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Public Access to Data From Federally Funded Research: OMB Circular A-110 and Issues for Congress

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ABSTRACT

This analytical report examines issues associated with the provision known as the Shelby amendment in P.L. 105-277 to make data from federally funded research available to the public through the procedures established under the Freedom of Information Act. It discusses the context of the legislation, including previous rules, the development by the Office of Management and Budget of revisions to OMB Circular A-110 required by the statute; issues that it raises for Congress; and related legislative activities, including H.R. 88. This report will be updated in response to new developments.

Public Access to Data From Federally Funded Research: OMB Circular A-110 and Issues for Congress

Summary

The results of scientific studies are often used in making government policy decisions. While the studies are often published, traditional federal research funding policies have not required the data on which they are based to be made available publicly. Such policies generally require researchers to share data and physical samples with other scientists after publication of the research. A rider, called the Shelby amendment, that was attached to the Omnibus Appropriations Act for FY1999, P.L. 105-277, mandated OMB to amend Circular A-110 to require federal agencies to ensure that "all data produced under a [federally funded] award will be made available to the public through the procedures established under the Freedom of Information Act [FOIA]." The amendment authorizes user fees. OMB was required to make changes and release a revised circular; subsequently agencies that choose to do so will issue their own "conforming rules." OMB published proposed revisions for comment in February and August; the final revision was issued September 30, published in the *Federal Register* on October 8, 1999, and took effect on November 8, 1999. The amendment originated from disputes about access to research information used in a federal regulation. It is a significant change from traditional practice, since, while permitted, federal agencies typically do not require grantees to submit research data and, pursuant to a 1980 Supreme Court decision, agencies did not have to give the public access under FOIA to research data they did not possess as part of agency records.

To balance the need for public access while protecting the research process, OMB's revision limits the kinds of data that will be made accessible (it excludes personal and business-related confidential data) and limits applicability to federally funded data produced under an award that has been published or cited by a federal agency and used in developing an agency action that has the force and effect of law. Opponents of the amendment say that FOIA is an inappropriate vehicle to allow wider public access since it will harm the traditional process of scientific research; human subjects will believe that the federal government might obtain access to confidential information; researchers will have to spend additional time and money putting data into a form required by the government, thereby interfering with ongoing research; and private sector cooperation and funding for government/university/in-dustry partnerships will be jeopardized.

Proponents of the amendment say that "accountability" and "transparency" are paramount. The public should have a right to review scientific data underlying research funded by government taxpayers. Some believe that the OMB revision "narrows" the scope of public access to research data contrary to congressional intent and might be challenged in court. Senator Shelby said the final revision, "while still narrow in scope, is a good first step...." Some say that the OMB revision, not the provision in the law directing OMB to amend the circular, will be the legal predicate if there is a court challenge. Both Congress and OMB might seek continuing oversight. Legislation to withhold funding for implementation of the amendment was rejected. H.R. 88, a proposal to repeal the provision of the law, is pending.

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The results of scientific studies are often used in making governmental policy decisions. While the studies are often published, the data on which they are based have seldom been publicly available, even for federally funded research, especially if the study was performed by a nonfederal grantee. A provision in P.L. 105-277 changed that; it directed OMB to revise its Circular A-110 to make data from federally funded research governed by the circular available to the public through the Freedom of Information Act (FOIA, 5 U.S.C. 552; see also CRS Rept. 97-91).[1] Popularly known as the Shelby or Shelby-Aderholt amendment, it is a significant change from traditional practice. It is controversial and has raised several issues that the 106th Congress has been addressing through oversight and legislative proposals.

The fundamental issue is how to reconcile different public interests. On the one hand, the public interest requires that government-funded research is performed efficiently and effectively and that the rights of individuals involved in that research are protected. On the other hand, the public has an interest in examining the results of government-funded research and in verifying the soundness of the science underlying policy decisions. Those interests can conflict if, for example, public access makes the research more difficult or more expensive to perform.

Supporters of the amendment say that the public has a right to review all data produced from research supported by taxpayers, especially those used in developing federal policies such as regulations. Most opponents say that using FOIA to provide access to federally funded research will harm the process of scientific research by imposing additional costs and other burdens on researchers and by making participation in research less attractive to potential subjects and collaborators concerned about confidentiality. OMB said its revisions to Circular A-110 attempt to balance those interests.

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[1] *Congressional Record*, 105th Cong., 2nd sess., 1998, 19 October 1998: 11178. The FOIA may be found at 5 U.S.C. 552 (1994 and 1996 supp.). The provision was a rider attached to the Treasury and Postal section of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for FY1999, P.L. 105-277, enacted on October 21, 1998. It requires that OMB amend section __.36 (c) [intangible property] of OMB Circular A-110. Its principal sponsors were Senator Richard C. Shelby and Representative Robert B. Aderholt. For Circular A-110, see Office of Management and Budget, Circular A-110: *Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations*, 29 August 1997, [http://www.whitehouse.gov/OMB/circulars/A-110/A-110.html].

This report provides an analysis of the issues raised by the changes to Circular A-110 mandated in P.L. 105-277. The first section describes the basis for the relevant provision and how it and the proposed changes to Circular A-110 change access to federally funded research data. This is followed by a discussion of the issues raised by those changes and relevant activity in the 106th Congress.

Requirements of the Shelby Amendment

OMB circulars are applicable to the federal executive branch. OMB describes the intent and authority of OMB circulars as "[i]nstructions or information issued by OMB to Federal agencies. These are expected to have a continuing effect of two years or more."[2] Furthermore, OMB requires all agencies to observe the provisions of relevant circulars.[3]

Before passage of the Shelby amendment, Circular A-110 did not define *data*, but it permits the federal government to "obtain, reproduce, publish or otherwise use the data first produced under an award," and authorizes "others to receive, reproduce, publish, or otherwise use such data for Federal purposes" (Section_.36. "Intangible property"). Also, it does not define the word *record*, but pursuant to Section _.53, "Retention and access requirements for records," requires that records related to an award be kept for a minimum of three years from the date of submitting the expenditure report or allows the government to request transfer of records to its custody if it determines that records have "long term retention value." The same section permits agencies, unless required by statute, to limit public access to recipient records if the awarding agency can demonstrate that such records shall be kept confidential and would have been exempted from disclosure by FOIA if the records belonged to the federal awarding agency. Circular A-110 applies only to federal "grants to and agreements with institutions of higher education, hospitals, and other nonprofit organizations." It does not apply to grants and agreements with state and local governments, but "[f]ederal agencies may apply [it] to [grants awarded to] commercial organizations, foreign governments, organizations under the jurisdiction of foreign governments, and international organizations."

The Shelby amendment mandated OMB to modify Circular A-110 "to require Federal 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." Pursuant to the changes made to Circular A-110, if a request is made under FOIA, agencies will be required to obtain certain types of research data from grantees and provide the requester access to the data, if FOIA exemptions do not apply, and (as permitted by FOIA), the agencies may collect research data in anticipation of public requests for data. FOIA and the circular also provide for cost reimbursement via fees charged to persons who request data under FOIA.

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[2]At [http://www2.whitehouse.gov/OMB/circulars/index.html] .

[3]OMB Circular No. A-1, Revised, *Subject: Bureau of the Budget's System of Circulars and Bulletins to Executive Departments and Establishments*, August 7, 1952.

Rationale For the Change in Law

Passage of the Shelby amendment is rooted in a two-year effort, begun in 1997 in House committee discussions, to make federally funded research data accessible to the public.[4] A key element contributing to the effort was debate over the scientific basis of Environmental Protection Agency regulations to strengthen national ambient air quality standards for ozone and particulate matter. In particular, dispute focused on the unavailability of data underlying Harvard's Six Cities study, funded by the National Institutes of Health, that found a link between particulate air pollution and health.[5] Industry groups requested to review the data, but the researchers refused,

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[4]According to Kathy Casey, Office of Senator Shelby: " In 1997, a similar effort was made on the House side, in full committee. While it did not succeed, it was something that we were aware of and certainly supported. In early 1998, the Senator [Shelby], joined by other Members, Senators Lott, Campbell, and Faircloth, was interested in seeing some sort of effort by OMB to review the current policies for making federally funded research subject to public disclosure, and sought to include language in the Treasury and General Government Appropriations bill" ("Origins of Congressional Action Regarding Public Access to Data," AAAS-Federal Focus Briefing on Data Access, February 16, 1999). The language calling for OMB action evolved during 1998, from the first proposal, which called for a study of the issue, to the final language in P.L. 105-277, which required specific changes in Circular A-110. Specifically, S. 2312, the Treasury and Government Appropriations Act, 1999, required that the "Director of OMB submit a report within 180 days of enactment to the Senate Committee on Appropriations: (1) evaluating the implementation of specific government-wide procedures for making federal funded research results (including all underlying data and supplementary materials) available as appropriate to the public unless such research results are currently protected from disclosure under current law...." The accompanying Senate report 105-251 referred to language in OMB Circular A-110 that gave agencies the right to obtain data produced under an award, but concluded that "...these policies [sic] directives are not being implemented on a systematic basis. Although the National Aeronautics and Space Administration, the Public Health Service, and the National Science Foundation currently implement data sharing policies in order to permit wider assessment of the validity of the research results and to facilitate broader public understanding, other Federal agencies do not. 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" (Section on "OMB. Data Access," in Senate Committee on Appropriations, *Treasury and General Government Appropriation Bill, 1999, Report to accompany S. 2312,* 105th Cong., 2nd sess., 1998, S. Report. 105-251). This bill was incorporated into H.R. 4104 as an amendment. H.R. 4104 was passed in lieu of original S. 2312 (Sept. 3, 1998). H.R. 4104 as originally passed in the House did not contain language relating to data access (July 16, 1998). The conference report on H.R. 4104 (House Rept. 105-789) explained that the conferees "included new language to amend Section XX.36 of OMB Circular A-110 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" (Section on "OMB. Salaries and Expenses, in House Committee of Conference, *Making Appropriations for the Treasury Departments, ... for the Fiscal Year 1999..., Conference Report to Accompany H.R. 4104,* 105th Cong., 2nd sess., 1998, H. Rept. 105-789).

[5]See, for example, Douglas W. Dockery and others, "An Association Between Air Pollution and Mortality in Six U.S. Cities," *New England Journal of Medicine* 329 (1993): 1753-1759.

(continued...)

citing confidentiality agreements with the subjects. Subsequently, a procedure by which an independent group of scientists could review the data was developed, but the law's supporters believe that better access is needed.[6]

The amendment's supporters say two issues were raised by the EPA dispute. One was the need for *transparency* — that the public should have access to data that they paid for and that affects policy. The second related to *accountability* — that the public, not only peer reviewers or scientists, should have a right to examine the data on which agency regulations are based, since the data or interpretations of it might be incorrect, and regulations can be very expensive to implement and to comply with. Proponents have argued that data access is important to ensure that regulations are well-supported scientifically and do not carry an undue burden.[7]

Those issues are not new,[8] but they had been relatively quiet since the U.S. Supreme Court ruled in 1980 that a grantee's data were not agency records within the meaning of FOIA because the data had not been created or obtained by a federal agency. The case was *Forsham v. Harris.*[9] The legal issue presented was whether records that were created and retained by nonagencies, but which are in some way affiliated with an agency, may be classified as agency records. In *Forsham*, the Court established the minimum requirements for determining agency record status in the context of records created by nonagencies. In *Forsham*, a private organization of physicians sought to obtain the data underlying the report of a Department of Health, Education, and Welfare (HEW) grantee funded to conduct a study of diabetes treatment regimens. The plaintiffs alleged that the data they sought were agency records because 1) they were records of the grantee which received its funds from a federal agency and were subject to some supervision in the use of those funds; 2) the federal agency had authority under its grant agreement to have obtained the data had it chosen to do so; and 3) they formed the basis of the grantee's reports which were relied upon by the agency. The court found that Congress had purposely excluded federal grantees from the FOIA, and held that the private grantee was not an agency subject to the FOIA. The court also concluded that the required data were not agency

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[5](...continued)
See also, House Committee on Science, Subcommittee on Energy and Environment, *The Science Behind the Environmental Protection Agency's (EPA's) Proposed Revisions to the National Ambient Air Quality Standards for Ozone and Particulate Matter, Parts I-III,* Hearings, 105th Cong. lst sess., March 12 and May 7 and 21, 1997, 582-596.

[6]"Disclosure Law Worries Researchers," By Aaron Zitner, Boston Globe Staff, February 11, 1999. See also Roger O. McClellan, "An Industry perspective on the Proposed Revision" presented at AAAS-Federal Focus Briefing on Data Access, February 26, 1999 [http://www.aaas.org/spp/dspp/sfrl/projects/omb.htm].

[7]See, for example, the statement of William L. Kovacs, U.S. Chamber of Commerce, before the House Subcommittee on Government Management, Information, and Technology, House Committee on Government Reform, Hearing on H.R. 88, Regarding Data Available Under the Freedom of Information Act, 15 July 1999, pp. 2-3.

[8]See, for example, Judith Lowitz Adler, "The Impact of FOIA on Scientific Research Grantees," *Columbia Journal of Law and Social Problems* 17, no. 1 (1981): 1-44.

[9]445 U.S. 169, 179 (1980).

records within the meaning of FOIA because the data had not been created or obtained by a federal agency;[10] and "[t]he FOIA applies to records which have in fact been obtained and not to records which merely could have been obtained."[11] The Court suggested that the grantee's data could become agency records if it could be shown that the agency directly controlled the grantee's day-to-day activities.[12]

The legislative history of the amendment is sparse because no hearings were held on it before passage. The major indication of legislative intent, other than the language in the provision itself and the report language, is from Senate floor statements made at the time the amendment was adopted. However, on July 15, 1999, the Subcommittee on Government Management, Information, and Technology of the House Committee on Government Reform held a hearing on H.R. 88, a bill that would repeal the amendment. That hearing provided additional background. Proponents of the amendment cited the costs of compliance with federal regulations coupled with the lack of public review of the data used by agencies in developing regulations. They also cited concerns about the adequacy of peer and agency review mechanisms to validate scientific data for setting regulations.[13] Opponents cited concerns about possible violation of the privacy of human subjects, risks to

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[10]"Written data generated, owned, and possessed by a privately controlled organization receiving federal study grants are not 'agency records' within the meaning of the Act when copies of those data have not been obtained by a federal agency subject to the FOIA. Federal participation in the generation of the data by means of a grant from the Department of Health, Education, and Welfare (HEW) does not make the private organization a federal 'agency' within the terms of the Act. Nor does this federal funding in combination with a federal right of access render the data 'agency records' of HEW, which *is* a federal 'agency' under the terms of the Act." (Ibid., at 171.)

[11]Ibid., at 186.

[12]Ibid., at 180.

[13]For instance, an official of the U.S. Chamber of Commerce testified in support of the Shelby amendment and in opposition to H.R. 88, saying that the excessive cost of compliance with federal regulations — cited as $737 billion annually — coupled with the lack of public review of the data used by agencies in developing regulations, justifies support for more access (William L. Kovacs, statement of the U.S. Chamber of Commerce, before the House Subcommittee on Government Management, Information, and Technology, House Committee on Government Reform, Hearings on H.R. 88, Regarding Data Available Under the Freedom of Information Act, 15 July 1999, pp. 2-3). Another witness, Robert W. Hahn, of the AEI-Brookings Joint Center for Regulatory Studies, testified, "At present, analyses used in policy making are rarely checked carefully before big regulations are put in place." He also said, "the peer-review process...is frequently not adequate for major public policy decisions, such as those involved in regulation." He recommended "allowing greater access to information that pertains to the formulation of such regulations..." (Testimony, Robert W. Hahn, p. 2, at Hearing, Ibid.) At the same hearing, Michael Gough, of the Cato Institute, claimed that a study ultimately supporting a regulation was published in a refereed journal, but that upon replication it yielded different nonsupporting results. ("The Importance of Data Access for Science and Governance," at Hearing, Ibid.).

confidential proprietary information, misinterpretation of data, inhibitory effects on the research enterprise, and costs of compliance.[14]

Previous Federal Rules, Including FOIA

This section discusses traditional policies for access to data derived from federally funded research, relevant provisions of FOIA, and exemptions of FOIA.

Traditional Policies for Access to Data From Federally Funded Research

Traditionally, research performers funded by federal grants have been required to provide the agency with a grant completion report and a copy of the publication that resulted from their research, if there was one. As is discussed in this section, agencies have developed policies to encourage researchers to share their data with other researchers. However, agencies have not generally required researchers to provide the data used or collected to the federal agency that sponsored their research. Therefore while data may be available to other researchers, they have not been available to the public.

Those practices are based on principles and policies about governmental support of science. Many of the principles about federal support for science were discussed first in *Science, the Endless Frontier*, by Vannevar Bush, a science adviser to Presidents Franklin Roosevelt and Harry Truman, considered to be the document that established the basis of policy for governmental support of, and accountability for, extramural, especially academic, research by grants.[15] After World War II, Congress initiated large programs to fund scientific research because of its perceived immediate or future value to the nation. Post-World War II enactments (creating the National Science Foundation, the National Institutes of Health, and so forth) led to the development of programs of governmental grants for research and for education and training of scientists in U.S. colleges and universities. Scientists were largely given responsibility through the research funding agencies to select research grantees by means of peer and merit review procedures; many of the responsibilities for administrative and financial accountability for grants research were shifted to universities.

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[14]Testimony of Gary D. Bass, Executive Director, *OMB Watch*; Robert N. Shelton, Vice Provost for Research, University of California; and Harold E. Varmus, Director, National Institutes of Health, at Hearing, Ibid.

[15]See Vannevar Bush, *Science—the Endless Frontier, a report to the President on a Program for Postwar Scientific Research,* U.S. Govt. Print. Off., 1945, passim. For additional information, see (name redacted), *Federal R&D Funding: A Concise History,* August. 14, 1998, 15 p. , CRS report 95-1209 STM; U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science, A Technical Memorandum,* OTA-M-SET-34, February 1986, pp. 14-15; and Daniel S. Greenberg, *The Politics of Pure Science* (New York: The New American Library, 1967), Chap. vi.

Also in the postwar period, additional federal intramural laboratories were established to enable the conduct of applied or mission-relevant research, and private companies, funded mostly by government contracts, began research and development for the federal government. As a result, today, 76% of federally funded research and development (R&D) and 74% of federally funded research is performed extramurally, with universities being the single largest performer of federally funded research, usually by means of grants. The federal government is, in fact, the largest single supporter of research in universities. **See Table 1.** In summary, Congress, "in some instances, made a conscious decision to finance this research in the private sector [that is, in academic institutions, other nonprofit institutions, and industry], rather than to

Table 1. Percentage Shares of Federally Funded R&D and Research Awarded to Selected Performers, Calculated According to Percentages of Federal Obligations

1. Type of federally funded activity	**2. Performer**	**3. Percentage of activity in column 1 performed by performer in column 2**
Research and development (R&D)	Nonfederal performers, FY1999 preliminary[16]	76%
Research only	Nonfederal performers, FY1999 preliminary[17]	74%
Research only	Intramural performers, FY1999 preliminary	26%
Research only	Universities and colleges (39%) and nonprofit institutions, (8%) FY1999, preliminary[18]	47%
Research only	Universities and colleges, FY1999, preliminary[19]	39%
1. Type of activity	**2. Source of funds**	**3. Percentage of activity in column 1 provided by the federal government, as described in column 2**
All research performed by universities and colleges	Federal government, FY1998, preliminary[20]	59%

[16]Calculated from Table C-10, U.S. National Science Foundation, *Federal Funds for Research and Development, Fiscal Years 1997, 1998, 1999, Vol. 47,* 1998, (NSF 99-333).

[17]Calculated from Table C-18, Ibid., (NSF 99-333).

[18] Ibid.

[19]Excluding FFRDCs. Calculated from Table C-18, Ibid., (NSF 99-333).

[20]Calculated from Table B-2A and B-2B, U.S. National Science Foundation, *National Patterns of R&D Resources: 1998. An SRS Special Report,* 1999, (NSF 99-335).

create an alternative state system of research. In so doing it has attempted to preserve value peculiar to private systems...," including grantee autonomy, while incorporating federal interests.[21] A legal interpretation of these private interests relevant to grant research was discussed in *Forsham v. Harris*, including "the values of competitive priority and peer recognition..." and the preservation of "grantee autonomy."[22]

The system of federal grants to support scientific research reflects principles that scientists consider important to the conduct of research. Those include scientific peer review of data and findings, replication of research results, use of publications to award credit for discovery and interpretation of data, and protection of the process of scientific inquiry. Especially important to scientists is public discussion of preliminary findings and research data without the potential for interference by political interests that might act to oppose the research during the research process.

Even before passage of the Shelby amendment, Circular A-110 allowed agencies to obtain and use the data produced under an award and authorized others to use "such data for federal purposes" (OMB Circular A-110, __.36(c)). However, neither Circular A-110 nor other instruments set overall Federal policy about ownership of data produced under grant awards. In general researchers have acted as owners, and agencies have permitted them to act as owners, of data in that they retain them and control access to them.

Over time, federal agencies have developed their own separate policies that generally endorse sharing by the researchers of recorded information following publication of research results, with access limited to other researchers and with adequate safeguards for protection of confidential information relating to human subjects or confidential commercial information. Some agencies allow public access to research data via databases.[23] Several major research funding agencies (such as the National Science Foundation (NSF), the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the National Aeronautics and Space Administration (NASA)) encourage or require researchers to share raw data, slides, or physical samples with other researchers, usually, but not in all cases, after publication of research results. Agencies stipulate a variety of time periods for researchers to retain data, ranging from three to seven years; some require researchers to provide data automatically to other researchers, others do not.

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[21]Adler, "Impact of FOIA," 1-2.

[22]See also Adler, "Impact of FOIA," 1-3 and Alvin J. Lorman, Esq., Daniel R. Johnson, Esq., and Daniel F. O'Keefe, Jr., Esq., "Tilting the Balance in Favor of Disclosure: The Scope of the Medical Records Exemption to the Federal Freedom of Information Act," *Food Drug Cosmetic Law Journal* 43, (January 1988): 17-32.

[23]Excerpts of the various policies for the Food and Drug Administration, the National Science Foundation, the Public Health Service, the National Institutes of Health, the National Center for Health Statistics of the Centers for Disease Control and Prevention, the National Aeronautics and Space Administration, and the National Institute of Justice in the Department of Justice were reproduced by the Center for Regulatory Effectiveness in "I.3.1. U.S. Government Executive Branch Policies," at [http://www.thecre.com/access/comments/1-3-1.html].

For instance, the policy governing the National Institutes of Health, the federal agency that provides the largest amount of federal research funds (predominately in the life sciences) to universities and colleges, says "it is incumbent" upon supported researchers "to make results and accomplishments of their activities available to the public."[24] Results and accomplishments may or may not encompass data. The Public Health Service (PHS), which includes NIH, defines data developed in a PHS-supported project as "writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs, statistical records, and other research data."[25] Also, to expedite the process of biomedical research, PHS requires NIH grantees and contractors to make "unique research resources," including physical samples such as specific cell lines and cloned DNA, available to other researchers following publication or fulfillment of a contract. In certain cases researchers are expected to deposit data in data banks to permit efficient access to the scientific community.[26]

NSF is the second largest federal funder of research at universities and colleges. It supports research in all areas of science. From its inception in 1950 until 1989, NSF had no written policy on data sharing (except relating to Automated Data Processing (ADP), software and large databases, which were written beginning in 1969). Its early policies allowed nongovernmental scientist/grantees to use their own professional procedures and incentives to promote sharing of information. It expected grantees to share data consonant with the principles of scientific exchange and replication in scientific research. In 1984, the National Science Board of the National Science Foundation adopted a data sharing policy. In 1989, the findings of an NSF committee were incorporated into a written NSF data sharing policy that appears in NSF's grant and management documents. As a result, NSF grantees are not required, but are encouraged, to follow condition 37 of *Grant General Conditions*, dealing with "Sharing of Findings, Data, and Other Research Products." Peer/merit reviewers are asked to consider whether a researcher's previous data sharing practices are consistent with NSF policies when selecting new award winners.[27] NSF's policy on "Sharing of Findings, Data, and Other Research Products" reads

> a. NSF expects significant findings from research and education activities it supports to be promptly submitted for publication, with authorship that accurately reflects the contributions of those involved. It expects investigators to share with other researchers, at no more than incremental cost and within a reasonable time, the data, samples, physical collections and other supporting materials created or gathered in the course of the work. It also encourages awardees to share software and inventions or otherwise act to make the innovations they embody widely useful and usable. b. Adjustments and, where essential, exceptions may be allowed to

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[24]Section on "Publications" in Part 8, "Postaward Administration" in *PHS Grants Policy Statement*, (PHS GPS 9505).

[25]Ibid.

[26]"PHS Policy Relating to Distribution of Unique Research Resources Produced with PHS Funding," from Part 8, "Postaward Administration" in *PHS Grants Policy Statement*, (PHS GPS 9505).

[27]Interview, John C. Chester, NSF General Counsel office, September 13, 1999.

> safeguard the rights of individuals and subjects, the validity of results, or the integrity of collections or to accommodate legitimate interests of investigators.[28]

Some prominent nongovernmental science policy groups have long advocated the disclosure of research data, but generally only after publication, usually only to other researchers, and only if disclosure is balanced by protections for privacy and intellectual property rights. In 1985, the National Academy of Sciences report, *Sharing Research Data*, said, "Data relevant to public policy should be shared as quickly and widely as possible, in time with public release and following appropriate review." It recommended against using FOIA for that purpose. The Academy also published *Bits of Power: Issues in Global Access Scientific Data* (1997), which called for open exchange of data from research funded with tax dollars, without severe restrictions by intellectual property rights law. A recent statement of the Academy presidents urges professional societies, academic leaders, and industry to develop clear and workable standards of open communication in scientific research.[29] Various professional groups, such as the American Sociological Association, the American Economic Association, and other scientific associations, have developed policies encouraging or requiring sharing of data cited in articles published in their journals.[30] The American Association for the Advancement of Science (AAAS) Council, in early 1999, adopted a resolution stating that "it supports the public disclosure of scientific findings and regulatory decisions, at the appropriate time and with appropriate safeguards...."[31] Reflecting foresight and the reality of the public pressures that would come shortly, the Council on Governmental Relations (COGR), a prominent association of research universities, issued a paper in 1996 urging senior university officials to develop polices to respond to increasing pressures for public access to data from federally sponsored research. Noting that the tradition of FOIA exemptions might weaken, it stated, "Scientists may not be able to defend their 'rights' in the public's view, unless they can argue convincingly that reasonable limitations of release are actually in the public's interest."[32]

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[28]Document GC-1, October 1, 1998.

[29]"Actions Are Needed to Promote Research Sharing," Statement from Bruce M. Alberts, Kenneth I. Shine, and William A. Wulf, September 8, 1998.

[30] "Sociologists Take Note: Data Access and Proposed Use of FOIA," *Footnotes*, February 1999.

[31]Letter AAAS to Hon. Jim Kobe, chairman, Subcommittee on Treasury, Postal Services and General Government, House Committee on Appropriations, May 3, 1999.

[32]Council on Governmental Relations (COGR), "Policy Considerations: Access to and Retention of Research Data," Washington, D.C., 1996, 5.

FOIA and Its Exemptions

The Freedom of Information Act provides a procedure for any individual to obtain access to information in records held by federal executive agencies.[33] FOIA does not require the requester of information to give a reason for the request. It presumes that the public has a right to information held by government agencies, and allows access for any purpose, with the following exemptions (5 U.S.C. 552b):

1. information that is properly classified to be kept secret in the interests of national defense or foreign policy,
2. information on internal personnel issues,
3. information that is exempted from disclosure by other statutes,[34]
4. trade secrets and commercial or financial information that is privileged or confidential,
5. internal agency memos available only by litigation,
6. personnel, medical, or similar files, whose release would constitute an unwarranted invasion of privacy,
7. records or information compiled for law enforcement and whose release would compromise impartial adjudication or disclose information about law enforcement processes and related issues, [35]
8. information related to the supervision of financial institutions, and
9. geological and geophysical information and data, including maps, concerning wells.

The law allows, but does not require, the agencies to withhold or redact agency records pursuant to these exemptions.[36] In many cases, agencies may make discretionary disclosures of exempt information "as a matter of good public policy."[37]

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[33]For an explanation of FOIA procedures, see House Committee on Government Reform and Oversight, *A Citizen's Guide on Using the Freedom of Information Act and the Privacy Act of 1974 to Request Government Records*, 106th Cong., 1st sess., 1999, H. Rept. 106–50 (available from CRS in Congressional Research Service, *Freedom of Information Act/Privacy Act: a Guide to Their Use*, CRS InfoPack IP047F, n.d.). For a discussion of FOIA provisions and legislative history, see (n ame redacted), Coordinator, *General Management Laws: A Selective Compendium*, CRS Report RL30267, 28 July 1999, 35-39. FOIA does not apply to elected officials, to the judicial branch, or to the legislative branch.

[34]Exemption 3 applies if the statute "(A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld" (5 U.S.C. 552 (b) (3)).

[35]Exemption 7 has 6 qualifying subparts.

[36]In *Chrysler Corp.* v. *Brown* (441 U.S. 281) (1979), the Supreme Court held that "The FOIA is exclusively a disclosure statute and affords petitioner no private right of action to enjoin agency disclosure. The language, logic, and history of the FOIA show that its provisions exempting specified material from disclosure were only meant to permit the agency to withhold certain information, and were not meant to mandate non-disclosure."

[37]U.S. Attorney General to Heads of Departments and Agencies, 4 October 1993, memorandum, reprinted in Department of Justice, *FOIA Update* 14, no. 3 (Summer/Fall

(continued...)

The exemptions do not include any specific "public interest" provision,[38] and the Act "does not authorize withholding of information or limit the availability of records to the public, except as specifically stated." Also, some say that the courts have interpreted the exemptions narrowly, promoting disclosure.[39]

FOIA also permits agencies to charge requesters for the cost of complying, although agencies do not retain the reimbursements, which go to the Treasury. Only direct costs can be reimbursed, and they are limited at most to search, duplication, and review. Lower charges apply to certain classes of requesters, such as educational institutions and the media.

Before passage of the Shelby amendment, private performers of federally funded research were not required to provide federal agencies with raw data and related information in response to FOIA requests. However, if the funding agency obtained the data for "federal purposes,"[40] such as to investigate possible scientific misconduct, the data became agency records subject to FOIA. In addition, intramural research, performed *directly* by federal agencies, is accessible to the public, provided that none of the FOIA exemptions apply. About 26% of all federally funded research is intramural, **See Table 1.**

Relevant State Laws

Many states have enacted "right-to-know" laws. In some cases, those laws provide broader access to information from nongovernmental researchers than the changes to Circular A-110 would allow, but some are more restrictive. Some observers have cited experience with those laws in commenting on the changes. For instance, Georgia's open records law allowed R.J. Reynolds Tobacco Company to try to obtain the data records of a Georgia researcher's study showing that children between the ages of 3 and 8 identified the company's cartoon camel and linked it to cigarettes. The researcher refused to allow the children to be identified and interviewed as the company wanted. The case involved litigation and a conflict between the university administration and the researcher regarding the applicability of the state law. Subsequently the State passed a law to prohibit invasion of the

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[37](...continued)
1993), [www.usdoj.gov/oip/foia_updates/Vol_XIV_3/page3.htm].

[38]However, the courts have interpreted Exemption 6 to require that any viable privacy interests outweigh the public interest in "shed[ding] light on an agency's performance of its statutory duties..." (*U.S. Department of Justice* v. *Reporters Committee*, 489 U.S. 749 [1989]).

[39]Martin J. Silverman, "Administrative Law — Freedom of Information Act — Agency Records — Forsham v. Harris," *New York Law School Law Review* 27, no. 2 (1981): 643 – 644.

[40]In *Forsham v. Harris* (445 U.S. 169), the U.S. Supreme Court reaffirmed lower court rulings that denied access to information generated and retained by private grantees (see Silverman, "Administrative Law — the Freedom of Information Act," 635-662.

children's privacy, but the researcher resigned his position and abandoned the line of research he had been pursuing.[41]

Some state laws allow the release of specific kinds of scientific research data. California, Massachusetts, and Michigan have laws permitting the release of epidemiological data.[42] The laws vary and some are more restrictive than the changes permitted by the language of Shelby amendment. For example, the California Public Records Act, unlike FOIA, permits an agency to withhold a record if "on the facts of the particular case the public interest served by not making the record public clearly outweighs the public interest served by disclosure of the record."[43] The law also apparently allows researchers to negotiate directly with the requesting party to protect sensitive data.[44]

OMB's Proposed and Final Revisions of Circular A-110

The Shelby amendment required OMB to revise Circular A-110 by September 30, 1999. OMB published a proposed revision on February 4 and provided a 60-day comment period.[45] After reviewing more than 9,000 comments, OMB published a second proposed revision on August 11 and provided an additional 30-day comment period.[46] Language in both OMB draft revisions and the final revision arguably restrict the application of the term *data* more narrowly than in the Shelby amendment, which included "all data produced under an award." **(The language of the law and OMB's three versions are summarized in Table 2.)** The first, that is, February, proposed revision, would have applied only to data from research that had been both published and used in the development of policies or rules.[47] The second, or August, proposed revision, was somewhat more restrictive, in that it would have applied only to research that is used in the development of regulations, for which notice and comment is required under the Administrative Procedure Act (5 U.S.C. 553, et. seq.).

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[41]Paul M. Fischer, "*Fischer v. The Medical College of Georgia* and the R.J. Reynolds Tobacco Company: A Case Study of Constraints on Research, *New Directions for Higher Education,* 88 (Winter 1994): 33-43.

[42]Center for Regulatory Effectiveness, "CRE Comments on Data Access Rule I.3.5 State Legislation."

[43]California Government Code, sec. 6255.

[44]Testimony of Robert N. Shelton, Vice Provost for Research, University of California, before the Subcommittee on Government Management, Information, and Technology, House Committee on Government Reform, 15 July 1999.

[45]Office of Management and Budget, Notice, "Proposed Revision to OMB Circular A-110, 'Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Non-Profit Organizations'," *Federal Register,* 64, no. 23 (4 February 1999): 5684-5685.

[46]Office of Management and Budget, Notice, "Request for Comments on Clarifying Changes to Proposed Revision to OMB Circular A-110," *Federal Register,* 64, no. 154 (11 August 1999): 43786-43791. Available at: [http://www.whitehouse.gov/OMB/fedreg/2ndnotice-a-110.html].

[47]OMB, "Proposed Revision," 5684-5685.

The final revision was released on September 30, 1999 and published in the *Federal Register* on October 8, 1999.[48] It was effective on November 8, 1999. It broadened the applicability of the provision from "regulations" to research that has been published and used in "developing an agency action that has the force and effect of law...." The second proposed revision defined the terms *published* and *research data* and sought comments on whether the revision should apply only to regulations with impacts of $100 million or more. The final revision defined the term *published* as in the second proposed revision, but defined *research data* slightly more restrictively, replacing the term *files* with *information* , to prevent the release of video or audio tapes of research subjects. The implications of these differences in language are discussed below in the section on issues.

The Shelby amendment provides specifically for cost reimbursement via "a reasonable user fee equaling the incremental cost of obtaining the data" "if the agency obtaining the data does so solely at the request of a private party." The OMB language pertaining to this issue, which did not change through the three versions of the revisions, allows an agency to obtain reimbursement of the "full incremental cost of obtaining the research data," including the costs incurred by "the agency, the recipient [of the research funding], and applicable subrecipients," provided that the agency obtains the data "solely in response to a FOIA request." The supplementary information attached to the second proposed revision said agencies would be allowed to retain that fee "to reimburse themselves, recipients, and applicable subrecipients, for the costs they incur." OMB also requested comments on estimates of such incremental costs and on the ways that grant recipients might charge such costs to their awards. The supplemental information attached to the final revision explained a procedure agencies could use to obtain reimbursements for grantees but contained the same cost-reimbursement provisions as in the first and second proposed revisions.

Although the final revised circular became effective thirty days after publication in the *Federal Register*, federal agencies that issue conforming agency regulations will allow the public and interested parties to comment before they issue their own conforming rules, as governed by the Administrative Procedure Act.

Reaction to the Draft Revisions

OMB received over 9,000 public comments on the first draft revision, 55% supporting it, 45% opposing it. Over 3,000 comments on the second revision proposal were received.

Supporters of broad public access included the United States Chamber of Commerce; the National Rifle Association; the Association of Equipment Distributors; a group of Former Administrators of the Office of Information and Regulatory Affairs, Office of Management and Budget during the Bush and Reagan

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[48]Office of Management and Budget, Final Revision, "OMB Circular A-110, 'Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-profit Organizations," [September 30, 1999], *Federal Register*, 64, no. 195 (8 October 1999): 54926-54030.

Administrations; and the Eagle Forum.[49] Those groups argued for what the Senate sponsors discussed relating to *transparency* and *accountability* — a broad, wide-ranging provision that would provide the greatest degree of access to all types of research data and allow citizens and interest groups to examine the data supporting new government rules. Among other supporters, the *Wall Street Journal* stated in an editorial that "if scientists want to take taxpayer money to conduct research, they should know that one of their main obligations is to make certain the public has full confidence in the ways those results are used. The Shelby law is a reasonable compromise that will help ensure just that."[50]

Objections to widening access to research data via FOIA — focusing especially on the potential burdens to the scientific research community or costs to a federal agency — were raised by the directors of the National Science Foundation and the National Institutes of Health, the President of the National Academy of Sciences, and such groups as the American Association of Universities, and the American Association for the Advancement of Science Council.[51] Opposition has been reported also from the Pharmaceutical Research and Manufacturers of American (PhRMA), and the Semiconductor Industry Association.[52] There was opposition also from the Boston Chamber of Commerce.[53]

OMB responded to such concerns in the supplementary explanatory information attached to the second proposed and final revisions of Circular A-110. For instance, the supplementary information attached to the second proposed revision said,

> [In preparing the proposed revision,] 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 (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

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[49]"Strong Response for Proposed Circular Change," *Science and Technology In Congress*, June 1999, 2.

[50]"Science's Belated Complaint," *The Wall Street Journal*, June 7, 1999, editorial. See also: "Opponents of New Data Release Law Maintain Blocking Strategy if Passed, House Amendment Would Strengthen Research Argument," *Washington Fax*, June 16, 1999; "Secret Science," *Washington Times*, Feb. 11, 1999; Angela Antonelli, "Preserve the Public's Right to Know About Federally Funded Research, *The Heritage Foundation Executive Memorandum*, June 8, 1999.

[51]See for instance, "Will FOIA Hold Science Hostage?" *Psychological Science Agenda*, May/June 1999, 1-3. Additional information and hot links to other websites on both sides of the issue may be found at: [http://photon.mit.edu/A-110/index.html]. See also proceedings of the AAAS-Federal Focus, Inc. Briefing on OMB Revisions to Circular A-110, February 16, 1999 at [http://www.aaas.org/spp/dspp/sfrl/projects/omb.htm].

[52]"Opponents of New Data Release Law Maintain Blocking Strategy If Passed, House Amendment Would Strengthen Research Argument," *Washington Fax*, June 16, 1999.

[53]Paul Guzzi, president, Greater Boston (MA) Chamber of Commerce, Letter to OMB Regarding Proposed Revision to Circular A-11, April 5, 1999.

> process, and (3) implement a public access process that will be workable in practice.[54]

Similar language appeared in the supplementary information attached to the final revision.

OMB also said that it "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."[55] The desire for scientists to do research using the traditional scientific process also led OMB to allow grantees to withhold from agencies confidential business information and private personal information.[56] (**See Table 2.)**

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[54]Ibid., OMB, Proposed Revision, [August 5, 1999], August 11, 1999, p. 43786, at [http://www.whitehouse.gov/OMB/fedreg/2ndnotice-A-110.html].

[55] Ibid., p. 43786 and Final Revision, p. 54927.

[56]Proposed revision, p. 43787 and Final revision, p. 54928. These are similar to FOIA exemptions 4 and 6.

Table 2. Comparison of Language Relating to Data Availability in the Shelby Amendment, Proposed Revisions, and Final Revision to OMB Circular A-110 (emphasis added)

Legislative Provision in P.L. 105-277: *"...all data* produced under an award will be made available to the public through the procedures established under the Freedom of Information Act"		
FIRST OMB February 1999 Proposed Revision of Circular A-110	**SECOND OMB August 1999 Proposed Revision of Circular A-110**	**FINAL OMB September 30 , 1999 Final Revision of Circular A-110**
"...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."	"...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.... (i) *"Research data"* is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples). Research data also do not include (A) trade secrets, commercial information, materials necessary to be held confidential by a researcher *until 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 the research findings in support of a regulation (for which notice and comment is required under 5 U.S.C. 553).	"...in response to a Freedom of Information Act (FOIA) request for *research data relating to published research findings* produced under an award *that were used by the Federal Government in developing an agency action that has the force and effect of law,* the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA..... (i) *"Research data"* is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples). Research data also do not include (A) trade secrets, commercial information, materials necessary to be held confidential by a researcher *until they are published, or similar information which is protected under law,* and (B) personnel and medical *information and similar information* the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study. (ii) *"Published"* is defined as either when (A) research findings are published in a peer-reviewed scientific or technical journal, or (B) a Federal agency publicly and officially cites to the research findings *in support of an agency action that has the force and effect of law.* (iii) *"Used by the Federal Government in developing an agency action that has the force and effect of law"* is defined as when an agency publicly and officially *cites the research findings in support of an agency action that has the force and effect of law*.

Issues

The use of the Freedom of Information Act to provide access to data from federally funded research has produced arguments for both potential benefits and potential disadvantages. A frequently cited benefit is that the mechanisms, federal infrastructure, and case law for FOIA are well-established.[57] Opposition focuses on such issues as timing of access, need for access, the cost of administration, possible inadequacy of the protections provided by FOIA's exemptions, and potential for abuse.[58] Some suggest that requests should meet a public interest test before data are released.[59]

The issues raised by the amendment and the OMB revisions to Circular A-110 can be divided into four categories:

- whether the revision of Circular A-110 will make the desired information available to the public,
- whether the procedures established will adequately protect proprietary information and the privacy of human subjects,
- what the benefits and costs of fulfilling the provisions will be, and
- how the changes may affect the research process.

Those issues are discussed in more depth below, followed by a discussion of issues for Congress.

Will the Revision Make the Desired Information Available to the Public?

Several factors could affect the degree to which the intended goals of the Shelby amendment are achieved. They include

- the degree to which the proposed revisions to Circular A-110 fulfill the legislative intent of the amendment,
- what data will actually be made available, and
- how public access to data serve the public interest.

Do the Proposed Changes to Circular A-110 Meet the Legislative Intent of the Amendment? The language in the final revision to Circular A-110 clearly is narrower than that in the legislative provision **(Table 2).** While the amendment called for access to all data produced under a federal award, the final revision to Circular A-110 limits access to selected kinds of federally funded "research data relating to

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[57]Testimony of James T. O'Reilly, University of Cincinnati College of Law, Hearing on H.R. 88, 15 July 1999.

[58]Testimony of Robert N. Shelton, University of California, and Bruce Alberts, President of the National Academy of Sciences, Hearing on H.R. 88, 15 July, 1999.

[59]"FOIA is fundamentally flawed as the mechanism here, because it fails to require evidence from the data requestor that the disclosure of the data in question is in the public interest. Congress needs to do more investigation of this concern" (Statement of Alberts, Ibid.)

published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law." This version is more restrictive than the proposed language of the first revision, which would have limited release to federally funded research data relating to published research findings that were used in developing federal policy or rules, but less restrictive than the proposed language of the second revision, which would have limited applicability to published research findings that were cited in or used by the government in developing a regulation. OMB said that it based its first proposed revision on its interpretation of floor statements in support of the provision made by Senators Shelby, Trent Lott, and Ben Nighthorse Campbell.[60] However, those Senators cosigned a letter of April 5, 1999, to OMB Director Lew criticizing the narrow approach of OMB:[61]

> We believe that the clear intent of the statutory language, the accompanying report language and floor debate was to make "all" federally funded research data subject to FOIA, not just ... data which are used to support a federal rule or policy.

Additionally, OMB cited parts of a comment letter to the second revision submitted by Senators Shelby, Lott, Campbell, and Gramm "that the revision should not be limited to regulations, but should apply generally to 'federal actions that can dramatically impact the public'."[62]

In response to comments that application only to data directly related to regulations narrowed access contrary to congressional intent,[63] OMB in the final revision to Circular A-110 broadened applicability to when "a Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law." OMB said that would include actions in the form of administrative orders, but added "we think that agencies rarely rely on Federally funded research in the context of their administrative orders."[64] OMB said it "decided not to extend the scope of the revision to agency guidance documents and other issuances that do not have the "force and effect of law" because that would be difficult to implement.

It is possible that the OMB final rule will be subject to court challenges, since it limits public access to research data and is more restrictive than Congress apparently intended in passing the law. Some say that is a moot point since the OMB circular — not the provision in the law directing OMB to amend it — will be the legal predicate if there is a court challenge.[65]

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[60]*Congressional Record*, daily ed., 9 October 1998, 144 (141): S12134.

[61]"Strong Response for Proposed Circular Change," op. cit., p. 2.

[62]OMB, Final revision, [September 30, 1999], October 8, 1999, p. 54928.

[63]Ibid., p. 54928.

[64]Ibid., p. 54928-54929.

[65]Testimony of James C. Miller, Citizens for a Sound Economy, Hearing on H.R. 88, 15 July 1999.

What Data Will Be Made Available to the Public? The amendment said that FOIA would apply to "all data produced under an award," but did not define *data*. The first and second proposed OMB revisions were more restrictive than the language of the amendment **(See Table 2).** The first version used, but did not define, data. The second and final revisions did so.

What Is Meant by "Data"? Many in the scientific community expressed concern about how *data* should be interpreted — it might include not only final data, but also preliminary results, as well as e-mails, physical specimens, notes of researchers, and so forth. As discussed above, many federal agencies encourage or require researchers to share physical specimens, as well as data, with other researchers after the completion of a research project. Federal agency definitions such as those used by the NSF, NIH, and NASA define *data* as recorded information, regardless of form or medium. That can include computer software and copyrightable materials. The definitions of *data,* however, do not include physical specimens.[66]

In their April 5, 1999 letter to OMB Director Jacob Lew, Senators Shelby, Lott, and Campbell stated,

> 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. This would include all tangible information or materials, including but not limited to measurements, surveys and experimental details, and subsequent data treatments, including statistical analyses, obtained, performed and compiled by researchers under an award and used as the basis for reasoning, calculations, or conclusions (p. 3).

The second and the final revisions of Circular A-110 used the term *research data* defining it as stated in **Table 2.** The definition focused on recorded factual material needed to validate research findings, and specifically excluded several other kinds of information and materials, including physical samples about which commenters on the February proposed revision had expressed concern. However, arguably the second version would have permitted access to a film or video of interviews with subjects, which are both recorded data and samples. The final version seems to permit researchers to withhold access to such records.

The second proposed and the final revisions also excluded from the definition of research data, materials similar to two FOIA exemptions. Despite the objections of many, including sponsoring Senators, that exclusions "at the outset...[are]...inconsistent with the plain meaning of the law, and that these kinds of data could be exempted by an agency via the FOIA exemption process,"[67] OMB retained them in the final revision (See table 2). One exclusion, related to Exemption

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[66]The NIH definition can be found in the NIH Grants Policy Statement at [http://grants.nih.gov/grants/policy/nihgps/fnpart_ii.htm]. The NASA definition can be found at 14 C.F.R. 1260.29(a)(1). See also the Federal Acquisition Regulations (FAR)(48 CFR 27.401).

[67]"Comments to OMB on Proposed Clarifying Changes to Circular A-110," Letter of Senators Campbell, Lott, Gramm, and Shelby to OMB Director Lew, September 10, 1999.

4, is for "trade secrets, commercial information, materials necessary to be held confidential…until they are published, or similar information which is protected under law." The second revision had excluded "information which may be copyrighted or patented" (which commenters thought was too broad). The other exclusion is for "information" that "would constitute a clearly unwarranted invasion of personal privacy." The second revision had excluded "files" rather than "information," but OMB explained in the supplementary information attached to the final revision notice that many commenters said they feared that video or audio tapes of research subjects might not be considered to be in the form of a file and could be subject to disclosure, but that the word "information" covers such materials.

Thus, a grantee would not be required to submit excluded records to the funding agency. In addition, the agency would presumably subject the records that were submitted to further screening under the exemptions. OMB also noted that the courts have allowed agencies to withhold an "entire record...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....)."[68]

To What Activities Does the Provision Apply? The final OMB revision limits public access to research data consisting of "recorded" factual materials necessary to validate research findings, excluding preliminary analyses, drafts of scientific papers, plans for future research, peer reviews and communications. It also excludes physical objects such as laboratory samples, trade secrets and information required to be held confidential until publishing or similar information protected under law, and personnel and medical information that would constitute an unwarranted invasion of personal privacy. Furthermore, the materials have to have been published in a peer-reviewed journal or cited by an agency in support of an action that has the force and effect of law. (**See Table 2 for a complete definition.)**

Examination of funding sources indicates that about 47% of federally funded extramural research is potentially covered by Circular A-110 (**see Table 1**). It consists of federally funded research to universities and colleges and nonprofit performers, most of which is funded by grants. However, the data that would actually be made accessible to the public will likely come from a small proportion of federally funded research activities. Much of the scientific activity that Circular A-110 covers is basic research.[69] It is arguably likely that, under OMB's final revision, most basic research would not be accessible to the public under FOIA because of exemptions, the way *data* is defined, and the fact that most academic basic research is unlikely to produce results used in developing "an agency action that has the force and effect of law." However, much basic research is aimed at developing scientific principles that can lay the groundwork for applied research that is targeted at specific policies, actions, or regulatory issues.

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[68]OMB, Proposed revision, [August 5]. 11, 1999, p. 43786.

[69]For FY1998, universities and colleges received approximately $13.7 billion in federal funds for research and development, a large part of it for basic research. (Intersociety Working Group, *Research and Development FY2000, AAAS Report XXIV,* (Washington DC: American Association for the Advancement of Science, 1999) 65–66.

OMB also said in the supplementary information attached to the second revision that it might narrow data access only to regulations that meet a $100 million threshold level of impact, and it sought public comments on this suggestion. The supplementary material attached to the final revision said OMB would not limit the applicability only to agency actions that have an impact over $100 million, because it received comments of both strong support for and opposition to the $100 million threshold.

Some believe that much research used in developing "agency actions that have the force and effect of law" will still not be accessible to the public. That is because Circular A-110 does not cover contracts, which agencies must use if procuring services,[70] such as data which an agency knew from the outset would be used in developing specific agency actions, including regulations. Federal agencies would not be required under the amendment to obtain data from contracted research. Thus, such data would not be available to the public under FOIA unless the contract required that the data be provided to the agency. The circular also does not covers grants to state and local governments, so data from such awards would not be available under the amendment. In light of such considerations, some observers have proposed that OMB extend the revisions of Circular A-110 to both the Federal Acquisition Regulations (48 C.F.R. 1ff), which cover contracts, and Circular A-102, which covers grants and cooperative agreements with state and local governments.[71]

What Is Meant by "Published"? The first OMB revision limited applicability of the amendment to "data relating to published research findings...." It did not define *published*, which could be interpreted narrowly or broadly, as commenters noted. For example, it could apply only to papers published in scientific journals or to discussions of preliminary findings at meetings, data cited in papers sent out for peer review, e-mails, and so forth.

In their April 5 letter, Senators Shelby, Campbell, and Lott said that, while data from published research (defined "to include publication in a journal or the presentation of those findings to the media") should be released, "[i]f federally funded

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[70]"An executive agency shall use a procurement contract as the legal instrument reflecting a relationship between the United States Government and a State, a local government, or other recipient when — (1) the principal purpose of the instrument is to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the United States Government; or (2) the agency decides in a specific instance that the use of a procurement contract is appropriate" (31 U.S.C. 6303). For example, in a case involving a proposed study by the National Academy of Sciences "to provide information on risks and benefits of certain pesticides to help federal regulatory agencies, such as EPA, in analyzing prospective regulations," the Comptroller General ruled, "The proper funding mechanism should be a procurement contract,...since the primary purpose of the study is to acquire information for the direct benefit or use of the Federal Government" (Comptroller General, "Federal Grant and Cooperative Agreement Act of 1977 — Compliance — Cooperative Agreements — Procurement v. Cooperative Agreement — Criteria for Determining," *Decisions of the Comptroller General of the United States* 65 [1986]: 605.

[71]See, for example, "Analysis of the Second OMB Proposal Extending FOIA to Federal Grantees," *OMB Watch*, August 20, 1999 [http://ombwatch.org/npadv/a-110rev2.html].

prepublished data or findings are used by a federal agency to support a federal rule or policy, then...such data would also be made publically available under FOIA."[72]

In response, the second and final OMB revisions defined published research findings as those appearing in a "peer-reviewed scientific or technical journal" or publicly and officially cited in support of an agency action that has the force of law (or in the case of the second revision, cited in a regulation). Some critics have said that language would not resolve several problems. For instance, *OMB Watch* said "...the trigger should not be based solely on whether the agency simply cites the research in its support of the regulation. Rather, the trigger should be based on whether data from the cited research was part of the underlying assumptions or assessments used in developing the regulation."[73] NIH proposed narrowing access to "significant scientific findings":

> When a regulatory agency cites research in the regulatory process, that research may be critically or marginally applicable to that regulation. A brief review of regulations revealed that some cite hundreds of research studies, all of which would be subject to FOIA under this amendment. It would greatly reduce the burden of this legislation if access were afforded to data from only those studies that were critical in the formulation of the regulation.[74]

Another question still troubling to some, despite the language of the final revision, is what impacts public access will have on the ability of the researchers who develop a data set to benefit appropriately from the effort they have invested. Researchers often publish more than one paper from a set of data. Data cannot be copyrighted[75] and scientists have traditionally been reluctant to make data public until they have had an opportunity to analyze them fully and publish the results. Once data become publicly available, others might use them to publish analyses before the original researchers have the opportunity to do so.[76]

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[72]Letter from Senators Richard Shelby, Ben Nighthorse Campbell, and Trent Lott to Jacob J. Lew, Director, Office of Management and Budget, April 5, 1999. For additional analysis of the Senators' views, see: Angela Antonelli, "Preserve the Public's Right to Know About Federally Funded Research," *The Heritage Foundation Executive Memorandum,* June 8, 1999, 2.

[73]"Analysis of the Second OMB Proposal Extending FOIA to Federal Grantees, *OMB Watch,* August 20, 1999, [http://ombwatch.org/npadv/a-110rev2.html].

[74]"A-110: NIH Response to OMB, Memo to John Callahan, Assistant Secretary for Management and Budget from Director NIH, [August 1999] Available at: [http://grants.nih.gov/grants/policy/A-110/A-110_nihresponsetoomb0999.htm].

[75]Copyright law does not protect facts or discoveries. See, for example, Dorothy A. Schrader and (name redacted), "Intellectual Property Protection for Noncreative Databases," CRS Report 98-902, 15 September 1999.

[76]"Analysis of the Second OMB Proposal Extending FOIA to Federal Grantees, *OMB Watch,* August 20, 1999, [http://ombwatch.org/npadv/a-110rev2.html].

How Quickly Should Access to the Data Be Provided? Senators Shelby, Lott, and Campbell recommended to OMB that the public should have access in sufficient time to review underlying data before a rule or policy is issued.

> OMB should encourage agencies to: (1) notify the public of which studies will be used as early as is feasible in the rulemaking or policy development process; and (2) process all timely and relevant data requests before the public comment period on a proposed rule or policy closes. In addition,...clarification that risk assessments and other federal reports or surveys are covered independently under the proposed revision will also help by providing the public with a chance to review the underlying data supporting these government findings before they are used in a rulemaking process.[77]

The first, second, and final versions of the revisions to the circular proposed a "reasonable time" standard for the response to a request for research data. Some say that those who use FOIA to obtain data to comment on a proposed regulation may not obtain the data quickly enough to do so.[78] Typical comment periods for regulations are 30, 60, or 90 working days, although longer periods may be provided for complex rules.[79] In most cases, an agency would be required under FOIA to notify the requester within 30 working days (six weeks) whether it would comply with a request.[80] If it grants the request, it must comply "promptly" or it may be subject to legal action. Once the data are obtained, requesters must examine and possibly reanalyze them to develop comments. In defense of the "reasonable time" standard, OMB explained, in the supplementary information attached to the final revision, "Since OMB and the agencies do not yet have experience with implementing the public access process, we believe the 'reasonable time' standard, which allows consideration of the circumstances of a particular case, is appropriate. As OMB and

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[77]Letter from Senators Richard Shelby, Ben Nighthorse Campbell, and Trent Lott to Jacob J. Lew, Director, Office of Management and Budget, April 5, 1999, p. 2.

[78]Available at [http://grants.nih.gov/grants/policy/A-110/A-110_nihresponsetoomb0999.htm].

[79]The Administrative Procedure Act stipulates that an agency provide "interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments..." (5 U.S.C. 553 [c]). There is no uniform statutory requirement for the length of a comment period, although statutes may stipulate periods in specific cases. A 1993 executive order provides the following guidance: "[E]ach agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days" (President [Clinton], "Regulatory Planning and Review," Executive Order 12866, *Federal Register* 58, no. 190 [4 October 1993]: 51735).

[80]FOIA (5 U.S.C. 552 [a][6]) states that an agency must "determine within 20 days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of [a] request whether to comply...and shall immediately notify the person making [the] request..." In "unusual circumstances," such as "the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request," the agency is permitted an extension of up to "ten working days."

the agencies gain experience with the public access process, we may be able to develop further clarification on this point."[81]

How Long Should the Data Be Kept, and Who Should Keep Them? Section_53 of Circular A-110 requires that papers or records pertinent to an award (there is no specific requirement about data, but it is implied) must be retained for three years from the date of submission of the final expenditure report, and, that if the grantee holds it longer the federal government can still access it.[82] Thus, if the researcher kept records subject to the new circular for more than three years, the funding agency would be able to seek that information to respond to a FOIA request. If eligible research were officially cited or used in support of an agency action that has the force and effect of law, but more than three years after an award had ended, the data might no longer be available. However, in practice, scientists would seem unlikely to so quickly discard data from such important research.

Questions remain about who — whether the university or the researcher — should be the custodian of the data. That is important because the researchers who collected the data may leave the institutions where the research was conducted. According to the Council on Governmental Relations (COGR), various custodial arrangements could be considered:

> Custody could theoretically be placed at: a central facility; the department; the laboratory or with the individual principal investigator. At least one university (Harvard) has made the originating laboratory the custodian of research data.... Alternatively, universities may wish to assign custody of data to faculty and researchers, whether those individual reside at the home university or move to another institution. If so,...arrangements should specify that the custodian is responsible for providing access to the data as well as for providing adequate data storage. Such custodial arrangements should recognize ownership right and require the custodian to keep the data in trust, not moving or destroying it without appropriate advance notice and permission from the legal owner."[83]

How Will Public Access to Research Data Serve the Public Interest? The debate before and after passage of the Shelby amendment and the hearings held on H.R. 88 produced numerous reasons for widening public access to data from federally funded research. One is the "transparency" argument — that the public should have access to the data, since it was funded with taxpayer dollars. Other reasons are more

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[81]OMB, Final revision, p. 54929.

[82]The circular requires retention of "[f]inancial records, supporting documents, statistical records, and all other records pertinent to an award..." for three years. It also gives government representatives "the right of timely and unrestricted access to any books, documents, papers, or other records of recipients that are pertinent to the awards..." for "as long as records are retained" (Section __.53 [e]). Section __.36(c) states that the government can "[o]btain, reproduce, publish or otherwise use the data first produced under an award" unless the awarding agency waives that right and allows the government to authorize others to "receive, reproduce, publish, or otherwise use such data for Federal purposes."

[83]Council on Governmental Relations (COGR), "Policy Considerations: Access to And Retention of Research Data," 1996.

directly related to accountability and the processes and politics of U.S. policymaking that rely on scientific and technical information or judgments. As more, and more costly, public policy decisions are based on scientific and technical information, there will likely be more public scrutiny of the rationale for those decisions. That is especially true in controversial issues where different scientists might interpret research data and their policy implications differently or when opposing interest groups might bring conflicting scientific data to bear on decisionmaking. Some contend that public understanding of science and public financial support for science might be enhanced with more access to research data. Others say that more access would ensure confidence in the legitimacy of governmental actions.

Some say that peer review by other scientists may not be adequate to validate research, especially when findings affect important public policy decisions. That is crucial when research findings are based on "metaanalysis" or "research synthesis" — when a researcher develops a new policy-relevant research finding based on synthesizing the findings of many different research studies relating to the same topic.[84] Those research methods are increasingly used in policy analysis. Others question not only the techniques used in metaanalysis, but also the validity of the original research and findings. In addition, some segments of the public are skeptical of the government's ability to correctly represent, interpret, or present all relevant scientific findings, especially given recent disclosures about federal agency misrepresentation of medical experimentation, such as the Tuskegee experiments, relating to treatment of syphilis, and of radiation exposure levels around some nuclear research laboratories. There is also skepticism about federal agency findings and policies relating to research or research evaluations of subsidy or intervention programs in such diverse areas as science education and genetic engineering of crop seeds and other farm products. Advocates of public access say that, in cases like those, they should be given access to research data to replicate the analyses, to verify or refute the findings, or to evaluate methods used in conducting the research and interpreting the data. Interested members of the public seek the same kinds of access as other researchers often have to data, physical samples, specimens, and other records from federally funded research.

For most research, however, scientists find that independent evaluation of the raw data from a study is not necessary to evaluate the validity of the research. Federal agencies and the scientific community use several methods during the research process, with public involvement usually limited to later stages. Those evaluations usually do not involve examination by others of the raw data produced by the researchers. Before a grant for a scientific study is awarded, the granting agency generally performs a merit review of the proposed study, including an evaluation of the proposed methods of research and analysis. That review often involves evaluation of the proposal by independent scientists. As a study progresses, scientists usually report on progress, including preliminary findings, to their colleagues. Those findings may become public at that time if reported at scientific conferences attended by members of the press. Researchers may adjust methodologies or perform additional research based on the feedback they receive from colleagues. Once a study, or a

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[84]See for instance, Harris Cooper and Larry V. Hedges, eds., *The Handbook of Research Synthesis* (New York: Russell Sage Foundation, 1994), 573 pp.

particular stage, is completed, researchers usually prepare the results for publication. As part of that process, drafts of articles reporting the findings are usually evaluated by other scientists, who examine the methodology, analysis, and other elements. Once a paper is published, other segments of the scientific community and the public may respond to it, and they might challenge the premises, methodology, analyses, or conclusions. Such challenges might include other research aimed at testing the validity of the findings. The potential for such testing is one of the fundamental checks on validity provided by the scientific method. If independent researchers obtain the same results, that greatly strengthens the conclusions. If the results cannot be replicated, then the original conclusions were probably not correct.

However, replication can be difficult or even impossible for large-scale studies or those using unique sets of information, such as the Harvard Six Cities study cited earlier. Also, in some instances, regulatory or other decisions might need to be made before confirming experiments could be performed. It is for such cases that evaluation of the data by others can be especially important in judging the validity of the research.

Public access to such data may lead to several alternative evaluations being produced by interested parties. That should help validate conclusions and increase the likelihood that errors will be detected. According to some, it could lead to a "higher standard of review....[and] the end result of this approach will be a body of scientific work more rigorously tested and reliable."[85] However, evaluation of data is itself an area of expertise requiring skill and training. For example, statistical analysis can be done in many ways, and use of an inappropriate procedure can easily lead to spurious conclusions. Therefore, public assessment of the original and alternative evaluations may be difficult.

Will the Procedures Established Adequately Protect Proprietary Information and the Privacy of Human Subjects?

Some opponents of the amendment say that FOIA is an inappropriate vehicle because its exemptions would not provide adequate protections for research data that should not be made public. As is specified in the final revision to OMB Circular A-110, in responding to a FOIA request, a researcher or research institution may withhold from an agency data that consists of trade secrets, confidential information, or information that is protected by law, or personnel and medical information whose disclosure would be an unwarranted invasion of personal privacy. Those definitions are similar to FOIA Exemptions 4 and 6, but these data will not be sent to the agency for consideration for redaction. As will be discussed next, despite those protections, some researchers believe that human subjects data and proprietary data will not be adequately protected.

Protection of Proprietary Information and Trade Secrets. The final revision to the circular, like the second proposed revision, included language that excluded proprietary information and trade secrets from the research data that would have to

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[85]CRE, "Enhancements to the Scientific Enterprise," [http://www.thecre.com/access/comments/1-2-4.html]/

be sent to an agency to comply with a FOIA request. Specifically excluded are "trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law." All of the language after the word "until" was modified in the final revision in response to comments that too much information might be excluded by the second revision, which read "until results are published in a peer-reviewed journal, or information which may be copyrighted or patented." OMB explained in the supplementary information published with the revision that "to avoid unintended consequences, and to avoid having to sort out the complexities of copyright law (and how it might apply in various areas of Federally funded research)," the substitute language "is intended to ensure that the public access process will not upset intellectual property rights that are elsewhere recognized and protected under the law."[86]

In addition, the exemptions and other precedents associated with FOIA would seem to prevent public access under the Shelby amendment to trade secrets and confidential business information. Exemption 3 exempts from mandatory disclosure matters exempted from disclosure by other statutes. Exemption 4 specifically protects trade secrets and privileged or confidential business information. Commercially sensitive data in pending patents are also protected from disclosure by other statutes.[87] Also, the submitter of information may challenge its release through a reverse FOIA lawsuit.[88]

Some have complained that opportunities to compromise commercially relevant information could arise in the context of joint university/government/industry partnerships (even if the federal share of support is only 10%), since public access will not depend on "the level of funding or whether the award recipient is also using non-Federal funds."[89] There is also the view that some partnerships that include federally funded researchers "make strict requirements on the researcher not to share data

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[86]OMB, Final revision, p. 54928.

[87]See, for example CRE, "Intellectual Property Protection," [http://www.thecre.com/access/comments/2-2-2.html].

[88]The House Committee on Government Reform and Oversight explained that "Although there is no formal requirement under the FOIA, many agencies will notify a submitter of business information that disclosure of the information is being considered (See *Predisclosure Notification Procedures for Confidential Commercial Information*, Executive Order 12600, 3 C.F.R. 235[1988]). The submitter then has an opportunity to convince the agency that the information qualifies for withholding. A submitter can also file suit to block disclosure under the FOIA. Such lawsuits are generally referred to as "reverse" FOIA lawsuits because the FOIA is being used in an attempt to *prevent* rather than to *require* the disclosure of information" (House Committee on Government Reform and Oversight, *A Citizen's Guide on Using the Freedom of Information Act and the Privacy Act of 1974 to Request Government Records. First Report.* 105th Cong., 1st sess., 1997, H. Rept. 105-37, 16–17). However, the basis for such lawsuits is not FOIA, since agencies are not required to withhold information under the exemptions, but the Administrative Procedure Act and other relevant statutes (Department of Justice, *Freedom of Information Act Guide*, September 1998).

[89]OMB, Proposed revision, [August 5, 1999] August 11, 1999, p. 43787, citing statement of Senator Campbell, *Congressional Record*, v. 144, October 9, 1998, p. S12134.

further. Without such agreements, private researchers would not participate in these partnerships."[90] NAS President Alberts testified on this subject at hearings on July 15, 1999:

> For example, commercial interests that have a strong competitive interest in particular areas of research will now be able to use FOIA requests to obtain university-based research data for their own use and competitive advantage in an effort to dominate or control that area of research, ultimately discouraging independent university research in these areas. Where universities have industry partners for jointly sponsored research projects, commercial concerns can use FOIA requests to obtain research data from these projects to the detriment of the actual project sponsors, who are their competitors.[91]

He also said foreign governments would obtain data from federally funded basic research for use in their own R&D.[92] There is also concern about timing: "Under U.S. law, scientists have a year from the date of publication to file a patent application. Will allowing data to be publicly available through FOIA threaten a scientist's foreign patent rights?"[93]

According to the Council on Governmental Relations (COGR), considerable case law has grown around use and challenges under FOIA and indicates that "Exemption 4 has been effective in protecting university data."[94] "..[T]here are well-understood exemptions that serve to protect data that are important to universities for scientific or commercial reasons," according to COGR.[95] In fact, according to testimony of James T. O'Reilly, Visiting Professor of Law, University of Cincinnati College of Law, and author of *Federal Information Disclosure,* the protections afforded by the exemptions to FOIA and court and case law, together with agency rules and policies, have been viable in protecting privacy and commercial interests. In addition, he said, there are about 100 special exempting statutes. "The conflicts over specific research interests in medical device testing data, for example, have already been addressed in specific substantive laws."[96]

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[90]Statement of Director Varmus, 15 July 1999, p. 4.

[91]Statement of Dr. Alberts, 15 July 1999, pp. 4-5.

[92]Ibid.

[93]Mark S. Frankel, "Public Access to Data," *Science* 284 (19 February 1998), 1114.

[94]Specifically according to COGR,"Case law regarding use of Exemption 4 shows that two major tests are being used. Decisions regarding release of data are based on whether the provider is likely to experience 'competitive harm' as a result of the release. If universities desire to shield scientific raw data, protection may well hinge on the broad interpretation of 'competitive harm.' The second criterion traditionally used is the 'government impairment' test. Release is usually granted when courts find no danger that the Government would be unable to obtain information in the future or that release would cause substantial competitive injury." (COGR, "Legislation to Amend OMB Circular A-110....", p. 4.)

[95]Ibid.

[96]Testimony before the Subcommittee on Government Management, Information, and Technology, House Committee on Government Reform, July 15, 1999.

Nevertheless, others have recommended that OMB "require agencies to allow private sector participants in federally funded projects, who either contributed parts of the database to the project or participated in developing the database, an opportunity to make recommendations to the federal agency regarding which data should be withheld from disclosure pursuant to the FOIA exemptions."[97]

Protection of Personal Information About Volunteer Human Subjects. Many scientific studies involve volunteer human subjects. Concerns about protecting the privacy of those subjects has increased in recent years in conjunction with the increasing capabilities of information technology to integrate separate pieces of related information and the rapid pace of discoveries about human genetics.[98] Many observers believe that current protections for personal medical and health information (collected during medical treatment as well as during scientific research) are inadequate generally, and Congress has considered legislation to address such concerns.[99] Some analysts suggest that the potential for increased public access to health research data provided by the revision of Circular A-110 may increase those concerns.

The exclusion of certain personal information in the circular's definition of research data (**Table 2**) is intended to protect against unwarranted invasions of privacy. FOIA Exemption 6 provides additional protection, as does the Public Health Service Act.[100] However, FOIA permits, but does not require, agencies to withhold information covered by the exemptions, and courts have ruled that public interest in disclosure may outweigh privacy interests (see section on FOIA above). Therefore, some fear that information that a human research subject was told was confidential might become public. In addition, courts might reject the exclusions that OMB wrote into the definition of research data and require researchers to submit all data to the agency, which would then determine what personal information can be withheld.

Some have expressed concern that the sorting and analytical capabilities of information technology might permit human subjects to be identified even if personal identifiers were removed. According to NIH Director Varmus,

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[97]CRE, "Intellectual Property Protection," [http://www/thecre/com/access/comments/2-2-2.html].

[98]See, for example, B.P. Fuller and others, "Privacy in Genetics Research," *Science* 285 (27 August 1999): 1359–1361.

[99]See (name redacted) and Gina Marie Stevens, *Medical Records Confidentiality*, CRS Issue Brief IB98002, 15 September 1999.

[100]The act permits but does not require the researcher to protect a subject's privacy. "The Secretary [of Health and Human Services] may authorize persons engaged in biomedical, behavioral, clinical, or other research...to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals" (42 U.S.C. 241 [d]).

> FOIA would allow the government agency to remove obvious identifiers such as name, Social Security number, telephone number, but in a given data set it is quite feasible to identify subjects using other information. If the requestor knew a few items about an individual's history, such as place of birth, education occupation, marital history, or other general information, an individual could be identified. Such identification would then open up the whole research record, including personal medical information, to the requestor.[101]

A related concern of researchers is that potential volunteer human subjects, fearing that personal private information will not be protected, will be reluctant to participate in research projects. Experience over time will indicate whether the exclusions embodied in the term *research data* will resolve concerns about privacy and proprietary information.

What Will Be the Financial Benefits and Costs of Implementation?

Potential financial benefits associated with the Shelby amendment could result from savings from actions not required. Three kinds of costs are potentially associated with implementation: reimbursable costs, nonreimbursable costs, and costs associated with the litigation that could follow implementation. Each of them is discussed below.

Potential Benefits. The potential financial benefits of the amendment would be reflected in any net savings to the public and the private sector that could occur if implementation pursuant to Circular A-110 prevented agency actions having the force and effect of law if the benefits of the actions were determined incorrectly, or if the benefits did not justify the expense. This might include the net savings accruing from postponing or not imposing regulations or other standard setting requirements. These kinds of actions could result, according to some observers, in savings of billions of dollars annually.[102] It is also possible that wider public access to research data used in federal actions having the force and effect of law could facilitate public scrutiny and identification of errors, which, if corrected, might lead to improved federal actions and regulations. However, it is difficult to speculate about a range of cost savings in the absence of information about which actions might be subject to provisions of the law.

Reimbursable Costs. FOIA allows the federal government to recover reasonable costs of fulfilling requests, although reimbursements go to the Treasury, not to the agency that incurred the costs. The Shelby amendment and revision to Circular A-110 provided specifically for cost recovery, in addition to the normal reimbursement fees imposed upon the requestor for a FOIA request.

The February proposed revision to Circular A-110 did not indicate whether researchers and their universities or the federal agency would be reimbursed, or

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[101]Statement of Harold Varmus, M.D., Director, NIH, before the Subcommittee on Government Management, Information, and Technology Committee on Government Reform, 15 July 1999, p. 4.

[102]See footnote 13 above, statement of William Kovacs at hearings on H.R. 88, Regarding Data Available Under the Freedom of Information Act, 15 July 1999, pp. 2-3.

whether fees collected would go to the U.S. Treasury, as with reimbursements covered directly by FOIA. The second and final revisions said that agencies "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 an addition to any fees the agency may assess under the FOIA (5 U.S.C. 552(a)(4)(5))." The amendment itself is silent on whether the agency can retain the fee or whether it should go to the Treasury. However, the supplementary information attached to the second revision and the final revision explained that agencies may seek reimbursement from data requesters to reimburse the recipient and the agency for the costs of providing the data.[103]

Several objections were raised to the reimbursement provisions. *OMB Watch* said the proposed revision does not explain how reimbursement would occur if the agency fulfilling the FOIA request were not the grant-making agency or how to deal with reimbursement for the costs of providing data after a grant period was finished[104] and all funds had been expended.

Nonreimbursable Costs. Even though researchers may be reimbursed for maintaining and preparing data to satisfy FOIA requests, scientists have complained that FOIA access would substantially encumber researchers and universities with new responsibilities. According to the president of the National Academy of Sciences, "...federal research grantees are generally not well-equipped by inclination, training or experience to deal with the legal and definitional subtleties of 'data' and the bureaucratic responsibilities that go with being custodians of 'agency records' nor with the very substantial financial and administrative burdens of doing so."[105] In addition, some say that researchers who are likely to receive a request for information from an agency pursuant to FOIA would be forced to store and maintain their data in a form that could be understood. At the July 15 hearing on H.R. 88, NIH Director Varmus also testified that costs of centralizing and maintaining data could be staggering. In a letter to OMB commenting on the second proposed revision, he said, "The costs associated with providing data under this amendment are likely to be substantially greater than costs incurred to fulfill current FOIA requests" because of the expense of importing and exporting data sets, especially if software were custom-made for the research, and the costs of training agency FOIA officials to assess materials for exemptions, including "training in the substantive area covered by the research data as well as epidemiology and biostatistics."[106]

Some say that the provision will result in expansion of the federal bureaucracy because agencies are likely to have to create a new office to decide how to collect and

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[103]OMB, Proposed Revision, [August 5, 1999] August 11, 1999, p. 43791 and Final revision, [September 30, 1999] October 8, 1999, p. 54929.

[104] OMB Watch, "Analysis of the Second OMB Proposal Extending FOIA to Federal Grantees," August 20, 1999. Available at: [http://ombwatch.org/npadv/910comment.html].

[105]Letter from Bruce Alberts, President, National Academy of Sciences to the Honorable Jacob J. Lew, Director, OMB, January 16, 1999.

[106]"A-110: NIH Response to OMB," Memo to John Callahan, Assistant Secretary for Management and Budget from Director NIH, [August 1999], op. cit.

maintain research data and reimburse researchers. There may also be a need to create a central office at research universities to deal with FOIA requests forwarded by an agency.

Some have commented that much administrative work and researcher time will be needed to prepare data and any accompanying explanations for disclosure. The Federation of Behavioral, Psychological and Cognitive Sciences suggested that, to alleviate the costs associated with this possibility, federal agencies could "notify investigators whose work has been officially and publicly cited that their data meet the threshold for being subject to a FOIA request."[107] Then the institution could recover costs for the period during which data could be subject to FOIA. A similar suggestion of notifying researchers who need to retain data was made by NAS President Alberts in his letter to OMB on April 5. Some observers have said that the expenses to universities are likely to exceed the 26% cap on administrative costs as part of the indirect cost rate universities may charge as defined in OMB Circular A-21, "Cost Principles for Educational Institutions."[108] Therefore, universities would have to absorb the costs unless Circular A-21 were revised. In its second revision, OMB stated that it would consider such a revision and invited comments on costs. Supplementary information in the final revision said comments received on this issue focused on the need for a separate agreement between the awarding agency and the recipient to ensure reimbursement for the full incremental cost of responding. It explained a process that agencies might use and said that OMB would consider revising Circular A-21 if the process did not work.

Costs of Litigation. Another issue of concern focuses on the potentially large costs of litigation about implementation of the new rules as researchers, the government, the public, and interest groups seek to clarify the meanings of ambiguous terms and to determine whether agencies and funding recipients are complying appropriately, especially in those cases where requests are denied. Some complain that large amounts of money may be spent on lawsuits to deal with interpretations of specific cases.

How Might the Changes Affect Needed Research?

It is possible that the changes will have little impact on research. Agencies may determine that only a few actions having the force and effect of law cited or used grantee-generated research data that would be open to public access via the revisions to Circular A-110. In a September 10 letter to OMB, Senators Shelby, Campbell, Phil Gramm, and Lott said that although OMB's exclusion of business and personal information from its definition of research data that is maintained in the final revision

> ...may seem an innocent restatement of the FOIA exemptions, it creates a troubling outcome by allowing researchers and agency officials broad discretion to interpret these new exceptions outside of FOIA and the case law that has evolved under FOIA. Given that terms such as privacy and confidential business information are

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[107] Letter from David Johnston to F. James Charney, OMB, September 1, 1999.

[108] See archived CRS IB91095, "Indirect Costs at Academic Institutions: Background and Controversy; archived issue brief."

> highly subjective, the results could be disastrous for the public's ability to access important information. For instance, the main reason provided by research institutions for not releasing the raw data supporting the particulate matter epidemiology studies is the need to protect the privacy of the research subjects despite the fact that personal identifiers could be redacted. The OMB proposed revision should rely on the FOIA exemptions and the case law which have evolved over time in applying these exemptions rather than allowing ad-hoc and inconsistent decisionmaking....[109]

If there were only a few public requests for such data, neither researchers nor their institutions might experience any major changes resulting from the amendment. However, the amendment might stimulate more independent reanalysis of data, or methods used to evaluate data, from covered research. It may also inspire more efforts by researchers to explain the bases of their findings to the public. Or it may generate more public scrutiny of the content and quality of scientific and technical data used in making federal policies.

But some observers worry that costs, concerns about protection of personal and proprietary information, and the potential for abuse could inhibit scientists from performing needed research. As noted above, concerns have been raised that subjecting research data to FOIA will make human subjects reluctant to participate in studies (or, if they do, to provide sensitive medical and other information to the researchers), and will make some scientists reluctant to engage in research likely to be subject to FOIA requests. Some researchers say that study participants might refuse to participate if they know that the federal government would see personal data about them. There is also the view that despite privacy protections and the constraints on obtaining human subjects data that are in the final revision to Circular A-110, research would be compromised, since researchers would be obligated to inform study participants that the information they provide might not remain confidential and could be sent to the government.[110] According to NIH Director Varmus,

> Such intrusions could stop promising scientific research in its tracks, and the mere threat of such intrusions could impede the Nation's efforts to recruit its most talented students into publicly-supported research. For example, imagine what would happen if HIV-infected patients thought their condition might be revealed by someone using the new requirements to examine raw experimental data. Patients would not participate in clinical trials if they believed there was an opportunity for their infected status to be revealed. Progress toward treatment of the disease would be stymied.[111]

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[109]"Comments to OMB on Proposed Clarifying Changes to Circular A-110 Revision," Letter to Jacob Lew, Director, OMB, September 10, 1999, from Senators Sen Nighthorse-Campbell, Senator Richard Shelby, Senator Trent Lott, and Senator Phil Gramm, [http://www.senate.gov/~Shelby/press/prsrs283.htm].

[110]Views of Bruce Alberts, April 5, 1999 letter to OMB, pp. 13–14 . Similar views were expressed by Gary D. Bass, OMB Watch, in testimony before the House Committee on Government Reform, Subcommittee on Government Management Information and Technology, July 15, 1999, p 3.

[111]Ibid.

Some observers fear that the effort required to respond to FOIA requests and uncertainties about how the data would be used might inhibit the conduct of research likely to be subject to the provision. Some even fear harassment — that groups opposed to particular types of research will impose excessive data reporting requirements on them:

> [I]f FOIA is extended to research data, special interest groups could make data requests solely for the purpose [of] creating the costs and disruptions that are inherent in gathering extensive amounts of raw research data. Under FOIA, the requestor would be the agency, not the group leading the campaign. The University would be obligated to undertake extensive work and involve the time of the targeted researchers, which would be the intention of the action, as well as utilize limited resources and staff time in fulfilling these mandated requests.[112]

A third area of concern is that the various costs associated with implementation could inhibit research. Time spent by researchers on complying with FOIA requests could not be spent on research, and researchers might decide not to pursue a particular line of research if they fear that it is likely to lead to burdensome FOIA requests, or to involvement in litigation associated with such requests. If research institutions find the financial burdens associated with compliance too great, they might discourage scientists from pursuing research likely to generate FOIA requests. Also, if agencies fear that compliance with FOIA requests will be too burdensome, they might cite less research in developing regulations or support less research that would be likely to generate requests.

Additional Issues for Congress

Attempts have been made in the 106th Congress to modify or repeal the amendment. In addition, it is possible that Congress and OMB may exercise oversight of implementation of the law by the federal agencies. These activities are discussed next.

Representatives James T. Walsh and David E. Price offered an amendment to the Treasury Appropriations Bill for FY2000 to deny funds to implement the law pending further study, possibly by the National Academy of Public Administration. The amendment was defeated 25-33 in an Appropriations Committee vote on July 14, 1999.[113] Hearings were held by the Subcommittee on Government Management, Information and Technology of the House Committee on Government Reform on July 15, 1999, on a bill introduced by the late Representative George E. Brown, Jr., to repeal the law. Representative Brown's efforts began in December 1998, when 23 House members, including six Republicans, wrote a letter to OMB Director Jack Lew warning about "a number of negative unintended consequences." Among the cosigners were the chairmen of the House appropriations subcommittees for NIH and

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[112]Shelton, Hearing on H.R. 88, 15 July 1999.

[113]"Effort to Block Access to Research Findings Under FOIA Fails. Administration to Release Revised Regulation Soon," *Washington Fax*, July 15, 1999. See also: "Opponents of New Data Release Law Maintain Blocking Strategy If Passed, House Amendment Would Strengthen Research Argument," *Washington Fax*, June 16, 1999.

NSF, as well as Members from the House Science Committee. Representative Brown subsequently introduced H.R. 88, a bill to repeal the provision of the law on data access.[114] No further action has occurred. Representative Rush Holt has assumed leadership on H.R. 88, following Representative Brown's death.[115]

In a press release commenting on the final revision to Circular A-110, Senator Shelby described it as "still narrow in scope" but as a "good first step to giving the American people access to the research and science used in federal policies...."[116] Reportedly, a spokeswoman for the Senator commented that he "may look at the issue again in the future, depending on how federal agencies put the new rules into effect."[117] Similarly, the supplementary information attached to the final revision said, "As OMB and the agencies develop experience with the revised Circular, changes to the data access process may be considered. These could range from technical and clarifying changes to substantive revision or rescission. OMB also endeavors to review each of its Circulars every three years." [118]

Oversight activities could focus on such issues as

- whether or not the objectives of the law are being met, or whether, by virtue of the definition of *research data*, *published*, and so forth, and other limitations in the revision of the circular, the public is being denied access to research data cited or used in important agency actions that have the force and effect of law;
- whether or not the research process is being helped or hampered by implementation of the law;
- whether or not the formulation of public policy involving science and technology is being helped or hampered by implementation of the law;
- whether or not industrial funding of research in universities for cooperative government/university/industry projects is suffering because of fears that public access to federally funded data might release confidential industrial information;
- whether or not the conduct of research involving human subjects is suffering because of fears that human subjects' privacy and confidentiality is being compromised; and
- whether or not the reimbursable and nonreimbursable costs of compliance are excessive or burdensome to requesters, researchers, universities, and federal agencies.

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[114]Extension of Remarks of Hon. George E. Brown, Jr., *Congressional Record*, January 7, 1999, E32-E33. See also, Bruce Agnew, "Freedom of Information: Scientific Leaders Balk at Broad Data Release," *Science*, January 15, 1999, pp. 307-309.

[115]See, for example, "Rep. Holt Leads Bipartisan Attack on Science Regulations," News from Congressman Rush Holt, October 8, 1999, 2 p.

[116]"Sen. Shelby Comments on OMB Final Revision to Circular A-110," Press Release, Office of Richard Shelby, October 8, 1999.

[117]Kenneth Skilling, "OMB's Final Version of A-110 Changes Includes Wide Definition of 'Research Data,' " *Daily Report for Executives* 195, October 8, 1999, p. A-34.

[118]OMB, Final revision, [September 30, 1999] October 8, 1999, p. 54927.

While some scientists seek to make more data available to the public, they say that FOIA is not appropriate and that other mechanisms should be used to make data available to other researchers and the public. There also are suggestions to modify the way data is stored and to fund more accessible data-collection storage and retrieval databases for scientists and for the public. NIH Director Varmus cited a number of those data repositories in his letter to OMB, commenting on the August version of OMB's proposed revision to Circular A-110, including the Inter-University Consortium for Political and Social Research and the National Center for Health Statistics. Proposals could be introduced to provide funds for developing additional databases of this sort.

Calls to modify Circular A-110 may continue, involving such issues as

- limiting access even more — such as to agency actions that meet the $100 million threshold of cost or impact; [119]
- determining whether the applicability of the policy espoused in the Shelby amendment should be extended to both the Federal Acquisition Regulations (48 C.F.R. 1ff), which cover contracts, and Circular A-102, which covers grants and cooperative agreements with state and local governments; and
- requiring recipients to prepare a list of withheld data so that a requester can challenge the propriety of the recipient's decision to withhold data or to develop a way to appeal if a requester believed data were withheld inappropriately.[120]

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[119]For instance, "Robert Hahn, director of the joint Center for Regulatory Studies, and Linda Cohen, an economics professor at the University of California at Irvine, suggest tailoring access to the documents. They believe there should be access to the information that results in regulations that have significant economic impact—such as the EPA's 1997 ozone and particulate matter standard, which would make current air-pollution rules more stringent — and an independent agency should be created to replicate the results of research before any standard becomes final." (Cindy Skrzycki, "The Regulators; Data Disclosure; Business Wants to Breach a Stonewall," *Washington Post*, June 11, 1999, E01.) Dr. Hahn testified on these points at the July 15, 1999 hearing.

[120]"CRE Comments to OMB on its August 11, 1999 Reproposal," letter to OMB Sept. 10, 1999 [http://www.thecre.com/access/cretoomb.html].

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