

Public Access to Data from Federally Funded Research: Provisions in OMB Circular A-110

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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 did not require the data on which they are based to be made available publicly. Such policies did, however, generally require researchers to share data and physical samples with other scientists after publication of the research. A rider, often called the Shelby Amendment or Data Access Act, that was attached to the Omnibus Appropriations Act for FY1999, P.L. 105-277, mandated the Office of Management and Budget (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 chose to do so issued their own conforming rules. The final revision was published in the *Federal Register* on October 8, 1999, and has not been changed in subsequent updates to the circular.

The Shelby Amendment originated from disputes about access to research information used in federal regulations. It was a significant change from traditional practice, since, while permitted, federal agencies typically did 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 relating to published research findings produced under a federal award and used in developing an agency action that has the force and effect of law. Opponents of the amendment said that FOIA is an inappropriate vehicle to allow wider public access, since it would harm the traditional process of scientific research; human subjects would believe that the federal government might obtain access to confidential information; researchers would 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/industry partnerships would be jeopardized.

Proponents of the amendment said that accountability and transparency are paramount: The public should have a right to review scientific data underlying research funded by government taxpayers. Some proponents argued that the amendment would result in significant savings. Some also believed that the OMB revision narrowed the scope of public access to research data contrary to congressional intent. Senator Shelby said the final revision, "while still narrow in scope, is a good first step...." Legislative efforts both to repeal the provision and withhold funding for its implementation failed.

The data available for this report suggest that the provision has not been commonly invoked in FOIA requests. To the extent that is the case, it supports the assessment that neither the benefits nor the concerns raised have materialized to a significant degree. That might change if usage increased, but the continuing movement toward increased public access to the results of federally funded research that has occurred independently of the 1999 revision to Circular A-110 may make its use in FOIA requests increasingly unnecessary.

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The results of scientific studies are used in making many governmental policy decisions. While the studies are often published, the data on which they are based may not be, even for federally funded research. Before 1999, academic and nonprofit performers of such research were permitted but not required to make their data available to the public through provisions of the Freedom of Information Act (FOIA, 5 U.S.C. 552; see also CRS Report R41933, *Freedom of Information Act (FOIA): Background and Policy Options for the 112th Congress*, by Wendy Ginsberg). In October 1998, a provision in P.L. 105-277 changed that, requiring that such data be made publicly available (112 Stat. 2681-495). [1]

To implement the new requirement in 1999, the Office of Management and Budget (OMB) had to reconcile potentially competing public interests. On the one hand, the public has an interest in verifying the soundness of the science underlying policy decisions. That may require open access to data from government-funded research, especially if those data are used in developing federal regulations.

On the other hand, the public has an interest in ensuring that government-funded research is performed efficiently and effectively and that the rights of individuals involved in that research are protected. Requiring FOIA access to federally funded research could impose additional costs and other burdens on researchers and risk making information about individual research subjects public.

This report[2] provides background on the 1999 revisions to federal policy, a discussion of the impacts of those changes, and an analysis of the issues raised by them. The first section describes the basis for the legislative provision and how the resulting changes affected access to federally funded research data. Following that is a discussion of agency policies and examples of access, although information available on the impacts of implementation was limited.[3] The final section discusses issues raised by the changes and their current status.

[1] H.Rept. 105-825. The provision was a rider attached to the Treasury and Postal section of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for FY1999. It required that OMB amend section 36 (c) [intangible property] of Circular A-110, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations" (2 C.F.R. 215). Its principal sponsors were Senator Richard C. Shelby and Representative Robert B. Aderholt. The provision is sometimes called the Shelby or Shelby-Aderholt Amendment. It has also been called the Data Access Act. A 2001 legislative provision, called the Information Quality Act or the Data Quality Act, was included in the Treasury and General Government Appropriations Act for FY2001 (P.L. 106-554). It is sometimes considered a companion to the Shelby Amendment but focused not on access but how agencies ensure that data they disseminate is of appropriate quality for its use. The later provision is therefore not discussed in this report (but see CRS Report RL32992, *The Endangered Species Act and "Sound Science"*, by M. Lynne Corn, Kristina Alexander, and Eugene H. Buck, and CRS Report RL32240, *The Federal Rulemaking Process: An Overview*, coordinated by Maeve P. Carey).

[2] This is an update of CRS Report RL30376, *Public Access to Data From Federally Funded Research: OMB Circular A-110 and Issues for Congress*, by Eric A. Fischer and Genevieve J. Knezo. Changes from that report focus mostly on developments since the report was last updated, November 1999.

[3] Time and resource limitations prevented CRS from surveying agencies and other stakeholders about impacts. See the section on "Implementation of and Response to the Revisions"

Background

The disposition of records from federally funded research by academic and nonprofit institutions is governed by OMB Circular A-110, which applies 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 does apply to subawards to covered organizations, and "[f]ederal agencies may apply [it] to [grants awarded to] commercial organizations, foreign governments, organizations under the jurisdiction of foreign governments, and international organizations."[4]

OMB circulars are "[i]nstructions or information issued by OMB to Federal agencies [with an]… expected … continuing effect of two years or more."[5] OMB requires all agencies to observe the provisions of relevant circulars.[6]

Both before and after the 1999 revision, Circular A-110 had provisions on retention of and access to records, including data, pertinent to an award:[7]

- Records must be kept for a minimum of three years from the date an awardee submits the final expenditure report, and agencies must request transfer of records with long-term retention value to their custody.
- Unless required by statute, awarding agencies are prohibited from limiting public access to recipient records unless the agency can demonstrate that such records must be kept confidential and would have been exempted from disclosure by FOIA if they belonged to the agency.
- Agencies can also "obtain, reproduce, publish or otherwise use the data first produced under an award," and authorize "others to receive, reproduce, publish, or otherwise use such data for Federal purposes."

The P.L. 105-277 provision, commonly referred to as 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. Also, to the extent 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.

[4] 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," 2 C.F.R. 215 (May 11, 2004). Grants and agreements with state and local governments are covered by Circular A-102. The circular does not define record. However, FOIA defines it broadly as information in any format, not just written information (42 U.S.C § 552(f)(2)). However, that does not include "tangible, evidentiary objects" (Department of Justice. Office of Information and Privacy, Freedom of Information Act guide (Washington, D.C.: U.S. Govt. Print. Off., 2007), p. 61.

[5] Office of Management and Budget, "Circulars," 2013, http://www.whitehouse.gov/omb/circulars_default.

[6] Office of Management and Budget, "Circular No. A-1 Revised: Bureau of the Budget's System of Circulars and Bulletins to Executive Departments and Establishments," August 7, 1952, http://www.whitehouse.gov/omb/circulars_a001/.

[7] 2 C.F.R. §§ 215.36 and 215.53.

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.[8] 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.[9] Industry groups requested to review the data, but the researchers refused, 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 believed that better access was needed.[10]

The amendment's supporters said that 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

[8] According to Kathy Casey, who was then with the 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 Senate version of the 1999 Treasury and Government Appropriations Act, would have 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[ly] 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 S.Rept. 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"). This bill was incorporated into H.R. 4104 as an amendment. H.R. 4104 was passed in lieu of original S. 2312 (September 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 (H.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").

[9] 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. 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.

[10] "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.

implement and to comply with. Proponents argued that data access is important to ensure that regulations are well-supported scientifically and do not carry an undue burden.[11]

Those issues were not new,[12] 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*.[13] 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. The plaintiffs were a private organization of physicians who had 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. They 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 was 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) the data 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 FOIA, and held that the private grantee was not an agency subject to FOIA. The court also concluded that the required data were not agency records within the meaning of FOIA because the data had not been created or obtained by a federal agency;[14] and "FOIA applies to records which have in fact been obtained and not to records which merely could have been obtained."[15] 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.[16]

The legislative history of the Shelby 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 Senate adopted the amendment. However, in the 106th Congress, 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 have repealed 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

[11] See, for example, the statement of William L. Kovacs, U.S. Chamber of Commerce, hearing before the House Committee on Government Reform, Subcommittee on Government Management, Information, and Technology, *H.R. 88, Regarding Data Available Under the Freedom of Information Act*, 1999.

[12] 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.

[13] 445 U.S. 169, 179 (1980).

[14] "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.)

[15] Ibid., at 186.

[16] Ibid., at 180.

developing regulations. They also cited concerns about the adequacy of peer and agency review mechanisms to validate scientific data for setting regulations.[17] Opponents cited concerns about possible violation of the privacy of human subjects, risks to confidential proprietary information, misinterpretation of data, inhibitory effects on the research enterprise, and costs of compliance.[18]

Policies for Access to Data from Federally Funded Research Other Than Provisions in Circular A-110

Research performers funded by federal grants have long been required to provide the agency with grant completion reports and copies of publications resulting from the research. Agencies have also developed policies to encourage researchers to share their data with other researchers. However, agencies did not traditionally require researchers to provide the data used or collected to the federal agency that sponsored the research. Therefore, those data were not generally 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. That document is considered by many observers to have established the basis of policy for governmental support of, and accountability for, extramural, especially academic, research by grants.[19] 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.

Also in the postwar period, additional federal intramural laboratories were established to enable the conduct of applied or mission-relevant research, and private companies began research and development (R&D) for the federal government. In FY2009 about half of the $133 billion in federal funding for R&D was for research. More than three-quarters of the R&D funds were extramural—provided to nonfederal researchers. Universities were the single largest performer of

[17] 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 at the time—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, *Hearing on H.R. 88*.). 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, 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," ibid).

[18] 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, *Hearing on H.R. 88*.

[19] See Vannevar Bush, *Science, the Endless Frontier*, 1945, http://www.nsf.gov/od/lpa/nsf50/vbush1945.htm.

federally funded research, receiving half of research funds, and industry was the largest performer of development, receiving more than two-thirds of those funds.[20] In short, 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 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,* 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 research in progress.

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 acted as owners, and agencies permitted them to act as owners, of data in that they retain them and control access to them.

Over time, federal agencies 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. Several major research funding agencies—such as the National Science Foundation (NSF), the National Institutes of Health (NIH), 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.[23]

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[20] National Science Foundation, *Federal Funds for Research and Development: Fiscal Years 2009–11*, NSF 12-318, July 2012, http://www.nsf.gov/statistics/nsf12318/. FY2009 is the most recent year for which reliable data are available

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

[22] See also Adler, "Impact of FOIA," 1-3 and Alvin J. Lorman, Daniel R. Johnson, and Daniel F. O'Keefe, Jr., "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] See, for example, National Aeronautics and Space Administration, *Guidebook for Proposers Responding to a Nasa Research Announcement (NRA) or Cooperative Agreement Notice (CAN)*, January 2013, http://www.hq.nasa.gov/office/procurement/nraguidebook/proposer2013.pdf; National Institutes of Health, "NIH Data Sharing Policy and Implementation Guidance," March 5, 2003, http://grants2.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm; National Science Foundation, *Award and Administration Guide: Chapter VI - Other Post Award Requirements and Considerations*, January 2009, http://www.nsf.gov/pubs/policydocs/pappguide/nsf09_1/aag_6.jsp.

For instance, the 1994 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, required supported researchers "to make results and accomplishments of their activities available to the public,"[24] although there was no specific requirement with respect to data per se. However, NIH grantees and contractors were required 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.

In 2003, NIH released a policy on sharing research data, requiring grant applications for amounts over $500,000 to address data sharing. The final notice states that "NIH expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers."[25] The plan must take into account relevant privacy requirements and other laws and regulations, which require, for example, removal of personally identifiable information. NIH does not require that data be released while the research is in progress, but it must be made available by the time of publication of the main results from the data.

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 NSF National Science Board adopted a data sharing policy. In 1989, the findings of an NSF committee were incorporated into a written data sharing policy that appeared in NSF's grant and management documents. Since the 1990s, NSF grantees have been expected to promptly submit findings for publication, and to "share with other researchers, at no more than incremental cost and within a reasonable time, the primary data, samples, physical collections and other supporting materials created or gathered in the course of [the] work."[26] Grantees are also "encouraged to share software and inventions."

One prominent move toward increased public access was a statement of principles from an international group of genomics researchers in 1996. It called for freely available public access to all information on the human genome that was produced at research centers performing genome sequencing at large scales.[27]

Some nongovernmental science policy groups have also long advocated the disclosure of research data to other researchers after publication if disclosure is balanced by protections for privacy and intellectual property rights. In 1985, a report from the National Research Council states, "Data relevant to public policy should be shared as quickly and widely as possible, in time with public

[24] Public Health Service, Grants Policy Statement (PHS GPS 9505), Part 8, "Postaward Administration," April 1, 1994, available at http://grants.nih.gov/archive/grants/policy/gps/8postnew.htm.

[25] National Institutes of Health, "NIH Data Sharing Policy and Implementation Guidance."

[26] National Science Foundation, *Award and Administration Guide*.

[27] National Academy of Sciences, *Ensuring the Integrity, Accessibility, and Stewardship of Research Data in the Digital Age* (Washington, DC: National Academy Press, 2009), http://www.nap.edu/catalog.php?record_id=12615.

release and following appropriate review."[28] A 1998 statement of the three Academy presidents urged professional societies, academic leaders, and industry to develop clear and workable standards of open communication in scientific research.[29]

Presaging the public pressures that would come with the enactment of the Shelby Amendment, the Council on Governmental Relations (COGR), an association of research universities, issued a paper in 1996 urging senior university officials to develop policies 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."[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] AAAS requires that authors submitting articles for publication in *Science* make "all data necessary to understand, assess, and extend the conclusions of the manuscript … available to any reader of *Science,*" as well as all computer codes "involved in the creation or analysis of data." It also requires that large data sets be deposited in and made available through a repository. Various other professional groups, such as the American Sociological Association, the American Economic Association, and other scientific associations, developed policies encouraging or requiring sharing of data cited in articles published in their journals.[32] In 2009, the publishers of *Nature* adopted, as a condition of publication, a requirement of authors "to make materials, data and associated protocols promptly available to readers without preconditions."[33]

A 2009 Academy report presented a broad "Data Access and Sharing Principle: Research data, methods, and other information integral to publicly reported results should be publicly accessible."[34] The report goes on to recommend,

> All researchers should make research data, methods, and other information integral to their publicly reported results publicly accessible in a timely manner to allow verification of published findings and to enable other researchers to build on published results, except in unusual cases in which there are compelling reasons for not releasing data. In these cases, researchers should explain in a publicly accessible manner why the data are being withheld from release.

[28] Stephen E. Fienberg, Margaret E. Martin, and Miron L. Straf, *Sharing Research Data* (Washington, DC: National Academies Press, 1993).

[29] Bruce Alberts, Kenneth I. Shine, and William A. Wulf, "Actions Are Needed To Promote Research Sharing," Statement, September 8, 1998, http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=s09081998.

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

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

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

[33] Nature Publishing Group, "Availability of Data and Materials," 2009, http://www.nature.com/authors/editorial_policies/availability.html.

[34] National Academy of Sciences, *Research Data in the Digital Age*.

It also recommended that each research field have a set of standards for sharing data, developed through a process involving not only researchers and their institutions but other stakeholders, such as sponsors, journals, and public interest organizations.

Also in 2009, a report for the National Science and Technology Council by an interagency working group referred to digital scientific data as "national and global assets" and recommended the development of a structured approach to preservation of and access to such data throughout the life cycle of the data. It stated that "preservation and access capabilities are critical to the progress of individuals, nations, science, and society." The report recommended that agencies develop data policies "to maximize appropriate information access and utility and to provide for rational, cost-efficient data life cycle management."[35]

The America Competes Reauthorization Act of 2010 (P.L. 111-358) required the Director of the Office of Science and Technology Policy (OSTP), via a working group, to coordinate agency policies "related to the dissemination and long-term stewardship of the results of unclassified research, including digital data and peer-reviewed scholarly publications, supported wholly, or in part, by funding from the Federal science agencies" (Sec. 103(a)). The act required a report to Congress, which was submitted in March 2012.[36] The report summarized results of a Request for Information soliciting public input on public access to digital data. Responses showed broad support for increasing public access and requiring funding proposals to include data management plans. The report also stated that most federal agencies did not have policies on public accessibility for "data generated through Federal grants, cooperative agreements, and some other types of funding mechanism."

In a February 2013 memorandum to federal agency heads, the OSTP Director affirmed the Obama Administration's commitment "to ensuring that … the direct results of federally funded scientific research are made available to and useful for the public, industry, and the scientific community. Such results include peer-reviewed publications and digital data."[37]It requires federal agencies funding more than $100 million in R&D annually to develop and implement plans for increasing public access to data generated after the effective date of the memorandum from unclassified research funded at least in part by federal funds.

The Freedom of Information Act and Its Exemptions

FOIA provides a procedure for any individual to obtain access to information in records held by federal executive agencies.[38] 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):

[35] National Science and Technology Council, Interagency Working Group on Digital Data, *Harnessing the Power of Digital Data for Science and Society*, January 2009, http://www.nitrd.gov/about/Harnessing_Power_Web.pdf.

[36] National Science and Technology Council, *Interagency Public Access Coordination*, March 2012, http://www.whitehouse.gov/sites/default/files/microsites/ostp/public_access-final.pdf.

[37] John P. Holdren, "Increasing Access to the Results of Federally Funded Scientific Research" Memorandum for the Heads of Executive Departments and Agencies, February 22, 2013, http://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf.

[38] For more information on FOIA and other federal laws pertaining to information access, see CRS. CRS Report 97-71, *Access to Government Information In the United States: A Primer*, by Wendy Ginsberg; Department of Justice, "DOJ Guide to the Freedom of Information Act (2009 Edition)," 2009, http://www.justice.gov/oip/foia_guide09.htm.

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,[39]
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,[40]
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.[41] In many cases, agencies may make discretionary disclosures of exempt information "as a matter of good public policy."[42]

The exemptions do not include any specific "public interest" provision,[43] and the act "does not authorize withholding of information or limit the availability of records to the public, except as specifically stated." Also, some observers say that the courts have interpreted the exemptions narrowly, promoting disclosure.[44]

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.

[39] 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)).

[40] Exemption 7 has six qualifying subparts.

[41] 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."

[42] 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 1993).

[43] 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]).

[44] See, for example, 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.

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,"[45] 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.

Relevant State Laws

All states have laws on public access to government information.[46] Some laws provide broader access to information from nongovernmental researchers than the changes to Circular A-110 would allow, but others 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 children's privacy, but the researcher resigned his position and abandoned the line of research he had been pursuing.[47]

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.[48] 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."[49] The law also apparently allows researchers to negotiate directly with the requesting party to protect sensitive data.[50]

OMB's Revision 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, 1999, and provided a 60-day comment period.[51]

[45] 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).

[46] For information on various state statutes, see, for example, Sunshine Review, "State Sunshine Laws," 2013, http://sunshinereview.org/index.php/State_sunshine_laws.

[47] 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.

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

[49] California Government Code, sec. 6255.

[50] Testimony of Robert N. Shelton, Vice Provost for Research, University of California, *Hearing on H.R. 88.*

[51] Office of Management and Budget, "OMB Circular A-110, Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Non-Profit Organizations," Proposed Revision, (continued...)

After reviewing more than 9,000 comments, the agency published a second proposed revision on August 11, 1999, and provided an additional 30-day comment period.[52] Language in both the draft and final revisions arguably restrict the application of the term *data* more narrowly than in the Shelby amendment, which included "all data produced under an award" (**Table 1**). The first version would have applied only to data from research that had been both published and used in the development of policies or rules. The second was somewhat more restrictive; 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.).

The final revision was released on September 30, 1999, and published in the *Federal Register* on October 8, 1999.[53] 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 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.

The final revised circular became effective in November 1999. Federal agencies that subsequently issued conforming agency regulations allowed the public and interested parties to provide additional comment, as governed by the Administrative Procedure Act.

(...continued)

Federal Register, 64, no. 23 (February 4, 1999): 5684-5685.

[52] Office of Management and Budget, "OMB Circular A-110, Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations," Request for Comments on Clarifying Changes to Proposed Revision on Public Access to Research Data, *Federal Register*, 64, no. 154 (August 11, 1999): 43786-43791.

[53] 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," Final Revision, *Federal Register*, 64, no. 195 (October 8, 1999): 54926-54030.

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 in the Office of Management and Budget during the Bush and Reagan Administrations, and the Eagle Forum.[54] 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."[55]

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 NSF and NIH, the President of the National Academy of Sciences, and such groups as the American Association of Universities, and AAAS.[56] Opposition was reported also from the Pharmaceutical Research and Manufacturers of American (PhRMA), the Semiconductor Industry Association[57] and the Boston Chamber of Commerce.[58]

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 process, and (3) implement a public access process that will be workable in practice.[59]

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

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

[55] "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.

[56] See for instance, "Will FOIA Hold Science Hostage?" *Psychological Science Agenda,* May/June 1999, 1-3. See also AAAS and Federal Focus, "Briefing on OMB Revisions to Circular A-110 Regarding Public Access to Data," February 16, 1999, http://www.aaas.org/spp/dspp/sfrl/projects/omb.htm.

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

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

[59] OMB, Request for Comments.

Table 1. Comparison of Language Relating to Data Availability in the Shelby Amendment, and Proposed and Final Revisions of OMB Circular A-110

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 Proposed Revision of Circular A-110, February 1999	Second Proposed Revision of Circular A-110, August 1999	Final Revision of Circular A-110, September 1999
... 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 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	*[Identical to Second Revision]*
in developing policy or rules,	in developing a regulation,	in developing an agency action that has the force and effect of law,
the Federal awarding agency shall, within a reasonable time, obtain	the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time,	*[Identical to Second Revision]*
the requested data so that they can be made available to the public through the procedures established under the FOIA."	the research data so that they can be made available to the public through the procedures established under the FOIA.... *[Note: Additional text refers to fees]*	*[Identical to Second Revision]*
	(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	*[Identical to Second Revision]*
	publication of their results in a peer-reviewed journal, or	they are published, or
	information which may be copyrighted or patented; and	similar information which is protected under law; and
	(B) personnel and medical files and similar files	(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.	*[Identical to Second Revision]*
	(ii) Published is defined as either when: (A) research findings are published in a peer-reviewed scientific or technical journal, or	

(B) a Federal agency publicly and officially cites the research findings in support of	*[Identical to Second Revision]*
a regulation.	an agency action that has the force and effect of law.
(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).	(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.

Source: P.L. 105-277, OMB.

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."[60] 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[61](see **Table 1**).

Two attempts to repeal the Shelby Amendment failed. A proposed amendment to the Treasury, Postal Service, and General Government Appropriations Bill, FY2000, to withhold funding for implementation was rejected by the House Appropriations Committee (H.Rept. 106-231) during markup. H.R. 88, introduced January 6, 1999, would have repealed the amendment. Subcommittee hearings were held in July, 1999,[62] but the bill died in committee.

Within a few months after promulgation of the revision, 16 agencies had incorporated the revision either via a rule or other means.[63] Research institutions have also established procedures for responding to FOIA requests relating to the revision.[64]

Implementation of and Response to the Revisions

In general, as discussed in the section on "Policies for Access to Data from Federally Funded Research Other Than Provisions in Circular A-110," the trend in data sharing since the enactment of the revisions to Circular A-110 has been toward increased access. A commonly expressed concern about the Shelby Amendment was that resulting FOIA requests would create a substantial burden on researchers and even inhibit needed research. That concern did not appear to materialize in the years immediately following the change to the circular. The Government Accountability Office (GAO) reported in 2003 that during the first three years after the revision,

[60] OMB, Final Revision.

[61] Ibid. These are similar to FOIA exemptions 4 and 6.

[62] House Committee on Government Reform, Subcommittee on Government Management, Information, and Technology, *Hearing on H.R. 88*.

[63] Government Accountability Office, *University Research: Most Federal Agencies Need to Better Protect Against Financial Conflicts of Interest* GAO-04-31, November 2003, http://www.gao.gov/new.items/d0431.pdf.

[64] Carol Blum, *Access to, Sharing and Retention of Research Data: Rights & Responsibilities* (Council on Governmental Relations, March 1, 2012), http://www.cogr.edu/viewDoc.cfm?DocID=151888.

only two agencies, NIH and EPA, had received FOIA requests under the provision, but none of them met the criteria of the revision.[65] Of the 42 requests, 11 were for data from projects funded before the effective date of the revision. Data for seven were not available because the FOIA file had been destroyed under record-retention rules, and the remainder were either for information other than data or were withdrawn. Unfortunately, CRS could not locate any more recent such assessments. One study[66] found only two requests to EPA under the Shelby Amendment between 2002 and 2012, one for studies relating to the use of the chemical perchlorate and the other for an analysis of data on lead toxicity. Both were granted. One, relating to data on the health effects of lead, involved some litigation, but information on costs or other impacts were not presented.

While CRS could find no evidence of widespread FOIA requests under the Shelby Amendment or significant impacts, either benefits or costs, associated with its implementation, it is possible that such impacts exist but are not available in the public sources CRS had access to for this report.[67] Indeed, some observers claim that serious negative impacts have occurred on research relating to regulatory issues.[68] Therefore, any conclusions about use or impact of the amendment should be regarded as tentative.

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.[69] Opposition has focused 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.[70] Some have suggested that requests should meet a public interest test before data are released.[71] While a number of the early concerns expressed about the revision to Circular A-110 do not appear to have materialized, some discussion of the issues raised may be useful, especially in the event that the provision becomes more widely used.

[65] Government Accountability Office, *University Research*.

[66] Lynn R. Goldman and Ellen K. Silbergeld, "Assuring Access to Data for Chemical Evaluations," *Environmental Health Perspectives* 121, no. 2 (December 11, 2012): 149–152.

[67] In performing research for this update to the 1999 report, CRS searched legal, scientific, and technology databases, and publications of scholarly, library, and scientific research organizations for information pertaining to FOIA requests for public access to federal agency scientific research data. However, time and resource limitations prevented CRS from surveying agencies, researchers, and other stakeholders about impacts.

[68] See, for example, Wendy Wagner and Rena Steinzor, eds., *Rescuing Science from Politics: Regulation and the Distortion of Scientific Research* (Cambridge: Cambridge University Press, 2006). The editors claim that the Shelby Amendment has been one of the mechanisms "used strategically to intimidate researchers and delay or halt their research" (p. 290). However, they do not discuss any specific cases where such intimidation or impedance has occurred.

[69] Testimony of James T. O'Reilly, University of Cincinnati College of Law, *Hearing on H.R. 88*.

[70] Testimony of Robert N. Shelton, University of California, and Bruce Alberts, President of the National Academy of Sciences, ibid.

[71] "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.).

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 has made the desired information available to the public,
- whether the procedures established adequately protect proprietary information and the privacy of human subjects,
- what the benefits and costs of fulfilling the provisions are, and
- how the changes affect the research process.

Has the Revision Made the Desired Information Available to the Public?

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

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

Did 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 was narrower than that in the legislative provision (**Table 1**). 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 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.[72] However, those Senators cosigned a letter of April 5, 1999, to OMB Director Lew criticizing the narrow approach of OMB:[73]

> 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.

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

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

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.'"[74]

In response to comments that application only to data directly related to regulations narrowed access contrary to congressional intent,[75] 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."[76] 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.

What Data Are Made Available to the Public?

The amendment said that FOIA would apply to "all data produced under an award," but did not define the word *data*. The first and second proposed OMB revisions were more restrictive than the language of the amendment (see **Table 1**). The first version used, but did not define, data. The second and final revisions did so.

Many in the scientific community expressed concern about how the term 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 defined 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.[77]

In their April 5, 1999, letter to then-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 1**. The definition focused on recorded factual material needed to validate research findings, and specifically excluded several other kinds of information and materials, including

[74] OMB, Circular A-110, Final revision.

[75] Ibid.

[76] Ibid.

[77] 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).

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,"[78] OMB retained them in the final revision. One exclusion, related to Exemption 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 submitted records 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 ...)."[79]

Some observers have argued that limiting public access to data from federally funded research may create imbalances in public debate about federal actions that fall under the Shelby Amendment in those cases where research funded by industries and other private-sector entities is also used. Data from such privately funded research would not be available under the revisions to Circular A-110. One suggested means of addressing an imbalance would be to expand the reach of the Shelby Amendment to cover all research used in such actions, whether federally or privately funded.[80] However, such a proposal would likely raise issues about the limits of federal authority and the applicability of the various FOIA exemptions that could be difficult to resolve.

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.

[78] "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.

[79] OMB, Circular A-110, Proposed revision.

[80] Wagner and Steinzor, *Rescuing Science from Politics*, op. cit.

Furthermore, the materials must 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.

Examination of funding sources indicates that only a small proportion of federally funded R&D is potentially covered by the revisions to Circular A-110. Much of the scientific activity that Circular A-110 covers is basic research.[81] Most basic research data is not 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. In addition, the continuing broad movement toward increasing public access to research data may eventually make the circular revision largely obsolete.

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 believed at the time that much research used in developing "agency actions that have the force and effect of law" would still not be accessible to the public. That is because Circular A-110 does not cover contracts, which agencies must use if procuring services,[82] 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 cover 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 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.[83]

[81] For data, see National Science Foundation, *Federal Funds for Research and Development: Fiscal Years 2009–11*.

[82] "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).

[83] 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.

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 the word *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, 1999, 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 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."[84]

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 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."[85] 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.[86]

Another question still troubling to some, despite the language of the final revision, was what impacts public access would 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[87] and scientists have traditionally been reluctant to make data public until they have had an opportunity to analyze them fully and publish the results. After data become publicly available, others might use them to publish analyses before the original researchers have the opportunity to do so.[88] Once again, however, the broad move toward increasing public access appears to be reducing such concerns.

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[84] 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.

[85] "Analysis of the Second OMB Proposal Extending FOIA to Federal Grantees," *OMB Watch*, August 20, 1999.

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

[87] Copyright law does not protect facts or discoveries. See, for example, CRS Report 98-902, *Intellectual Property Protection for Noncreative Databases*, by Dorothy M. Schrader and Robin Jeweler, September 15, 1999.

[88] "Analysis of the Second OMB Proposal Extending FOIA to Federal Grantees," *OMB Watch,* August 20, 1999.

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.[89]

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. Typical comment periods for regulations are 30, 60, or 90 working days, although longer periods may be provided for complex rules.[90] 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.[91] 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 the agencies gain experience with the public access process, we may be able to develop further clarification on this point."[92]

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.[93] Thus, if the researcher kept records subject to the new circular for

[89] 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.

[90] 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).

[91] 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."

[92] OMB, Circular A-110, Final revision.

[93] The circular requires retention of "[f]inancial records, supporting documents, statistical records, and all other records (continued...)

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.

Questions arose about who—whether the university or the researcher—should be the custodian of the data. Some funding agencies have responded by requiring that applicants for research funding submit data management plans that include custodianship.[94]

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 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 decision-making. 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.[95] 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 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 has also been 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

(...continued)

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."

[94] See also the discussion of stewardship in National Academy of Sciences, *Research Data in the Digital Age*.

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

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 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."[96] 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.

[96] Center for Regulatory Effectiveness (CRE), "Enhancements to the Scientific Enterprise," 1999, online document no longer available.

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

Some opponents of the amendment said 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.

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 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."[97]

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.[98] Also, the submitter of information may challenge its release through a reverse FOIA lawsuit.[99]

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[97] OMB, Circular A-110, Final revision.

[98] See, for example, Center for Regulatory Effectiveness (CRE), "Intellectual Property Protection," 1999, online document no longer available.

[99] 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 (continued...)

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."[100] There is also the view that some partnerships that include federally funded researchers "make strict requirements on the researcher not to share data further. Without such agreements, private researchers would not participate in these partnerships."[101] 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.[102]

He also said foreign governments would obtain data from federally funded basic research for use in their own R&D.[103] There was 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?"[104]

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."[105] "[T]here are well-understood exemptions that serve to protect data that are important to universities for scientific or commercial reasons," according to COGR.[106] 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 been addressed in specific substantive laws."[107]

(...continued)

other relevant statutes (Department of Justice, Freedom of Information Act Guide, September 1998).

[100] OMB, Circular A-110, Proposed revision, citing statement of Senator Campbell, *Congressional Record*, v. 144, October 9, 1998, p. S12134.

[101] Statement of Director Varmus, *Hearing on H.R. 88*.

[102] Statement of Dr. Alberts, ibid.

[103] Ibid.

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

[105] 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.)

[106] Ibid.

[107] *Hearing on H.R. 88*.

Nevertheless, others 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."[108] As with a number of the other concerns originally raised, there appears to be no evidence that the anticipated problems have in fact occurred to any significant extent.

Protection of Personal Information About Volunteer Human Subjects

Many scientific studies involve volunteer human subjects. Concerns about protecting the privacy of those subjects has continued to increase 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.[109] Many observers continue to believe that protections for personal medical and health information (collected during medical treatment as well as during scientific research) are inadequate generally, and Congress has enacted legislation to address such concerns.[110]

The exclusion of certain personal information in the circular's definition of research data is intended to protect against unwarranted invasions of privacy. FOIA Exemption 6 provides additional protection. 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 "The Freedom of Information Act and Its Exemptions" above). Therefore, some observers fear that information that a human research subject was told was confidential might become public.

Some have also 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 then-NIH Director Varmus,

> 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.[111]

A related concern of researchers was that potential volunteer human subjects, fearing that personal private information will not be protected, will be reluctant to participate in research projects. However, no evidence of such changes in participation were identified.

[108] CRE, "Intellectual Property Protection," op. cit.

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

[110] See, for example, CRS Report R40161, *The Health Information Technology for Economic and Clinical Health (HITECH) Act*, by C. Stephen Redhead.

[111] Statement of Harold Varmus, M.D., Director, NIH, *Hearing on H.R. 88*.

What Are the Financial Benefits and Costs of Implementation?

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.[112] 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, the use of the access provided by the revision to the circular does not appear to have been frequent enough to determine what savings might have accrued.

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 1999 proposed revision to Circular A-110 did not indicate whether researchers and their universities or the federal agency would be reimbursed, or 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 Shelby Amendment itself was 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 of the circular explained that agencies may seek reimbursement from data requesters to reimburse the recipient and the agency for the costs of providing the data.[113]

Several objections were raised to the reimbursement provisions. OMB Watch said the proposed revision did 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[114] and all funds had been expended.

Even though researchers may be reimbursed for maintaining and preparing data to satisfy FOIA requests, some scientists complained that FOIA access would substantially encumber researchers and universities with new responsibilities.[115] Some also said that the provision would result in expansion of the federal bureaucracy and overhead at research universities to deal with FOIA requests forwarded by an agency. Another issue of concern focused on the potential costs of litigation about implementation.

[112] See statement of William Kovacs, ibid.

[113] OMB, Circular A-110, Proposed Revision; OMB, Circular A-110, Final revision.

[114] OMB Watch, "Analysis of the Second OMB Proposal Extending FOIA to Federal Grantees," August 20, 1999.

[115] Letter from Bruce Alberts, President, National Academy of Sciences to the Honorable Jacob J. Lew, Director, OMB, January 16, 1999; "A-110: NIH Response to OMB," Memo to John Callahan, Assistant Secretary for Management and Budget from Director NIH, August 1999.

Some commented that much administrative work and researcher time would be needed to prepare data and any accompanying explanations for disclosure. Some observers said that the expenses to universities would likely exceed the 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." 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. As with other claims and concerns near the time of the revision, there appears to be little evidence of such impacts to date.

How Might the Changes Affect Needed Research?

In a September 10, 1999, 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 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....[116]

If there were only a few significant public requests for such data, as appears to be the case, neither researchers nor their institutions might experience any major changes resulting from the amendment. However, proponents thought that the amendment might stimulate more independent reanalysis of data, or methods used to evaluate data, from covered research, and that 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.

Conclusion

The Shelby Amendment was controversial at the time of enactment, but both claims of benefits and concerns about negative impacts do not appear to have materialized. The broader movement by federal funders, researchers, and other stakeholders toward increased public access to data from federally funded scientific research may have contributed to the apparently low impact of

[116] "Comments to OMB on Proposed Clarifying Changes to Circular A-110 Revision," Letter to Jacob Lew, Director, OMB, September 10, 1999, from Senators Nighthorse-Campbell, Richard Shelby, Trent Lott, and Phil Gramm.

the amendment. The extent to which the amendment's enactment influenced that trend could not be determined. While many of the issues raised, although of historical interest, may seem moot or otherwise resolved at present, a significant increase in FOIA requests under this provision might revive them in the future.

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