

Request for Information: Public Access to Peer-Reviewed Scholarly Publications, Data and Code Resulting From Federally Funded Research

Submitted by: Anthony D. So,* MD, MPA, Professor of the Practice and Joshua Woo,* Undergraduate Student, Innovation + Design Enabling Access (IDEA) Initiative, Department of International Health, Johns Hopkins Bloomberg School of Public Health and Transformative Technologies and Institutions theme, Johns Hopkins Alliance for a Healthier World; Caitlin Carter,* MLIS, Scholarly Communication Informationist, Johns Hopkins University and Medicine Welch Medical Library

We welcome the opportunity to respond to the White House Office of Science and Technology Policy's Request for Information on "Public Access to Peer-Reviewed Scholarly Publications, Data, and Code Resulting from Federally Funded Research." To this issue, we bring the perspectives of a University professor and researcher, student and librarian.

I. Current Limitations to Effective Communication of Research Outputs

In a time of COVID-19, the critical importance of rapid and unimpeded access to research findings has never been clearer. By contrast to the SARS pandemic less than two decades ago, the pace of research on COVID-19 is exponentially faster (see **Figure 1**). During the SARS outbreak in 2003, [over ninety percent of the SARS-related research entered the published literature after the outbreak had subsided](#). Today COVID-19 research is rolling out in preprints at a furious pace. As of May 4th, medRxiv and bioRxiv already had over 2700 COVID-19 SARS-CoV-2 preprint publications. Rapid dissemination has been essential to the country's, as well as the global, response to COVID-19 by making readily available findings on health technologies to combat COVID-19, from PPE and diagnostics to drugs and vaccines. The fact that many closed-access journals have opted voluntarily to make COVID-19 journal articles open supports why access to government-funded research is in the public's interest.

However, it should not take a pandemic to ensure access to government-funded research. The NIH Public Access policy currently requires all publicly funded research to be made openly available within 12 months of publication. Meanwhile, the Bill and Melinda Gates Foundation, one of our nation's largest foundation funding biomedical research, requires the [immediate publication of funded work, without any embargo period](#). Even with COVID-19 research being made freely available upon publication, many of the key research findings related to the care of these patients remain behind paywalls. While as many as [1 in 7 COVID-19 patients reportedly experience secondary bacterial infections and half of all COVID-19 deaths showing secondary](#)

*The opinions expressed herein are our own and do not necessarily reflect the views of The Johns Hopkins University.

[infections](#), healthcare providers still face barriers accessing relevant journal literature. Whereas almost 90% of “COVID-19” articles are available open access, only 58% of articles on “secondary bacterial infections” over the past 10 years are available open access. Similarly, only 41% and 34% of articles on “hydroxychloroquine” and “ventilator-associated pneumonia,” respectively, are freely available as open access over the past ten years.**

Number of papers published

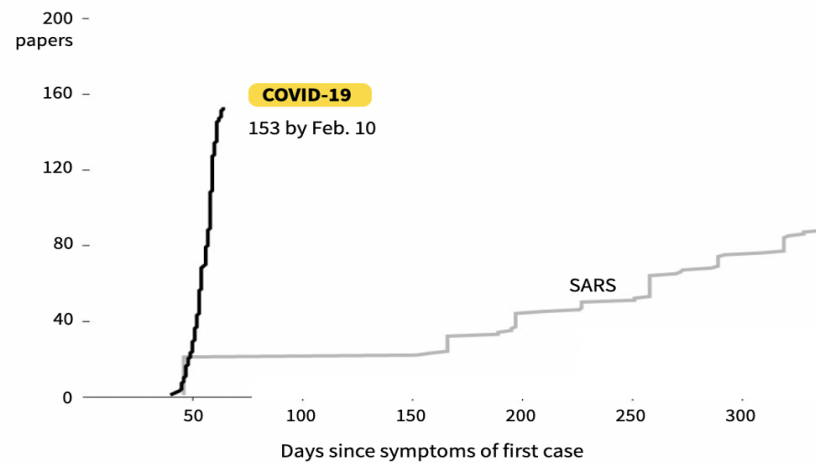


Figure 1: Number of papers published in SARS and COVID-19 pandemics

Adapted from: Sharma, Manas, et al. Speed Science: The risks of swiftly spreading coronavirus research. *Reuters Graphics* 2020.

As the pandemic has demonstrated, the challenges of modern-day medicine and public health interconnect the world. By contrast to U.S. government-funded researchers, European investigators are supported by [funders, as seen in cOAlition S](#), that have more consistently embraced the immediate open access to funded research. Such [open access research secures higher citation rates](#). So in the United States, a one-year embargo on research only disadvantages researchers funded by U.S. government funding agencies, embargoing the results of their research behind subscription paywalls and limiting their dissemination and citation by others for an entire year. The embargo period on the federal government’s public access policy should be eliminated. Government-funded research should be immediately available to the public upon publication, and if journals would like to have the opportunity of disseminating such research, the final version published in the journal should be made available to PubMed Central as part of an open access repository and also flagged as being freely available on the journal’s website. Peer reviewed scholarly research should be openly licensed and machine readable to ensure the ability for secondary analysis and collaboration.

** These figures of open access, by search term, were determined using the Web of Science database.

II. Fair returns on taxpayer-funded research results

The U.S. NIH has put in place some normative guidance to ensure taxpayer-funded research results are made available in a timely way that maximizes access. The Bermuda Rules committed investigators in the Human Genome Project to share sequencing results of any DNA base pair sequence within 24 hours of completion to GenBank, a public database. By making such information publicly available, this created a record of prior art and helped to prevent patenting of these building blocks of knowledge. The NIH Working Group on Research Tools flagged in 1998 the “growing difficulties and delays in negotiating the terms of access to research tools” and set important norms to “[promote free dissemination of research tools without legal agreements whenever possible.](#)” However, the Bayh-Dole Act of 1980 is the cornerstone framework that governs the dissemination of research funded by the U.S. federal government. By patenting and licensing intellectual property resulting from federally funded inventions, grantees facilitate the commercialization of such technologies. Apart from requirements such as the grant of a non-exclusive, paid up license to the invention to the U.S. government, such inventions must be disclosed to the federal agency funding the work, and inventors must acknowledge such government support in any patent application.

While the U.S. Department of Commerce tightened these obligations under the revised Bayh-Dole Rule in 2018, greater transparency of pharmaceutical R&D is needed during the FDA registration process. A case in point is Truvada and Descovy, drugs used for pre-exposure prophylaxis (PrEP) for HIV prevention. The U.S. government has alleged that Gilead, its manufacturer, has refused to reach a licensing agreement for patents developed from government-supported research and has acted in a manner that is “[malicious, wanton, deliberate, consciously wrongful, flagrant, and in bad faith.](#)” The government maintains that Gilead has realized lucrative gains, with treatment costs exceeding \$20,000 a year for each patient, while not declaring any government support in the development of the product. This has resulted in a government lawsuit against Gilead on grounds of [patent infringement and profiteering off hundreds of millions of taxpayer dollars that went into public PrEP research.](#) And despite Gilead’s retaliatory lawsuit against the United States, the fact still stands that taxpayers paid twice: both for the [CDC research and again to pay Gilead billions for PrEP through the sale of Truvada.](#)

Open access to publicly funded research can create, though, conditions that contribute to significant returns on government investment. The Human Genome project, for example, has [generated an economic return of \\$796 billion on a \\$3.8 billion investment](#)--a return of investment of \$141 in economic activity for every \$1 of taxpayer money invested. A defining core value of the Human Genome Project was the effort to make its findings freely available, including through the Bermuda Rules.

III. Public access—key to American science leadership and competitiveness

Amidst the COVID-19 pandemic, [government officials around the world, as well as funders and publishers](#), have called for open access. However, other public health emergencies have not been met by such commitments. In 2015, those addressing the Ebola crisis in Liberia published an [open letter](#) in the *New York Times* arguing that the failure to appreciate the risk of this deadly disease occurring in Liberia, in part, resulted from the relevant literature being hidden behind journal subscription paywalls. Had the 1982 paper warning of this risk been freely available, its findings might have been actionable, and follow-on research, conducted before the crisis set in. Going open access, only after a pandemic is upon us and only for a narrow corridor of health information, would be a short-sighted approach to ensuring fair returns and continued research leadership in the United States, let alone preparing for the next pandemic.

Even in the United States, institutions have increasingly been [unable to afford access to the scholarly literature](#) despite contributing to the creation of this knowledge base. By contrast, medical journal publishers have realized [year-on-year profit margins as high as 36%](#), greater than returns even by high-tech firms such as Apple, Amazon or Google in that year. Since most published journal research is either government-funded or indirectly subsidized through philanthropies benefiting from public tax relief, this amounts to a corporate subsidy at taxpayer expense. U.S. taxpayers, in effect, pay twice--once for the research to be conducted and again to access the results of these publicly funded studies.

IV. Supporting effective innovation ecosystems

The tail of the COVID-19 pandemic is likely to linger for years to come, but of concern, the commitment of closed access journals may well be less lasting than the disease threat. In fact, commercial publishers like Elsevier and Springer made their COVID-19 research only temporarily open access--a condition that may sunset at some point and [return this work behind a subscription paywall](#).

Rather than relying on authors and academic institutions to pay article processing fees, the U.S. government could [set aside a portion of the costs of research grants towards supporting open access journals](#). Such a system could provide each year an upfront subsidy to journals or services that curate the quality of published research. This pool of funding could be apportioned to such journals or curated services based on factors such as the circulation, the value and quality of publicly funded research in its pages, the cost-effectiveness of the dissemination achieved, or other measures. This approach could also provide a platform for philanthropies and other potential sources of research financing to support open access publication.

Just over a decade ago, the Institute of Medicine's report on [*The U.S. Commitment to Global Health: Recommendations for the Public and Private Sectors*](#) called upon the research community to “promote global knowledge networks and the open exchange of information and tools that enable local problem solvers to conduct research to improve the health of their own populations.” Those words seem almost prophetic today, knowing how interconnected and entwined the challenge of global health is across borders.

In the interval, we have made considerable advances in this direction. The Food and Drug Administration Amendments Act (FDAAA) of 2007 requires that NIH-funded clinical trials must disclose clinical trial results in ClinicalTrials.gov within a year of the trial's completion. Major research funders from the Wellcome Trust and the Bill and Melinda Gates Foundation to the Indian Council of Medical Research and the UK Medical Research Council have committed to the principles behind the [WHO Joint Statement on Public Disclosure of Results from Clinical Trials](#). The Johns Hopkins School of Medicine has developed [streamlined clinical trial registration guidelines](#), which could serve as a potential model that both meets FDAAA requirements and goes further in practically implementing the principles in the WHO Joint Statement. Building on such efforts, the U.S. NIH has the opportunity to lead and usher in a global commitment to open clinical trials.

We thank OSTP for its leadership in exploring next steps and encourage you to implement an immediate open access policy for the results of publicly funded research.