10.4403/jlis.it-8628) advocating the systemic transition of scientific research to open dissemination, more than 15 years later OA has only reached approximately 31% of published literature

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*Address correspondence to: Rachael G. Samberg (rsamberg@berkeley.edu). Abbreviation used: OA, open access.

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(Piwowar et al., 2019), and progress toward a systemic transformation remains slow. Yet what is new is the potential for more rapid and impactful change, as new collaborative OA publishing models have taken shape.

To date, much of the growth of OA in scholarship has been propelled by the author processing charge (APC) model, in which authors (or their institutions/libraries or research funders) pay a fee to publishers (ranging from several hundred dollars to more than \$6000) on acceptance of a manuscript to cover the costs of publication and replace revenue the publishers would have derived from subscription sales. The APC model, or a variation of it, is likely to remain an efficient and viable path to OA in the biomedical and other well-funded sciences, where funder mandates (such as Plan S) may be applicable. Yet the APC model introduces sometimes unnavigable roadblocks for scholars and institutions: a financial barrier to publishing affordable to few; perverse incentives for publishers to release larger numbers of articles; and a potential new revenue stream from which publishers could double dip alongside historically lucrative library subscriptions. (Double dipping can take place in some hybrid OA models in which subscription journals also publish some articles OA through payments of APCs, without issuing commensurate subscription reductions/discounts. The practice of reducing or discounting subscriptions based on APCs that have been paid is called offsetting.) But scholarship is much broader than the biomedical sciences, and there is an imperative to find effective means for sustaining OA publishing in the less funded sciences, social sciences, and humanities.

A number of alternative models to support OA publishing have begun to materialize—ones in which scholarly publishers are entering into cooperative arrangements with academic libraries (Wise and Estelle, 2019). Although currently limited by discipline and content type, models such as SCOAP3 (http://scoap3.org), the Open Library of the Humanities (www.openlibhums.org), and Knowledge Unlatched (www.knowledgeunlatched.org) are already providing important empirical examples of effective cooperation. Also of particular appeal is Subscribe to Open (S2O), which has already demonstrated success (Annual Reviews, 2020) and is being piloted by a rapidly growing number of societies (American Society Cell Biology, 2020; International Water Association, 2020). S2O allows publishers to transition from gated access to OA one year at a time by offering a journal's current subscribers continued access at a regular subscription discount (Crow et al. 2020). If current subscribers participate, content covered by that year's subscription is made OA. If participation is insufficient—for example, if some subscribers delay renewing in the expectation that they can gain access without participating—then the content remains paywalled. Because the publisher does not guarantee that the content will be OA unless all subscribers participate in the offer, institutions that value access must either subscribe conventionally (at full price) or participate in S2O (at a discount) to ensure continued access. The offer is repeated yearly, with the opening of each year's content contingent on sufficient participation.

Building models such as \$20 on the basis of collective action principles—best described in Mancur Olson's seminal work, *The Logic of Collective Action* (Olson, 1965)—can help to secure long-term stability. Olsen describes how groups can support the provision of public goods through coordinated action, as the nonexcludability and nonrivalry of benefits means that one person's contribution automatically benefits other potential contributors (Olson, 1965). While recognizing the risk of free riding (i.e., benefiting from the good without contributing to its provision), Olson contends that collective action can succeed with adequate coordinating mechanisms. Applying

collective action theory and practice to the design of cooperative OA models between libraries and publishers can help to lower organizing costs, increase the resources available to fund open content, and reduce risk through limiting free ridership (Crow, 2015).

Investment in cooperative arrangements does not require that cash-strapped libraries discover a new influx of money as their collection budgets continue to shrink, but rather that they purposefully redirect traditional subscription funds toward publishing support. Recent work (Naim, 2019) found that in entering into cooperative OA arrangements, libraries were more closely aligned with non-profit publishers (scientific societies, in particular), where the two parties shared closer value alignment.

This finding should be positive and reassuring news for society publishers. Although many have inked agreements with commercial publishing partners to sustain revenue, they continue to uphold their respective missions, which remain well aligned with the values of the academy, and present appealing investment opportunities for universities, research institutions, and libraries. Scholarly societies, in particular, feel vulnerable in the current climate of commercial dominance of scholarly publishing, compounded by increasing demands from the funder community and scholars alike to explore sustainable OA strategies. The subscription model has enabled many society publishers to generate surpluses, which have become central to the support of society activities such as member education, research grants, and public engagement. Yet libraries have indicated willingness to engage in expenditure-neutral models with society publishers, effectively indicating that their publishing surpluses are not under scrutiny, provided there is some financial transparency, and that surpluses fund activities that advance the discipline (Brundy et al., 2019; Naim, 2019).

As society journal subscriptions have largely been bundled for libraries through aggregating intermediaries, libraries and societies have a rather nascent understanding of each other's needs. As such, these cooperative arrangements, at least for some time, may require a two-way demonstration of trust: on one hand, libraries working together to provide assurances of sustained financial support, and on the other, societies' willingness to experiment with discarding subscriptions. To forge bilateral trust, education about and further development of scalable and cooperative OA publishing models is needed.

That is precisely what organizations such as Society Publishers' Coalition (SocPC) are trying to achieve. With over 85 member societies, SocPC is working to ensure an orderly and sustainable transition for nonprofit learned societies to open scholarship. Through education about and development of new transitional publishing models, SocPC is working to support scale and efficiency in cooperative approaches and help societies gain leverage in negotiating with libraries and consortia—thereby securing the focus and prioritization that are typically reserved for commercial publishers. Members of SocPC, such as the Biochemical Society, have already launched several OA pilots and have successfully initiated dialog across the sector regarding the essential and precarious place of learned societies (Brainard, 2019; Legge, 2020). Wise and Estelle (2019) provide a thorough overview of the OA models available to scholarly societies.

Another such group building trust between societies and libraries is Transitioning Society Publications to Open Access (TSPOA), co-chaired by the three authors. TSPOA largely focuses on bringing together stakeholders to catalyze and support society transitions. Members come from a range of library, academic, consortia, and publisher backgrounds and are united in their interest in seeing societies transition sustainably to an open world. TSPOA's work

takes the form of direct consultations, advocacy, and education. For example, in the fall of 2019, TSPOA partnered with SocPC to present a three-part webinar series examining issues facing learned societies as they seek to move their publications to OA as well as the emerging open business models that can be used (Transitioning Society Publications to Open Access, 2019). Consultations have taken place with a number of self-publishing societies, from smaller societies that may have only one publication to larger societies with large portfolios of publications. But consistent in TSPOA's approach is the desire to harness the good will that exists in the library community for mission-focused society publishers while simultaneously recognizing the growing urgency of expanding OA.

This urgency has only grown during the current public health crisis surrounding COVID-19. In the time of this pandemic, academic publishers have recognized OA as the optimal mechanism for achieving rapid progress toward solutions on many fronts, including vaccines, therapeutics, and disease epidemiology. Prompted by the Wellcome Trust, dozens of publishers and content providers (commercial and noncommercial alike) have agreed to make COVID-19-related research either immediately OA, or at least freely available for the duration of the outbreak (Wellcome Trust, 2020). These gestures of access, funded primarily by research library subscriptions, acknowledge not only that the paywalled system is suboptimal, but also that open access to scientific articles and datasets is critical to solving global problems and saving lives. Cooperative publishing arrangements represent a viable path forward for society publishers to transition to OA as the default standard for disseminating research. This not only will equip the scientific community to better respond to future challenges, but also will further accelerate the advancement of research and scholarship as a whole.

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