SMG 2126.5

FDA Staff Manual Guides, Volume III – General Administration

External Relations

Public Access Requirements for Intramural Researchers and FDA Authors of Scholarly Publications Based on FDA-Funded Scientific 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 2126.6 sets forth the other subset of policies and procedures implementing recommendations from OSTP's memoranda—those related exclusively to extramural scientific research.

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 scholarly publications authored or co-authored by FDA staff based on FDA-funded scientific research and will, when effective, replace those aspects of SMG 2126.4 - Access to Results of FDA-Funded Scientific Research (2015 SMG) that address requirements associated with certain scholarly publications meeting that description. 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 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 members should in most cases ensure: (1) that final manuscripts of scholarly publications, as defined below, that they author or co-author are made available in a free full-text archive as soon as practicable after formal publication and (2) that, with limited exceptions, the scientific data underlying such scholarly publications—to the extent disclosable under federal law—are included in the manuscript or posted to a free publicly-facing digital repository at the same time.

Until January 1, 2026, the 2015 SMG, which—among other things—sets forth requirements for certain scholarly publications, remains in effect.

3. Definitions

A. Authorizing Official (AO)

The "FDA staff member" who approves a proposed "data management plan" for "intramural research" either because they have assigned or funded the research on behalf of an agency program or because they otherwise have authority to approve the DMP through designation by a "Center" or by virtue of adequate oversight of such research as a manager or supervisor.[2] A "Center" may designate a specific individual or official to approve "DMP[s]" for all, or certain categories of, "intramural research" conducted by "FDA Staff" at that "Center." Alternatively, several appropriate "FDA staff members" may fill the role of AO for specific "intramural research" projects, e.g., supervisors or managers with adequate oversight of the "intramural research" projects at issue.

B. 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 (NCTR), Office of the Commissioner, Office of Inspections & Investigations, and Oncology Center of Excellence.

C. Concurring Official

An official designated by a "Center" to render decisions on behalf of that "Center" with respect to whether making the "scientific data" underlying specific "scholarly publications" available to the public is not in the federal interest. For the Office of the Commissioner, the Concurring Official is the Director of the Office of Scientific Integrity. For all other "Centers" (including NCTR), the Concurring Official is the head of that "Center" or their designee.

[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.

D. Data Management Plan (DMP)

A document describing how FDA staff engaged in “intramural research” 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.

E. 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.”

F. 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).

G. FDA Author(s)

One or more FDA staff members who will be or are credited as authors or co-authors in a “scholarly publication” based on a contribution to the research or the manuscript itself.

H. FDA-Funded Research

Any “scientific research” that was funded in whole or in part by FDA, including “intramural research.”

I. FDA Staff or FDA Staff Member(s)

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

J. 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 and permissibly posted pursuant to any authorship agreement with the publisher.

K. 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.

L. Full-Text Archive

A large-scale, 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.”

M. Intramural Research

Any “scientific research” conducted by “FDA staff” as part of their official duties, whether or not conducted in collaboration with others outside the agency or as part of a larger project that includes research conducted by non-FDA staff.

N. 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.

O. Scholarly Publication

Any formal, peer-reviewed publication authored or co-authored by one or more FDA staff members that is based on “FDA-funded research,” including articles in scholarly journals, book chapters, editorials, and summaries or transcripts of conference presentations.

P. Scientific Data

Digitally recorded factual material generated by “FDA-funded 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.

Q. 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 data generated by others (such as data received by FDA as part of an application for market authorization or application for exemption from marketing restrictions for investigational use) or collecting factual information about events occurring outside the context of controlled experiments or other scientific studies (such as aggregating electronic healthcare data used by FDA in product safety evaluation).

R. User Guide

An internal webpage managed and updated by the FDA Library Staff with oversight by the Office of Scientific Integrity, that provides guidelines, templates, and information to “FDA Staff” to help ensure compliance with this SMG and to improve the efficiency of such compliance on an ongoing basis.

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

A. DMP Requirements for Intramural Research

Before engaging in intramural research, FDA staff should ensure development of a proposed data management plan (DMP) for approval by an appropriate authorizing official (AO) and may proceed with the intramural research only after approval of the DMP.

FDA staff requesting approval of intramural research from a supervisor or manager or research funds via intramural grants should, when feasible and practicable, provide a proposed DMP as part of the process for such requests. At the very least, FDA staff should outline data management costs as part of the process for making such requests to enable agency officials to assess the availability of adequate resources for such data management given the scope and duration of the planned intramural research. Before assigning intramural research, agency officials should consider ensuring development of a tentative DMP for purposes of making a similar assessment.

In deciding whether to approve, fund, or assign intramural research, agency officials should consider both data management costs and the resources necessary to make the scientific data generated by the intramural research available to the public pursuant to the requirements described below if such research results in a scholarly publication. These considerations might include the resources necessary to ensure redaction of privileged information and long-term storage of the data in a data repository.

For development of a proposed DMP, FDA staff members may use the agency-wide template for DMPs, available in the User Guide. Centers may also develop their own DMP templates for intramural research. Regardless of how developed, however, a proposed DMP should include the following elements:

- a list of all FDA staff members conducting the intramural research and a digital persistent identifier for each;

- a certification that each FDA staff member involved in the intramural research has completed training on the responsible conduct of scientific research within the previous four years;

- 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 intramural 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 intramural research results in a scholarly publication.

The appropriate AO for approving a proposed DMP for intramural research will typically be the agency official who either assigns the research to FDA staff as a supervisor or manager or grants a request to conduct such research, whether as manager or supervisor or as an official deciding whether to provide funds for such research (via an application process or otherwise).[3] A Center may also designate officials to approve DMPs for all, or certain categories of, intramural research conducted by FDA staff at that Center. Only FDA staff members who have completed training on the responsible conduct of scientific research within the last four years should approve a DMP for intramural research.

[3] All formal status updates, progress reports, or reports of results to a supervisor, manager or Agency funding source should include a statement of compliance with the approved DMP or a description of and reasons for any departures from the approved DMP. Managers and funding sources should consider deviations from approved DMPs and address any concerns with the FDA staff involved in the intramural research. Supervisors, managers, and funding sources may consider prior compliance with this SMG in evaluating future requests to conduct research and administering performance appraisals.

If intramural research is being conducted by FDA staff at multiple Centers, all FDA staff members involved in the research should ensure that an AO acceptable to their Centers has approved the DMP for the intramural research.

In rare cases, FDA staff may indicate in a proposed DMP for intramural research—or an AO might conclude—that making scientific data underlying a scholarly publication resulting from such 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 approving a DMP 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 AO should seek concurrence from the appropriate Center's Concurring Official, who will notify the Director of Office of Scientific Integrity of any resulting concurrence and the underlying rationale.

B. Scholarly Publications and Underlying Scientific Data

FDA authors should ensure that the final manuscript for a scholarly publication and associated metadata are posted to a full-text archive as soon as practicable after the formal publication date. FDA authors should also generally ensure by such time that the scientific data underlying the scholarly publication (including associated metadata) are made available in a data repository or included within the final manuscript itself. For more details regarding the requirements for scholarly publications and the underlying scientific data, FDA authors should consult OSTP's 2022 Memo.

1. Final Manuscript and associated metadata

FDA authors should, when appropriate and consistent with the law, ensure that the final manuscript and associated metadata for a scholarly publication appear in a full-text archive as soon as practicable after the formal publication date.[4]

[4] Scholarly publications authored by Agency employees do not carry copyright protections in the United States but may be protectable outside of the United States (see 17 U.S.C. § 105). Although an author could nonetheless—in theory--opt to enter into an agreement with a publisher that provides the publisher with exclusive rights to make the publication available to the public, this SMG generally prevents an FDA author from entering into such an agreement with a publisher. In other words, FDA would typically view entering into such an agreement to be inconsistent with the requirements of this SMG.

FDA authors should consult the User Guide for current practices and acceptable options for ensuring that final manuscripts and associated metadata for scholarly publications are posted to a full-text archive as soon as practicable after the formal publication date, but the typical options include:

- 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;[5]

- uploading the final manuscript and associated metadata directly to PMC via the NIH Manuscript Submission System (NIHMS);

- relying on another FDA author or FDA staff member to upload the final manuscript and associated metadata to PMC or other full-text archive;

- working with other appropriate Agency personnel, such as a Contracting Officer's Representative (COR) or staff within the Office of Acquisition and Grants Services (OAGS), to ensure —pursuant to the terms of a funding instrument such as a cooperative agreement or contract—that an extramural researcher involved in the FDA-funded research upload the final manuscript and associated metadata to PMC or another full-text archive;[6]

- using software applications managed by the FDA Library Staff—to the extent the User Guide indicates that such software applications are available—to ensure that the final manuscript and associated metadata are uploaded to PMC or other full-text archive; and

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).

[5] FDA authors should consult the User Guide for information regarding which scientific journal publishers post scholarly publications to PMC pursuant to a written agreement with the National Library of Medicine
[6] Please see SMG 2126.6, "Public Access Requirements for Extramural Research."

2. Scientific data and associated metadata

   FDA authors of scholarly publications should ensure that—except to the extent disclosure is prohibited by law or other federally mandated policies—the scientific data underlying such publications (insofar as the data were generated by FDA-funded research) and the associated metadata are made available to the public in a data repository as soon as practicable after the formal publication date.[7] The scientific data and associated metadata made available in a data repository should comport with any DMP approved for intramural research.

   If an FDA author believes that making non-privileged scientific data underlying a scholarly publication available to the public via a data repository in a timely manner is so impracticable or inconsistent with the interests of the federal government (based on administrative burden or other factors) that such public availability is not feasible, practicable, or appropriate, the FDA author must seek concurrence from the Concurring Official for their Center, who will notify the Director of the Office of Scientific Integrity of any resulting concurrence and the underlying rationale.[8]

   FDA authors should consult the User Guide for current practices and acceptable options for ensuring that scientific data and associated metadata are made available to the public in a data repository by the formal publication date, with the typical options including:

   - working—or relying on another FDA author or FDA staff member to work—with FDA Library Staff or the Office of Data, Analytics, and Research to post the scientific data and metadata at openFDA;

   - working with other appropriate Agency personnel, such as a COR or staff within OAGS, to ensure—pursuant to the terms of a funding instrument such as a cooperative agreement or contract—that an extramural

[7] FDA authors should consult disclosure specialists in their Centers in determining the extent to which federal statutes, regulations, and policies prohibit disclosure of certain information or data to the public. Statutes bearing on FDA's disclosure of certain information to the public (such as trade secrets, confidential commercial information, and personal privacy information) include the Federal Food, Drug, and Cosmetic Act, 21 USC 331(j); Freedom of Information Act, 5 U.S.C. § 552(b); Privacy Act, 5 U.S.C. § 552a; and Trade Secrets Act, 18 U.S.C. § 1905. *See also* 21 CFR part 20 (describing Agency requirements and limitations regarding public disclosure of Agency records and information).
[8] An FDA author need not undertake this process for concurrence if they obtained such concurrence at the DMP stage for intramural research.

researcher involved in the FDA-funded research make the scientific data and associated metadata available via a data repository; [9]

- using software applications—to the extent the User Guide indicates that such software applications are available—to ensure that the scientific data and associated metadata are uploaded to openFDA or other data repository; and

- 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.

6. Implementation, Oversight, and Compliance

A. Centers

Centers will take steps to ensure compliance with this SMG by all FDA staff within their organizations. By January 31 of each calendar year, beginning on January 31, 2027, all Centers except for the Office of the Commissioner will:

- report to the Director of the Office of Scientific Integrity all scholarly publications by FDA authors within their organizations in the preceding calendar year and

- provide detailed information with respect to: (a) the full-text archive to which each final manuscript and associated metadata have been posted and (b) the data repository to which the scientific data and associated metadata for each scholarly publication have been posted (unless a Concurring Official made a contemporaneous finding that doing so was impracticable or inconsistent with the interests of the federal government).

B. FDA Library Staff

The FDA Library Staff (FLS) will assist FDA authors and other FDA staff in complying with the requirements of this SMG by, among other things, maintaining and updating the User Guide to be consistent with agency practices and, when feasible, subscribing to or licensing software applications and databases that may ease burdens associated with compliance.

[9] Please see SMG 2126.6, “Public Access Requirements for Extramural Research.”

C. Office of Scientific Integrity

The Office of Scientific Integrity (OSI) on behalf of the Office of the Chief Scientist (OCS), collaborates with FLS and, as necessary, 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 or significant modifications to the User Guide. OSI will also:

- work with other offices within OCS and FLS to monitor compliance with this SMG within the Office of the Commissioner and

- receive reports from all other Centers with respect to such compliance, as described above. When OSI identifies a scholarly publication that it believes does not comply with this SMG, OSI will contact the FDA author(s) to discuss compliance, assist with any suggested remediation, and provide a deadline for any suggested remediation.

If OSI and the FDA author(s) are unable to reach alignment with respect to appropriate remediation, OSI will work informally with supervisors and/or managers for the relevant Center(s) to determine next steps.

Finally, consistent with the requirements of this SMG, the Director of OSI will serve as the Concurring Official for the Office of the Commissioner and receive notifications of concurrences from the Concurring Officials for all other Centers.

7. Effective Date

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

8. Document History - SMG 2126.5 Public Access Requirements for FDA Authors of Scholarly Publications Based on FDA-Funded Scientific 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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