SMG 2126.6

FDA Staff Manual Guides, Volume III – General Administration

External Relations

Public Access Requirements for Extramural Research

Effective Date: 01/01/2026

1. Purpose

This Staff Manual Guide ("SMG") sets forth a subset of FDA's policies and procedures related to implementation of memoranda issued by the White House's Office of Science and Technology Policy (OSTP) in 2013 and 2022 and outlines FDA's commitment to openness and transparency by making the results of the Agency's scientific research widely available to the public.[1]

On August 25, 2022, OSTP issued a memorandum (2022 Memo) to the heads of executive departments and agencies entitled "Ensuring Free, Immediate, and Equitable Access to Federally Funded Research," which built on the policies set forth in a preceding OSTP memorandum issued in 2013 (2013 Memo) entitled "Increasing Access to the Results of Federally Funded Scientific Research." The 2013 Memo directed federal agencies with scientific research and development budgets greater than $100 million per year (such as FDA) to provide free public access to Agency-funded, peer-reviewed scholarly publications and their underlying data. The 2022 memo supplemented the 2013 memo by, among other things, recommending that, as appropriate and consistent with applicable law,

[1] SMG 2126.5 sets forth the other subset of policies and procedures implementing recommendations from OSTP's memoranda—those related to intramural scientific research and scholarly publications authored by FDA staff.

agencies subject to the policy make such scholarly publications available to the public at the time of formal publication—as opposed to by twelve months later—and further clarifying the circumstances under which the underlying scientific data must be made available for free via a public-facing data repository.

Access to the results of FDA-funded scientific research furthers the Agency's mission to protect, promote, and advance public health. Making scholarly publications and their underlying data accessible for the critical review, replication, and verification by the public promotes robust and open communication within the scientific community.

2. Policy

This SMG addresses FDA's implementation of the 2022 Memo with respect to extramural scientific research funded by the Agency and scholarly publications based on such research and will, when implemented, replace those aspects of SMG 2126.4 - Access to Results of FDA-Funded Scientific Research (2015 SMG) that address certain requirements associated with such extramural research. For purposes of this SMG, "scientific research," as further defined below, is the systematic process of collecting and generating data through observation and experimentation to understand, explain, or prove a theory or phenomenon through use of appropriate methodology. The term does not include analysis of data generated without FDA funding.

This SMG reflects FDA's efforts to follow recommendations in OSTP's 2022 Memo with current resources. Without additional funding and resources, however, requiring extramural researchers or FDA staff to adhere to those recommendations may—depending partly on whether the policies of scientific journal publishers evolve in response to the 2022 Memo—become untenable and may cause the agency to conclude in specific instances or categories that full compliance with the policies and procedures is inappropriate, inconsistent with federal interests, and/or infeasible for the Agency.

Beginning January 1, 2026, consistent with the procedures outlined below, FDA staff should in most cases ensure: (1) that the terms of funding instruments for extramural research—such as contracts, grants, and cooperative agreements—address how scholarly publications resulting from such research and the scientific data underlying such scholarly publications—to the extent disclosable under federal law—will be made available to the public for free and (2) that extramural researchers develop and implement data management plans

consistent with the terms of such funding instruments. Until January 1, 2026, the 2015 SMG, which—among other things—sets forth similar requirements for peer-reviewed journal articles and data management plans in the context of extramural research, remains in effect.

3. Definitions

A. Center(s)

One or more of FDA's Center for Biologics Evaluation & Research, Center for Devices & Radiological Health, Center for Drug Evaluation & Research, Center for Tobacco Products, Center for Veterinary Medicine, Human Foods Program, National Center for Toxicological Research, Office of the Commissioner, Office of Inspections & Investigations, and Oncology Center of Excellence.

B. Data Management Plan (DMP)

A document describing how "extramural researchers" will handle "scientific data" for a specific research project both during the research and after completion—to ensure that all "scientific data" generated by the research are correctly formatted, annotated, and organized from the outset of the research project.[2]

C. Data Repository

A database for "scientific data" and associated "metadata" located on a physical device or in a digital space that is accessible to the public for free and is easily searchable. To the extent practicable, the database must comply with the National Science and Technology Council's "Desirable Characteristics of Data Repositories for Federally Funded Research."

D. Digital Persistent Identifier (PID)

A current digital identifier that is globally unique, persistent, machine resolvable and processable and has an associated metadata schema, such as an Open Researcher and Contributor ID (ORCID).

[2] Quotation marks throughout this section indicate that the quoted terminology is defined elsewhere in this section. This section defines terms for operation within this SMG only and is not intended to define terms for other purposes beyond this SMG.

E. Extramural Research

Any “scientific research” conducted by organizations or individuals who are not “FDA staff” pursuant to a “funding instrument,” whether or not conducted in collaboration with “FDA Staff” or as part of a larger project that includes research conducted by “FDA Staff.”

F. Extramural Researcher(s)

Any individual or organization engaged in “extramural research” and subject to the terms of a “funding instrument.”

G. FDA Staff or FDA Staff Member(s)

FDA employees, political appointees, contractors, fellows, and/or trainees.

H. Final Manuscript

A machine-readable version of a “scholarly publication” that has been accepted for publication and that includes all changes made during the peer review process (but does not necessarily include copy and style edits or formatting changes). If machine-readable, the final published version of a “scholarly publication” suffices as a final manuscript when available.

I. Formal Publication Date

The date on which an outside publisher first makes a “scholarly publication” available in its entirety to readers either via appearance on a website or in hard copy or some other digital form.

J. Full-Text Archive

A digital repository for “final manuscript[s]” of “scholarly publication[s]” (and usually other scientific literature) that enables the public to search for such manuscripts and review them at no cost, such as PubMed Central® (PMC) at the United States National Institutes of Health's National Library of Medicine. For purposes of this SMG, a full-text archive includes any associated index that enables the public to search “metadata” for “scholarly publications.”

K. Funding Instrument

A contract, grant, or cooperative agreement (*see* 31 USC 6303-6305, 35 USC 201(b)) that: (1) provides funding, equipment, and/or other assets to an organization or individual outside FDA for purposes of supporting “extramural research” and (2) sets forth the terms for such “extramural research.”

L. Metadata

Digital information associated with a “scholarly publication” or “scientific data” that describes such publication or data and makes it uniquely identifiable and more easily searchable and retrievable. Metadata for “scholarly publication[s]” and “scientific data” often include the author names, affiliations, title, journal or book title, publication date, contact information, sources of funding, and funding acknowledgements (some of which may be drawn from what is known about the “scholarly publication” before the “formal publication date”). The metadata for both a “scholarly publication” and “scientific data” should include at minimum the “digital persistent identifier[s]” associated with any individual who is or will be credited as an author in the “scholarly publication” and an identifier for the individual work, such as, but not limited to, a digital object identifier.

M. Program Officials or POs

Any and all “FDA staff” involved in planning “extramural research,” developing Agency announcements regarding “funding instrument[s],” establishing the terms for such “funding instrument[s],” approving or finalizing “funding instrument[s]” overseeing or monitoring “extramural research,” and/or taking appropriate steps to ensure compliance with “funding instrument[s].” The term could include, for example, “FDA staff” in a “Center,” such as scientists, who initiate the process for funding “extramural research,” personnel within the Office of Acquisitions and Grant Services who have a role in the process for the “funding instrument,” and any Contracting Officer’s Representative (COR) associated with the “funding instrument.”

N. Scholarly Publication

Any formal, peer-reviewed publication that is based, at least in part, on “extramural research,” including articles in scholarly journals, book chapters, editorials, and summaries or transcripts of conference presentations.

O. Scientific Data

Digitally recorded factual material generated by “extramural research” and commonly accepted by the scientific community as being sufficient to validate and replicate findings generated by “scientific research.” Scientific data do not include preliminary materials underlying the data or lab notebooks, preliminary analyses, drafts, plans for future research, peer review reports, communications with colleagues, and physical objects such as lab specimens, artifacts, or field notes.

P. Scientific Research

The systematic process of collecting and generating data through observation and experimentation to understand, explain, or prove a theory or phenomenon through use of appropriate methodology. For purposes of this SMG, scientific research does not include evaluating or analyzing pre-existing data or collecting factual information about events occurring outside the context of controlled experiments or other scientific studies (such as aggregating electronic healthcare data).

4. Application

Centers and FDA staff should implement and follow the general requirements and procedures set forth in this SMG. Centers may supplement and expand on this SMG to meet their specific needs through issuance of written standard operating procedures, so long as those procedures do not conflict with the general principles and policies set forth in this SMG.

5. Responsibilities and Procedures

In deciding whether to approve or fund extramural research, Program Officials should consider both data management costs and the resources necessary to make the scientific data generated by the extramural research available to the public pursuant to the requirements of this SMG if such research results in a scholarly publication.

A. Agency Announcements

When FDA funds extramural research, Program Officials should ensure that any public announcement soliciting applicants to conduct such extramural research sets forth clear expectations that applicants will provide detailed plans for posting

the final manuscript for any scholarly publication resulting from such research (along with the associated metadata) to a full-text archive as soon as practicable after the formal publication date. The announcement should also contemplate that applicants will submit a proposed approach for making the scientific data underlying any such scholarly publication and associated metadata available to a data repository as soon as practicable after the scholarly publication is posted or ensure that all scientific data are available within the final manuscript itself. Whenever feasible and appropriate, POs should encourage submission of a Data Management Plan (DMP) as part of the application process. At a minimum, the announcement should provide clear expectations that applicants will develop and implement a DMP that accounts for how all scientific data generated by the extramural research will be collected, organized, and stored for purposes of satisfying the requirement that such data will be made available to the public via a data repository.

B. Funding Instrument Terms

When finalizing a funding instrument for extramural research on behalf of the agency, POs should ensure that the terms of such funding instrument require both that extramural researchers notify appropriate POs at FDA if the extramural research results in a scholarly publication and that the extramural researchers make any such scholarly publication and the underlying scientific data available to the public consistent with requirements of this SMG. Those terms should include conducting the extramural research pursuant to either a DMP that POs authorized during the application process or a DMP authorized by POs after the award of the funding instrument but before the start of the extramural research. POs should take all necessary and appropriate steps to ensure that extramural researchers satisfy the terms of funding instruments with respect to making scholarly publications and the underlying scientific data available to the public.

C. Data Management Plans (DMPs)

As noted above, the terms of funding instruments for extramural research should require extramural researchers to obtain FDA authorization of a Data Management Plan before they begin the extramural research. Before authorizing a DMP, POs should ensure that an FDA staff member with appropriate scientific expertise who has completed training on the responsible conduct of scientific research within the last four years has reviewed the DMP and approved it on the basis that the DMP is appropriate for the extramural research at issue. The DMP should include the following elements:

- a list of all individuals conducting the extramural research and a digital persistent identifier for each;

- a description of how the scientific data will be structured and organized, including file formatting;

- a description of the steps to be taken to protect private, privileged, or otherwise confidential information;

- a commitment, when appropriate, to make scientific data supporting any scholarly publication resulting from such extramural research freely available to the public to the extent permissible under all applicable laws and federally mandated policies; and

- plans for storing and archiving the data and, if appropriate, making the scientific data available to the public via a data repository if the extramural research results in a scholarly publication.[3]

D. Scholarly Publications

When POs receive notification from an extramural researcher, or otherwise discover, that extramural research has resulted in a scholarly publication, they should take all appropriate and necessary steps to ensure that, consistent with the terms of the applicable funding instrument, extramural researchers have directly or indirectly made the final manuscript and associated metadata for such scholarly publication available in a full-text archive as soon as practicable after the formal publication date.[4] The options for extramural researchers typically include:

[3] In rare cases, POs may tentatively find that making the scientific data generated by extramural research available to the public via a data repository is not feasible, practicable, or appropriate, (i.e., because the interests of the federal government—based on administrative burden or other factors—do not support making such scientific data available). Before authorizing a DMP for extramural research that does not provide for making all non-privileged scientific data available to the public via a data repository if the research results in a scholarly publication, an approving official should obtain concurrence from the Director of the Office of Scientific Integrity.

[4] The mere existence of an agreement with a publisher that provides the publisher with exclusive rights to make the publication available to the public will not be an adequate ground to avoid compliance with this requirement. As a result, this SMG generally prevents an extramural researcher from entering into such an agreement with a publisher.

- relying on the formal publisher—consistent with its written policies and procedures, written assurances, or an agreement with the National Library of Medicine—to upload the final manuscript and associated metadata to PMC or another full-text archive;

- making the final manuscript and the associated metadata available via a full-text archive hosted, managed, and overseen by the extramural researcher and/or a third party; and

- relying on FDA staff who have been credited as authors on the scholarly publication to post the final manuscript and associated metadata directly to PMC via the NIH Manuscript Submission System (NIHMS).[5]

Pursuant to the terms of the funding instrument, the final manuscript and/or associated metadata should link to scientific data made available in a data repository consistent with the requirements below except under circumstances when the final manuscript contains all the scientific data underlying the scholarly publication.

E. Scientific Data

When POs receive notification from an extramural researcher, or otherwise discover, that extramural research has resulted in a scholarly publication, they should take all appropriate and necessary steps to ensure that the extramural researcher has satisfied the terms of the applicable funding instrument with respect to making the scientific data available to the public. To do so, consistent with the authorized DMP, the extramural researcher must usually—as soon as practicable after the formal publication date—directly or indirectly make available to the public in a data repository the scientific data underlying such scholarly publication (insofar as the data were generated by the research funded by FDA and except insofar as the disclosure is prohibited by law or other federally mandated policies). The extramural researcher must also include metadata associated with the scientific data. Typical options for extramural researchers include:

- relying on the publisher—consistent with its written policies and procedures or written assurances—to make the scientific data and metadata available in a data repository;

[5] Please see SMG 2126.5, "Public Access Requirements for FDA Authors of Scholarly Publications Based on FDA-Funded Scientific Research."

- making the scientific data and associated metadata available via a data repository hosted, managed, and overseen by the extramural researcher and/or a third party; and

- working with FDA staff who have been credited as authors on the scholarly publication to post the scientific data and metadata at openFDA.[6]

6. Implementation and Oversight

A. Centers

Centers will take steps to ensure compliance with this SMG by all FDA staff within their organizations.

B. Office of Acquisition and Grants Services

The Office of Acquisition and Grants Services oversees, and provides advice and guidance on, the process for initiating and finalizing funding instruments for extramural research and works with other POs to take all necessary and appropriate steps to ensure that extramural researchers satisfy the terms of the funding instruments under which such research is conducted.

C. Office of Scientific Integrity

The Office of Scientific Integrity (OSI) on behalf of the Office of the Chief Scientist, collaborates with other agency components to address issues raised by FDA staff or Centers with respect to this SMG and to evaluate and develop agency-wide strategic measures either to promote agency efficiency in complying with this SMG or to reduce resources necessary for such compliance. These responsibilities include assisting in convening and leading working groups on any proposed revisions to this SMG. Consistent with the requirements of this SMG, the Director of OSI will also make determinations for the Agency with respect to whether considerations regarding administrative burden and other factors weigh against making scientific data and associated metadata available via a data repository.

[6] Please see SMG 2126.5, "Public Access Requirements for FDA Authors of Scholarly Publications Based on FDA-Funded Scientific Research."

7. Effective Date

The effective date of this staff manual guide is January 1, 2026.

8. Document History - SMG 2126.6 Public Access Requirements for Extramural Research

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	12/19/2024	N/A	OCS/OSI	Steven Kozlowski, M.D., Acting Chief Scientist, Office of the Chief Scientist

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