COGR

an organization of research universities

COUNCIL ON GOVERNMENTAL RELATIONS

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Mr. F. James Charney
Policy Analyst
Office of Management and Budget
Room 6033
New Executive Office Building
Washington, D.C. 20503

Dear Mr. Charney:

This letter presents the comments of the Council on Governmental Relations (COGR), an association that includes in its membership 144 research intensive universities in the United States. We are responding to the proposed revision to OMB Circular A-110, published in the Federal Register on February 4, 1999. The proposed rulemaking reflects a statutory mandate for broad access by the general public to data created with federal support, with the Freedom of Information Act (FOIA) to serve as the implementing vehicle.

Commenting on this proposal is an extraordinarily complex task. Concerns about the possible consequences which could result from the statute as well as from OMB's proposal for its implementation should not be misunderstood as opposition to the basic goal of sharing data with the public. The COGR member universities strongly endorse sharing of research data. However, in view of the many serious adverse impacts which could result from proceeding as proposed, we urge OMB to defer implementation of the proposed rules until a comprehensive assessment of the possible impact of this proposal has been made, involving the Congress, federal agencies and researchers, who are likely to be most seriously affected. This is the only way to forestall many dangerous, unintended consequences of using FOIA as a mechanism for sharing research data.

Endorsement of Data Sharing

Ironically, it is because of the strong commitment to sharing and dissemination of research results for the benefit of the general public, that the universities in our membership oppose this particular Congressional mandate as well as the proposed OMB rulemaking implementation. The generation and dissemination of new knowledge is one of the fundamental

principles of academic institutions. The freedom to publish is strongly defended by universities every day in negotiations of research agreements. Closely tied to this is our obligation to protect the freedom to publish and share data on behalf of students whose education is enriched as they participate in research. These examples show that our member universities are committed to act as well as speak in the strongest terms to assure public accountability for research results irrespective of whether those results were obtained with federal or private support.

Concerns About the Broad Statutory Mandate

There is unanimous agreement in our membership, reflecting the convictions of scientists from a variety of different disciplines and their administrative support staff, that the statutory language is too broadly stated and that the use of FOIA procedures is not the right tool. Employing FOIA to access underlying research data will result in substantial changes to the conduct of research. These consequences were not explored when the statute was adopted and cannot be mitigated by the narrower proposed implementation as proposed by OMB. The deep concerns of the scientific community have been eloquently articulated in public statements by the National Science Board, the National Academy of Sciences and others. We endorse their comments. Because indiscriminate and premature release of raw data is not an unqualified public benefit, we anticipate problems will result in three areas: negative impact on scientific research, serious loss of protection of individual privacy, and intolerable decreases in public-private partnerships in research. Each of these points is further elaborated below.

a) **Impact on Scientific Research** - Scientists cannot be expected to work on the controversial issues which are important to society without the ability to protect their raw data throughout all stages required for proper evaluation and peer review. The early forced release of raw data may result in external pressures which would place the very integrity of scientific research at risk; permit misrepresentations which mislead the public; result in premature reactions which could create public health and safety hazards; disrupt the continuity of federal agency research missions; and unfairly attack the reputation of individuals involved in research and, thereby, discourage scientists from continuing cutting-edge research.

   The OMB proposal, which is based on access by the public only to data from published studies, which have been used for agency purposes of policy or rulemaking, offers only limited reassurances. Too many questions remain unanswered, including fundamental issues such as: When do data have to be released? What constitutes publication? How would data archives be affected? How much related information would have to be released in order to make the requested data understandable? How are currently differing definitions of data to be reconciled? What would be the guiding principles for such revisions?

In addition, legal questions regarding ownership of data arise. OMB has been directed to turn over privately held data, created with federal assistance to the total discretion and disposition of federal agencies. At a substantive level, this charge to OMB may be interpreted as an unfair taking of intellectual property, in violation of the Fifth Amendment.

Data are building blocks for innovation. In passing the Bayh-Dole Act, Congress realized the value of research and placed the producer of the research results in control over their disposition with respect to their reasonable release and future use by the public. The Act protects against premature release of data, which would undercut that purpose. Unless this conflict between Congressional policy regarding technology transfer and policy regarding data dissemination is resolved, the resulting uncertainty and loss of protection might well persuade scientists to avoid federal funding for certain kinds of cutting edge research. The federal agencies' research mission would clearly suffer from such developments.

b) **Impact on the participants in research** - Research subjects will be discouraged from joining clinical trials and research protocols because of the legitimate fear that their personal data may not be adequately protected, even if exemptions under FOIA were invoked. The statute raises grave concerns regarding the privacy rights of U.S. citizens. The rights to personal privacy clash with the rights to public access. The current trust between federal agencies and individual citizens participating in federally funded research studies will be fatally damaged if promises of confidentiality were abrogated.

We are also concerned about the negative impact on the continuity of medical research studies. The turning over of data in human subjects' studies, for which universities have promised confidentiality, constitutes a devastating breach of good faith with research subjects, collaborators, and private sector partners. The National Institutes of Health, with its vast array of clinical trials and wide range of studies in human diseases involving human subjects, has addressed the complications arising from the legislation. We share NIH's concern that, if the new legislation is allowed to stand, the privacy of human subjects is not assured.

FOIA exemptions do not extend to groups, communities and institutions. We believe that all participants in medical research must be protected not only for the sake of their personal privacy, but also because their participation makes medical progress possible and, thereby, serves an important public purpose. Alternate ways need to be found to allow interested parties to examine data underlying published research reports, without loosening the protections of the research participants without whom the studies could not be carried out.

c) Loss of collaborative partnerships - A major victim of unintended consequences may be the current collaboration between universities and its many partners in research. These include not only private industry, but also a variety of foundations, charitable organizations and voluntary health groups. The States have invested increasing resources in university research, much of which is co-mingled with federal sources, or expressly leveraged in new federal-industry joint programs.

During the past decade, federal policy has changed to involve public-private cooperation. Examples include the Engineering Research Centers, consortia, Small Business Technology Transfer (STTR) and Small Business Innovation Research (SBIR) initiatives. Private parties will not agree to cooperate with public institutions if this means that the data they bring to the cooperative effort, or the data that results from that effort, can be subject to arbitrary and premature release. The likely loss of intellectual property protection is a severe drawback and if the statute were allowed to stand, would substantially undercut existing federal policy.

We believe that adverse consequences in all these areas are inevitable. The community has neither reliable studies nor practical experience to assure that, if applied in this expanded manner, the exemptions of FOIA would provide sufficient protection for its legitimate concerns. Finally, there is no reassurance that the more narrowly focused OMB implementation would survive a legal challenge on grounds that it is not sufficiently responsive to statutory intent.

Consideration of FOIA

The academic community's assessment of the effectiveness of FOIA is based on the Act's current purpose and scope, which is limited to providing access to federal "agency records." It seems unlikely that prospective use of FOIA as a vehicle for dissemination of new research data could be accomplished without a fundamental reassessment of purpose and restructuring of its provisions.

Since the FOIA law and exemptions were not crafted with the intent to cover university research data, in the possession of university grantees, an untested application of the current Act would be a risky undertaking. It will create enormous uncertainty regarding the relevance and applicability of the exemptions. More importantly yet, it will place the grantee universities completely at the mercy of agency interpretations after the new data are transmitted.

The need to review the nature of the exemptions is reinforced when one considers the wide range of items currently referred to as data. The more traditional forms include writings in notebooks, in medical records, computer drawings, and records of interviews, printouts from machines, photographs, films or slides. In addition, however, there is computer code and there are databases and videotapes of family studies. There is software and in the biological sciences, a

variety of cells, biological materials and chemical compounds. NIH and scientists have repeatedly failed to arrive at a comprehensive, mutually satisfactory definition of data. Even if the definitional issues were resolved, how are these types of data to be treated by the existing categories of exemption? To what extent is explanatory documentation to be provided with the data?

Equally worrisome challenge faces the federal agencies: Questions will have to be answered regarding how much data would have to be requested from the principal investigator? From collaborating parties? Would interim results be included? Data not in tangible form but disseminated at public meetings? Data on which grant applications are based? Data referred to in progress reports to the government? Which of these data would be protectable and with which justification?

Another element of uncertainty is added because the U.S. Supreme Court decision in Forsham v. Harris , will no longer govern. It had determined that data generated by federally funded grantees are not "agency records" and, therefore, not subject to FOIA disclosure. The true impact of the new expanded application of FOIA, mandated by the legislation, will emerge slowly, as case law builds, testing the strength of the exemptions with regard to disclosure of scientific data. In addition, we have little confidence that OMB's proposal to limit disclosure to "published" data will withstand legal challenges under FOIA. A 1996 D.C. Circuit Court decision held that data could not be withheld until after publication had occurred. (87 F.3d 508, 521).

The Scope and Cost of Compliance

The attempt by OMB to focus these releases to data from published research used in developing policy or rules in turn raises questions. In a long-term study, there may be no logical boundaries for data release. What data are reasonably considered related to publication: all data, related to developing the hypothesis, or only those supporting the experiment?

The cost of compliance cannot be assessed until questions regarding the nature of data and agency responsibility have been settled. In the long run, the greatest expense may not be the duplication of data, nor the evaluation process that precedes decisions regarding the appropriateness of release, but the impact on the willingness of scientists to subject their data to such controls.

Alternatives

We conclude that if data sharing is not conducted in an appropriately structured manner, substantial adverse consequences for research could result. These consequences were not fully considered during the adoption of P.L. 105-277 because the legislation was not subjected to the usual deliberative legislative process. The need for such careful deliberation has been recognized

in a prior version of the legislation, which contained a mandate for a one-year study of the implications of the amendment as proposed. We agree with Senator Shelby, the main proponent of the legislation that such a study is needed. Therefore, OMB should defer rulemaking until the results of such a study are available. The National Academy of Sciences would be well equipped to undertake this assessment. By structuring it to involve the entire scientific community, especially as represented by scientific societies and their many disciplines and their traditional differences, the study would enable a thorough debate about the best way of sharing information with the public, to the satisfaction of both providers and recipients of scientific results.

In addition, we urge that OMB seek an Administration request for hearings on P.L. 105-277 so that Congress can learn first hand about the grave concerns in the academic community. We also urge that the federal agencies and the Office of Science and Technology Policy be involved in the assessment. As supporters of research in a variety of academic disciplines, they combine an intellectual overview and a public service perspective that is essential to help shape policy for access to and dissemination of data developed with federal support.

In Conclusion

We appreciate the efforts of OMB to be sensitive to the needs of sound scientific research policy as it struggles to try to find ways to implement this complex and significant legislative mandate. Nevertheless, as the foregoing discussion shows, COGR's membership concludes that, although well intended, implementation of the legislation cannot be structured to protect the public's interest in sound scientific research. We, therefore, strongly urge that the current regulatory process be redirected, in order to allow members of the scientific community, the federal agencies and Congress an opportunity to develop alternative proposals to achieve the mutually desired public policy goal.

We thank you for this opportunity to express our comments.

Sincerely,

Milton Goldberg