ALL FEDERAL RESEARCH AGENCIES TO UPDATE PUBLIC ACCESS POLICIES

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U.S. Health Care and FDA Alert

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On 25 August 2022, the Office of Science and Technology Policy (OSTP) released a guidance memorandum instructing federal agencies with research and development expenditures to update their public access policies. Notably, OSTP is retracting prior guidance that gave discretion to agencies to allow a 12-month embargo on the free and public release of peer-reviewed publications, so that federal funded research results will be timely and equitably available at no cost. The memo also directs affected agencies to develop policies that:

1. Ensure public access to scientific data, even if not associated with peer-reviewed publications;
2. Ensure scientific and research integrity in the agency's public access by requiring publication of the metadata, including the unique digital persistent identifier; and
3. Coordinate with OSTP to ensure equitable delivery of federally funded research results and data.

KEY COMPONENTS OF GUIDANCE:

Updating Public Access Policies

Federal agencies will need to develop new, or update existing, public access plans, and submit them to OSTP and the Office of Management and Budget (OMB). Deadlines for submission are within 180 days for federal agencies with more than US$100 million in annual research and development expenditures, and within 360 days for those with less than US$100 million in expenditures.

Agencies will need to ensure that any peer-reviewed scholarly publication is free and available by default in agency-designated repositories without any embargo or delay following publication. Similarly, OSTP expects the access polices to address publication of any other federally funded scientific data, even if not associated with peer-reviewed scholarly publications. As a concession, federal agencies are being asked to allow researchers to include the “reasonable publication costs and costs associated with submission, curation, management of data, and special handling instructions as allowable expenses in all research budgets.[1]”

Ensuring Scientific Integrity

To strengthen trust in governmentally funded research, the new or updated policies must transparently communicate information designed to promote OSTP's research integrity goals. Accordingly, agencies are instructed to collect and make appropriate metadata available in their public access repositories, including (i) all author and co-author names, affiliations, and source of funding, referencing their digital persistent identifiers, as appropriate; (ii) date of publication; and (iii) a unique digital persistent identifier for research output. Agencies

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should submit to OSTP and OMB (by 31 December 2024) a second update to their policies specifying the approaches taken to implement this transparency, and publish such policy updates by 31 December 2026, with an effective date no later than one year after publication of the updated plan.

IMPLICATIONS FOR THE NATIONAL INSTITUTES OF HEALTH (NIH), OTHER FEDERAL AGENCIES, AND THEIR GRANTEES

The NIH is expected to update its Public Access Policy, potentially along with its Data Management and Sharing Policy to conform with the new OSTP guidance. Universities, academic medical centers, research institutes, and federally funded investigators should monitor agency publications of draft and revised policies in order to update their processes to ensure continued compliance.

In doing so, affected stakeholders may want to consider and comment to relevant federal agencies on the following issues in their respective public access policy development:

- Federal agency security practices to prevent foreign misappropriation of research data;
- Implications for research misconduct investigations and research integrity;
- Any intellectual property considerations without a 12-month embargo, especially to the extent this captures scientific data not yet published in a peer-review journal; and
- Costs allowable research budgets to support these data management and submission expectations.

K&L Gates' Health Care and FDA practice regularly advises universities and academic medical centers on research compliance and related regulatory matters and is able to assist in this regard.

FOOTNOTES

[1] Office of Science and Technology Policy, Memorandum for the Heads of Executive Departments and Agencies: Ensuring Free, Immediate, and Equitable Access to Federally Funded Research at p. 5 (25 August 2022) available at https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf

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