

Federal Register Notice re OMB Circular A-110



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON D.C. 20503

OFFICE OF MANAGEMENT AND BUDGET

OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations"

AGENCY: Office of Management and Budget, Executive Office of the President

ACTION: Final Revision

SUMMARY: This notice finalizes the revision to OMB Circular A-110, required by a provision of OMB's appropriation for fiscal year (FY) 1999, contained in Public Law 105-277. The provision directs OMB to amend Section ____ .36, Intangible property, of the Circular "to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act" (FOIA). Pursuant to the direction of the provision contained in Public Law 105-277, OMB published a Notice of Proposed Revision on February 4, 1999 (64 FR 5684), and a request for comments on clarifying changes to the proposed revision on August 11, 1999 (64 FR 43786). We received over 9,000 comments on the proposed revision and over 3,000 comments on the clarifying changes.

After a review of the comments on the clarifying changes, as well as the comments on the proposed revision, OMB is issuing this final revision to the Circular, as required by the provision contained in Public Law 105-277.

DATES: The revised Circular is effective November 6, 1999.

ADDRESSES: You may obtain the full text of the Circular, the text of this notice, and the text of the February 4th and August 11th notices on OMB's home page (/OMB), under the heading "Grants Management." You may obtain copies of Public Law 105-277 on the Library of Congress's home page (<http://thomas.loc.gov>).

FOR FURTHER INFORMATION CONTACT: F. James Charney, Policy Analyst, Office of Management and Budget, at (202) 395-3993. Please direct press inquiries to OMB's Communications Office, at (202) 395-7254.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Statutory Direction to Amend Circular A-110

Congress included a two-sentence provision in OMB's appropriation for FY 1999, contained in Public Law 105-277, directing OMB to amend Section _____.36 of the Circular "to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act." The provision also provides for a reasonable fee to cover the costs incurred in responding to a request. The Circular applies to grants and other financial assistance provided to institutions of higher education, hospitals, and non-profit institutions, from all Federal agencies

In directing OMB to revise the Circular, Congress entrusted OMB with the authority to resolve statutory ambiguities, the obligation to address implementation issues the statute did not address, and the discretion to balance the need for public access to research data with protections of the research process. In developing this revision to the Circular, OMB seeks to implement the statutory language fairly, in the context of its legislative history. This requires a balanced approach that (1) furthers the interest of the public in obtaining the information needed to validate Federally-funded research findings, (2) ensures that research can continue to be conducted in accordance with the traditional scientific process, and (3) implements a public access process that will be workable in practice.

OMB recognizes the importance of ensuring that the revised Circular does not interfere with the traditional scientific process. Science and technology are the principal agents of change and progress, with over half of the Nation's labor productivity growth in the last 50 years attributable to technological innovation and the science that supports it. Although the private sector makes many investments in technology development, the Federal Government has an important role to play -- particularly when risks appear too great or the return to companies too speculative. Its support of cutting-edge science contributes to new knowledge and greater understanding, ranging from the edge of the universe to the smallest imaginable particles. When the Federal Government changes the requirements that apply to researchers whom it funds, it needs to ensure that the changes do not interfere with cutting-edge science and the benefits that such science provides to the American people.

During the revision process, many commenters expressed concern that the statute would compel Federally-funded researchers to work in a "fishbowl" in which they would be required to reveal the results of their research, and their research methods, prematurely. They argued that this could prevent researchers from operating under the traditional scientific process. As in many other fields of endeavor, scientists need to deliberate over, develop, and pursue alternative approaches in their research before making results public. When a scientist is sufficiently confident of their results, they publish them for the scrutiny of other scientists and the community at large. Accordingly, in light of this traditional scientific process, we have not construed the statute as requiring scientists to make research data publicly available while the research is still ongoing.

B. OMB's Two Requests for Public Comment on the Proposed Revision

To address implementation issues, OMB published two notices in the Federal Register requesting public comment on the proposed revision to the Circular. Interested parties can consult these notices, which provide extensive background information, for a more complete understanding of the final revision. The original proposal appeared on February 4, 1999 (64 FR 5684). It would have revised Section ____36 of the Circular to read as follows:

"(c) The Federal Government has the right to (1) obtain, reproduce, publish or otherwise use the data first produced under an award, and (2) authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes. In addition, in response to a Freedom of Information Act (FOIA) request for data relating to published research findings produced under an award that were used by the Federal Government in developing policy or rules, the Federal awarding agency shall, within a reasonable time, obtain the requested data so that they can be made available to the public through the procedures established under the FOIA. If the Federal awarding agency obtains the data solely in response to a FOIA request, the agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the data. This fee should reflect costs incurred by the agency, the recipient, and applicable subrecipients. This fee is in addition to any fees the agency may assess under the FOIA (5 U.S.C. 552(a)(4)(A))."

OMB received over 9,000 comments in response to the proposed revision. Commenters offered strongly differing views on the provision contained in P.L. 105-277. Those who supported the statutory provision stated that the public has a right to obtain research data that have been funded with tax dollars, particularly when the research findings were used by the Federal Government in developing policy or rules. These commenters also expressed the view that making this data available for public review and validation would improve the scientific process. Commenters who opposed the provision contained in P.L. 105-277 stated that they support the concepts of full disclosure and open access to information. They acknowledged that the traditional scientific process operates by requiring researchers to subject their findings to the scrutiny of the scientific community and the general public, so that those findings may be validated, corrected, or rejected. However, they expressed concern that the approach

required by P.L. 105-277 would significantly impair scientific research. In their view, individuals and businesses would be reluctant to agree to participate in research, since the participants' personal privacy and proprietary information could not be assured of confidential treatment.

Many commenters on the original proposal asked OMB to clarify four concepts found in the proposed revision: "data," "published," "used by the Federal Government in developing policy or rules," and cost reimbursement. OMB agreed that clarification was needed for these concepts. On August 11, 1999, OMB published a second notice (64 FR 43786), requesting public comment on clarifications to the proposed revision:

"(c) The Federal Government has the right to: (1) obtain, reproduce, publish or otherwise use the data first produced under an award; and (2) authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

"(d) (1) In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing a regulation, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA. If the Federal awarding agency obtains the research data solely in response to a FOIA request, the agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data. This fee should reflect costs incurred by the agency, the recipient, and applicable subrecipients. This fee is in addition to any fees the agency may assess under the FOIA (5 U.S.C. 552(a)(4)(A)).

"(2) The following definitions are to be used for purposes of paragraph (d) of this section:

"(i) *Research data* is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate researching findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples). Research data also do not include: (A) trade secrets, commercial information, materials necessary to be held confidential by a researcher until publication of their results in a peer-reviewed journal, or information which may be copyrighted or patented; and (B) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

"(ii) *Published* is defined as either when: (A) research findings are published in a peer-reviewed scientific or technical journal; or (B) a Federal agency publicly and officially cites to the research findings in support of a regulation.

"(iii) *Used by the Federal Government in developing a regulation* is defined as when an agency publicly and officially cites to the research findings in support of a regulation (for which notice and comment is required under 5 U.S.C. 553).

The August 11th notice explained these clarifications were intended to implement the statute in a manner that (1) furthers the interest of the public in obtaining the information needed to validate Federally-funded research findings, (2) ensures that research can continue to be conducted in accordance with the traditional scientific process, and (3) implements a public access process that will be workable in practice. OMB received over 3,000 comments in response to the clarifying changes.

After considering the views and concerns of all the commenters, OMB now issues a final revision to the Circular. Although the final revision resembles the clarifying changes proposed on August 11, 1999, it reflects additional changes in response to the public comments

Issuance of this final revision meets the statutory requirement imposed by OMB's appropriation for FY 1999 within the time in which it has legal effect. As OMB and the agencies develop experience with the revised Circular, changes to the data access process may be considered. These could range from technical and clarifying changes to substantive revision or rescission. OMB also endeavors to review each of its Circulars every three years.

II. Comments on the Clarifying Changes to the Proposed Revision

A. Research Data

A number of commenters objected that the proposed definition of "research data" would transfer authority to determine which records are exempt from mandatory disclosure under FOIA from Federal agencies to recipients. It was not OMB's intent to transfer the agency's FOIA exemption authority to recipients. Rather, we were providing a definition for what constitutes research "data," a term that is not defined in the provision contained in Public Law 105-277. We have always understood that it would be the recipient, not Federal agency staff, who would identify the research data in the recipient's files which are responsive to a FOIA request. In the over 12,000 comments OMB received on the proposed revision, we are not aware of any suggestion that Federal agency staff should perform the search of a recipient's offices to identify responsive research data. The fact that the recipient is responsible for searching for, and identifying, the research data does not mean the Circular has transferred the agencies' responsibility to recipients. When the recipient searches files for responsive research data, pursuant to Section .___36(d), and in so doing applies the definition of "research data," the recipient is not exercising the agencies' authority under FOIA to determine exemptions. Rather, the recipient is simply identifying the research data that must be provided to the agency. The Federal awarding agency would retain its right to ask the recipient for additional information, if it believed the recipient's submission was not complete.

Several commenters expressed concern because the proposed definition of "research data" excluded "information which may be copyrighted or patented." These commenters believed the proposed language was too broad. They argued that, under copyright law, a wide range of materials "may be" copyrighted, and therefore that such a test could have unintended consequences for the scope of the public access process. In reviewing this language, we note that the protections available in the other parts of the definition (in particular, those protecting "trade secrets" and "commercial information") broadly protect the intellectual property rights of researchers. The proposed definition was not intended to create additional protections for intellectual property, but rather to ensure that existing protections continue to be respected. To avoid unintended consequences, and to avoid having to sort out the complexities of copyright law (and how it might apply in various areas of Federally-funded research), the final revision substitutes "similar information which is protected under law" for "information which may be copyrighted or patented." This language is intended to ensure that the public access process will not upset intellectual property rights that are elsewhere recognized and protected under the law.

Many commenters suggested a change to the definition of "research data" to ensure that appropriate data were protected from disclosure, no matter what the format. Their suggestion was to replace the word "files" with the word "information" in the phrase "[p]ersonnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." Examples of research data that might not be considered to be in the form of a "file" include video or audio tapes of research subjects. We agree with this technical change and have included it in the final revision to the Circular.

Several commenters noted that the definition of "research data" excluded "materials necessary to be held confidential until publication of their results in a peer-reviewed journal." However, since this language is not exactly the same as that used in the definition of "published," ("either when: (A) Research findings are published in a peer-reviewed scientific or technical journal; or (B) A Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law") it appeared that the two might be in conflict. We have revised the definition of "research data" to avoid any conflict between the two definitions.

Finally, several commenters asked for a clarification to the revision pertaining to research data already available to the public. They suggested that if a request is made for research data the recipient has already made available to the public, through a data archive or other means, further action should not be necessary. Since this principle is used when a Federal agency responds to FOIA requests, it makes sense to apply it in this case as well. However, the Federal awarding agency should respond to the FOIA request with directions on how the requester can access the publicly available research data.

B. Used by the Federal Government in Developing a Regulation

A number of commenters objected to the definition which applied the revision to research data that are used by the Federal Government in developing a "regulation." These commenters had generally been satisfied with the language found in the proposed revision ("used by the Federal Government in developing policy or rules"), because it had been used by congressional sponsors during the legislative consideration of Public Law 105-277. However, these commenters believed that the clarifying changes significantly narrowed the scope of the revision.

As we explained in the August 11th notice, its clarification was intended "to ensure that members of the public can obtain the information needed to validate those Federally-funded research findings on which Federal agencies rely when they take actions that have the force and effect of law, while at the same time ensuring that the provision contained in Public Law 105-277 can be administered in a manner that is workable for members of the public, Federal agencies and their recipients" (64 FR 43791). We sought to refer to agency actions that have "the force and effect of law" when it included "a regulation (for which notice and comment is required under 5 U.S.C. 553)" in the proposed definitions. While it is true that agencies also take actions that have "the force and effect of law" when they issue administrative orders (e.g., decisions issued by administrative law judges), we think that agencies rarely rely on Federally-funded research in the context of their administrative orders. Nevertheless, in response to the comments, we have changed the revision to refer to "an agency action that has the force and effect of law" rather than to "a regulation."

We believe this change addresses the concerns of most commenters. We note that a comment letter from Senators Shelby, Lott, Campbell, and Gramm stated that the revision should not be limited to regulations, but should apply generally to "federal actions that can dramatically impact the public." Agency actions that have "the force and effect of law" certainly represent "federal actions that can dramatically impact the public." Indeed, it is through actions that have the force and effect of law that an agency (in the words of one business association) "imposes costs, mandates, restrictions, obligations and responsibilities on the regulated community." However, as stated in the August 11th notice, we have decided not to extend the scope of the revision to agency guidance documents and other issuances that do not have the force and effect of law. We continue to believe that the public interest in such access is less than where the agency is taking action that has the force and effect of law, and that the revision would not be workable in those circumstances. Some commenters, who argued for a broader application, nevertheless were sympathetic to OMB's desire that the public access provision be workable. For example, one commenter stated that "the reproposal may be a workable *first step* in implementation. OMB could start with its August position and see how the system works."

A number of commenters raised a concern about whether requesters would be able to obtain the research data sufficiently in advance of when public comments are due on proposed regulations. These commenters offered various suggestions for how the Circular might be revised to address this concern. In the prior two notices, OMB has proposed a "reasonable time" standard for the response to a request

for research data. Since OMB and the agencies do not yet have experience with implementing the public access process, we believe the "reasonable time" standard, which allows consideration of the circumstances of a particular case, is appropriate. As OMB and the agencies gain experience with the public access process, we may be able to develop further clarification on this point.

Finally, in the August 11th notice, OMB also requested comment "on whether limiting the scope of the proposed revision to regulations that meet [a] \$100 million [impact] threshold would be appropriate" (64 FR 43791). Such a limitation received strong support, as well as strong opposition from commenters. For now, we have decided not to limit the scope of the revision to agency actions that have an impact in excess of \$100 million. As OMB and the agencies develop experience from implementing the revision, we may revisit this issue

C. Published

Commenters generally supported the proposed definition of "published." Some in the research community were more supportive of the first part of the definition (when "[r]esearch findings are published in a peer-reviewed scientific or technical journal") rather than the second part (when "[a] Federal agency publicly and officially cites the research findings in support of" an agency action). However, those who support the provision in Public Law 105-277 argued that the second part is necessary to ensure that the public can have access to the data that underlies Federally-funded research findings on which agencies rely to support their actions. We continue to believe that both parts of the definition are important to successful implementation of a data access provision that furthers the interest of the public in obtaining information while ensuring that research can continue to be conducted in accordance with the traditional scientific process. The only change that has been made to the definition of "published" is to make conforming revisions to reflect the previously-discussed change from "used by the Federal Government in developing a regulation" to "used by the Federal Government in developing an agency action that has the force and effect of law."

D. Cost Reimbursement

Many commenters, particularly recipients of Federally-funded research awards, expressed concern about the reimbursement mechanisms available under the proposed revision. In cases where the award's funding period expires before a request is made, neither the direct nor indirect methods of charging would allow reimbursement. Comments generally focused on the need for a separate agreement between the Federal awarding agency and the recipient, which would cover the full incremental cost of responding to the request. The process for such an agreement could work as follows:

When a request is received by the Federal awarding agency, it would pass the request on to the recipient for an assessment of the costs of complying. Once the recipient has estimated an amount, the

Federal awarding agency can apply its existing standards for requesting appropriate prepayments from the requester, as with the FOIA fee. When the recipient transmits the responsive research data to the agency, it should include an accounting for the associated costs. The Federal awarding agency will then seek reimbursement from the FOIA requester and reimburse the recipient.

If we determine that this mechanism is not adequate, we will consider revising OMB Circular A-21, "Cost Principles for Educational Institutions," as necessary to ensure that recipient institutions are reimbursed for the incremental costs of complying with the provision contained in Public Law 105-277.

E. Record Retention

Some commenters questioned whether the final revision would impose additional record retention requirements on recipients. The final revision only affects Section .___36, which does not discuss recordkeeping responsibilities. Section .___53, Retention and access requirements for records, requires that "[f]inancial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for a period of three years from the date of submission of the final expenditure report." In addition, "[t]he Federal awarding agency...ha[s] the right of timely and unrestricted access to any books, documents, papers, or other records of recipients that are pertinent to the awards...The rights of access in this paragraph are not limited to the required retention period, but shall last as long as records are retained." Therefore, if a recipient chooses to keep records longer than three years, the recipient must make them available for review in response to requests from the Federal awarding agency.

F. Effective Date

Many commenters sought clarification on the effective date for the final revision. As stated above, the revised Circular is effective thirty days after it appears in the Federal Register. The revised Circular is effective for awards issued after the effective date and those continuing awards which are renewed after the effective date.

G. Projects Funded from Multiple Sources

Some commenters asked whether the final revision would apply in situations where research was funded not only by the Federal Government but also by other entities. As noted in the proposed revision, the legislative history to the provision contained in Public Law 105-277 indicates that "the amended Circular shall apply to all Federally-funded research, regardless of the level of funding or whether the award recipient is also using non-Federal funds." 144 Cong. Rec. S12134 (October 9, 1998) (Statement of Sen. Campbell). This statement is consistent with OMB's longstanding interpretation of the Circular which holds that it is applicable to all recipients, regardless of whether they also receive non-Federal funds.

H. Procurement Contracts

Some commenters asked whether the final revision would apply to research that is funded by a Federal agency through a procurement contract. However, the Circular does not apply to procurement contracts. Section ____2(e) of the Circular defines "award," and specifically excludes "contracts which are required to be entered into and administered under procurement laws and regulations."

Issued in Washington, DC, September 30, 1999.

/s/

Jacob J. Lew

Director

As directed by OMB's appropriation for FY 1999, contained in Public Law 105-277, OMB hereby amends Section ____36 of OMB Circular A-110 by revising paragraph (c), redesignating paragraph (d) as paragraph (e), and adding a new paragraph (d) to read as follows:

____36 Intangible property

* * * * *

(c) The Federal Government has the right to:

- (1) obtain, reproduce, publish or otherwise use the data first produced under an award; and
- (2) authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

(d) (1) In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA. If the Federal awarding agency obtains the research data solely in response to a FOIA request, the agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data. This fee should reflect costs incurred by the agency, the recipient, and applicable subrecipients. This fee is in addition to any fees the agency may assess under the FOIA (5 U.S.C. 552(a)(4)(A)).

(2) The following definitions apply for purposes of paragraph (d) of this section:

(i) *Research data* is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples). Research data also do not include:

(A) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and

(B) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

(ii) *Published* is defined as either when:

(A) Research findings are published in a peer-reviewed scientific or technical journal; or

(B) A Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

(iii) *Used by the Federal Government in developing an agency action that has the force and effect of law* is defined as when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.