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Data Wars: How Superseding *Forsham v. Harris* Impacts the Federal Grant Award Process

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I. INTRODUCTION

In 1997, the Environmental Protection Agency (EPA) tightened its standards for air quality control based on the findings of Harvard's School of Public Health's Six Cities Study.[1] Consequently, new air quality standards imposed large financial burdens on certain industries.[2] Scientists and other interested parties from General Motors (GM), the Chemical Industry Institute of Technology (CIIT), the Air Quality Standards Coalition (AQSC),[3] and Congress, requested that the EPA release the Harvard data for

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1. George D. Thurston, *Mandating the Release of Health Research Data: Issues and Implications*, 11 TUL. ENVTL. L.J. 331, 335 (1998). The Harvard Six Cities Study was a longitudinal epidemiologic study that began in 1974. The study examined the effects of ambient sulfur oxides and particulate matter on the respiratory systems of children and adults. The study participants were selected from the following six cities: Watertown, MA; Harriman, TN; Steubenville, OH; St. Louis, MO; Portage, WI; and Topeka, KS. Frank E. Speizer, *Asthma and Persistent Wheeze in the Harvard Six Cities Study; Environmental and Occupational Asthma*, 98 CHEST 191S5 (1990).

2. Thurston, *supra* note 1, at 335.

3. *See id.* at 337. The AQSC is comprised of more than 500 corporations and interest groups, including oil, steel, trucking, and auto companies.

retesting and validation.[4] The EPA rejected the requests because the National Institute of Health, the Office of Scientific Integrity, and the Health Effects Institute (HEI) already reviewed the original investigators' actions and data for scientific integrity.[5] Their evaluations confirmed the validity of the data and methodology.[6] However, under pressure, the EPA eventually recommended that the Harvard researchers release the data to the interested government and scientific parties.[7] The Harvard researchers responded by allowing the HEI, an unbiased research group, to review the data.[8]

The EPA denied subsequent requests by other parties to review the data.[9] In response to the denials, Senator Richard Shelby[10] included a one-sentence amendment to a four thousand-page appropriations bill that was passed into law.[11] That one sentence materialized as an amendment to the Office of Management and Budget (OMB) Circular A-110.[12] The final amendment to this Circular effectively superseded the Supreme Court's holding in *Forsham v. Harris*[13] making all data produced by a study funded, or partially funded, with federal grant money subject to disclosure under the Freedom of

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4. *See id.* at 336.

5. *Id.* at 337-38. The investigations were initiated due to allegations of misconduct and inappropriate analyses.

6. *Id.* at 338.

7. *Id.*

8. *See id.* at 338-39. The Health Effects Institute, established in 1980, is an independent, non-profit corporation that aims to provide impartial findings on the health effects of pollutants. *The Health Effects Institute Homepage, at* http://www.healtheffects.org (last modified Jan. 24, 2001).

9. Thurston, *supra* note 1, at 338.

10. Richard C. Shelby is a Republican Senator from Alabama. LEADERSHIP DIRECTORIES, INC., 25 CONGRESSIONAL YELLOW BOOK 188 (1999).

11. Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, 112 Stat. 2681, 2681-495 (1998).

12. *See infra* notes 29-35 and accompanying text (describing the role of the OMB and the role of OMB Circulars in federal grant awards).

13. 445 U.S. 169, 176-78 (1980) (holding that raw data gathered by independent researchers under a federal grant award were not agency records subject to disclosure under the FOIA despite the fact that the data were relied upon by a federal agency in taking certain actions and holding that independent researchers awarded federal grant money were not agencies for the purpose of the FOIA).

Information Act (FOIA).[14]

The final amendment to OMB Circular A-110 leaves researchers vulnerable. Since the majority of FOIA requests are commercial in nature and in scope,[15] commercial requesters may take advantage of a loophole left open by the amendment to this Circular.[16] Grant recipients will be forced into a role traditionally reserved for federal agencies.[17] Moreover, the discretionary grant, itself, becomes unattractive as it will be fraught with difficulties for researchers.[18]

This Comment will explore the tension between the FOIA and the ideal of open government, and the countervailing societal interests of intellectual freedom, scientific inquiry, and the political process.[19] This conflict can be seen in the context of a data access debate that has resonated since *Forsham* was decided in 1980.[20] Part II will provide introductory information, define grants and grant conditions, provide an overview of the FOIA, and discuss *Forsham* and the relevant OMB Circular[21] revisions. Part III will discuss the implications of the revisions, and Part IV will conclude with a recommendation for the OMB to revise the final amendment to OMB Circular A-110 based on several potential remedies that can speak to the concerns of those on both sides of the data wars debate.[22]

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14. Philip J. Hilts, *A Law Opening Research Data Sets Off Debate*, N.Y. TIMES, July 31, 1999, at A1; *see infra* notes 36-57 and accompanying text (providing a definition and summary of FOIA).

15. JAGER, *infra* note 105 and accompanying text (showing that the majority of FOIA requests are from businesses).

16. *See infra* Part III.A (articulating the scope of the loophole).

17. *See infra* Part III.B (discussing how grantees are expected to behave like government agencies).

18. *See infra* Part III.C (probing the possibility that the discretionary grant will become extinct).

19. This comment will not explore the important topic of privacy issues at risk as a result of the amendment to OMB Circular A-110. For example, one privacy concern associated with the amendment to OMB Circular A-110 is protecting the confidentiality of study participants.

20. *Forsham*, 445 U.S. at 169.

21. *See infra* Part II.A.2 and accompanying text (explaining the purpose of OMB Circulars).

22. *See infra* Part IV (concluding by suggesting compromises that may appeal to both grant recipients and FOIA requesters).

II. BACKGROUND

A. Discretionary Grants[23]

A grant is loosely defined as "financial assistance authorized by federal law to support autonomous programs . . . which the federal government does not dictate but does wish to encourage."[24] The types of grants affected by the amendment to OMB Circular A-110 are discretionary grants. Researchers apply for money, usually in the form of a discretionary grant, to fund their research projects. A discretionary grant is a type of federal grant that is given at the will of the federal awarding agency.[25] A principal investigator applies for a grant, and a federal granting agency has the discretion to choose grantee(s) from a pool of applicants.[26] In addition, the granting agency sets the amount of the grant and the conditions of the funding.[27]

1. Grant Conditions

The conditions imposed on grantees are often multi-layered. There are government-wide conditions, agency-wide conditions, as well as special conditions.[28] Of particular importance in this Comment, is the mandatory deference to OMB Circulars imposed by agencies and its impact on grantees.

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23. Discretionary grants are also known as project grants. PAUL G. DEMBLING & MALCOLM S. MASON, ESSENTIALS OF GRANT LAW PRACTICE § 2.04(b) (1991).

24. *Id.* § 2.02.

25. *Id.* § 2.04(b) (explaining that the federal awarding agency can either refuse to award the grant to an applicant or it can award the grant with or without conditions imposed on the grantee).

26. *Id.*

27. *Id.*; *see also id.* § 9.02(a) (explaining that discretionary grants are direct grants in the sense that the federal funds awarded are given directly to the grantee).

28. *Id.* §§ 11.01-.02.

2. OMB[29] Circulars

OMB Circulars were created pursuant to statute and include recommendations to the agency[30] as grantor. Circulars set out uniform rules for agencies to follow as a way of standardizing agency and grantee procedures with respect to grant awards.[31] These uniform rules are not binding on the grantee unless incorporated by reference into a grant, or formally adopted by the agency as a condition of all grant awards.[32] Grant conditions are included in the grantor's award letter.[33] When a grantee accepts the grant money, the grantee then has an obligation to comply with the conditions set forth explicitly or implicitly by the awarding agency.[34]

OMB Circulars generally contain cost and administrative requirements.[35] OMB Circular A-110, titled "Uniform Administrative Requirements for Grants and Cooperative Agreements with Institutions of Higher Education,

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29. The OMB coordinates programs "within and among Federal departments and agencies," including the administration of procurement policies, regulations, and procedures. UNITED STATES GOVERNMENT MANUAL 100 (1999-2000).

30. 5 U.S.C.A. § 552(f) (West 1996 & Supp. 1999) (defining agency as "includ[ing] any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government . . . or any independent regulatory agency").

31. DEMBLING & MASON, *supra* note 23, § 13.02 (describing the statute that gives rise to OMB interpretive guidelines); *see also* 31 U.S.C.A. § 6307 (West Supp. 1983).

32. DEMBLING & MASON, *supra* note 23, § 9.08(a) (describing how some grant conditions may be implicitly incorporated into a grant where the grantee is certain to be aware that circulars dictate grant conditions).

33. *Id.* § 12.02 (explaining that grant conditions can come from OMB Circulars, policy manuals, and published rules; the grant award letter may specify the priority of the documents to abide by in case there is a conflict among them).

34. *Id.* § 11.09 (mentioning that assuring compliance with grant conditions may or may not involve the signature of the grantee promising compliance).

35. *Id.* § 11.06 (noting that OMB Circulars set out uniform rules for agencies to follow as a way to standardize agency and grantee procedures with respect to grant awards).

Hospitals, and Other Nonprofit Organizations," is the circular impacted by Shelby's amendment that now requires disclosure under the FOIA.[36]

B. The Freedom of Information Act

1. The Goals of the Act

The FOIA, enacted in 1966, allows ordinary American citizens access to agency records of the federal government's executive branch.[37] The drafters of the FOIA recognized society's strong interest in open government[38] and the tension inherent in making disclosure its main objective.[39] This tension manifests itself in issues such as privacy and confidentiality, and has increased as information has become available at the desktop through the technology of the Information Age.

2. Summary of the Act

The FOIA allows individuals and groups to request agency records without a reason or justification for their request.[40] Any individual or group making an appropriate

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36. 5 U.S.C. § 552 (1994); The FOIA created a "statutory right of access to government information." U.S. DEPARTMENT OF JUSTICE, FREEDOM OF INFORMATION ACT GUIDE & PRIVACY ACT OVERVIEW 3 (1997) [hereinafter FOIA GUIDE].

37. Pat Shockley, *The Availability of "Trade Secret" Protection for University Research*, 20 J.C. & U.L. 309, 322 (1994) (explaining that "[t]he policy supporting the FOIA is that a democratic society requires an informed, intelligent electorate"); FOIA GUIDE, *supra* note 36, at 3 (noting that access to government information allows accountability and better government).

38. FOIA GUIDE, *supra* note 36, at 3 (explaining that "open government can conflict with other important interests of the general public, such as the public's interest in . . . the preservation of the confidentiality of sensitive personal, commercial, and governmental information").

39. *See id.* at 3, 4 (noting that "[i]t is this task of accommodating countervailing concerns, with disclosure as the predominant objective, that the FOIA seeks to accomplish").

40. FOIA GUIDE, *supra* note 36, at 26 (citing Forsham v. Califano, 587 F.2d 1128, 1134 (D.C. Cir. 1978) for the proposition "that while factors such as need, interest, or public interest may bear on agency's determination of order of processing, they have no bearing on individuals'

FOIA request, excluding federal agencies, is entitled to agency records.[41] An appropriate request must reasonably describe the records sought, so that agency employees are able to gather the data, expending a reasonable amount of effort.[42]

Agency-specific guidelines for FOIA requests must be followed in addition to the statutory requirements of the FOIA.[43] The FOIA requires that an agency provide notice, within ten days, of whether the agency is granting or denying a request for access to agency records.[44] The agency has the right to extend the processing time for an additional ten days or longer upon written notice.[45] The requester may seek administrative or judicial review if an agency denies access to data or fails to meet the statutory time requirements.[46] An agency denial must include reasons for the denial as well as information about the requester's right to appeal.[47] One common reason for denial of a FOIA request is that agencies are not required to create records in order to complete a FOIA request.[48]

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rights of access under FOIA").

41. 5 U.S.C.A. § 552(a) (West 1996 & Supp. 1999); FOIA GUIDE, *supra* note 36, at 25 (listing "foreign citizen[s], partnerships, corporations, associations, and foreign or domestic governments" as well as state agencies, as eligible to make a FOIA request, whereas federal agencies are ineligible because they are specifically excluded from the definition of "person" in the statute); PAUL M. SCHWARTZ & JOEL R. REIDENBERG, DATA PRIVACY LAW 112 (1996) (contrasting the FOIA with the Privacy Act of 1974, 5 U.S.C.A. § 552(a) (West 1996 & Supp. 1999), which governs the processing of personal information by agencies).

42. 5 U.S.C.A. § 552(a)(3)(A) (West 1996 & Supp. 1999).

43. *Id.* § 552(a)(3)(B), (a)(4)(A), (a)(6)(A); FOIA GUIDE, *supra* note 36, at 23 (explaining that each agency is required to publish its regulations for gaining access to its records under FOIA).

44. *Id.* § 552(a)(6)(A)(i).

45. *Id.* § 552(a)(6)(B).

46. *Id.* § 552(a)(6)(C).

47. *Id.* § 552(a)(6)(A)(i).

48. 45 C.F.R. § 612.5 (1998) (quoting the National Science Foundation's policy on record creation stating that: "A record will not be created by compiling selected items from other documents at the request of a member of the public nor will a record be created by analysis, computation or other processing specifically for the requesting party. If such analysis or computation is available in the form of a record, copies shall be made available as provided in this regulation."); NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 161-62 (1975) (holding that the FOIA

There is no damage remedy available to FOIA requesters who have been denied access to agency records.[49]

In general, all "agency records" are subject to the FOIA.[50] In order to differentiate agency records from other types of agency documents not subject to the FOIA, a two prong test has been outlined by the Supreme Court: "'Agency records' are documents which are (1) either created or obtained by an agency, and (2) under agency control at the time of the FOIA request."[51] There are, however, exceptions to the general rule of full disclosure of agency records under the FOIA.[52] The exemptions relevant here include, in broad terms, exemptions for information required to be withheld by statute[53] and personal information in personnel or medical files.[54]

Personal information in personnel, medical, or similar files is exempt when disclosure would be an invasion of personal privacy.[55] Because records may not, on their face, appear to be personal in nature, the "similar files" exemption was created.[56] It has been defined broadly as any information that "applies to a particular individual."[57]

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imposes no duty to create records).

49. FOIA GUIDE, *supra* note 36, at 51.

50. 5 U.S.C.A. § 552(a)(6)(A)(i) (West 1996 & Supp. 1999).

51. FOIA GUIDE, *supra* note 36, at 21.

52. The exemptions are non-disclosure of (1) information that would threaten national security or foreign policy, (2) information concerning internal personnel rules and practices of the agency, (3) information withheld by statute, (4) trade secrets or personal financial information that is privileged or confidential, (5) inter-agency or intra-agency memorandums or letters not available in the civil discovery context for litigation involving the agency, (6) information about people in "personnel and medical files and similar files . . . [that] would constitute a clearly unwarranted invasion of personal privacy," (7) data compiled for law enforcement purposes that would interfere with trial fairness, law enforcement proceedings, or "constitute an unwarranted invasion of personal privacy," (8) information relating to the operation or regulation of financial institutions, and (9) geological and/or geophysical data regarding wells. 5 U.S.C.A. § 552(b) (West 1996 & Supp. 1999).

53. *Id.* § 552(b)(3).

54. *Id.* § 552(b)(6).

55. FOIA GUIDE, *supra* note 36, at 234.

56. *Id.*

57. *Id.* at 235 (citing United States Dep't. of State v. Washington Post Co., 456 U.S. 595 (1982)).

In 1980, a Supreme Court case limited FOIA disclosure of data produced by federal grantees.[58] The amendment to OMB Circular A-110 had the impact of superseding this holding.[59]

C. *Forsham v. Harris*

1. Facts of the Case

The University Group Diabetes Program (UGDP), a group comprised of private physicians and scientists, conducted a long-term study of various diabetes treatment regimens.[60] In the process, the study created more than 55 million records documenting the treatment of one thousand diabetic patients over a five to eight year period.[61] The initial results of the study showed that two drug regimens were associated with a higher risk of death by cardiovascular disease compared with the other drug regimens studied.[62] In response, the Food and Drug Administration (FDA) issued a statement that these two drugs should be used in limited circumstances and it proposed labeling changes to warn patients.[63] Meanwhile, a professional debate over the validity of the findings ensued.[64]

The most vocal critic of the study was the Committee on the Care of the Diabetic (CCD), a national association of physicians, who asked UGDP for the raw data to review the

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58. *See* Forsham v. Harris, 445 U.S. 169 (1980).

59. *See generally*, FOIA GUIDE, *supra* note 36 (providing the materials each agency must make available to the public).

60. *Forsham*, 445 U.S. at 172 (explaining that the UGDP study was funded by fifteen million dollars in federal grant money between 1961 and 1978).

61. *Id.*

62. *Id.* at 174 (pointing out that the two scrutinized drugs were tolbutamide and phenformin hydrochloride).

63. *Id.* (discussing labeling changes for tolbutamide and phenformin hydrochloride to require a "warning that oral hypoglycemics should be used only in cases of adult-onset, stable diabetes that could not be treated adequately by a combination of diet and insulin").

64. *Id.*

findings.[65] UGDP did not release the data. Instead, the granting agency, the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD),[66] contracted with the Biometric Society,[67] an independent association of researchers, to validate the study; the findings showed that the "results were mixed, but moderately strong."[68]

2. Lower Courts' Decisions

After exhausting all of their administrative remedies through the agency,[69] including a series of FOIA requests and subsequent denials, CCD brought suit to compel the Department of Health, Education, and Welfare (HEW) to make the raw data available.[70] The district court granted summary judgment in favor of the defendants using the rationale that the raw data consisted of patient records which did not fall within the FOIA's definition of agency records.[71] The court of appeals affirmed for the same reason, and also found "that although NIAMDD is a federal agency, its grantees are not federal agencies, and, therefore, not subject to the FOIA."[72]

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65. *Id.* at 169.

66. In terms of agency hierarchy, NIAMDD fell within the Department of Health, Education, and Welfare (HEW). The HEW was redesignated as the Department of Health and Human Services (DHHS) pursuant to the Department of Education Organization Act of 1979. UNITED STATES GOVERNMENT MANUAL 294 (1980-1981).

67. *Forsham*, 445 U.S. at 173 (describing the Biometric Society as a private grantee). The Biometric Society, now known as the International Biometric Society, is comprised of researchers interested in developing and applying effective statistical techniques to research data. 1 ENCYCLOPEDIA OF ASSOCIATIONS 775 (Tara E. Sheets ed., 33d ed. 1997).

68. *Forsham*, 445 U.S. at 173-74.

69. *Id.* at 175 (noting that an administrative law judge (ALJ) found, through access to the raw data, that phenformin was not safe and ordered it to be withdrawn from the market).

70. *Id.* at 176.

71. *Id.*

72. *Id.* at 173-76; *see also* Shockley, *supra* note 37, at 328 (comparing the federal FOIA, where public universities are not considered agencies for federal purposes, with state freedom of information laws, where public universities may be considered agencies).

3. The Supreme Court Decision

The Supreme Court affirmed the decisions of the lower courts:[73] "[W]ith due regard for the policies and language of the FOIA, we conclude that data generated by a privately controlled organization which has received grant funds from an agency . . . but which data has not . . . been obtained by the agency, are not 'agency records' accessible under the FOIA."[74] The opinion noted that Congress intentionally excluded private grantees from the definition of "agency" in order to maintain grantee autonomy.[75] The legislative history of the FOIA shows that the drafters intended to "keep federal grantees free from the direct obligations imposed by the FOIA."[76]

Further, the Court recognized that acquiring data for the direct benefit of the federal government took on characteristics of a procurement contract, or a contract for specific services, not a grant.[77] The Court pointed out that "Congress expressly requires an agency to use 'procurement contracts' when the principal purpose of the instrument is the acquisition . . . of property or services for the direct benefit of the Federal Government . . ."[78] The

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73. *Forsham*, 445 U.S. at 187.

74. *Id.* at 178, 184 (Although the FOIA does not define "agency record," a definition used during FOIA Senate hearings described it as "includ[ing] all papers which an agency preserves in the performance of its functions.").

75. *Id.* at 179-80 (stating that "Congress could have provided that the records generated by a federally funded grantee were federal property . . . [b]ut Congress has not done so").

76. *Id.* at 182.

77. RALPH C. NASH, JR. et al., THE GOVERNMENT CONTRACTS REFERENCE BOOK: A COMPREHENSIVE GUIDE TO THE LANGUAGE OF PROCUREMENT 409 (2d. ed. 1998) (defining a procurement contract as "a contract between the Government and a private party to provide supplies or services"); *Compare* 31 U.S.C.A. § 6303 (West Supp. 1983) (describing the principal purpose of procurement contracts as the "[acquisition of] . . . property or services for the direct benefit or use of the United States Government"), *with* 31 U.S.C.A. § 6304 (West Supp. 1983) (describing the principal purpose of a grant agreement as "[transferring] a thing of value to the . . . recipient to carry out a public purpose of support or stimulation authorized by a law . . . instead of acquiring . . . property or services for the direct benefit or use of the United States Government").

78. *Forsham*, 445 U.S. at 180 (citing the Federal Grant and Cooperative Agreement Act of 1977, 41 U.S.C. § 503 (1976 ed., Supp. II)).

consequences of eliminating the distinction between these two types of government grants changes the relationship between grantor and grantee to a contractual one, threatening the future of government funded independent research.

Another point highlighted by the Court was the fact that HEW never physically obtained the records. *Forsham* clarified the awarding agencies' rights with respect to data disclosure: HEW was welcome to exercise its right to obtain the records and turn them over, but was not compelled to do so[79] because the FOIA does not require an agency to obtain records to complete a disclosure request.[80]

4. Superseding the *Forsham* Holding

a. The Language of OMB Circular A-110 Prior to P.L. 105-277[81]

OMB Circular A-110__.36(c)[82] formerly allowed awarding agencies the option of obtaining, reproducing, publishing or using the data produced by its award to a grantee. If an outsider wanted to review such data, the agency had the discretion to compel such disclosure. The passage of P.L. 105-277 into law triggered Shelby's amendment to OMB

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79. *Id.* at 181-82 (stating that HEW regulations do retain a right to acquire the documents . . . and until that right is exercised, the records are only the "records of grantees").

80. *Id.* at 186 (showing that both the HEW regulations and the Congressional intent of the FOIA consider an agency record to be a record physically in the possession of an agency); *See* FOIA GUIDE, *supra* note 36, at 49.

81. Norwood J. Jackson, *Memorandum for the Record, Recompilation of OMB Circular A-110* (*revised* November 19, 1993 and published at 58 Fed. Reg. 62992 (1993), *amended by* 62 Fed. Reg. 45,934 on (1997)), *available at* http://www.whitehouse.gov/OMB/circulars/a110/a110.html (outlining OMB circular A-110___.36(c), relating to Intangible Property, in its pre-Shelby amendment form for purposes of comparison with later amendments to it: "Unless waived by the Federal awarding agency, the Federal Government has the right to . . . (1) [o]btain, reproduce, publish or otherwise use the data first produced under an award . . . [and] (2) [a]uthorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.").

82. *Id.*

Circular A-110 which eliminated agency discretion concerning disclosure. Awarding agencies now must compel grantee disclosure.

b. *The Language of P.L. 105-277*[83]

Senator Shelby's amendment required:

> . . . 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 . . .[84]

c. *OMB Circular Revision One and Two*

The first proposed amendment to OMB Circular A-110___.36(c) provided a broad license for disclosure of research data and, as a result, over nine thousand comments from interested parties flowed forth expressing concern about the impact of such broad disclosure.[85] The

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83. Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, 112 Stat. 2681, 2681-495 (1998).

84. *Id.*

85. *Proposed Revision, OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations"* (issued Jan. 26, 1999), *available at* http://www2.whitehouse.gov/OMB/fedreg/a-110rev.html (stating that: The Federal Government has the right to (1) obtain, reproduce, publish or otherwise use the data first produced under an award, and (2) authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes. In addition, in response to a Freedom of Information Act (FOIA) request for data relating to published research findings produced under an award that were used by the Federal Government in developing policy or rules, the Federal awarding agency shall, within a reasonable time, obtain the requested data so that they can be made available to the public through the procedures established under the FOIA. If the Federal awarding agency obtains the data solely in response to a FOIA request, the agency may charge the requester a reasonable fee

second proposed revision came in response to comments submitted by interested parties.[86] Both waves of comments

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equaling the full incremental cost of obtaining the data. This fee should reflect costs incurred by the agency, the recipient, and applicable sub-recipients. This fee is in addition to any fees the agency may assess under the FOIA (5 U.S.C. § 552(a)(4)(A))).

86. *Request for Comments on Clarifying Changes to Proposed Revision on Public Access to Research Data, OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations"* (issued Aug. 5, 1999), *available at* http://www2.whitehouse.gov/OMB/fedreg/2ndnotice-a110.html (stating that:

> (c) The Federal Government has the right to (1) obtain, reproduce, publish or otherwise use the data first produced under an award, and (2) authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.
>
> (d)(1) In addition, in response to a Freedom of Information Act (FOIA) request for data relating to published research findings produced under an award that were used by the Federal Government in developing a regulation, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA. If the Federal awarding agency obtains the data solely in response to a FOIA request, the agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data. This fee should reflect costs incurred by the agency, the recipient, and the applicable sub-recipients. This fee is in addition to any fees the agency assess under the FOIA (5 U.S.C. § 552(a)(4)(A)).
>
> (d)(2) The following definitions are to be used for purposes of subsection (d)
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> (i) "Research data" is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate researching [sic] findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues . . . trade secrets, commercial information, materials necessary to be held confidential by a researcher until publication of their results in a peer-reviewed journal . . . [or] files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.
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> (ii) "Published" is defined as either when (A) research findings are published in a peer-reviewed scientific or technical journal, or (B) a Federal agency publicly and officially cites to the research findings in support of a regulation.
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> (iii) "Used by the Federal Government in developing a regulation" is defined as when an agency publicly and officially cites to the research findings in support of a regulation (for which notice and comment is required under 5 U.S.C. § 553)).

raised general concerns about the impact of the amendment on scientific research, the privacy of research subjects, the proprietary interests of researchers, and the ability of researchers to follow through with a research plan without interruption caused by the release of data collected prior to analysis and publication.[87] The comments also called for clarifications or definitions of "data," "published," and "used by the Federal Government in developing policy or rules."[88] These definitions are crucial to delineating exactly what type of data has to be released, and at what point in the research process it must be disclosed.

These clarifications were addressed in the final revision[89]

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87. *Id.*

88. *Id.*

89. *Final Revision to OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations"* (issued Nov. 6, 1999), *available at* http://www2.whitehouse.gov/OMB/fedreg/a110-finalnotice.html [hereinafter OMB Circular A-110] (stating that:

> As directed by OMB's appropriation for FY 1999, contained in Public Law 105-277, OMB hereby amends Section ___.36 of OMB Circular A-110 by revising paragraph (c), redesignating paragraph (d) as paragraph (e), and adding a new paragraph (d), to read as follows: ___.36 Intangible Property

(c) The Federal Government has the right to:

> (1) obtain, reproduce, publish or otherwise use the data first produced under an award; and
>
> (2) authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

(d) (1) In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA. If the Federal awarding agency obtains the research data solely in response to a FOIA request, the agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data. This fee should reflect costs incurred by the agency, the recipient, and applicable sub-recipients. This fee is in addition to any fees the agency may assess under the FOIA (5 U.S.C. § 552(a)(4)(A)).

(d)(2) The following definitions apply for purposes of paragraph (d) of this section:

> (i) "Research data" is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following:

to OMB Circular A-110, although the final revision presents a host of other problems discussed in Sections III-IV *infra*.

III. The Research Loophole and Other Implications

A. The Research Loophole

The pendulum has swung from one extreme, no disclosure, to the other extreme, full disclosure, without anticipating the implications of the revision to OMB Circular A-110. During both *Forsham* and more recently in the Harvard Six Cities Study, researchers faced opposition by corporations and industries who feared substantial economic loss as a result of policies initiated from research findings.[90] *Forsham* and the Harvard Six Cities Study are

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

(A) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and

(B) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

(ii) "Published" is defined as either when:

(A) Research findings are published in a peer-reviewed scientific or technical journal; or

(B) A Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

(iii) "Used by the Federal Government in developing an agency action that has the force and effect of law" is defined as when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.)

90. *See supra* notes 1-9, 57-73 and accompanying text (outlining the facts of the Harvard Six Cities Study controversy and the factors leading to the *Forsham* litigation). Another related controversy, surrounding tobacco advertising, ensued when the results of a study were published in 1991 by Paul M. Fisher in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION. The findings showed that children were attracted to R.J. Reynolds' (RJR) character Joe Camel, in which it was determined that more than half of the

examples of professional debates that embrace the spirit of open government.[91] However, the changes brought on by the new OMB policy leave researchers vulnerable in ways that are contrary to this spirit. The broad definition of "agency action" results in disclosure of preliminary research that becomes subject to the FOIA and threatened by the forces of interested parties.

The pertinent portion of the OMB Circular A-110 revision states:

> [I]n response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA.[92]

This amendment is misleading for a number of reasons. First, the requirement that research data be "published" before being subjected to the FOIA *appears* to prevent disclosure of preliminary research. "Published," as defined

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children participating in the study recognized Joe Camel and associated the character with cigarettes. These findings implicated the company in its efforts to attract young tobacco purchasers. The article points out that children are, according to market researchers, "consumers in training" and brand awareness acquired during childhood dictates product preferences made throughout life. RJR responded by contracting analysts to replicate the study. The research data supporting the study was subpoenaed and released by the Medical College of Georgia despite the protestations of Fischer. Although Fischer's findings were criticized by tobacco industry consultants at the time of the controversy, his research has been verified by other researchers including RJR. RJR has since admitted that the company's advertising targeted children. *See* Thurston, *supra* note 1, at 342-43; Paul M. Fischer, *Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe the Camel*, 266 JAMA 3145 (1991); Paul M. Fischer, *Recognition of Cigarette Advertisement Product Logos*, 277 JAMA 532 (1997).

91. *See supra* notes 36-57 and accompanying text (describing the purpose of the FOIA).

92. OMB Circular A-110, *supra* notes 83-90.

by the amendment, means "[r]esearch findings [that] are published in a peer-reviewed scientific or technical journal; *or [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.*"[93] The amendment's definition of "publish" includes the traditional notions of publishing for the purpose of circulation, but also includes instances where preliminary findings show cause for governmental concern. Publication in peer-reviewed journals connotes complete, polished work. On the other hand, the point at which an agency publicly and officially cites to research findings may be at a point where preliminary findings are all that is available. Preliminary findings are often an indication of outcomes while not necessarily being conclusive. For example, when dealing with health and safety issues, the government may be justified in taking temporary precautions based on preliminary findings until more research is thoroughly completed. At the same time, precautionary measures should not necessarily mean that disclosure is imperative.

Second, the amendment fails to define "agency action."[94] Due to the fact that almost all grant related research is policy oriented in one way or another, most of this data will be "officially cited" in the creation of government policy through an "agency action" and will, therefore, be subject to disclosure under the FOIA.[95] An official citation to research findings may seem, on its face, a rational time for disclosure. However, OMB Circular A-110's failure to include a definition of "agency action" compels deference to the definition in the Administrative Procedure Act (APA).[96] Under this definition, an "agency action" includes a partial "rule, order license, sanction, relief or the equivalent or

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93. *Id.* (emphasis added).

94. *See* 5 U.S.C.A. § 551(13) (West 1996 & Supp. 1999) (defining agency action to "include . . . the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act").

95. OMB Circular A-110, *supra* note 89 (outlining the final revision to OMB Circular A-110).

96. *See* Administrative Procedure Act, 5 U.S.C.A. § 551 (West 1996 & Supp. 1999).

denial thereof, or failure to act."[97]

Unfortunately, the APA's definition of "agency action" is too broad for application in a research setting.[98] For example, the court in *Industrial Safety Equipment Ass'n v. EPA*,[99] held that an agency statement setting forth a rule of law, imposing an obligation, determining rights or liabilities, or fixing legal relationships is an "agency action."[100] In *In re Complex Blood Bank Litigation*,[101] the court held that a decision by the Department of Health and Human Services not to make an employee available for a deposition by private parties, was also an agency action for purposes of the APA.[102] In *Cableamerica Corp. v. FTC*,[103] the court held that the FTC's request for more information from Cableamerica about a merger, pursuant to the Hart-Scott-Rodino Act, was an "agency action" under the APA.[104]

Clearly, the APA's definition of "agency action" is too inclusive for the fair administration of justice under OMB Circular A-110. An agency[105] that officially cites data produced under a grant in developing an "agency action" opens the door for disclosure of the data through the FOIA.[106] This means, for example, that controversial *preliminary* research officially cited in carrying out an agency action is subject to disclosure. The government is most likely to rely on preliminary data where there is a potential health or safety concern. Although it is the

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97. *Id.*; *see also* 2 AM. JUR. 2D *Administrative Law* § 468 (1994) (stating that an agency action occurs "when an administrative agency promulgates a rule through its usual rulemaking proceedings; issues an order pursuant to an adjudication; grants, renews, denies, revokes, suspends, annuls, withdraws, limits, amends, modifies, or conditions a license; grants or denies relief; or imposes a sanction").

98. 5 U.S.C.A. § 551(13) (West 1996) (providing a definition of agency action).

99. 656 F.Supp. 852 (D.C. Cir. 1997).

100. *Id.* at 855.

101. 812 F.Supp. 160 (N.D. Cal. 1991).

102. *Id.* at 162.

103. 795 F.Supp. 1082 (N.D. Ala. 1992).

104. *Id.* at 1085-86.

105. *See* 5 U.S.C.A. § 552(f) (West 1996 & Supp. 1999) (providing a definition of agency).

106. *See* OMB Circular A-110, *supra* notes 83-90.

government's prerogative to make policy based on its own preliminary findings in the absence of a health or safety concern, grantees do not have the same authority; while preliminary findings are often an indicator of outcomes, they are not always conclusive. Any preliminary research results that may have a negative impact on industry groups become vulnerable to attack by industry lobbyists who fear the economic impact of new laws or regulations. The research in *Forsham* dealt with the risks of two drugs already on the market,[107] while the research in the Harvard Six Cities Study supported tightening regulations for particulate matter; both of these threatened costly changes to powerful industry groups.

It is clearly in the public's best interest to have laws and regulations based on quality research; however, the new policy set forth in OMB Circular A-110 may actually promote the opposite. First, data cited in support of an agency action may be peripheral to the regulatory change, but still subject to FOIA disclosure. Second, researchers will become discouraged by the possibility that an agency's "official citation" to their findings in developing an agency action may force the disclosure of their data prematurely. Preliminary findings officially cited in an agency action, for example, may be exploited to promote researcher harassment in the form of multiple, time-consuming requests. This is especially pertinent because the grantee bears the entire burden of each disclosure request.[108] Research that is unpopular among commercial groups may be subject to unnecessary FOIA requests. Since this burden will fall on the grantee, multiple requests could become overwhelming, proving too difficult for research staff to handle and spoiling a researcher's yield of publishable results. This outcome is highly probable because studies that tracked requests since the FOIA's inception showed that the majority of FOIA requesters were commercial entities.[109] Furthermore, commercial

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107. Forsham v. Harris, 445 U.S. 169, 171 (1980).

108. *See* OMB Circular A-110, *supra* notes 83-90.

109. *See* Shockley, *supra* note 37, at 329; 2 MELVIN F. JAGER, TRADE SECRETS LAW § 12.02 (1994) (stating that "contrary to the best intentions of

requesters' access to data is valuable to them since different analytical methods can be employed to manipulate findings that support industry biases.

B. Are Grantees Expected to Behave Like Government Agencies?

Overturning *Forsham* means that grantees have become an extension of the granting agency. Under *Forsham*, the absence of raw data in the granting agency's possession meant that the raw data was not an "agency record."[110] In other words, the agency was not required to obtain data from the grantee to comply with a FOIA request because it was not required to create an agency record.[111] Due to OMB's revision to Circular A-110, however, the grant recipient is automatically compelled to disclose data when an agency receives a request. This mandated compliance means that, *ipso facto*, grant recipients are now an extension of awarding agencies.

As a general rule, "the FOIA does not apply to entities that are neither chartered by the federal government [n]or controlled by it."[112] In *Independent Investor Protective League v. New York Stock Exch.*,[113] the court held that the New York Stock Exchange, despite being subject to heavy government regulation, is not an agency of the federal government.[114] Similarly, grant recipients, while heavily regulated by the awarding agency, should be neither considered nor treated as a government agency.[115] The revision to OMB Circular A-110 forces grant recipients to

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Congress, the largest percentage of requests for documents under the FOIA does not come from the press, the academic community, or researchers seeking to ferret out mismanagement or questionable decisions . . . [they] have been made by businesses").

110. *See Forsham*, 445 U.S. at 171.

111. *Id.*

112. FOIA GUIDE, *supra* note 36, at 18-19 (citing H.R. REP. NO. 93-1380, at 14 (1974)).

113. 367 F. Supp. 1376, 1377 (S.D.N.Y. 1973), *aff'd*, Leytman v. New York Stock Exch., 1995 WL 761843, at *2 (E.D.N.Y. Dec. 6, 1995).

114. *Id.*

115. *See* 5 U.S.C.A § 552(f) (West 1996 & Supp. 1999) (providing a definition of agency).

play the role of agent under the control of its awarding agency.

Under the final revision to OMB Circular A-110, the grantor's physical possession of the data is now required to make a FOIA request.[116] Furthermore, the OMB provisions have included a cost recovery mechanism for grantees who are compelled to comply with the request,[117] strongly suggesting that responding to each individual FOIA request, previously an agency function, will become entirely the burden of the grantee.

Contrary to the congressional intent of the FOIA,[118] grantees are now subject to the obligations of the FOIA despite the absence of language including the grantee in the statutory definition of an agency. As a result, the grantee becomes more like a government controlled establishment.

C. The Death of the Discretionary Grant?

The death of the discretionary grant is imminent as the distinction between grants and procurement contracts becomes murky,[119] and as the incentive for researchers to seek grants and reap the benefits of the fruits of their labor disappears. Grants are the means used to stimulate projects that serve the public good. A grant does not imply that the government is the purchaser of the grantee's work.[120] However, performing research for the direct benefit of the government, or to make research available on demand, changes the relationship between grantor and

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116. *See* OMB Circular A-110, *supra* notes 83-90.

117. *See id.*

118. *Supra* notes 74-76 and accompanying text (discussing Congress' intent to exclude grantees from the definition of agency).

119. Representative George Brown, *Letter to Congress RE: FR Doc. 99-2220: Proposed Revision to OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations", at* http://www.house.gov/science_democrats/archive/gbona110.htm (last modified Apr. 2, 1999), (stating that the revision essentially turns all grants into procurement contracts with Federal ownership of everything associated with the grant).

120. Thurston, *supra* note 1, at 348.

grantee to a contractual one, resembling the role of a contractee in a procurement contract.[121] Treating raw data produced under a grant as a product purchased or controlled by the government, for all practical purposes, changes a grant into a procurement contract.[122] A grant with a research agenda that is "encouraged" by the government will reach the procurement contract-like threshold when the data is implicated in support of public policy perceived as threatening to industry groups.

Another contributing factor to the possible death of the discretionary grant is the mandated disclosure of data to third party requesters after its first public appearance.[123] The raw data associated with a study is the embodiment of years of work by the principal investigator and/or the research team. The arduous grant application process begins with a research idea, and culminates with its incarnation as a grant proposal.[124] Research outcomes are generally published in peer review journals and books, and each data set generally produces multiple publications.[125] If, however, there is mandated disclosure of data after its initial public appearance, the government may remove the incentive for researchers to carry out research activities that serve the public good. It is no secret that the researchers most likely to be impacted by OMB Circular A-110 are the class of researchers seeking tenure, staff privileges, or some equivalent status. Disclosure of their raw data will allow others to use the data before the yield of their work is complete, and may jeopardize the property interests granted by Congress and enjoyed by researchers.[126] This will inhibit research that may

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121. 31 U.S.C.A. § 6303 (West 1994) (describing the principal purpose of procurement contracts as the "acqui[sition of] . . . property or services for the direct benefit or use of the United States Government").

122. Nash, *supra* note 77, at 409 (defining a procurement contract as "a contract between the Government and a private party to provide supplies or services").

123. Thurston, *supra* note 1, at 347.

124. *Id.*

125. *Id.* (pointing out that the Harvard Six Cities Study data set has produced more than one hundred peer review articles).

126. *Id.* at 348 (citing the National Technology Transfer and Advance-

otherwise promote answers to complex social problems and, in turn, change public policy.

IV. CONCLUSION

Under the FOIA, access to agency records of the federal government's executive branch allows individual citizens, organizations, and partisan political parties, to "check" on those who govern.[127] FOIA, the embodiment of open government, is a highly praised public policy.[128] Indeed, each state has passed its own freedom of information laws.[129] This is a reflection of the value placed on open government in a contemporary democracy. In that light, there is no suggestion in this Comment that access to raw data used in federally funded grant research should not be available for investigation or that it should go without validation. The philosophy behind the FOIA, providing American citizens the opportunity to inform themselves about the public behavior of those who govern, reflects revered ideals.

What *is* at stake here, as outlined in parts III(A)-(C) *supra*, are warnings that were not heeded and outcomes that were not foreseen. Research data is now subject to the overreaching scope of the OMB Circular Amendment, grant recipients must behave like an extension of the federal awarding agency, and grant recipients bear the administrative burden of disclosure. It is my contention that, in the absence of changes to this OMB policy, the discretionary grant will become extinct as it becomes fraught with difficult burdens and diminishing rewards.

One remedy for problems associated with the OMB Circular Amendments, is the formation of an administrative board to appoint a revolving committee comprised of researchers, OMB staff, representatives of

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ment Act of 1995 as an example of the government support for extending ownership and licensing rights for intellectual property produced with federal support).

127. *See* 5 U.S.C.A. § 552 (West 1994).

128. *See supra* notes 36-38 and accompanying text (discussing the drafters' theory behind the FOIA).

129. JAGER, *supra* note 109, § 12.01.

industry groups, and others to evaluate the issues associated with a request for data opposed by researchers. A disclosure denial will trigger a committee evaluation of the researchers' concerns and the requester's interests.

The committee will balance the burden on the researchers against the benefits of immediate or future disclosure. The committee will have full power to grant, deny, or postpone access to the data. Postponement is a remedy that will allow researchers more time to publish findings or realize any other property interests associated with the data. But, each decision will be made in the absence of haste with informed decision-makers representing interests from all groups. This will ensure that decisions are made for the sake of research validation, not research harassment.

Another solution is to clearly define what agency actions trigger FOIA disclosure pursuant to OMB Circular A-110. As it stands now, for example, data can be cited in support of an agency action even though that data may actually be peripheral to the agency action. The mere mention of the data, however, can result in disclosure.

Finally, OMB should encourage researchers to share data. This is achievable in a variety of ways, but one model is through the preparation of public use data.[130] Public use data is either a subset of a larger data set or an entire data set with redacted information. In the case of human subject research this is especially important; protecting personal information to avoid deductive disclosure is a high priority.[131]

A successful model of data sharing is the Inter-University Consortium for Political and Social Research (ICPSR), an

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130. *National Longitudinal Study of Adolescent Health, Addhealth Homepage, at* http://www.cpc.unc.edu/projects/addhealth/datasets.html (last modified Nov. 8, 2000) (showing, for example, that the Addhealth public use data consists of one half of the core sample chosen at random).

131. *Id.* (defining deductive disclosure as: [T]he discerning of an individual respondent's identity and responses through the use of known characteristics of that individual . . . [so that] if a person is known to have participated in ANY survey, then a combination of his or her personal characteristics will allow an individual to determine which record corresponds to that individual).

archive of shared social science data that is prepared for public use.[132] A Council is elected by ICPSR's members to oversee its administration and policies for data access.[133] Data is deposited by researchers or institutions and ICPSR prepares the data for public use. Sharing public use data through an archive may be one of many ways to protect researchers and the integrity of the research process, while also providing open access to data that impacts public policy. These potential remedies attempt to harmonize the interests of FOIA requesters and grantees while remaining true to the ideal of open government and the legislative intent of the FOIA.

132. *See Inter-University Consortium for Political and Social Research Homepage, at* http://www.icpsr.umich.edu/INTRA/index.html (last visited July 21, 2001), (providing a mission statement and information about the organization as well as searchable archive of data available to member institutions).

133. *Id., at* http://www.icpsr.umich.edu/ORG/about.html (last visited July 21, 2001) (providing information about ICPSR's Council and history of the institution).