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OMB [Office of Management and Budget] [Circular] A-110

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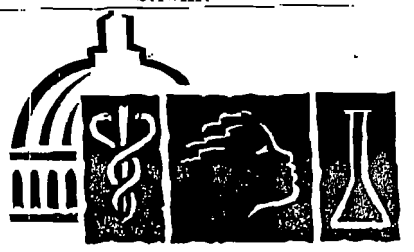

WOMEN'S HEALTH RESEARCH
COALITION

September 10, 1999

F. James Charney
Policy Analyst
Office of Management and Budget
New Executive Office Building, Room 6025
Washington, DC 20503

Dear Mr. Charney:

On behalf of the Women's Health Research Coalition (WHRC), we are submitting the following response to your request for comments regarding the proposed revision of OMB Circular A-110, the "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and other Non-Profit Organizations," which would amend the Federal standards governing public access to research information. Thank you for the opportunity to participate in this essential process.

The Women's Health Research Coalition is a program of the Society for Women's Health Research. It is comprised of some of the leading academic-based researchers in women's health from throughout the United States and Canada. The purpose of the Coalition is to promote and encourage policies and funding that benefit the field of women's health research. As a result, this revision of OMB Circular A-110 is of particular interest and concern to the Coalition.

As you know, the revision of Circular A-110 stems from the passage last fall of the FY1999 Omnibus Appropriations bill, which included a provision to expand the applicability of the Freedom of Information Act (FOIA) to all data acquired through Federally-funded research, irrespective of whether that information is in the possession of the Federal government at the time of the request.

Let us state clearly at the outset that the WHRC supports full disclosure and open access to information through the established scientific process. At the same time, the WHRC is opposed to this provision of the law. We believe that it represents an ill advised and rash solution to something that may, in fact, not be a problem. The unintended consequences of using a statute passed for one purpose to achieve another could be severe and could hamper the incredible scientific enterprise that has been developed over the past Century in the United States. The Coalition will continue to work diligently for the repeal of this provision through the enactment of H.R. 88 or some other similar legislative vehicle.

1828 L Street, NW Suite 625 Washington, D.C. 20036 Telephone 202.223.8224 Fax 202.833.3472

Nevertheless, we are writing today to comment on the latest revision to Circular A-110 as published by the Office of Management and Budget in the *Federal Register* on August 11, 1999. It is the considered position of the Women's Health Research Coalition that this revision represents a significant improvement over the original draft in several different areas and will serve to mitigate some of the most pernicious effects of the law, as enacted.

Specifically, the Coalition is supportive of the inclusion of definitions for the terms "research data," "published" and "used by the Federal Government in developing a regulation." It is our belief that this will move the process forward by creating some clearer meaning to the intent of the revision.

We were particularly pleased to see the list of exclusions in the definition of "research data" and read those exclusions to make clear that it is the Federal Government's policy that the confidentiality of medical records of those persons participating in a funded study will not be compromised in any way by this revision. This is a critical issue for all research, but for women's health research in particular, as the lack of other protections in Federal law for the confidentiality of medical data is already creating a reticence on the part of some women to participate in clinical trials. Any lessening of confidentiality as a result of this revision would constitute a gross threat to the future of women's health research.

Similarly, the revision's use of the word "regulation" rather than "policy or rules" puts this provision squarely in a structured governmental process and lessens the possibility of misinterpretation by one Federal government agency or another. It is our expectation that the Office of Management and Budget will be diligent in its review of Federal agencies' draft regulations to ensure that this provision is being appropriately applied and should consider a requirement including identification in the body of a draft regulation as to what information is and is not subject to this provision.

We strongly believe that the scientific research enterprise represents the greatest achievement of our society and the greatest hope for the future. Any provision of law, or any other action by the government, that lessens its beneficial impact is a threat that needs to be taken very seriously. The Women's Health Research Coalition will remain vigilant in protecting that enterprise, particularly as it relates to the critical medical and research issues surrounding the health and well being of women.

Thank you for the opportunity to comment on this proposed revision. We appreciate your thoughtful consideration of our position.

Sincerely,

Andrea Dunaif, MD
Director of Women's Health
Brigham and Women's Hospital
WHRC Co-Chair

Margaret McLaughlin, PhD
Director of Research
Magee Women's Research Institute
WHRC Co-Chair

Fredrick J. Charney
07/13/99 03:44:52 PM

Record Type: Record

To: Jason E. Franklin/OPD/EOP@EOP

cc:
Subject: A-110 and Research Data

As we discussed, here is a DRAFT second notice on the A-110 research data issue. This document is still being reviewed by OMB policy officials, and cannot be made public. - jimmy


2nd79.wpd

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 Additional Comments on Proposed Revision

SUMMARY: This notice offers interested parties an additional opportunity to comment on 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 P.L. 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 sought clarification of four concepts found in the proposed revision: "data," "published," "used by the Federal Government in developing policy or rules," and "reasonable fee". In response to these comments, OMB has developed proposed definitions for these concepts and seeks comment on them.

DATES: Comments must be received by **[30 days after publication in the Federal Register]**.

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. Multiple copies of the same letter, signed by the same person, will not be counted as separate comments. 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 P.L. 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. Background

A. Public Law 105-227: P.L. 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." P.L. 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 is "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 is 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 P.L. 105-277, OMB published a Notice of Proposed Revision to the Circular on February 4, 1999 (64 FR 5684). To implement the statute, OMB proposed to amend Section ____.36(c) of Circular A-110 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 P.L. 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: 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.

Of the comments received during the comment period, 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; each amounted to less than one percent of the total comment.

Of those comments received during the comment period, 55 percent supported implementation of P.L. 105-277 in the form of the proposed revision while 37 percent opposed the language of P.L. 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 whether the provision contained in P.L. 105-277 was good public policy. In particular, commenters who supported the statutory provision stated that the public has a right to obtain research data that has been funded with tax dollars. These commenters also expressed the view that making this data available for public review would improve the scientific process. Commenters who opposed the statutory provision stated that they support the concepts of full disclosure and open access to information. However, these commenters expressed concern about the approach required by P.L. 105-227. Primary among these concerns was that research would be significantly impaired because individuals and businesses would no longer agree to participate in research, since personal and proprietary information would be subject to public disclosure.

OMB does not believe Congress intended to legislate a fundamental change to the traditional scientific process when it enacted the two sentences in P.L. 105-227 that require OMB to amend the Circular. For example, as is the case with many other fields of endeavor, scientists

perform their work in 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. 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).

In this same vein, and in accordance with the statements by proponents of the provision contained in P.L. 105-277, OMB believes that Congress does not consider the traditional scientific process to be generally inadequate for ensuring that other scientists and the community at large have an opportunity to scrutinize, and offer criticism of, a scientist's research and the conclusions that he or she has drawn from that research. Rather, the proponents expressed concern about the extent to which Federal agencies rely on findings from Federally-funded research in their development of regulations. *See, e.g.*, S. Rep. No. 521, 105th Cong. 2nd Sess. ___ (1998) ("Given the prevalent use of Government funded research data in developing regulations and Federal policy, it is important that such data be made available to other interested Federal agencies and to the public on a routine basis for independent scientific evaluation and confirmation."); 144 Cong. Rec. S9914 (Statement of Sen. Shelby) (September 3, 1998) (same); 144 Cong. Rec. S12134 (Statement of Sen. Shelby) (October 9, 1998) ("The lack of public access to research data feeds general mistrust of the government and undermines support for major regulatory programs. This measure was long overdue and it represents a first step in ensuring that the public has access to all studies used by the Federal Government to develop Federal policy."). Accordingly, the proposed revision stated that public access would pertain to "data relating to published research findings produced under an award that were used by the Federal

Government in developing policy or rules."

II. Proposed Clarification of Four Concepts

Many commenters asked OMB to provide clarifying definitions of four concepts found in the proposed revision: "data," "published," "used by the Federal Government in developing policy or rules," and "reasonable fee." OMB agrees that clarifying definitions are needed for these concepts and believes development of the final revision will be advanced by requesting additional public comment on these concepts.

A. "Data": A large number of comments concerned the fact that neither the provision contained in P.L. 105-277 nor the proposed revision define the term "data." 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 propriety 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 believed that they would no longer be able to promise confidentiality to persons who agree to

participate in research studies.

One commenter who supported the provision contained in P.L. 105-277, and argued for a broad interpretation of "data," nevertheless agreed that "[f]inancial records and other personal data of individual researchers should be excluded from the definition of data in the revised Circular." Another comment letter, from three Members of Congress who support the provision contained in P.L. 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 the underlying legislative goal of the provision contained in P.L. 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 on which Federal agencies rely in developing regulations, while at the same time ensuring the privacy of research subjects and proprietary interests of researchers and their research partners. Accordingly, OMB proposes to define "research data" as "any underlying raw information 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." 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; or (B) personnel and medical files and similar files the disclosure or which would constitute a clearly unwarranted invasion of personal

privacy, or that which 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, one comment letter, from three Members of Congress who support the provision contained in P.L. 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 pre-mature 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: when data are distributed as part of the journal's peer-review process, when a researcher makes a presentation at a scientific meeting open to the public, or 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" too 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 noted 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.

At the same time, commenters who support the provision contained in P.L. 105-277 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 is 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 three Members of Congress who support the provision contained in P.L. 105-227. The Members 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 publically 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 the underlying legislative goal of the provision contained in P.L. 105-277, OMB has developed and seeks comment on a proposed definition of "published." In framing this definition, OMB has sought to ensure that that members of the public can obtain the information needed to validate those Federally-funded research findings on which Federal agencies rely in developing regulations, 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. 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 the research findings in support of a regulation."

C. "Used by the Federal Government in Developing Policy or Rules": A large number of

commenters requested clarification on what is meant by "used by the Federal Government in developing policy or rules." Commenters who support the provision contained in P.L. 105-277 argued for an expansive interpretation, under which "policy or rules" would include such things as agency surveys, risk assessments and reports, while "used" would refer to when the agency first relies internally on the findings. Commenters who oppose the provision contained in P.L. 105-277 argued for a narrower interpretation, under which "policy or rules" would refer to agency regulations, while "used" would refer to the agency's public and official citation of the research findings in support of the agency action.

Taking into account the concerns that commenters expressed, and the underlying legislative goal of the provision contained in P.L. 105-277, OMB has developed and 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," and to provide a definition for this phrase. 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 in developing regulations, while at the same time ensuring that the provision contained in P.L. 105-277 can be administered in a manner that is workable for Federal agencies and their recipients. Under the proposed definition, Federally-funded research findings are "used by the Federal Government in developing regulations" when an agency publicly and officially cites the research findings in support of a regulation (i.e., a statement of general applicability and future effect, which the agency intends to have the force and effect of law), which may occur at any stage in the rulemaking process." This definition borrows from the definition of "regulation" contained in Executive Order 12866, "Regulatory Planning and Review."

D. "Reasonable Fee":

Many commenters sought clarification about the "reasonable fee" agencies may charge,

according to the provision contained in P.L. 105-277. OMB believes the "reasonable fee" is intended to be separate from the FOIA fee an agency could assess under 5 U.S.C. 552(a)(4)(A). Under the Miscellaneous Receipts statute (31 U.S.C. 3302), Federal receipts must be deposited in the General Fund of the Treasury unless another statute directs that the receipts be deposited in another account (e.g., in an agency appropriation account). In the FOIA, Congress provided for the collection of fees for responding to FOIA requests, but did not direct that the fees be deposited in another account; accordingly, FOIA fees are deposited in the General Fund. Similarly, while the provision contained in P.L. 105-227 authorizes agencies to collect fees for the additional cost of responding to these requests, it does not direct that the fees be deposited in another account; accordingly, fees collected under the provision contained in P.L.105-227 would be deposited in the General Fund. In other words, under current law the "reasonable fee" authorized by P.L. 105-277 cannot be reimbursed to the Federal awarding agency, the recipient, and applicable subrecipients. Although P.L. 105-277 authorizes agencies to charge the fee, OMB believes a legislative change must be made to allow Federal awarding agencies to retain the fee (rather than depositing it in the General Fund).

These fees will be reimbursable (either as direct or indirect costs) to recipients under the applicable OMB Cost Principles Circular (A-21, "Cost Principles for Educational Institutions" and A-122, "Cost Principles for Non-Profit Organizations"). However, in order to allow for reimbursement to institutions of higher education, OMB intends to revise Circular A-21 to allow reimbursement for costs related to data requests without violating the Circular's existing 26 percent cap on reimbursement of administrative expenses. (Non-profit institutions operating under Circular A-122 do not have a cap on administrative expenses.) This revision to Circular A-21 would permit agencies to reimburse those institutions of higher education who are already at the 26 percent cap for the additional administrative costs that they might incur in responding to requests made possible by the provision contained in P.L. 105-277. However, unless a change is made to the law to allow this reimbursement to come directly from the fees by the FOIA

requester, the reimbursement would have to be taken from the agencies' grant funds, which would have the practical effect of redirecting scarce Federal research funds away from program activity (i.e., the conduct of research).

OMB seeks comments on the "reasonable fee," including (1) estimates of potential costs of Federal agencies, their recipients, and applicable subrecipients, and (2) the mechanisms available to recipients to charge the fee to their awards (e.g., direct versus indirect charge).

OMB encourages interested parties to provide comment 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, to be published after the close of the comment period.

In conclusion, pursuant to the direction contained in P.L. 105-277, OMB is proposing to revise Circular A-110 as shown below.

Issued in Washington, D.C., July , 1999.

DRAFT

Norwood J. Jackson

Acting Controller

Pursuant to the direction of P.L. 105-277, OMB hereby proposes to amend Section ____.36 of OMB Circular A-110 to read as follows:

(a) [No change]

(b) [No change]

(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 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)).

(2) The following definitions are to be used for purposes of subsection (d):

(i) "Research data" is defined as any underlying raw information 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. Research data also does 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; or (B) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted

invasion of personal privacy, or that which 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 a regulation.

(iii) "Used by the Federal Government in developing a regulation" is defined as when an agency publicly and officially cites the research findings in support of a regulation (i.e., a statement of general applicability and future effect, which the agency intends to have the force and effect of law), which may occur at any stage in the rulemaking process.

(e) [Re-designation of text currently in section 36(d)]

SHOW: ALL THINGS CONSIDERED (8:00 PM ET)

August 17, 1999, Tuesday

LENGTH: 1071 words

HEADLINE: SCIENTISTS CONCERNED THAT PRIVACY OF RESEARCH STUDY SUBJECTS MAY BE IN JEOPARDY

ANCHORS: NOAH ADAMS

REPORTERS: JOHN NIELSEN

FYI (from Daniel)

BODY:

NOAH ADAMS, host:

This is NPR's ALL THINGS CONSIDERED. I'm Noah Adams.

These days, even incremental scientific advances are sometimes supported by log books full of measurements and calculations. The public hardly ever sees this information, but that could soon change. This fall, the White House Office of Management & Budget is expected to make it much easier for private citizens to see the raw data used in government supported research, even if it includes personal health information. Supporters of the idea say it's a good way to insure that government regulations are based on sound science. Critics say the scientific process will be compromised. NPR's John Nielsen has the story.

JOHN NIELSEN reporting:

When the Environmental Protection Agency moved to restrict emissions of ozone and soot two years ago, the business community was furious, arguing that it could cost them hundreds of billions of dollars to comply. At an oversight hearing, EPA administrator Carol Browner responded to this criticism by slapping a big stack of peer-reviewed air pollution studies down on the table in front of her.

Ms. CAROL BROWNER (Administrator, Environmental Protection Agency): There are included here 185 studies on ozone, 86 studies on particulate matter. Literally, study after study indicating that our current air standards are not adequately protecting the public's health and that they should be strengthened.

NIELSEN: Browner's critics, including Republican Senator James Inhofe of Oklahoma, are not particularly impressed by gestures like these.

Senator JAMES INHOFE (Republican, Oklahoma): Too often, government officials, both elected and appointed, hide behind scientists when proposing policy decisions.

NIELSEN: Inhofe and his colleagues say they've wondered a lot about the quality of some of those studies. In particular, they've questioned a paper that links premature death to small particles of soot. The federal government has never seen the data that was used to support that study or the mathematical models that were used to draw conclusions from it. Douglas Dockery, a Harvard professor of public health and one of the principle authors of the study, says that's

just the way it has to be. He says the data in question consists primarily of death certificates and sensitive personal health records, materials that probably wouldn't have even been made available to Dockery in the first place if he hadn't made the people who agreed to participate in this study a promise.

Professor DOUGLAS DOCKERY (Harvard): The promise was that any information they provided to us would be kept confidential and not be made available to other people, at least in an identifiable form; that it would only be presented in summary tables and so forth.

NIELSEN: Leading Republicans in the House and the Senate say that's not good enough for them. They think the public should have a right to see raw data collected by scientists who receive federal funding. Last fall, Republican Senator Richard Shelby of Alabama pushed the law in that direction when he quietly added a one-sentence rider to a massive appropriations bill at the last minute. The rider ordered the Office of Management & Budget to expand the Freedom of Information Act, or FOIA, to include all private data collected by scientists who receive federal funding. Depending on how that word data is defined, this may include e-mail, personal notebooks, telephone logs and even diaries. Sources at the EPA say the president had misgivings about the FOIA change, but signed the appropriations bill anyway.

Business lobbyists like C. Boyden Gray, a former White House chief of staff, say this change could be a milestone in the history of regulatory reform. When businesses are asked to spend billions of dollars conforming to a new rule, Gray says they want to be sure they're not wasting their money.

Mr. C. BOYDEN GRAY (Former White House Chief of Staff): And there are examples. Asbestos is one. EPA ordered all the asbestos removed from the schools, and it turned out that did a lot more harm, exposed a lot more children to asbestos than would've been exposed if they'd simply shellacked what was there and left it. So this is what those of us who've been in these issues in government worry about.

NIELSEN: Research work used by agencies like the EPA is already peer reviewed, but economist Bob Hahn of the American Enterprise Institute says that system has its limits. Hahn says he has probably peer reviewed 30 papers over the years.

Mr. BOB HAHN (Economist): And I've never actually put up an academics model and replicated it. What I look for is some obvious errors in the paper or the approach that would suggest why it's a problem. Otherwise, I'll say, Accept the paper.'

NIELSEN: He thinks that practice is commonplace and economically dangerous. He describes the FOIA expansion as a kind of economic fail-safe for the business community.

Hahn does think there are some potential problems with this plan, which has not yet been finalized by the Office of Management & Budget. He worries, for instance, that unscrupulous scientists might try to FOIA other people's databases and use them for their own research. But others have deeper concerns. Dan Greenbaum, director of an independent organization called the Health Effects Institute, says more people may refuse to participate in controversial studies if they don't think their privacy can be assured. He also thinks the authors of these studies should prepare themselves for a tidal wave of corporate second guessing.

Mr. HAHN: And the implications of going through all of those studies in fine-grain detail is that you'd be spending a good chunk of what scientific resources exist solely reanalyzing existing data rather than creating new studies. Having said that, getting closer scrutiny of some makes sense.

NIELSEN: Concerns like these appear to be spreading through the scientific community. The director of the National Institutes of Health has warned that the change could have a chilling effect on the quality of medical research. The president of the Association of American Universities says the change will help tobacco companies, handgun makers and others discourage researchers from addressing controversial topics. EPA administrator Browner thinks that was the whole idea. In her view, this FOIA expansion is neither a fail-safe mechanism, nor an act of regulatory reform.

Ms. BROWNER: It is nothing but a rouse to take down federal funding of important scientific research to prevent EPA and any other federal agency from setting tough public health standards.

NIELSEN: The Freedom of Information Act allows government agencies to protect the privacy of individuals by blacking out names and places. But Douglas Dockery of Harvard says he's not sure that will help him. He says his study is rendered meaningless when the private data is removed. If it isn't removed and the government gets its hands on it, class-action lawsuits are almost sure to follow. John Nielsen, NPR News, Washington.

LANGUAGE: English

LOAD-DATE: August 18, 1999

USC
UNIVERSITY OF SOUTHERN CALIFORNIA

DIVISION OF HEMATOLOGY

Kenneth Norris Cancer Hospital
1441 Eastlake Avenue
NOR-M/S 34
Los Angeles, California 90033
FAX (323) 865-0060

School of Medicine

Medicine, Division of Hematology

TO: Daniel Montoya

Fax #: (202) 456-2438

Number of pages (5) including cover page

FROM: Alexandra Levine, MD

Phone #: ( )

Comments: Send to menters of Exec Committee & Research Committee with the Note:

FYI - we must fight this one

PACHA?

University of Southern California
1441 Eastlake Avenue
NOR MS 34
Los Angeles, c:\heme\fax_sheet.wpd
California 90033
Tel: 213 764 3950
Fax: 213 764 0060

Date: January 11, 1999
To: AAUP Government Relations Network
From: Ruth Flower, Director of Government Relations
Re: FOIA Access to Researchers' Data -- Repeal Introduced

THE PROBLEM:

As we reported in December, the Omnibus Appropriations bill passed late last year included two sentences that could have a tremendous impact on publicly funded research. These two sentences would allow individuals (and corporations) to use the Freedom of Information Act to gain access to researchers' raw data, whenever the research is funded by a federal grant.

The language provides: "that the Director of the [Office of Management and Budget] amend... Section --.36 of OMB 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." A second sentence allows a "reasonable user fee" to be charged for the release of data.

STATUS of the bill:

This bill has already passed. In order for the new law to be implemented, the Office of Management and Budget must adopt the regulations that the bill describes. OMB is moving quickly to implement this language, and expects to have regulations out for public comment very soon. To keep the new law from being implemented, we must persuade the Office of Management and Budget to hold a full public debate on the regulations, and/or seek repeal. We need your help with both actions.

WHAT CAN WE DO ABOUT IT?

1. Public Response to OMB. We expect OMB to release its regulations "for comment" very soon. It is critical that the agency hear many responses from researchers who would be affected by this change in the law. We will alert

you as soon as we hear that the regulations have been released. We wil
l
post updates on the AAUP Government Relations Web Site
(www.aaup.org/govrel.htm), and send out brief alerts via this listserv.

2. Repeal Strategy. On January 6 Representative George Brown (D-CA),
ranking Democrat on the House Science Committee, introduced a bill (H.R
. 88)
to repeal this provision, pointing out that it would require "the prema
ture
release of research results." He introduced the repeal legislation "to
protect researchers from harassment." His office has asked for our he
lp.

a. To obtain a copy of the repeal legislation, and to see Representati
ve
Brown's remarks upon introducing the bill, go to AAUP's Government Rela
tions
web site. There is a link there to the Science Committee's Democratic
page.

b. Write (or send an e-mail message) to your own representative expres
sing
your support of this repeal legislation. Few members of Congress hav
e
heard of this "two-sentence attack" on the academic freedom of research
ers.
Those who have heard of it may see it only as appropriate sharing of
publicly funded information. (What have you got to hide? What's the p
roblem?)

Tell them what would happen to your research; tell them what you think
the
effect might be on publicly supported research generally. Write just a
paragraph or two about the potential for abuse -- use examples from you
r own
experience or from the experiences of colleagues.

c.. Write to your senators to let them know about the issue. As of no
w,
there is no repeal bill in the Senate, but we are looking for intereste
d
sponsors.

3. "Spread the Word" Strategy. Tell your colleagues about this issue.
Urge
them to take action and to check the AAUP Government Relations web site
regularly for updates.

HOW LONG WILL IT TAKE?

A quick letter to your representative should take only about 20 minutes. Add an introductory remark or two, and send it off to your two senators -- another 10 minutes. How long would it take you to respond to a FOIA request for your data?

BACKGROUND:

This new law, no more than two sentences long, raises long lists of complex questions. AAUP members are well aware of situations in which opponents of research results attack and harass the researchers by demanding full access to a database that represents years of work product, and of situations in which profit can be reaped from applications of data originally compiled for non-profit research educational purposes. Among the concerns identified by Katharina Phillips of the Council on Government Relations are these: "Scientists argue that early data release will endanger their chances to get published in peer reviewed journals; scientists fear for the protection of their human subjects; mentors worry about their students losing their dissertations."

WHAT ELSE CAN WE DO?

Do you receive government research funds, or rely on publicly-supported research? Can you give examples of problems that would arise from being required to release your raw data to the public upon request? If you can relate a specific instance in which your own research data was sought inappropriately by an outside party, send your story to Skip Stiles, Minority Staff Legislative Director, House Science Committee, 822 O'Neill House Office Building, Washington D.C. 20515-6301. These stories can be very powerful and persuasive in the effort to repeal this ill-considered legislation.

****

The Senate Capitol switchboard number is 202-224-3121, the House number is
202-225-3121. Many members of Congress are available by email, and the Government Relations Office has a current list. The office also has a list
of home offices of Senators and Representatives. Please contact the office
to get the appropriate address or phone number.

Ruth Flower, Director
Government Relations
American Association of University Professors
Telephone: 202-737-5900 x 3029
Fax: 202-737-5526
e-mail: rflower@aaup.org

OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO:	FROM:
James Charney	Todd Summers
COMPANY:	DATE:
OMB	January 27, 1999
FAX NUMBER:	TOTAL NO. OF PAGES INCLUDING COVER:
5-4915	
PHONE NUMBER:	
5-7582	
RE:	
OMB A-110	

☒ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

As we discussed. I would appreciate updates as they are available.

736 Jackson Place
Washington, DC 20503
(202) 456-2437
(202) 456-2438 (fax)

TALKING POINTS ON REVISIONS TO OMB CIRCULAR A-110

- Public Law 105-277 (the FY 1999 Omnibus Appropriations Act) directed OMB to revise Circular A-110 to require Federal awarding agencies "to ensure that all data produced under an [research] award will be made available to the public through the procedures established under the Freedom of Information Act." While the legislative language is silent on the deadline for OMB revision of A-110, floor statements indicate that Congress wanted the revision to go to the *Federal Register* within 90 days of the bill's enactment (i.e., January 19, 1999).

- Despite serious concerns about the potential impact of the provision on Federally-funded research, the Administration is required to implement the provisions of P.L. 105-277.

- Federal agencies currently have the right to obtain research data from Federal grantees, but rarely do so. Such data generally could not be released under FOIA because agencies do not have it. However, Federal agencies routinely encourage the sharing of research results as part of the collaborative scientific process.

- As required by P.L. 105-277, OMB will publish a proposed revision in the *Federal Register* in early February which will include a request for public comments. This is an opportunity for all interested parties to register their concerns about the provision as well as to identify the critical issues OMB should consider.

- The proposed revision limits the reach of FOIA requests to "data relating to published research findings produced under an award that was used by the Federal Government in developing policy or rules." This limitation is based on floor statements in the Senate.

- It is important to recognize that even as research data become available under FOIA, the statutory exemptions that allow Federal agencies to withhold requested information are still applicable. These exemptions, which cover such things as medical records and national security documents, prevent unwarranted invasions of personal privacy.

- The Administration opposes any intrusion into privacy and is committed to ensuring that changes in the requirements for publicly available data have minimal impact on Federally-funded research.

- Members of Congress from both parties -- including Rep. John Porter, Chairman of the House Labor/HHS/Education Appropriations Subcommittee, and Rep. George Brown, ranking member of the House Science Committee -- have together urged OMB to implement the revision without causing "undue burden or creating barriers to the continued pursuit of new knowledge through Federally-funded research."

- Depending on the comments that are submitted through the *Federal Register* process on the proposed changes to A-110, Congress could consider the impact of the new law. Public comment on the proposed revision is expected to be heavy. On January 8, Rep. Brown introduced a bill (H.R. 88) to repeal the provision.

- Given our significant concerns, the Administration will consider its options.

CIRCULAR A-110 REVISION ON ACCESS TO RESEARCH DATA

Question 1: I understand that OMB is about to revise Circular A-110 in a way that will undermine research efforts and privacy rights across the country. Why are you making these changes and what is the status of the change?

Answer: OMB is making the change pursuant to the direction of Congress.

OMB has sought to minimize any potential negative impacts of the required changes.

Title III of the Treasury and General Government Appropriations Act of 1999 (Public Law 105-277) directed OMB to amend Circular A-110, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations." The change to A-110 would require Federal awarding agencies to ensure that all data produced under an award will be made available to the public in accordance with procedures established under the Freedom of Information Act.

OMB staff have drafted a Notice of Proposed Revision to Circular A-110. The Notice is clearing OMB and will be published in the *Federal Register* very soon. The Notice provides for the normal 60-day comment period so that affected parties have a reasonable period to review and respond to the proposal.

Background: Currently, Federal agencies have the right to obtain research data from their grantees but may choose to waive it. If the Federal agency chooses not to obtain the data, it is not subject to a FOIA request. The Congressional requirement will keep Federal agencies from waiving their right to the data.

Federal agencies, the research community, and members of Congress have raised concerns about the requirement, specifically, the definition of data, impact on future research, and additional administrative and financial burden. To address these concerns, the Notice states that when a FOIA request is received, a Federal agency shall obtain only data that

- was produced under a research award;
- relates to published findings; and
- was used by the Federal Government in developing policy or rules.

Prepared by: Jimmy Charney (x 57582)

CIRCULAR A-110 REVISION ON ACCESS TO RESEARCH DATA

Question 2: Will data produced under every Federal award be available to the public?

Answer: No. The proposed revision states that only data relating to published research findings that were used by the Federal Government in developing policy or rules will be made available.

Background: The language in P.L. 105-277 is broad enough to require an affirmative answer to the question posed above. However, statements made during floor discussion of this issue provide three key limitations to the reach of the provision.

The limitation to only data "used by the Federal Government in developing policy or rules" was taken from a statement by Senator Lott (144 Cong. Rec. S12134) (October 9, 1998). Senator Shelby (the author of the requirement) made a similar statement, noting that 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." Id.

The limitations to "research data" and "published data" also came from Senate floor statements about this issue.

Prepared by: Jimmy Charney (x 57582)

CIRCULAR A-110 REVISION ON ACCESS TO RESEARCH DATA

Question 3: How can we be assured that this provision will allow for adequate safeguards of the right to personal privacy established under the Privacy Act? How about the possibility that this provision will allow the release of government documents that should not be in the public domain?

Answer: The Freedom of Information Act contains nine statutory "exemptions" which allow a Federal agency to withhold information sought under a FOIA request. Federal agencies have guidelines and procedures on the use of these exemptions. The proposed revision makes it very clear that these statutory exemptions could be used by a Federal agency to withhold grantee data if they believed it fell within one (or more) of the nine exemptions. For example, grantee research data relating to national security information may be covered by a FOIA exemption.

The Privacy Act would prohibit the release of a research study participant's medical records, unless the participant agreed to such a release.

Background: It is important to note that researchers continue to have concerns about the release of data. There is a question as to the resources available to the Federal agency in making determinations on the appropriateness of releasing grantee data. Both manpower and expertise are of concern.

Also, even though the FOIA exemptions will be applied by the Federal agencies before any data is released, researchers are concerned about losing sole control of sensitive data. Even one inappropriate release of data could impact future research.

Prepared by: Jimmy Charney (x 57582)

CIRCULAR A-110 REVISION ON ACCESS TO RESEARCH DATA

Question 4: What role do the Federal agencies play in this new process? For what are they responsible?

Answer: While significant new duties would be placed on the agencies as a result of the statute, the agencies would have the same role in implementing this provision as they have in implementing revisions to OMB's grants management circulars.

OMB's practice is to seek agency input and assistance in the development of revisions to OMB's grants management circulars. OMB has been working with the agencies in the development of the proposed revision, and looks forward to receiving agency comments in response to the *Federal Register* notice.

Once OMB has finalized a revision to a grants management circular, the role of the agencies is to implement the revised provisions -- that is, ensure that the revised provisions are carried out in that agency's grant programs. This would also be the case here. Agencies that receive a FOIA request for data covered by the revision would have to obtain the data and make it available to the public in accordance with the rules and procedures that apply under FOIA.

Background: Once a Federal awarding agency has received a FOIA request for data held by a grantee, they must first determine whether the requested data relates to published research findings that were used by the Federal Government in developing policy or rules. The agency will then ask their grantee for access to the requested data. (Note that the Federal agency already has a right to request this data under current A-110 policy.) The Federal agency will then make a determination if any of the sought data should be withheld under one of the nine statutory exemptions of FOIA.

P.L. 105-277 provides that a fee can be charged to the FOIA requestor for the cost of obtaining the data. The proposed revision clarifies that this fee should include costs incurred by the grantee and applicable sub-grantees. It is not clear how the grantee will be reimbursed for their costs, or what process the Federal agency will undertake to collect this fee from the FOIA requestor.

Prepared by: Jimmy Charney (x 57582)

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: Proposed Revision

SUMMARY: This notice offers interested parties an opportunity to comment on 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 OMB 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" (FOIA). The Act further states that "if the agency obtaining the data does so solely" in response to a FOIA request, the agency "may authorize a reasonable user fee equaling the incremental cost of obtaining the data." Pursuant to the direction of P.L. 105-277, OMB is proposing to revise Circular A-110 as shown below.

DATES: Comments must be received by [Insert date 60 days after date of publication in the FEDERAL REGISTER].

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. If possible, please include a word processing version of comments on a computer disk. Comments may also be submitted via E-mail to: fcharney@omb.eop.gov. Please include the full body of E-mail comments in the text of the message and not as an attachment. Please include the name, title, organization, postal address, and E-mail address in the text of the message.

FOR FURTHER INFORMATION CONTACT: F. James Charney, Policy Analyst, Office of Management and Budget, at (202) 395-3993.

SUPPLEMENTARY INFORMATION: Public Law 105-277 includes a provision that directs OMB to amend Section __.36 of OMB 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." P.L. 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 is "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").

In describing the foregoing provisions of P.L. 105-277, congressional proponents stated that it 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 also 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 explained 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 is 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.

The proposed revision to Section ___.36 of Circular A-110 implements the requirements of P.L. 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. Pursuant to the direction of P.L. 105-277, 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 procedural and substantive rules that govern FOIA requests. These standard FOIA rules include the statutory concept of what constitutes a "record" and the statutory "exemptions" (found in 5 U.S.C. 552(b)) from the FOIA's requirement to disclose records. Accordingly, after obtaining and reviewing the requested data, the agency will 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. For example, FOIA Exemption 6, 5 U.S.C. 552(b)(6), exempts "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy". 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 (5 U.S.C. 552(a)(4)(A)).

OMB recognizes that this proposed revision required by P.L. 105-277 raises a number of important issues. Accordingly, OMB encourages interested parties to provide comment at this time so that any concerns may be addressed in OMB's development of the final revision to the Circular, to be published after the close of the comment period.

In conclusion, pursuant to the direction contained in P.L. 105-277 OMB is proposing to revise Circular A-110 as shown below.

Issued in Washington, D.C., January 26, 1999.

Norwood J. Jackson

Acting Controller

Pursuant to the direction of P.L. 105-277, OMB hereby proposes to amend Section ____.36(c) of OMB Circular A-110 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)).

Implementation Schedule
Proposed Revision of A-110
as required by Public Law 105-277

October 19, 1998	Public Law 105-277 enacted
December 8	Draft Notice of Proposed Revision provided to agencies
December 11	Written comments due from agencies
December 23	Notice placed in clearance
January 19, 1999	90-days after enactment; Senate "expectation" for OMB action
January 26	Director signs-off on Notice

February 4	Notice scheduled for publication in *Federal Register*
February 8	OMB response letters to congressional inquiries sent (with copy of the Notice)
April 5	60-day comment period ends
May 3	Draft Notice of Final Revision (and response to comment)
June 1	Notice placed in clearance
July 5	Notice published in *Federal Register* (including requirement for agency adoption within 90-days)
July 1 - Oct 1	Agency adoption
October 19	1-year after enactment; Senate "expectation" for agency action

TALKING POINTS ON REVISIONS TO OMB CIRCULAR A-110

- Public Law 105-277 (the FY 1999 Omnibus Appropriations Act) directed OMB to revise Circular A-110 to require Federal awarding agencies "to ensure that all data produced under an [research] award will be made available to the public through the procedures established under the Freedom of Information Act." While the legislative language is silent on the deadline for OMB revision of A-110, floor statements indicate that Congress wanted the revision to go to the *Federal Register* within 90 days of the bill's enactment (i.e., January 19, 1999).

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- Given our significant concerns, the Administration will consider its options.

Original requirement from HR 4328, later P.L. 105-277, the Omnibus Approps Act

Todd -

5-4915

I hope this packet helps. Let me know if you need anything further.

Jim
5-7582

Please Call Me On This

OFFICE OF ADMINISTRATION

SALARIES AND EXPENSES

For necessary expenses of the Office of Administration, including services as authorized by 5 U.S.C. 3109 and 3 U.S.C. 107, and hire of passenger motor vehicles, $28,350,000.

OFFICE OF MANAGEMENT AND BUDGET

SALARIES AND EXPENSES

For necessary expenses of the Office of Management and Budget (OMB), including hire of passenger motor vehicles and services as authorized by 5 U.S.C. 3109, $60,617,000, of which not to exceed $5,000,000 shall be available to carry out the provisions of chapter 35 of title 44, United States Code: Provided, That, as provided in 31 U.S.C. 1301(a), appropriations shall be applied only to the objects for which appropriations were made except as otherwise provided by law: Provided further, That none of the funds appropriated in this Act for the Office of Management and Budget may be used for the purpose of reviewing any agricultural marketing orders or any activities or regulations under the provisions of the Agricultural Marketing Agreement Act of 1937 (7 U.S.C. 601 et seq.): Provided further, That none of the funds made available for the Office of Management and Budget by this Act may be expended for the altering of the transcript of actual tes-

timony of witnesses, except for testimony of officials of the Office of Management and Budget, before the Committees on Appropriations or the Committees on Veterans' Affairs or their subcommittees: Provided further, That the preceding shall not apply to printed hearings released by the Committees on Appropriations or the Committees on Veterans' Affairs: Provided further, That the Director of OMB amends Section—.36 of OMB 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: Provided further, 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: Provided further, That OMB is directed to submit a report by March 31, 1999, to the Committees on Appropriations, the Senate Committee on Governmental Affairs, and the House Committee on Government Reform and Oversight that: (1) identifies specific paperwork reduction accomplishments expected, constituting annual five percent reductions in paperwork expected in fiscal year 1999 and fiscal year 2000; and (2) issues guidance on the requirements of 5 U.S.C. Sec. 801(a)(1) and (3); sections 804(3), and 808(2),

Text of Sec 36 of A-110 as currently approved.

Full text available at address above.

receipt of a final inventory. The final inventory shall list all equipment acquired with grant funds and federally-owned equipment. If the Federal awarding agency fails to issue disposition instructions within the 120 calendar day period, the recipient shall apply the standards of this section, as appropriate.

(iii) When the Federal awarding agency exercises its right to take title, the equipment shall be subject to the provisions for federally-owned equipment.

___.35 Supplies and other expendable property.

(a) Title to supplies and other expendable property shall vest in the recipient upon acquisition. If there is a residual inventory of unused supplies exceeding $5000 in total aggregate value upon termination or completion of the project or program and the supplies are not needed for any other federally-sponsored project or program, the recipient shall retain the supplies for use on non-Federal sponsored activities or sell them, but shall, in either case, compensate the Federal Government for its share. The amount of compensation shall be computed in the same manner as for equipment.

(b) The recipient shall not use supplies acquired with Federal funds to provide services to non-Federal outside organizations for a fee that is less than private companies charge for equivalent services, unless specifically authorized by Federal statute as long as the Federal Government retains an interest in the supplies.

___.36 Intangible property.

(a) The recipient may copyright any work that is subject to copyright and was developed, or for which ownership was purchased, under an award. The Federal awarding agency(ies) reserve a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

(b) Recipients are subject to applicable regulations governing patents and inventions, including government-wide regulations issued by the Department of Commerce at 37 CFR part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements."

(c) Unless waived by the Federal awarding agency, the Federal Government has the right to (1) and (2).

(1) Obtain, reproduce, publish or otherwise use the data first produced under an award.

(2) Authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

(d) Title to intangible property and debt instruments acquired under an award or subaward vests upon acquisition in the recipient. The recipient shall use that property for the originally-authorized purpose, and the recipient shall not encumber the property without approval of the Federal awarding agency. When no longer needed for the originally authorized purpose, disposition of the intangible property shall occur in accordance with the provisions of paragraph ___.34(g).

___.37 Property trust relationship. Real property, equipment, intangible property and debt instruments that are acquired or improved with Federal funds shall be held in trust by the recipient as trustee for the beneficiaries of the project or program under which the property was acquired or improved. Agencies may require recipients to record liens or other appropriate notices of record to indicate that personal or real property has been acquired or improved with Federal funds and that use and disposition conditions apply to the property.

Procurement Standards

___.40 Purpose of procurement standards. Sections ___.41 through ___.48 set forth standards for use by recipients in establishing procedures for the procurement of supplies and other expendable property, equipment, real property and other services with Federal funds. These standards are furnished to ensure

The precious few floor statements on this issue.

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funding bill. Based on that assurance, and knowing of the many other strong provisions retained in the conference report, I will vote for passage. But I do so with great disappointment at how this bill has been altered in the last few days and great hope that the democratic decisions overturned will be restored in the final omnibus appropriations measure.

One last note. I want to thank the staff members who have worked so tirelessly to bring this bill to the floor. Pat Raymond and Tammy Perrin of Senator CAMPBELL's staff have always been helpful and professional in their dealings with us—their demeanor has allowed us to put this bill together in a truly bipartisan way. Paul Bock, my chief of staff, approached this bill as he does everything: with intelligence and a healthy sense of humor. And my deepest gratitude is for my clerk, Barbara Retzlaff, who has boundless energy, complete mastery of the programs she monitors, and incredible patience—with me and with this year's torturous negotiations. Thank you all.

PUBLIC ACCESS TO GOVERNMENT RESEARCH DATA

Mr. LOTT. Mr. President, I would like to take a moment to thank the Senator from Alabama and the Chairman of the Treasury and General Government Appropriations Subcommittee for their diligent efforts to develop legislation that will provide the public with access to federally funded research data. The Conference Report for the Treasury and General Government Appropriations Act for FY 99 currently before us requires the Director of 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. This provision represents a critical step forward in assuring that the public has access to the research and underlying data used by the Federal government in developing policy and rules.

Mr. CAMPBELL. I thank the Majority Leader and my colleague from Alabama for his leadership on this issue. The gentleman is correct. The language included in the Conference Report will require Federal agencies to make all Federally funded research data available to the public through procedures established by the Freedom of Information Act. The 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. If the awarding agency must obtain the data from the recipient of the award, the provision specifically states that the awarding agency may authorize a reasonable user fee equaling the incremental cost of obtaining the data. It is my expectation that the Director of OMB to make the required changes within 90 days of enactment and that awarding agencies to issue new regulations implementing the amended Circular within one year of enactment. As is true with the existing OMB Circular A-110, 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. I want to thank my colleague from Alabama for his leadership on this important issue and his efforts to safeguard the public's right to know.

Mr. SHELBY. I thank the Majority Leader and Chairman CAMPBELL for their support. The lack of public access to research data feeds general public mistrust of the government and undermines support for major regulatory programs. This measure was long overdue and it represents a first step in ensuring that the public has access to all studies used by the Federal government to develop Federal policy.

• Ms. MOSELEY-BRAUN. Mr. President, I want to note my disappointment that the permanent relief for Haitian refugees that I and many others in this body have worked to make law has been dropped from the Treasury Appropriations Conference Report.

This effort began last year during debate of the D.C. Appropriations bill, which included language that granted certain Central Americans access to the "suspension of deportation" procedure, but Haitians were not granted this access. And you may recall that while I supported granting relief to the affected class of Central Americans, I, along with several of my colleagues here in the Senate and the House, fought vigorously for additional provisions for Haitian refugees.

Although we were unsuccessful in that effort, we later introduced S. 1504, Haitian Immigrations Fairness Act of 1997, legislation that would provide Haitian refugees permanent residency status. During the course of this year, this legislation was reported favorably out of the Judiciary committee and passed by the Senate as a provision of the Treasury-Postal Appropriations Fiscal Year 1999 bill. Eventually, this language was agreed to by the Conferees on the Treasury-Postal Appropriations bill. Unfortunately, due to last-minute, close-door maneuvering and negotiations, there is no Haitian relief included in the Conference Report that we are voting on today.

This legislation is vitally important to the several thousand Haitian men, women, and children who came here in the wake of the military coup in Haiti that in 1991 toppled the democratically elected government of that country. That coup was followed by a period of military dictatorship in Haiti marked by atrocious human rights abuses, including systematic use of rape and murder as weapons of terror. The International Civilian Mission, which has monitored human rights conditions throughout Haiti, documented this tragedy, including horrors so awful as to be almost imaginable.

To allow such human rights violations to occur so close to home while doing nothing would have been inconsistent with the stated goals of our foreign policy. So in 1991, the U.S. took in persons fleeing Haiti at Guantanamo Bay, Cuba. After intense screening, many of these individuals were paroled into the U.S. to apply affirmatively for asylum. Between the 1991 and May of 1992, over 30,000 Haitians were interviewed. Under one-third of these individuals were paroled into the U.S. to seek asylum.

Around Memorial day in 1992, Bush issued the "Kennebunkport Order," ending the asylum screening process at Guantanamo Bay, an action which became an issue during the 1992 presidential elections. A refugee program began operating in Port-au-Prince. This practice continued until 1994, when President Clinton reinstated a screening process in military hospital ship in Kingston Harbor, Jamaica. Democracy was restored in Haiti in the fall of 1994.

The individuals that I am talking about today are the children, wives, brothers, and sisters of soldiers and activists who stood up for democracy in Haiti. They fled to this country for refuge. They played by our rules. In the time that they've been here, they've built homes, paid taxes, had families in our country. These individuals are owed nothing less than treatment equal to that already provided to the Eastern European and Central European refugees residing in our Nation.

I regret that the Conferees decided at the last moment to strip the Haitian refugee relief provision from the Treasury-Postal Appropriations bill, but I would like to urge Senators LOTT and DASCHLE to consider adding this provision to any omnibus appropriations measures that may be considered in the upcoming days.•

Mr. MCCAIN. Mr. President, I want to thank the managers of this bill for their hard work in putting forth this legislation which provides federal funding for numerous vital programs. However, I am sad to say, once again, I find myself in the unpleasant position of speaking before my colleagues about unacceptable levels of parochial projects in another appropriations Conference Report.

Earlier this year, I came to the Senate floor and highlighted the numerous earmarks and set asides contained in the Senate version of this bill. That bill contained $826 million in specifically earmarked pork-barrel spending. That was a $791 million increase over last year's pork-barrel spending total for this bill, which only contained $34.25 million in wasted funds.

While the Senate bill contained an unacceptable amount of pork, this conference report is even worse. It contains $1.5 billion in specially earmarked pork barrel spending. This is almost double the amount of pork