This revision increases by $72,276,278 the previous deferral of $100,581,381 in the United States Emergency Refugee and Migration Assistance Fund, Department of State, resulting in a total deferral of $172,857,659. This increase results from the deferral of new budget authority provided for FY 1999 in the FY 1999 Emergency Supplemental Appropriations Act (P.L. 106–31).

DEFERRAL OF BUDGET AUTHORITY

Report Pursuant to Section 1013 of P.L. 93–344

Agency: DEPARTMENT OF STATE
Bureau: Other.
Account: United States emergency refugee and migration assistance fund [1] (11X0400)

New budget authority: *$195,000,000
Other budgetary resources: *75,412,337
Total budgetary resources: *270,412,337

Amount deferred for entire year: *172,857,659

Justification: This deferral withholds funds available for emergency refugee and migration assistance for which no determination has been made by the President to provide assistance as required by Executive Order No. 11922. Funds will be released as the President determines assistance to be furnished and designates refugees to be assisted by the Fund. This deferral action is taken under the provisions of the Antideficiency Act (31 U.S.C. 1512).

Section 501(a) of the Foreign Relations Authorization Act of 1976 (Public Law 94–141) and section 414(b)(1) of the Refugee Act of 1980 (Public Law 96–212) amended section 2(c) of the Migration and Refugee Assistance Act of 1962 (22 U.S.C. 2601) by authorizing a fund to enable the President to provide emergency assistance for unexpected urgent refugee and migration needs.

Executive Order No. 11922 of June 16, 1976, allocated all funds appropriated to the President for emergency refugee and migration assistance to the Secretary of State, but reserved for the President the determination of assistance to be furnished and the designation of refugees to be assisted by the Fund.

Estimated programmatic effect: None.

[FR Doc. 99–20700 Filed 8–10–99; 8:45 am]

BILLING CODE 3110–01–P

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: Request for Comments on Clarifying Changes to Proposed Revision on Public Access to Research Data.

SUMMARY: This notice offers interested parties an opportunity to comment on clarifying changes to a proposed revision to OMB Circular A–110, ''Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations.'' Public Law 105–277 directs 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'' (FOIA). Pursuant to the direction of Public Law 105–277, OMB published a Notice of Proposed Revision on February 4, 1999.

OMB received over 9,000 comments on the proposed revision. Many of these comments raised serious concerns about the impact Public Law 105–277 and the proposed revision would have on the conduct of scientific research. In part, these concerns arose from questions as to how expansively or narrowly the proposed revision would be interpreted and applied. In raising these questions, commenters on both sides of the debate sought clarification of four concepts found in the proposed revision: ''data,'' ''published,'' ''used by the Federal Government in developing policy or rules,'' and cost reimbursement.

In response to these comments, and in order to advance implementation of the requirements of Public Law 105–277, OMB has developed proposed clarifying definitions for the first three of these concepts and is providing additional background discussion regarding the fourth. In framing these definitions, OMB has used its discretion to balance the need for public access to research data with protections of the research process. Specifically, OMB seeks to further the interest of the public in obtaining the information needed to validate Federally-funded research findings, ensure that research can continue to be conducted in accordance with the traditional scientific process, and implement a public-access process that will be workable in practice. OMB will consider all comments received in response to this notice, and the comments received in response to the prior notice, in its development of the final revision to the Circular. OMB intends to publish the final revision on or before September 30, 1999. It is not necessary to re-submit comments already provided to OMB.

DATES: Comments must be received by September 10, 1999.

ADDRESSES: Comments on this proposed revision should be addressed to: F. James Charney, Policy Analyst, Office of Management and Budget, Room 6025, New Executive Office Building, Washington, DC 20503. Comments may be submitted via E-mail (grants@omb.eop.gov), but must be made in the text of the message and not as an attachment. Since OMB will consider all comments that it receives, it is not necessary to send multiple copies of a comment letter to different officials in the Executive Branch. The full text of Circular A–110, the text of this notice, and the text of the February 4, 1999, Notice of Proposed Revision, may be obtained by accessing OMB's home page (http://www.whitehouse.gov/OMB), under the heading ''Grants Management.'' Copies of Public Law 105–277 can be obtained by accessing 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. Press inquiries must be directed to OMB's Communications Office, at (202) 395–7254.

SUPPLEMENTARY INFORMATION:

I. Approach to Implementation

Congress included a two-sentence provision in Public Law 105–277 that directs OMB to amend Circular A–110 ''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 the 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. Therefore, the proposed revision will affect the full range of research activities funded by the Federal Government.

In response to the provision contained in Public Law 105–277, OMB published a Notice of Proposed Revision to the Circular on February 4, 1999 (64 FR 5684). OMB received over 9,000 comments on the proposed revision. Many of these comments (including many of those from the scientific community) raised serious concerns about the effect the provision contained in Public Law 105–277 and the proposed revision would have on scientific research. They sought protection for the privacy of research

[1] This account was the subject of a similar deferral in FY 1998 (D98–7).

* Revised from previous report.

subjects and the proprietary interests of scientists and their research partners. They also emphasized that scientists must be able to pursue their research efforts to their conclusion, without the premature release of their research data.

Science and technology are the principal agents of change and progress, with over half of the Nation's economic productivity 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 are 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.

In implementing the provision contained in Public Law 105–277, OMB seeks to (1) Further the interest of the public in obtaining the information needed to validate Federally-funded research findings, (2) ensure that research can continue to be conducted in accordance with the traditional scientific process, and (3) implement a public-access process that will be workable in practice.

To this end, OMB earlier proposed to require public access to ''data relating to published research findings produced under an award that were used by the Federal Government in developing policy or rules.'' It intended these clarifications to ensure public access to data supporting the Federally-funded research findings upon which agencies rely, without upsetting the traditional scientific process by requiring researchers to release their data prematurely.

As in many other fields of endeavor, scientists need a private setting where they are free to deliberate over, develop, and pursue alternative approaches. When a scientist completes research, he or she publishes the results for the scrutiny of other scientists and the community at large. In light of this traditional scientific process, OMB does not construe the statute as requiring scientists to make research data publicly available while the research is still ongoing, because that would force scientists to ''operate in fishbowl'' and to release information prematurely. *Cf. Wolfe* v. *Department of Health and Human Services,* 839 F.2d 768, 773 (D.C. Cir. 1988) (en banc) (Congress in enacting the FOIA did not force government officials to ''operate in a fishbowl''); *Montrose Chemical Corp. of Calif.* v. *Train,* 491 F.2d 63, 66 (D.C. Cir. 1974) (same). OMB also understands the need of researchers to assure confidentiality to those who voluntarily agree to participate in Federally-funded research. Accordingly, OMB's proposed revision would allow agencies to withhold personal privacy and confidential business information pursuant to the FOIA ''exemptions'' in 5 U.S.C. 552(b). For example, under FOIA exemption 6, 5 U.S.C. 552(b)(6), an agency is not required to release ''personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.'' As the Supreme Court explained in U.S. Dep't of Justice v. Reporters Committee of the Freedom of the Press, 489 U.S. 749 (1989), certain types of privacy information can be protected as a categorical matter, without regard to individual circumstances. *Id* at 776–780. Moreover, in accord with exemption 6's express protection for their medical records, courts have found that individuals have a strong privacy interest in medical records. *See McDonnell* v. *United States,* 4 F.3d 1227, 1251–1254 (3rd Cir. 1993); *Plain Dealer Pub. Co.* v. *U.S. Dep't of Labor,* 471 F. Supp. 1023, 1027–29 (D.D.C. 1979). In addition, courts have held that, although the redaction of names or other individual identifiers may be sufficient in some cases to protect privacy, an entire record may be withheld if necessary to ensure privacy (e.g., in a case where, notwithstanding the redaction of names or other personal identifiers, an individual's identity could still be inferred from other information). *See Alirez* v. *NLRB,* 676 F.2d 423, 428 (10th Cir. 1982); *Whitehouse* v. *U.S. Dep't of Labor,* 997 F. Supp. 172, 175 (D. Mass. 1998).

Notwithstanding these clarifications in the earlier proposal, commenters from the scientific community expressed serious concerns about the impact Public Law 105–277 would have on their research activities. In part, these concerns arose from questions as to how expansively or narrowly the statute and the proposed revision would be interpreted and applied. In raising these questions, commenters on both sides of the debate sought clarification of four concepts found in the proposed revision: ''data,'' ''published,'' ''used by the Federal Government in developing policy or rules,'' and cost reimbursement.

In order to advance implementation of the requirements of Public Law 105–277, and to provide the greater clarification that the commenters requested, OMB seeks public comment on proposed clarifying definitions for the first three concepts, and its additional background discussion regarding the fourth.

II. Background

A. Data Access Provision Contained in Public Law 105–277

Public Law 105–277 includes a provision that directs 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.'' Public Law 105–277 further provides that ''if the agency obtaining the data does so solely at the request of a private party, the agency may authorize a reasonable user fee equaling the incremental cost of obtaining the data.''

According to congressional floor statements made in support of the provision, its aim is to ''provide the public with access to federally funded research data'' that are ''used by the Federal Government in developing policy and rules.'' 144 Cong. Rec. S12134 (October 9, 1998) (Statement of Sen. Lott); *see id.* (Statement of Sen. Shelby) (the provision ''represents a first step in ensuring that the public has access to all studies used by the Federal Government to develop Federal policy''). The congressional proponents further explained that the provision requires OMB ''to amend OMB Circular A–110 to require Federal awarding agencies to ensure that all research results, including underlying research data, funded by the Federal Government are made available to the public through the procedures established under the Freedom of Information Act.'' *Id.* (Statement of Sen. Lott). The proponents stated 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.'' *Id.* (Statement of Sen. Campbell). They also noted that ''[t]he Conferees recognize that this language covers research data not currently covered by the Freedom of Information Act. The provision applies to all Federally funded research data regardless of whether the awarding agency has the data at the time the request is made'' under the FOIA. *Id.* Under the Supreme Court's decision in *Forsham* v. *Harris,* 445 U.S. 169, 179–80 (1980), data that are in the files of a recipient of a Federal award, but not in the files of a Federal agency, would not otherwise be available under FOIA.

B. OMB's Proposed Revision to Circular A–110

In response to the congressional direction in Public Law 105–277, OMB published a Notice of Proposed Revision to the Circular on February 4, 1999 (64 FR 5684) to amend Section ____.36(c) 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)).

In the preamble to the notice, OMB provided an explanation of the proposed revision. As the notice outlined, the proposed revision implements Public Law 105–277 by providing that, after publication of research findings used by the Federal Government in developing policy or rules, the research results and underlying data would be available to the public in accordance with the FOIA. The proposed revision requires Federal awarding agencies, in response to a FOIA request, to obtain the requested data from the recipient of the Federal award. Since the agency must take steps to obtain the data, the agency is afforded a reasonable time to do so. Once the agency has obtained the data, the agency will then process the FOIA request in accordance with the standard FOIA procedural and substantive rules. The agency will therefore have to determine whether any of the FOIA exemptions, which permit an agency to withhold requested records, would apply to some or all of the data. If the Federal awarding agency obtained 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.

C. Public Comments Called for Clarification

OMB received approximately 8,350 comments during the 60-day public comment period. Additionally, OMB received approximately 800 comments after the close of the comment period. OMB will consider the comments received in response to the prior notice, and the comments received in response to this notice, in developing the final revision to the Circular.

Of the comments received, 55 percent were submitted by individual members of the public, without any organizational identification. Individual researchers working at institutions of higher education accounted for 36 percent of the comments. The remainder of the comments came from other non-profit research organizations (three percent), professional associations (two percent), commercial research organizations (one percent), and official comments from institutions of higher education (one percent). OMB also received comments from Members of Congress, Federal agencies, employees of State governments, and law firms.

Of those comments received, 55 percent supported implementation of Public Law 105–277 in the form of the proposed revision while 37 percent opposed the language of Public Law 105–277 and the proposed revision. The remaining eight percent of those commenting had serious concerns about the proposed revision, suggesting that it be modified in some substantial way.

Commenters offered strongly differing views on the provision contained in Public Law 105–277. Commenters 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 Public Law 105–277 stated that they support the concepts of full disclosure and open access to information. In their comments, they explained 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. They expressed concern that the approach required by Public Law 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.

III. Proposed Clarification of Concepts

Many commenters 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 agrees that clarification is needed for these concepts and believes development of the final revision, pursuant to the direction of Public Law 105–277, will be advanced by requesting additional public comment.

A. ''Data''

A large number of comments addressed the fact that the term ''data'' is not defined in either the provision contained in Public Law 105–277 or in the proposed revision to the Circular.

Commenters from the scientific community expressed concern that ''data'' might be interpreted expansively to include such things as lab specimens (e.g., cell cultures, tissue or plant samples), a researcher's lab notebooks, working papers, phone logs and electronic mail, or a researcher's financial records. These commenters stated that requiring researchers to turn over such materials would be extremely burdensome and would harm the scientific process. Commenters from the scientific community raised the additional concern that requiring public access to research ''data'' would result in the public disclosure of highly private information about individuals (e.g., information about the medical condition or treatment of research subjects) and the proprietary business information (e.g., intellectual property) of their research partners. In this regard, these commenters were not reassured by the fact that the Federal awarding agency would be able to withhold information that falls within the existing FOIA exemptions that permit agencies to withhold personal and confidential business information. See 5 U.S.C. 552(b). Notwithstanding the applicability of these FOIA exemptions, the commenters from the scientific community asserted that they would no longer be able to promise confidentiality to persons who agree to participate in research studies.

Commenters supporting the provision contained in Public Law 105–277 agreed that the term ''data'' needs to be defined. One argued for a broad interpretation of ''data,'' but agreed that ''[f]inancial records and other personal

data of individual researchers should be excluded from the definition of data in the revised Circular.'' A comment letter from Senators Shelby, Lott, and Campbell, who support the provision contained in Public Law 105–277, stated that ''data'' should be defined ''based on how the term is commonly used in the scientific community and the ultimate goal of this provision. At a minimum, data should include all information necessary to replicate and verify the original results and assure that the results are consistent with the data collected and evaluated under the award.''

Taking into account the concerns that commenters expressed, and in order to advance implementation of the requirements of Public Law 105–277, OMB has developed and seeks comment on a proposed definition of ''research data''. In framing this definition, OMB has sought to ensure that members of the public can obtain the information needed to validate Federally-funded research findings, while ensuring the privacy of research subjects and proprietary interests of scientists and their research partners. OMB proposes to define ''research data'' in a way that does not require recipients to transmit information which, in their judgment, includes ''trade secrets, commercial information,'' or ''personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.'' The Federal awarding agency would retain its right to ask the recipient for additional information, if it believed the recipient's application of these principles was improper.

Accordingly, OMB proposes to define ''research data'' 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 excludes physical objects such as laboratory samples. Moreover, under the proposed definition, ''research data'' would exclude ''(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 or which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular research subject in a research study.''

B. ''Published''

Commenters generally supported OMB's clarification that public access pertains to ''published'' research findings. For example, a comment letter from Senators Shelby, Lott, and Campbell, who support the provision contained in Public Law 105–277, stated that ''the OMB reference to published findings is not inconsistent with the underlying statute'' and that ''this limitation to data related to published research findings will ensure that the provision does not disrupt the research process by forcing the premature release of data before the study is completed.''

Notwithstanding the general support for a publication requirement, a significant number of commenters raised questions regarding when research findings have been ''published.'' While there was a general consensus that research findings are ''published'' when they appear in a peer-reviewed scientific or technical journal, commenters asked whether research findings could be considered to be ''published'' at an earlier time. Examples of earlier definitions of ''published'' include: (1) When data are distributed as part of the journal's peer-review process; (2) when a researcher makes a presentation at a scientific meeting open to the public; or (3) when data have been otherwise made available to the public (e.g., through a press release or a presentation to the media). In particular, commenters from the scientific community expressed the concern that defining ''published'' expansively could lead to premature release of data as well as misunderstandings and false claims about what research proves. These commenters also noted that requiring researchers to make their data publicly available prematurely could also prevent future publication in some peer-reviewed journals, and may limit a researcher's patent rights. Additionally, commenters argued that the willingness of private sector organizations to enter into partnerships would be reduced unless their proprietary data can be protected. Other researchers feared harassment from groups that do not support certain scientific methods or those that do not support certain areas of research.

Commenters who support the provision contained in Public Law 105–277 were generally sympathetic to these concerns. However, many expressed the concern that, if ''published'' meant only publication in a peer-reviewed journal, Federal agencies would be able to rely on research findings that have been released to the agency (while not having yet been published in a peer-review journal), but interested members of the public would not be able to obtain the data that are necessary to validate these findings. As one commenter stated, under that scenario ''award recipients would be able to avoid disclosure of data otherwise available to the public merely by failing to submit the data to a formal peer review publication.'' This concern was also raised in the comment letter from Senators Shelby, Lott, and Campbell, which stated that ''[if] federally-funded pre-published data or findings are used to support a federal policy or rule, then the final revision should ensure that such data would also be made publicly available under FOIA. If the data are sufficiently sound to support a federal policy or rule, then they should be able to bear public scrutiny and disclosure * * *. This point is critical to ensuring that our federal rules and policies are based on good science and research findings.''

Taking into account the concerns that commenters expressed, and in order to advance implementation of the requirements of Public Law 105–277, OMB has developed and seeks comment on a proposed definition of ''published.'' In framing this definition, OMB has sought to ensure that members of the public can obtain the information needed to validate Federally-funded research findings, while at the same time ensuring that researchers will continue to be able to engage in the traditional scientific process without fear that they could be forced to release their research prematurely. OMB has also framed this definition based on the understanding that Federal agencies generally rely on research findings that have been peer-reviewed, because until they have been peer-reviewed, research findings may be inherently unreliable. OMB solicits comments on these issues.

Accordingly, OMB proposes to define ''published'' research findings 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'' an agency action.

C. ''Used by the Federal Government in Developing Policy or Rules''

Many commenters requested clarification on what is meant by ''used by the Federal Government in developing policy or rules.'' Commenters who oppose the provision contained in Public Law 105–277 argued for an interpretation under which ''policy or rules'' would refer to

agency regulations, and ''used'' would refer to the agency's public and official citation of the research findings in support of the agency action. Commenters who support the provision contained in Public Law 105–277 argued for a more expansive interpretation, under which ''policy or rules'' would include such things as agency guidance, surveys, risk assessments and reports, and ''used'' would refer to when the agency first relies internally on the findings—or perhaps even earlier. Referring to situations where ''studies are funded, performed, and published with a clear anticipation that the data in the study will be useful in connection with future government rulemaking or policy development,'' one commenter argued that, in some regulatory situations, such data ''clearly should be available for public scrutiny before the formal regulatory proceedings begin.'' This commenter, though, went on to state that ''OMB should also define a meaningful carve-out for activities that do not influence the development of regulations or policy.'' In explaining this ''carve-out'' approach, the commenter stated that, in contrast to situations where a published study is cited by an agency, ''[w]here materials are merely submitted by the public and not cited by the government decision makers, however, the issue is less clear. In such cases it is often difficult or impossible to determine what studies the government has ''used'' in shaping policy.'' Based on this commenter's view that ''all data adverse to the position of a party impacted by regulatory action should be susceptible of honest scrutiny,'' the commenter addressed the problem of how to identify when research findings are ''used''—when they have not been cited—by concluding that ''if materials are submitted in the course of rulemaking or other government policy formulation, those data should be made available to the public.''

OMB believes that the provision contained in Public Law 105–277 should be implemented in a manner that respects the general framework of the traditional scientific process, and is workable in practice. In this regard, the operating principles that OMB adopts in its revisions to section ____.36 of the Circular should be relatively easy to administer (by the public, Federal agencies, and recipients), should rely on existing processes whenever possible, and should not result in uncertainties and disagreements when they are applied to the facts in individual cases. Based on our review of the comments, OMB believes that the provision contained in Public Law 105–277 can be implemented in the context of the agencies' promulgation of regulations, but that considerable implementation problems would arise if the scope of the provision contained in Public Law 105–277 extended to such agency actions as guidance, surveys, assessments, and reports.

When an agency promulgates a regulation, it does so through the well-established rulemaking process. Through notices in the **Federal Register** (typically proposed and final rulemaking notices), an agency explains regulations and seeks and reacts to public comments. As was pointed out by commenters who support the provision contained in Public Law 105–277, agencies generally cite the sources that support their regulations, often including findings from Federally-funded research in their rulemaking notices published in the **Federal Register.** In so doing, the agency relies on the research findings—in an official and public manner—to explain and justify the agency's regulatory actions to the public, to Congress, and to the courts. Many commenters argued that members of the public should be able to obtain the data that underlies these research findings. This allows the public to seek to validate the findings, evaluate the regulation, submit comments to the agency on the proposed regulations, or seek judicial review of the final regulations.

Among the commenters who addressed this issue, there was a general consensus that the case for the public obtaining the underlying research data is strongest when an agency cites Federally-funded research findings to support the agency's issuance of a regulation. In promulgating a regulation, the agency acts with the force and effect of law. In citing to the research findings to support the agency's regulatory decision, the agency is relying—publicly and officially—on those findings. Indeed, that reliance is given legal significance by the courts during any review of the regulation.

The comments also indicated that an agency's citation to research findings in support of a regulation allows the process to be administered most readily and easily. In such cases, the public access provision should clearly be applicable. Any uncertainty can be resolved by an inspection of the agency's rulemaking records.

When one moves outside the regulatory context and into other areas of agency action, the comments provided less of a justification for the application of the provision contained in Public Law 105–277. It also becomes less clear how members of the public and the agencies would be able to determine when public access would be required in individual cases.

Commenters who support the provision contained in Public Law 105–277 argued that the public should have access to data used in agency guidance, surveys, assessments, and reports, when the data comes from research funded by the Federal taxpayers. Arguably, the need for public access to data would be less for agency actions that do not have the force and effect of law or are not subject to judicial review.

OMB is concerned that a broader proposal would be problematic. It is not clear how the provision contained in Public Law 105–277 would operate in practice outside the regulatory context. When agencies undertake less formal agency action they often do not prepare and issue accompanying explanatory preambles that outline the basis and underlying factual support for the action. In the absence of a formal record that explains the agency's action, it would be far more difficult for the public and the agencies to determine, in individual cases, whether particular research findings were ''used'' by the agency in ''developing'' the agency action. For example, from the comments that we received on the proposed revision, an agency might be viewed as having ''used'' research findings if those findings: (1) Were relied upon in an internal agency memorandum sent to a decision maker; (2) were discussed in an agency staff level communication, such as an email message; or (3) were simply available for the agency staff to read, regardless of whether there was any evidence that the staff relied upon the findings in carrying out their work. In sharp contrast with identifying agency reliance in the regulatory context, none of these tests could be applied readily and easily by members of the public and the agency for determining, in individual cases, whether research data would be publicly available under the provision contained in Public Law 105–277. Instead of being able to rely on the public record, these tests would entail a fact-intensive inquiry into the agency's internal deliberations. This inquiry would be burdensome and time-consuming, and would intrude into the agency's deliberative process.

In sum, based on the comments that OMB has received, it does not appear that the provision contained in Public Law 105–277 can be readily and easily implemented outside of the regulatory context. Given the considerable implementation difficulties, and the lesser public interest in obtaining the

underlying research data when the agency is not taking action that has the force and effect of law, OMB does not believe that the public interest would be served by extending the provision contained in Public Law 105–277 beyond the regulatory context.

Accordingly, in order to advance implementation of the requirements of Public Law 105–277, OMB seeks comment on a proposal to replace ''used by the Federal Government in developing policy or rules'' with ''used by the Federal Government in developing a regulation.'' ''Regulation'' refers to the well-established and long-standing definition of a regulation for which notice and comment is required under the Administrative Procedures Act (5 U.S.C. 553). In framing this proposal, OMB has sought 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.

In addition, based on its experience with reviewing agency regulations, OMB believes the public interest in having access to research data is likely to be greatest in the case of those regulations that have the most substantial impact on society. One existing method for identifying these regulations is whether a regulation meets a $100 million impact threshold. This approach is similar to those required by the Unfunded Mandates Reform Act (Public Law 104–4, 2 U.S.C. 1532, 1535) and the Congressional Review Act (Public Law 104–121, 8 U.S.C. 801(a)(3), 804(2)). Therefore, OMB requests comments on whether limiting the scope of the proposed revision to regulations that meet the $100 million threshold would be appropriate. In particular, commenters should identify current and past regulatory actions that do not meet the $100 million threshold, but where they believe the public would have benefitted from having access to the underlying research data sufficiently to justify burdens on, or risks to, the traditional scientific process.

D. Cost Reimbursement

Many commenters sought clarification about the ''reasonable fee'' agencies may charge, pursuant to the provision contained in Public Law 105–277. OMB believes the ''reasonable fee,'' which is intended to cover the cost of obtaining the requested data, is separate from the FOIA fee an agency could assess under 5 U.S.C. 552(a)(4)(A). In light of the congressional intent that Federal agencies and researchers be reimbursed by the requester for the costs that they incur in responding to the request, OMB has concluded that agencies may retain this new fee, in order to reimburse themselves, recipients, and applicable subrecipients, for the costs they incur.

OMB seeks comments on (1) Estimates of potential incremental costs to be incurred by Federal agencies, their recipients, and applicable subrecipients in carrying out the proposed revision, and (2) the mechanisms available to recipients to charge to their awards the costs that they would incur (e.g., ''direct'' versus ''indirect'' charge, or by contract).

After receiving comments, OMB will consider revising OMB Circular A–21, ''Cost Principles for Educational Institutions,'' as necessary to ensure recipient institutions are reimbursed for the incremental costs of complying with the provision contained in Public Law 105–277.

OMB encourages interested parties to provide comments on these four concepts at this time so that any concerns may be addressed in OMB's development of the final revision to the Circular, pursuant to the direction of Public Law 105–277. OMB intends to publish the final revision on or before September 30, 1999.

Issued in Washington, D.C., August 5, 1999.

Norwood J. Jackson,

Acting Controller.

Pursuant to the direction of Public Law 105–277, OMB proposes to amend Section ____.36 of OMB Circular A–110 by revising paragraph (c), redesignating paragraph (d) as paragraph (e), and adding 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 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).

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