

Access to Research Data through the Freedom of Information Act (FOIA)

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The scientific community was caught unaware in late October 1998 when the voluminous Omnibus Budget Bill, passed by Congress in its final days of session, included two brief but sweeping sentences that called for public access to all data produced under Federal funds, using the Freedom of Information Act (FOIA) as the vehicle.(1)

This paper examines the political background that generated this statute, the the rule-making process in the Office of Management and Budget (OMB), the influence of extensive and aggressive public comment, and OMB's final publication of new rules granting access to certain research data through FOIA. Given the scope of the statute and the focused modification of federal grant requirements, the tenure of OMB's approach is regarded as uncertain.

I. Background

The Freedom of Information Act, passed in 1966, requires the government to provide its records to the public upon request. (2) Under FOIA, "agency records" must be disclosed unless covered under one or more of the nine exemptions that are specified in the law. There are no limitations governing who can make FOIA requests.

In a key decision in 1980, the Supreme Court ruled that a federal agency is not required under FOIA to make available research data funded by that agency if the agency does not have actual possession of the data. (3) While a grant term may stipulate that the granting agency has the right to request the data, data are not a "federal record" for FOIA purposes. From a refusal to share research data rose the political impetus to find a mechanism to have Federally-funded research data available for public scrutiny.

For over twenty-five years Harvard University scientists have been engaged in a massive longitudinal study (called the "Six Cities Study") tracking health/mortality data. Harvard's analysis supported a strong relationship between public health and atmospheric pollution, forging the lynch pin of the EPA's proposed updated clean air standards.

Smoke-stack states and industries were in favor of more relaxed clean air and water requirements, asserting that the data upon which EPA based its standards were flawed and should be re-examined by industrial scientists. By challenging the interpretation of the Six Cities data, those interested in lowering EPA proposed standards hoped to delay the implementation of the new standards. The EPA did not have the study data in its possession and neither did NIH, which had funded much of the data collection for the Six Cities Studies. Harvard University researchers refused requests from EPA to provide the data based on assurances of confidentiality that had been promised to study participants. Unless the Forsham decision (3) could be overturned, the agencies did not have the right to obtain and retain research data that could then be accessible under FOIA.

Senator Richard Shelby (R-Alabama) publicly had expressed his concern about the estimated \$40-\$150 billion cost to industry of the proposed EPA standards. He suggested that in the absence of availability of the study data that EPA had cited in promulgating its standards there was no public accountability of the government-funded researchers. In the hurried workings at the end of October, Senator Shelby inserted two critical sentences into Public Law 105-277. The new law directed OMB to amend OMB Circular A-110 *Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations* "to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act." Agencies were also given the opportunity to recover their administrative costs in obtaining and providing the data. These sentences are generally described as the Shelby Amendment (4).

Initial Reactions

In recent years researchers' accountability and the public's right to know has spurred growth in congressional regulations for federally funded research, including scientific integrity and financial conflict of interest. Supporters of the Shelby Amendment argued that providing access to data assures an opportunity for validation, re-interpretation and accountability. These goals seem worthy and even beneficial but, raw data may also be misleading, misinterpreted and dangerous for both scientists and the public. In a letter to OMB Director Lew the president of the Association of American Medical Colleges expressed the sentiment of many academics that "although the intent of the legislation is appealing at first reading, ... (it) fails to recognize the complexity of the research process and the nature of research data themselves." (5) The letter suggested that as the legislative language was inspired by federal rulemaking so access to research data should "be confined to research data that form the basis for regulations or other federal rulemaking." The letter also raised the cost burden to the grantee community. Cohen's letter did not comment on the additional burden on researchers' time and productivity that such responses to agency requests for data were certain to command.

II. OMB's Proposed Implementation

When OMB published its proposed implementation in the Federal Register February 4, 1999, the sweeping statutory language was narrowed to "published" data used in "developing policy or rules." (6) However even OMB's wording raised questions in the absence of key definitions of terms. The research community's anxiety was directed to the choice of FOIA as the tool to access data held by grantees. (7) The exemptions of FOIA were presumed by congressional supporters of the Shelby amendment to assure that inappropriate release of data would be suppressed. It is not at all clear that these exemptions would protect intellectual property of researchers, assure obligations of confidentiality already promised to human subjects, or protect the confidential information shared with collaborators on research funded in part through federal support. No FOIA exemption appeared to protect organizations that may have divulged privileged institutional data in exchange for commitments of confidentiality. In any event, confidentiality would be breached in the process of data transmission from the grantee to the agency. The cost to the grantee of responding to the agency's request was not addressed in OMB's proposed rule-making.

Significant Agency Responses

The National Science Board issued a statement on the sharing of research data that urged the repeal of the Shelby amendment. (8) NSF reminded OMB that it already had a publicly accessible data-sharing policy: it expects researchers to publish and share data and supporting materials. NSF was deeply concerned that the government-university-industry partnerships it had strongly advocated could be soured. NSF feared that productive, innovative scientists would steer away from federal research support, which could impede the development of new technologies. (9)

NIH posted a lengthy discussion paper on its website examining through model research scenarios many of the concerns and questions raised by the use of FOIA as well as OMB's implementing language. NIH reminded OMB that fees collected from FOIA administration went to the U.S. Treasury so that the financial burden of managing data access through FOIA would be the agency's.

Research Community Responses

The community's comments reasoned that any implementation had to balance the integrity of scientific inquiry with public accountability. The dangers of sharing preliminary data and the disruption of industrial collaborative research were common points. Access by foreign competitors to federally funded research could also result in a loss of competitive advantage, both scientific and economic. Letters to OMB from the Council on Governmental Relations, the American Association of Universities, the National Academy of Sciences, and the American Association of Medical Colleges sounded consistent themes of deep reservation with FOIA as the appropriate tool, the adequacy of protection of sensitive information under the exemptions as currently available in FOIA, the distractions of nuisance challenges designed to discredit scientists, and the burdensome costs both to scientific productivity and grantee institutions. (10)

Senate Leadership Response

In a letter to OMB of April 5th, Senators Shelby, Nighthorse-Campbell, and Lott commented about the deficiencies in OMB's proposed narrowing of the intent of the statute.(11) The authors wanted OMB to assure that if pre-publication data had been used to support a federal rule or policy then "such data should be able to bear public scrutiny and disclosure." The Senators believed that academics' concerns about privacy of research subjects were unfounded based on agency experience to date with FOIA but that even if such problems arose they should be addressed through amendments to FOIA.

Corporate Responses

Burdened with the cost of compliance with EPA's clean air standards and concluding that EPA had been overzealous in its proposed strict standards, industries were enormously pleased with Shelby's amendment. On March 23, the Chamber of Commerce posted a 'call to action' on its website.(12) The site says, "if implemented properly this rule will do more for regulatory reform than all the legislation passed in the last 10 years. [It] ...will allow the public to challenge the agency based on the facts as determined by the research, not just on the information the agency selects as appropriate to support its policy position. With such data in public hands, agencies will have a much harder time imposing regulations on the business community without substantial evidence." The website described how challenges to a wide variety of data underlying various EPA policies could be used to slow down or actually eliminate such regulations, extending to all areas of federal regulation.

The Press Weighs In

The contentious dialogue between researchers and companies attracted considerable press attention. A *Washington Times* editorial said, "OMB should insist on releasing tax-funded scientific data from its regulatory fetters."(13) AAAS suggested that the should not only support sound science but also that "Congress should hold hearings in the light of day so that all interests are openly discussed ...providing public access to data while ensuring the continued flow of benefits from scientific research" (14) The *Los Angeles Times* urged OMB to find a balance, saying "The White House should find a middle course, implementing Shelby's law in a way that encourages freedom of information while not jeopardizing patent and privacy rights."(15)

In an editorial of June 7th, 1999 the *Wall Street Journal* described the scientific community's concerns about access to raw data and the potential for harassment, concluding that "if scientists [have] 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 way those results are used."(16)

III. OMB's Response to Comments

In August of that year, OMB published a second version of implementing regulations.(17) OMB's response examined case law governing FOIA and access to federally funded research in the process of responding to concerns about the potential for the FOIA exemptions to provide protections for research data. The revised regulations expanded A-110 to confirm that the government has the right to obtain research data from grantee organizations in response to a FOIA request under certain definitions and circumstances. OMB defined "data" and "published" but ultimately the key to access was tied specifically to that data "used by the federal Government in developing policy or rules."

In developing its definitions, OMB concluded that some limitations of access were necessary to assure the integrity of the research process. Access to data should not disrupt the research process by forcing premature release of data before a study is completed; but if data are sufficiently sound to support a federal policy or rule, then they should be able to bear public scrutiny and disclosure.

OMB also raised several questions regarding the financial burdens such FOIA requests would impose on Federal agencies, their recipients, and applicable subrecipients in carrying out the proposed revision. OMB sought comment about the mechanisms available to recipients to charge to their awards the costs that they would incur.

Response to OMB's Revised Regulations

The scientific and university communities received OMB's second version of implementing regulations with general satisfaction.(18) Limiting access to data used by the federal government in regulation and rule making excluded most basic research data from FOIA access. Typical comment letters from the research community described the proposed regulations as the best implementation of a poorly considered law (19)

Responses to OMB's call for comment about the cost of response to a FOIA request typically noted that these costs and unpredictable. They concluded that only a fee structure based on the specific FOIA request offered the opportunity for reasonable reimbursement.(20)

OMB's Final Regulations

OMB's final revision, published in the October 8th Federal Register, confirms the applicability of access to data produced with federal support that are "used by the Federal Government in developing an agency action that has the force and effect of law."(21)

Scientists should be familiar with key definitions and parameters of the public's new FOIA rights.

"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 analysis, drafts of scientific papers, plans for future research, peer reviews, or communication with colleagues. This "recorded" material excludes physical objects (e.g. laboratory samples). Research data also do not include:

- (A) *Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published or similar information which is protected under law; and*
- (B) *Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.*

"Published" is defined as either when "(A) Research findings are published in a peer-reviewed scientific or technical journal; or (B) A Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law. "

No FOIA request for research data is governed by this new rule unless the data has been cited in support of an agency action that has the force and effect of law, and any such data has to have been produced since the effective date of the new rule.

V. Agency Implementation

On March 16, 2000, the agency implementation was published in the *Federal Register*.(22) Agencies adopted OMB's language essentially verbatim. The new rules apply only to new awards and continuation awards made after the effective date, April 15, 2000.

Since NSF incorporates A-110 by reference into its Grant Conditions-1(GC-1) (and NSF was satisfied with the final OMB implementing language), it was effective as stated in the Federal Agency, i.e. November 8, 1999.

NIH which has consistently been opposed to a broad-based interpretation of the Shelby Amendment, has been the leading grant funding agency to advise scientist and grantee organizations of the impact of the new A-110 rules. NIH posted guidance on its web site <http://www.nih.gov/grants/oer/htm>, reviewing the definitions and providing an overview of the FOIA process (23)

The burden to agency FOIA offices, agency program staff and grantee institutions and researchers is a serious problem. Cost reimbursement is a complex matter for all the involved parties. How are fees calculated and recovered? How are fees paid to agency distributed? No guidance is currently available on this subject.

VI. Challenges to the Regulations

The *Boston Globe* reported that William Kovacs, vice president for environmental and regulatory affairs at the Chamber as saying "OMB decimated the congressional intent by limiting the information that has to be made available." (24) Many believe that eventually OMB's narrow interpretation of the statutory language will be litigated. Should EPA, DOT or other agencies introduce new expensive regulations for clean air, clean water, auto emission or other transportation safety measures, and the affected parties are denied access to underlying research data, the challenge would be inevitable.

If or when that happens, and if OMB's regulations were to be overturned, the debate over the rule-making process would begin again.

VII. Prospects for Grantee Organizations/Researchers

Some researchers are already concerned about direct requests from public groups or private corporations in anticipation of such inquiries being allowable through FOIA. Scientists are advised to refer any inquiries to institutional research administrators, legal counsel or other senior administrative officials before sharing any data. (24) When FOIA requests are legitimate, they will come to the scientist and the grantee organization from the Federal agency that supported the research, not the public requestor.

Institutions are advised to develop data retention, sharing and usage policies. Such policies should provide guidance to investigators and research staff about the institution's expectations in these critical areas. Case studies about what kind of research may have regulatory impact should be developed and disseminated to. Studies with obvious links to public policy, such as harmful drugs, atmospheric pollutants, auto safety, gun control, are likely candidates. PIs whose work has been cited by government agencies in past rule making may be good resources to research colleagues as data retention policies are evaluated and implemented.

Clear and direct policies for responsible data maintenance will assist researchers and grantee organizations in complying with future A-110 requirements and FOIA requests for data. Scientists should be careful to retain data in formats with appropriate documentation, to archive data or to place data in other publicly accessible forums, facilitating reasonable access, without excessive financial and productivity consequences. Support for these data options is an allowable direct cost in a grant budget.

FOIA Officers at federal agencies should be considered a resource for administrators. They have been managing the FOIA process for many years and have experienced counsel to offer about how the law is interpreted.

Conclusion

As long as FOIA is the vehicle for access, grave reservations about the disruption of research productivity within Federal grantee organizations will persist. This is likely to be a long and contentious process involving the definition and redefinition of public policy. Increased public accountability and access to research data are inevitable. The path, however, is still convoluted and quite muddy with no evidence of a viable alternative to FOIA.

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References

1. 1998 Shelby Amendment to the Treasury Omnibus Bill (PL 105-277):
"Provided further that the Director of OMB amends Section .36 of OMB Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act: Provided further, That if the agency obtaining the data does so solely

at the request of a private party, the agency may authorize a reasonable user fee equaling the incremental cost of obtaining the data:.....

2. Freedom of Information Act (5 U.S.C. section 552). FOIA exemptions are discretionary in that an agency can choose to release records even after it has determined the record falls within one or more of the exemptions. Individual research funding agency FOIA rules indicate how that agency has interpreted the exemptions. Links to agency FOIA web sites can be found at <http://www.usdoj.gov/foia/other-age.htm>
3. FORSHAM v. HARRIS, 45 U.S. 169, 63 L.Ed. 2d 293, 100 S.Ct. 978 (1980)
4. OMB Circular A-110 implements agency obligations for the administration of grants and cooperative agreements. The Shelby amendment directed that A-110 be modified to require access by agencies to grant-funded research data through FOIA. A-110 has no applicability to contracts. Federal Acquisition Regulations governs contracts, including access and retention to data developed under federal contracts.
5. Jordan J. Cohen, M.D. on behalf of American Association of Medical Colleges, letter to OMB Director Jacob Lew, December 9, 1998.
6. Federal Register, 1999, 64, 5684-85.
7. Science, 2/19/99, "Public Access to Data," page 114, editorial by Mark Frankel; C&E News, April 12, 1999, "Research Data Disclosure," L. Raber.
8. "On Sharing of Research Data", Statement of the National Science Board, adopted February 18, 1999 at the NSB's 352nd meeting in Los Angeles, CA.
9. Rita Colwell (Director of NSF) letter to OMB Director Jacob Lew, February 22, 1999
10. Milton Goldberg, on behalf of Council on Governmental Relations, letter Mr. F. James Charney, OMB, March 17, 1999; Bruce Alberts, President, National Academy of Sciences, letter to F. James Charney, OMB, April 5, 1999. Jordan Cohen, American Association of Medical Colleges, letter to F. James Charney, OMB, March 24, 1999; American Chemical Society, Science & Society Project, "Regulatory Issues: Access to Scientific Information" June 8, 1999. Mark Frankel, Charles Fromm (Center for Regulatory Effectiveness), MES, Joanne Tornow AAAS Fellow, OSTP
11. U.S. Senators Richard Shelby, Ben Nighthorse-Campbell, and Trent Lott, letter to Jacob Lew, OMB, April 5, 1999.
12. U.S. Chamber of Commerce/GAIN (Grassroots Action Information Network) web site. <http://www.uschamberoorb/policy/6-environment/issues/737/ac990323.htm> "Secret Science," Washington Times, February 11, 1999
13. "Give the Release of Research Data a Second Look," Mark Frankel, Washington Times, February 22, 1999
14. "Finding Research Balance" Los Angeles Times Editorials 2/27/99
15. "Science's Belated Complaint" Wall Street Journal, Editorial, June 6, 1999. (and in response "Scientists Need Privacy Too," Thomas J. Price, Executive Director, American Association of Engineering Societies, Letter to the Editor, Wall Street Journal, June 28, 1999)
16. Federal Register, 64 43786-43791, August 11, 1999, Request for Comments on Clarifying Changes to Proposed Revision on Public Access to Research Data.
17. Milton Goldberg, Council on Governmental Relations, letter to F. James Charney, OMB, September 1, 1999; Robert Zimmer, University of Chicago, letter to F. James Charney, OMB, September 8, 1999; Jack Lowe, Cornell University, letter to F. James Charney, OMB, August 31, 1999.
18. U.S. Senators Ben Nighthorse-Campbell, Trent Lott, Richard Shelby and Phil Gramm, letter to Jacob Lew, OMB, September 10, 1999.
19. COGR letter *vide supra*
20. Federal Register, October 8, 1999 64, 195, 54926-54930, Final Revision to OMB A-110, - .36 Intangible Property, required by provision contained in Public Law 105-277.
21. Federal Register, 65, March 16, 2000 Agency Implementation of A-110
22. Susan Cornell, Freedom of Information Officer, NIH, in presentation "Public Access to Research Data: recent Changes to OMB Circular A-100 and the Freedom of Information Act (FOIA), National Council of University Research Administrators National Meeting, Washington, D.C., November 6, 2000
23. "Suit likely over Research Done with Federal Funds" Aaron Zitner, Boston Globe, 12/10/00 page D01
24. American Physical Society, March 21, 2000. Invited Paper "Public Access to Federally Funded Research Data: How New Freedom of Information Act Requirements Affect Academic Researchers" Mary Ellen Sheridan Session E5: Physics and the Law.