

Plan to Increase Access to Results of FDA-Funded Scientific Research

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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I. Background and Purpose

FDA is responsible for protecting the public health by

- assuring the safety and efficacy of human and veterinary drugs, biological products, and medical devices;
- assuring the safety of our Nation's food supply, cosmetics, and products that emit radiation; and
- regulating the manufacturing, marketing, and distribution of tobacco products.

Beyond these core regulatory functions, FDA promotes the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information it needs to use medical products and foods to maintain and improve their health. Moreover, FDA plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by working to ensure the security of the food supply and by fostering development of medical products to respond to deliberate as well as naturally occurring emerging public health threats.

Sound science underlies all that the agency does. Access to reliable scientific and technological information is central to FDA's mission and the agency's regulatory efforts. FDA must rely on the best available science to make difficult decisions with respect to FDA-regulated products. In making those decisions, an unbiased presentation and full analysis of the relevant scientific data, including its uncertainties, is absolutely critical. Establishing and maintaining the integrity of the scientific process and of scientific data is crucial to the agency's ability to arrive at sound decisions and to maintain public trust.

Public access to the results of FDA-funded scientific research furthers the agency's public health mission. The broad availability of scientific information and underlying data allows for the critical review, replication, and verification of findings that are central to the scientific method. Making research findings and the digital data supporting those findings accessible and analyzable promotes robust and open communication with the scientific community thereby bolstering the credibility of scientific findings and the regulatory decision-making based upon those findings. The availability of agency scientific information advances public health by sparking scientific discovery, including prompting the scientific community to address critical challenges in medical product development. Facilitating the free flow of information underlying the agency's decision-making and advances in regulatory science, to the extent permitted by law, allows the public, Congress, media, and industry to better understand FDA's decisions and the scientific basis for its regulatory decision-making.

In June 2009 FDA expressed its commitment to transparency as a tool for the protection of public health by launching an agency-wide Transparency Initiative. ¹ While the agency has embraced the values of

¹ See <http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/default.htm>

openness and transparency, the agency's role as a regulator does present restrictions on the full and free disclosure of scientific data. For example, FDA is limited in whether, how, and when it may disclose certain information submitted to the agency as part of investigational new drug or other marketing applications. Even in its capacity as a research institution, the agency can face restrictions on the disclosure of information and data. For example, the agency may conduct research based on data submitted by third parties related to medical products or conduct research to develop data to support ongoing regulatory decision-making or administrative or criminal investigations that would be precluded from disclosure. In general, the agency is restricted from disclosing information by statute, regulation, and policy, 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 ongoing criminal or administrative investigations;
- personal privacy information; and
- national security and other classified information.

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. FDA shares the objectives of transparency and maximizing public access to FDA funded research. Accordingly, it has developed this plan for public access to FDA-funded peer-reviewed publications and digitally stored data.

On May 9, 2013, the President issued an executive order, "Making Open and Machine Readable the New Default for Government Information" (Open Data Executive Order). The same day, the Office of Management and Budget issued an accompanying memorandum, "Open Data Policy—Managing Information as an Asset" (Memorandum M-13-13) that issues directives and guidance to executive agencies regarding the steps to be taken in making government data open and machine-readable. While the Open Data Executive Order and associated Memorandum M-13-13 constitute a distinct initiative from the OSTP effort to increase public access to federally funded research, it similarly asks executive agencies to expand access to government information.

The HHS Memorandum accompanying this plan describes the Department-wide efforts to comply with the Open Data Executive Order and Memorandum M-13-13. Moreover, FDA's Office of Informatics and Technology Innovation has recently launched its openFDA open data initiative (<http://open.fda.gov>). OpenFDA will make FDA's publicly-available datasets accessible in a structured, machine-readable

format. As one of its first accomplishments, the initiative has provided a search-based Application Programming Interface (API) to make it possible to find both structured and unstructured content online. The API also provides a tool to allow software developers to build their own applications (such as mobile phone apps or interactive websites) that can quickly search, query, or pull public information instantaneously and directly from publicly-available datasets on openFDA. Four datasets have been made available in openFDA related to adverse events, recalls, and product labeling. Several websites already make routine use of data on openFDA. OpenFDA is in its early stages, but the agency will be listening closely to the public, researchers, industry, and all other users for their feedback on how to make openFDA even more useful in promoting and protecting the public health.

While FDA recognizes that the agency and Departmental open-data efforts overlap with, and may expand upon, FDA's plan to increase access to FDA-funded research, this document maintains its focus on implementing the specific requirements of the Public Access Memo. In particular, the document centers on making FDA-funded or –conducted, peer-reviewed, scientific articles freely available to the public and ensuring that FDA intramural and extramural researchers conduct research under approved data management plans.

II. Definitions

Peer-Reviewed Article

For the purposes of this plan, the phrase “peer-reviewed article” is defined as an article describing original scientific research findings published in a scholarly scientific journal that has been peer-reviewed prior to publication.

Final peer-reviewed manuscript

For the purposes of this plan, “Final peer-reviewed manuscript” is defined as an author's final manuscript of a peer-reviewed article that has been accepted by the journal for publication without a requirement for further modification.

Final published article

For the 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.

Article Metadata

For the purposes of this plan, 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.

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 plan:

- 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, WHO Medical Device Single Audit data)
- data received by FDA 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 that restrict the release and/or sharing of the data;
- materials necessary to be held confidential by a researcher until published to ensure the acceptance of research for publication;
- data or information not available for disclosure pursuant to statute or regulation as described in Section I, above; and
- technical and administrative data.²

² FDA recognizes that in some cases software, administrative data, and other tools may be necessary to interpret data and should be accounted for in data management plans described in Section IV.b.i, below.

Nothing in this definition of data imposes requirements on researchers to digitize information as part of compliance with agency publication or data access policies.

FDA Center

For the purposes of this plan, the terms, “FDA Center” or “Center”, are used to 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, the 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.

III. Scope and effective dates

- a. The policies related to public access to scientific publications described in the plan below will apply to peer-reviewed articles accepted for publication on or after October 1, 2015 and authored
 - i. in whole or in part, as a result of funding from FDA through a grant, contract, or cooperative agreement first awarded on or after October 1, 2015, or
 - ii. by an FDA employee as part of his or her assigned duties.

- b. The policies related to data management described in the plan below will apply to scientific research commenced after October 1, 2015 and conducted
 - i. in whole or in part, as a result of funding from FDA through a grant, contract, or cooperative agreement first awarded before the research commences but not before October 1, 2015; or
 - ii. in significant part by an FDA employee as part of his or her assigned duties.

- c. Additional considerations regarding plan scope and applicability
 - This plan and the subsequently implemented policies impose no requirements on researchers to publish research findings, although this is certainly encouraged, as appropriate. As described in

Section IV.a, below, publication access requirements will be triggered only if a researcher chooses to publish research findings in a peer-reviewed scientific journal.

- Pursuant to the scope set out above, policies developed under this plan will require intramural and extramural researchers to operate under approved data management plans. This description of plan scope does not, however, dictate the extent of researcher data management, preservation, or sharing. As described in Section IV.b, below, the agency will look to the practices and norms of the scientific disciplines and communities engaged in the research, as well as applicable restrictions on disclosure, when evaluating data management plans.
- Public access policies developed under this plan will not impose requirements on publications authored or research commenced before the above effective dates.
- FDA recognizes the burdens for researchers that may arise where research is subject to public access policies from multiple federal agencies. Duplicative or conflicting publication access and data management requirements might result from interagency research collaboration, multiple funding sources, or where FDA provides funds to another agency for the purposes of awarding a grant, contract, or cooperative agreement. In the course of implementing this plan, FDA will consider how, when, and whether to apply the FDA policy to research that is otherwise subject to public access policies from other agencies. Interagency public access implementation working groups could provide a forum to consider and address these issues government-wide.
- Some FDA grants to institutions or consortia permit those entities to subsequently contribute resources and funds to other entities performing individual research projects. In the course of implementing this plan, FDA will consider more fully to what extent the public access requirements will apply to researchers receiving such assistance from FDA grantees, and to what extent the grantee will bear responsibility for public access compliance.

IV. Public Access Requirements

a. Peer Reviewed Articles and Article Metadata

i. General Requirements

To the extent feasible and consistent with law, agency mission, resource constraints, and US national, homeland, and economic security, FDA will develop and update policies and procedures to ensure that peer-reviewed articles as defined above and within the scope of this plan are freely available to the public in a centralized article repository no later than 12 months after publication. The policies will further ensure that article metadata are immediately publicly available upon publication.

FDA employee authors of scientific articles covered by the scope of this plan and grantees and contractors receiving FDA funds resulting in scientific articles covered by the scope of this plan, will be responsible for ensuring that a final version of the peer reviewed article—either the final published article or the final peer-reviewed manuscript—and a set of standard article metadata (to be identified by the agency) are deposited into an FDA-designated scientific article repository.

In collaboration with the Department and other HHS Operating Divisions, FDA will develop grant, cooperative agreement, and contract terms related to the deposit of research articles and related metadata to be employed in research grants, cooperative agreements, and contracts (and related documents, such as funding announcements) across the Department.

ii. Scientific Article Repository

FDA will use PubMed Central (PMC)—the NIH digital archive of biomedical and life sciences journal literature, developed and operated by the National Library of Medicine—as its designated scientific article repository in complying with the requirements in the Section 3 of the OSTP Memo. Moreover, FDA will use the NIH Manuscript Submission System (NIHMS) as a mechanism for allowing researchers to submit the final, peer-reviewed version of their articles for inclusion in PMC. Use of NIHMS, PMC, and the association of PMC with the PubMed citation catalog, will satisfy the following publication repository requirements in the OSTP Memo:

- employ mechanisms to help prevent unauthorized mass redistribution of scholarly publications (OSTP Memo Section 3);
- allow the public easy search, access, and analysis of peer-reviewed articles and article metadata for publications covered by the scope of this plan (OSTP Memo Section 3.b);
- ensure full and free access to peer-reviewed articles' metadata upon first publication in a format that ensures interoperability with current and future search technology. Article metadata will be listed in the PubMed database upon first publication, and, as with all citations stored in PubMed, linkage to the full-text of the article is maintained (both a link to the full text of the article in PMC—after the conclusion of the embargo period—and, where possible, to the publisher website upon publication) (OSTP Memo Section 3.b);
- maximize potential for 1) integration with other public and private repositories and archives and 2) public reuse of article text by stakeholders consistent with applicable licenses (OSTP Memo Section 3.d.i);
- ensure proper author and publisher attribution (OSTP Memo Section 3.e);
- provide for long-term preservation and access to article content without charge (OSTP Memo Section 3.f.i);

- use widely-available and nonproprietary archival formats for text and associated content (OSTP Memo Section 3.f.ii);
- provide access to materials in compliance with Section 508 of the Rehabilitation Act (OSTP Memo Section 3.f.iii); and
- enable integration and interoperability with other Federal public access archival solutions and other appropriate archives (OSTP Memo Section 3.f.iv).

For details on the way in which PMC and NIHMS satisfy the requirements of the OSTP Memo, please refer to Section II of the NIH’s “Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research.”

The decision to employ PMC as the designated article repository expresses the agency’s commitment to collaborate with the private sector in pursuing its public access policies. PMC is a public-private partnership to preserve and make public full-text articles published in scientific journals. PMC, operated by the National Library of Medicine at NIH, actively engages with publishers to proactively make their content freely available to the public and to assist NIH researchers in complying with the statutory public access requirements applicable to their work. According to NIH, approximately 1,500 journals contribute the full content of their journals to PMC regardless of whether any particular article is required to be hosted in PMC pursuant to the NIH Public Access policy.³ FDA’s decision to have peer-reviewed articles included in PMC expands the scope and importance of the article repository and should further encourage publishers to use PMC to make their articles publicly available and actively contribute to the PMC public-private collaboration. Furthermore, FDA’s decision to contribute its scientific publications to the existing and robust PMC manuscript repository amplifies and maximizes the agency’s research investment and the investments of NIH and other agencies in the PMC repository.

iii. Article Embargo Period

The OSTP Memo asks agencies to use a 12-month, post-publication embargo period for agency-funded or conducted peer-reviewed articles unless the agency has reason to develop an alternative embargo period that furthers the objectives of the OSTP Memo and addresses the unique challenges faced by the agency and associated scientific disciplines. At this time, FDA sees no reason to depart from the 12 month embargo.

As described in the HHS’s Guiding Principles and Common Approach for Enhancing Public Access, the Department will set out specific procedures for interested stakeholders to petition for a change to the embargo period for a specific scientific field by demonstrating that the current embargo period for

³ See <http://www.ncbi.nlm.nih.gov/pmc/>

research in that field would be inconsistent with the principles of the OSTP Memo. FDA will contribute (along with other HHS Operating Divisions as appropriate) to the resolution of petitions regarding embargo periods for peer-reviewed articles in scientific fields in which FDA conducts or funds research.

b. Digital Data

To the extent feasible and consistent with applicable law and policy; agency mission; resource constraints; U.S. national, homeland, and economic security; and the objectives listed below, digitally formatted scientific data resulting from unclassified research supported wholly or in part by Federal funding should be stored and publicly accessible to search, retrieve, and analyze. FDA intends to increase public access to digital data supporting FDA-conducted or -funded research findings and to further the goals and requirements of the OSTP Memo while recognizing and protecting intellectual property rights and proprietary interests, including protections from disclosure of trade secret or confidential commercial information, and personal privacy information. Specifically, FDA plans to do the following:

- set out requirements that intramural and extramural researchers conduct research under approved data management plans;
- assess existing agency data management and data sharing practices to potentially serve as the basis for future modifications to data management and open data policies; and
- address data preservation and repository needs for FDA and FDA-related scientific communities.

i. Data management plan requirements

FDA will create or modify agency policies to require that data management plans be developed and followed by both intramural and extramural researchers. FDA expects that data management plans will include, but not be limited to, a description of the

- types of data to be produced or collected in the study;
- metadata that will be used to describe and accompany stored data sets;
- data structuring and formatting that will be used;
- data security measures that will be used and the data that the researcher plans to keep confidential based upon any applicable restrictions on data disclosure, including those identified in Section I, above;

- applicable requirements, if any, to share the collected research data or make it publicly available; and
- plans for data storage, archiving, public access, and long-term preservation, including a description of the way in which shared digital data will be discoverable, retrievable, and analyzable (to the extent a researcher believes that long-term preservation and/or public access to data is not justified or appropriate, researchers must provide an explanation based upon balancing the relative value of long-term preservation and/or access and the associated cost and administrative burden).

The agency will coordinate with other operating divisions within HHS and agencies government-wide in identifying data management plan templates and best practices in data management plan development. FDA anticipates that this process will involve input from stakeholders including, but not limited to, private data repositories, universities, libraries, publishers, users of Federally-funded research results, civil society groups, and researchers. The agency will look to the practices and norms of the scientific disciplines and communities engaged in the research as models for appropriate data management.

FDA recognizes the value of public access to the digital data it generates. Consistent with the OMB Open Government Directive, the Open Data Executive Order, and OMB Memorandum M-13-13, FDA research datasets are presumed to be publicly accessible and are subject to the dataset inventory requirements in Memorandum M-13-13.⁴ As such,

⁴ Pursuant to the Federal Open Data Project Implementation Guide (Implementation Guide) (<https://project-open-data.cio.gov/implementation-guide>), FDA created an enterprise inventory of agency datasets and contributed that listing to the HHS enterprise inventory by November 30, 2013. Consistent with the Implementation Guide, FDA has been expanding upon and enriching its enterprise inventory, as well as cataloguing datasets associated with major IT investments with a focus on strategically important datasets that can be made publicly available. The HHS and FDA Open Data initiatives have identified a significant number of datasets catalogued on HealthData.gov that are publicly-accessible or accessible with restrictions. The FDA-specific public data listing can be found at <https://open.fda.gov/data.json> and is reproduced at HealthData.gov. The comprehensive enterprise inventory, including datasets not publicly-accessible, is provided quarterly to OMB through the OMB Integrated Data Call. Earlier this year, to further the agency's focus on opening agency datasets to the public, FDA launched its openFDA initiative as a mechanism for making FDA's publicly-available datasets accessible in a structured, machine-readable format pursuant to an API.

As the agency expands and enriches its data catalogs consistent with Memorandum M-13-13, it will work with HHS to focus efforts on incorporating its largest and most strategically significant research datasets into the public data listing for publication on openFDA and Healthdata.gov. The metadata for scientific data will include, at a minimum, the common core metadata schema in use by the Federal government, found at <https://project-open-data.cio.gov/>.

- Researchers, as part of submitted data management plans, will be expected to commit to sharing digital data underlying their research findings upon publication of the findings in a peer-reviewed article;
- The agency will ensure that FDA employees and FDA-funded researchers not operating pursuant to an investigator-initiated grant follow applicable open data requirements developed by the agency and Department pursuant to Memorandum M-13-13; and
- The agency will support FDA employees and FDA-funded researchers in depositing digital data in publicly accessible data repositories upon publishing the associated research findings in a peer-reviewed article, unless this requirement has been waived in the approved data management plan. In particular, the agency will identify and publicize ways that researchers can make datasets accessible, retrievable, and analyzable.

Given the presumption of openness of agency data, the agency will employ methods for research data disclosure to maximize access to digital data, while

- preserving the integrity of the data;
- adhering to applicable legal or regulatory restrictions on information disclosure, such as those identified in Section I, above; and
- balancing the value of public access to the data and the associated cost and administrative burden of modifying datasets to allow disclosure.

Such methods of disclosure may include creation of datasets that de-identify human subjects, or redaction or aggregation of datasets prior to sharing.

In general, FDA will not house publicly accessible agency research datasets that would be made publicly available pursuant to agency public access policies. Rather, FDA expects that, in accordance with their data management plans, researchers would make datasets publicly accessible in discipline specific data repositories, wherever available. For example, many agency molecular biologists currently deposit datasets that contain novel nucleotide sequences into GenBank (<http://www.ncbi.nlm.nih.gov/genbank/>). The agency anticipates that agency researchers who have used GenBank in the past to store sequence data would continue to use GenBank as the mechanism for compliance with the data accessibility policies and approved data management plans. The agency believes that the storage of datasets in discipline specific repositories, where available, aids in their discoverability, accessibility, and analyzability in context and combination with similar datasets. In addition, FDA will explore the development of a research data commons, a shared space for research output, including data, software, and narrative associated with biomedical research, both basic and clinical. A data commons tool would provide additional opportunities and resources for providing access to agency research datasets.

Extramural Researchers

FDA will develop new policies and procedures, for both acquisition and grants, to require all grantees and contractors seeking an FDA-funded contract award or grant to conduct scientific research to submit a data management plan. The submitted data management plans will be reviewed on their merits as part of agency grant and acquisition decisions. In evaluating the submitted data management plans, the agency will, as appropriate, weigh the value of the long-term preservation of, and access to, data against the associated cost and administrative burden. The developed agency policies will expressly allow extramural researchers to include planned data management costs in their proposals. Furthermore, FDA will develop new policies and procedures to require all FDA-funded researchers not operating pursuant to an investigator-initiated grant to comply with applicable open data requirements developed by the agency or Department pursuant to Memorandum M-13-13.

In collaboration with the Department and other HHS Operating Divisions, FDA will develop grant and contract terms related to data management requirements (as described in Section IV.b.i, above) to be employed in research grants and contracts (and related documents such as funding announcements) across the Department.

Intramural Researchers

The agency will develop and/or modify policies and procedures to require FDA intramural researchers to conduct research consistent with an approved data management plan, applicable open data requirements developed by the agency or Department pursuant to Memorandum M-13-13, and other agency principles regarding data management and sharing. Center management will review data management plans on their merits in making decisions to approve and fund research. In evaluating submitted data management plans, Center management will, as appropriate and permitted by law and policy, weigh the value of the long-term preservation of and access to data against the associated cost and administrative burden. Moreover, agency policies will allow intramural researchers to include planned data management costs, as appropriate, in research proposals to be considered and approved by Center management.

- ii. Assessment of data management practices and identification of opportunities for additional data sharing

FDA will assess the agency's current data management and sharing practices, requirements, capabilities, and opportunities. This review—along with information the agency obtains from submitted data management plans—may serve as the basis for further iterations of agency policies regarding data preservation and data sharing.

FDA expects that the agency review of data management and sharing practices will

- inventory the types and volume of research conducted by FDA Centers and other operational components, both intramural and extramural;
- identify existing agency data management and sharing practices, requirements, and available resources; and
- identify any categories of FDA-funded or -created data that should be routinely made publicly available because its disclosure furthers the public health or FDA mission, does not impede core regulatory functions or undermine regulatory decision-making, and is not restricted from disclosure by the considerations described in Section I, above.

iii. Identification of data management needs and strategies for leveraging data management resources

The agency is currently engaged in collaborative efforts with other government agencies, public-private partnerships, and academia aimed at the creation of data standards and the establishment and use of data repositories. FDA plans to build on such efforts to leverage existing data management and sharing resources both within and outside the agency. In particular, to the extent feasible and consistent with resource constraints, the agency plans to

- develop strategies to expand the current use of data management resources both within and outside the agency, including through public-private partnerships, and leverage existing public and private repositories and information systems; and
- encourage cooperation with the private sector, including, where appropriate, expanding upon existing public-private partnerships, to
 - improve data access and compatibility and develop approaches for the appropriate attribution of datasets;
 - as feasible and appropriate, provide training, education, and workforce development for FDA-related, scientific communities to improve the quality of data management, analysis, storage, preservation, and stewardship, through workshops, seminars, conferences, and supporting existing training and education efforts regarding data management currently directed by other HHS operating divisions; and
 - identify important long-term data preservation needs for FDA-related scientific communities.

V. Compliance Mechanisms

a. Education

Solicitations and grant announcements serve as the means of informing the public of the government's needs and available assistance programs. Prior to the award of any FDA-funded contract or grant to conduct scientific research, prospective contractors and grantees will be informed of the public access requirements through the posting of FDA solicitations to FedBizOps (for contracts) and Grants.gov (for grants). The agency will explore other strategies, including outreach programs, for ensuring the relevant scientific communities are educated on the public access requirements. FDA will participate in HHS-sponsored public meetings designed to educate the scientific community on the public access requirements being implemented by HHS operating divisions.

Agency policies, procedures, guidelines, and strategies developed to implement the OSTP memo will inform intramural researchers about their obligations to 1) ensure the public availability of published peer-reviewed articles and 2) operate under an approved data management plan. In order to ensure compliance, FDA will educate current agency researchers on the new requirements and will provide data management and publication access orientation to new agency researchers.

The agency recognizes that efficient and effective administration of the FDA public access requirements will require significant training of agency employees responsible for 1) technical evaluation of grant and contract proposals for scientific research and 2) ongoing management and oversight of research grants and contracts. These training and education efforts will be emphasized in implementation of this plan.

b. Compliance and Enforcement

Extramural Research

FDA will ensure grantee and contractor compliance with planned publication access and data management requirements by requiring, as a term and condition of the grant or contract award, periodic reporting to contracting officer representatives and program officers as a part of regular grants and contract management. Extramural researchers will periodically report

- all published articles resulting from research funding and the unique FDA manuscript repository identifier associated with the article; and
- the status of data collection and preservation, including deviation from the approved data management plan.

Failure to comply with the publication access and data management requirements—including the periodic reporting requirements—may serve as grounds to terminate the contract or cancel the grant. This decision rests with the contracting or grants management officer and will be made only after a careful review of all relevant facts and circumstances, and with appropriate consultation with the program office administering the grant or contract.

Prior to funding new grant and contract awards or continuing non-competing continuation awards, FDA will confirm awardees are in compliance with the FDA Public Access Policy. FDA will not award a grant or contract until an awardee has come into compliance with the policy.

Intramural Research

FDA will develop policies and mechanisms to require the reporting of the final publication citation and the unique identifier assigned by PMC, the FDA-designated scientific article repository, for employee-authored articles covered by the scope of this plan. Agency policies will further require researchers to periodically report to supervisors the status of data collection, preservation, and access pursuant to approved data management plans, as well as compliance with applicable open data requirements developed by the agency and Department pursuant to Memorandum M-13-13. Center management will consider compliance with public access requirements in evaluating an employee's subsequent research proposals.

The agency will determine whether and to what extent compliance with the public access requirements and applicable open data requirements developed pursuant to Memorandum M-13-13 will be expressly considered in performance reviews of agency researchers.

Measurement of Agency Performance in Implementation of Public Access Requirements

Measurement of agency performance in implementation of the public access requirements for both the data and publication access components will be calculated from the compliance reporting by intramural and extramural researchers, as described above.

FDA will further consider the feasibility of evaluating overall agency success of the publication access program by drawing upon publisher information regarding the total number of peer-reviewed articles resulting from FDA funding or authored by FDA employees for a given period. The agency believes that comparing this information with the total publications deposited in PMC over the same time period would provide an overall publication access compliance rate. Monitoring this compliance rate over time is likely to provide insight into the effectiveness of the agency's publication access program. FDA will report public access compliance rates on its website annually starting at the conclusion of FY 2016.

VI. Plan Implementation

a. Roles and Responsibilities in Implementation

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 have ultimate responsibility for implementing the agency's data and publication access plan. With significant assistance from the Office of Scientific Integrity, OPHSA will, among other things, convene and lead implementation working groups, delegate tasks, orchestrate work by and input from FDA Centers and operational components, and direct implementation strategy.

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 to promote FDA's public health mission by strengthening the credibility of the agency's science and science-based decision-making.

OSI will provide substantial assistance to OPHSA in the administration of the implementation process and provide input to OPHSA, as necessary, on implementation strategy.

Senior Science Council

The Senior Science Council (SSC) provides advice and guidance to the agency and center 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 plan. Furthermore, OPHSA has recruited members of implementation working groups from the SSC and seeks advice from the SSC on appropriate working group participants.

Office of Acquisitions and Grants Services

The Office of Acquisitions and Grants Services (OAGS) is responsible for negotiating, awarding and managing all contracts, grants, and interagency agreements. OAGS is also responsible for writing acquisition policy and providing strategic business advice and support to our stakeholders.

OAGS will provide input and expertise related to acquisition and grants management to OPHSA as part of implementation working groups. Furthermore, OAGS will take the lead in amending and/or developing grants or acquisition policy as needed to educate extramural researchers and hold grantees and contractors accountable to publication and data access requirements.

Office of Informatics and Technology Innovation

The Office of Informatics and Technology Innovation (OITI), led by the Chief Health Informatics Officer, examines and employs innovative concepts, tools, and technologies to support the agency's mission of promoting and protecting America's public health. OITI also has the primary goal of working with its sibling, the Office of Information Management, in addressing the technology needs and challenges of the FDA Centers and providing the best possible support for their individual missions. OITI's IT initiatives are governed by the CIO Council (see description of the organization below).

OITI is leading agency efforts to comply with the Open Data Executive Order and Memorandum M-13-13 that are related to this publication and data access plan. As part of this initiative, OITI has recently launched its openFDA initiative, to enable wider and more effective collaboration around publicly available data released by FDA for a variety of research. Additionally, the enterprise architecture and data standards staffs in OITI 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.

Chief Information Officer Council

Among other duties, the FDA Chief Information Officer Council (CIO Council) oversees all IT decisions that affect the FDA in whole or in part, and promotes FDA compliance with Departmental or White House mandates. In the course of implementing the Public Access Plan, the CIO Council will be consulted regarding the proposed policies, mechanisms for implementation, and budget structure and be asked to endorse them.

FDA Centers

FDA Centers 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 are also the agency components primarily responsible for the conduct and funding of agency scientific research.

FDA Centers will provide OPHSA important expertise regarding agency intramural and extramural research programs and the associated Center policies in implementation of the public access policies. FDA Centers will further lead efforts within their respective Centers to inventory research programs and the current data sharing and data management practices.

b. Resources

The direct costs associated with initial implementation of this plan and ongoing management of the public access requirements are not fully known and may vary depending upon decisions made during

implementation. FDA is committed to implementing the plan with current resources and expects to deploy funds appropriated directly to the Office of the Commissioner. Generally, no user-fees collected from regulated industry will be directly used in plan implementation. Implementation decisions and progress may be constrained by the availability of funds.

c. Proposed Timeline

Action	Target Date
Finalize and Publish “FDA Plan to Increase Access to Results of Federally Funded Scientific Research”	TBD
Convene Public Access Policy Implementation Steering Committee	COMPLETE
Convene agency Scientific Publication Access and Data Management Working Groups	COMPLETE
Selection of scientific article repository and manuscript submission system	COMPLETE
Completion of Publication Access and Data Management Policies	Summer 2015
Operational scientific article repository and manuscript submission system	Sept. 2015
Intramural and extramural researchers begin deposit of peer-reviewed articles in scientific article repository	Oct. 2015
Begin submission and review of data management plans as part of grant proposals, contract negotiations, and intramural research proposals	Fall 2015
Begin award of grants and contracts subject to data management plan requirements	Jan. 2016
Begin annual reporting of public access compliance rates	Oct. 2016
Agency assessment of data management practices and identification of opportunities for additional data sharing (beyond compliance with M-13-13)	2017 and following
Participation in HHS Operating Division efforts regarding identification of data management needs and strategies for leveraging data management resources	Ongoing
Participation in interagency data and publication access plan implementation working groups	Ongoing

VII. Public Consultation and Interagency Coordination

a. Public Consultation

FDA was a cosponsor of, and participated in, the public consultation sessions convened May 14-17, 2013 at the National Science Foundation. FDA appreciated the important comments from all participants,

and in particular the input from both the scientific and publisher communities. FDA has considered this public input in drafting this plan and will continue to consider the input during plan implementation.

FDA will post the final agency publication and data access plan on the FDA website and will welcome any comments or feedback on the plan. Furthermore, FDA will comply with any public consultation requirements that may arise during plan implementation.

b. Interagency Coordination

Given the frequency with which federal research is funded by multiple agencies, interagency coordination is important in helping extramural researchers comply with the varying public access requirements. As such, FDA has participated in interagency working groups convened by both OSTP and HHS in the development of this plan. FDA will continue to participate in similar interagency working groups that are convened for the purposes of coordinating plan implementation.

VIII. Applicable Legal Authorities and Policies

Federal statute, regulations, and policy provide the authority 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)
- 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. § 201 et seq.
- 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, “Increasing Access to the Results of Federally Funded Scientific Research” (Feb. 22, 2013)
- President Barack Obama, Memorandum for the Heads of Executive Departments and Agencies, “Transparency and Open Government” (Jan. 21, 2009)
 - Office of Management and Budget Director, Peter Orszag, Memorandum for the Heads of Executive Departments and Agencies, “Open Government Directive” (Dec. 8, 2009)
- Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations, 45 CFR Part 74
- Federal Acquisition Regulations System, Solicitation Provisions and Contract Clauses, 48 CFR Part 52
- FDA Regulations, Public Information, 21 CFR Part 20 (and other regulations cross-referenced therein)
- FDA Regulations, Protection of Privacy, 21 CFR Part 21
- FDA Staff Manual Guide 9001.1, Scientific Integrity at FDA (Feb. 3, 2012)
- FDA Staff Manual Guide 2126.3, Review of FDA-Related Articles and Speeches (Apr. 30, 2010) (“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.”)