

August 8, 2001

Ms. Brooke Dickson
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, D.C. 20503.

Subject: Proposed Guidelines for Ensuring and Maximizing
the Quality, Objectivity, Utility and Integrity of Information
Disseminated By Federal Agencies. (66 FR 34489)

Dear Ms. Dickson:

I am writing to inform you that Michigan State University supports the position of the Council on Governmental Relations (COGR), of which it is a member, on the proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated By Federal Agencies. As you know, COGR is an association of 144 research-intensive universities in the United States. It is a source of critical information on current and emerging issues for its members and the agencies sponsoring their research activities. COGR is a leading advocate for policies that support the conduct of research at the highest standards and sound and informed decision-making on issues affecting the research and education community. COGR works with federal agencies and research sponsors to develop a common understanding of the impact that policies, regulations and practices may have on the research and training programs conducted by the membership.

P.L. 106-554, Section 515, requires the Office of Management and Budget (OMB) to prepare policy and guidance to federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by federal agencies. We strongly support OMB's basic philosophy that the agencies should adopt common sense systems that minimize the burden of implementation by relying as much as possible on established agency procedures and processes.

We have reviewed the proposed guidance from the specific focus of our research university membership. Given OMB's reliance on the Paperwork Reduction Act (PRA) and OMB Circular A-130, we understand that these requirements are imposed on agencies and not directly on recipients of federal support, with a few exceptions. However, research universities generate much of the scientific information that is critical to federal agencies in the material they distribute. Under the proposed guidelines, some agency dissemination of scientific information arising from research conducted at universities has the potential to be treated in a manner that could be quite damaging to the government-university research partnership by discouraging the sharing of qualified research information and thereby potentially denying the public and



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others the ultimate benefit of the information. With its comment letter, COGR highlights the areas that concern the research universities and urges OMB to consider our arguments for revising the guidance prior to final publication.

Background: Types and Nature of Scientific Information and Processes

A brief overview of the scientific information that would be subject to this guidance provides the necessary background for understanding our concerns and belief that certain types of scientific information warrant special consideration in the proposed implementation of these guidelines. Information produced within an academic institution could fall under these guidelines in at least four ways. First, the most common of these is information produced under contract with a Federal agency for a variety of purposes, including research, surveys, evaluations and epidemiology studies. As a procurement for the benefit of the government, such information would be collected under the PRA and the procuring agency would have ultimate responsibility for the quality of the data.

The second category is information produced by an institution, but summarized and disseminated in an agency publication. Because the agency has responsibility for the quality and utility of this summary information, OMB's policy and guidance should not provide an affected person an opportunity to seek and obtain correction of the original underlying information.

The third category includes agency publications of excerpts or entire passages of scientific work that are taken from progress reports, applications, presentations or other material submitted by federally funded researchers. This kind of publication should not be considered information because it is provided to the agency in a form that is usually not suitable for formal publication and not intended for dissemination to the public. Such "preliminary" or "in progress" reporting is not considered as established fact by the provider. OMB should encourage agency guidelines to provide for appropriate disclaimers or qualifiers when the agency chooses to disseminate this type of information.

Fourth, publications subjected to peer review have already met the scientific community's traditional and effective criteria of objectivity, reproducibility, the clarity of presentation and integrity of data. Many research-supporting agencies currently rely on the peer review process for the consideration of projects to fund and to renew. There is intensive peer review competition prior to agency funding of research projects and scrutiny of ongoing projects prior to renewal. The same standards are applied ultimately in the assessment of programmatic productivity. Journals are strengthening their review prior to publication to assure that only the best projects with the most promising research results are disseminated. This peer review process sets the highest standards for quality, objectivity, utility and integrity. The most effective way for agencies to implement the statute is to recognize and adopt these traditional scientific standards as the exclusive basis for disseminating peer-reviewed information.

Specific Issues

The standard for accurate, clear, complete and unbiased information.

COGR agrees with OMB that information must be presented within its proper context, and that the sources of the disseminated information need to be identified (to the extent possible consistent with confidentiality protections). With respect to scientific information, which is not specifically addressed in the statute, OMB directs federal agencies at V.B.ii.a. as follows:

“With respect to scientific research information, the results must be substantially reproducible upon independent analysis of the underlying data.”

Elsewhere in the guidance, OMB recognizes the potential for the delay of dissemination and considerable cost increases resulting from such independent analysis. This is a valid concern. For the reasons stated above, experience shows that there is no need for independent analysis in the case of peer-reviewed data so that, in these circumstances, the guidelines should not apply. OMB should urge that all federal agencies accept the peer review process as equivalent to or prior validation of quality standards. If the reference to scientific research information under V.B.ii.a of the guidelines is to remain, it should be rephrased as follows:

“With respect to scientific research information, the peer review process meets the standard for independent verification.”

For other, non-peer-reviewed information, we suggest that OMB direct agencies to develop useable criteria for independent analysis which take into consideration the cost effectiveness and the adverse impact on the public likely to result from delays in information dissemination.

Utility

The statute requires that OMB provide guidance on the standard of utility of information disseminated by the government. In interpreting the statute, OMB postulates that the information should be useful to all users of the information, including the public. OMB also suggests that utility should include a sliding scale of quality depending on the uses to which the research results will be put. For scientific information, the potential utility is often unknown at the early stage, subject to further research, and ongoing verification. Moreover, science does not recognize a sliding scale of quality. Therefore, if the test for utility of the scientific research includes a quality standard, that standard should be whether the information is complete and accurate in all material respects.

The expectation at section V.1.A. in the proposed guidelines that information be uniformly useful to all members of the public cannot be met by any agency. Different expectations of utility separate the needs of the scientist from those of the citizen. The scientific community does not find any utility in redacted, popularized material. Scientists expect that they themselves will publish their research data or that the agency will make un-redacted data available or collect it in databases with limited access and appropriate proprietary protections to encourage collaborations for scientific use. An example is the Human Genome Project.

Therefore, we suggest instead that the test for usefulness be tied to the agency's need to achieve its mission as suggested by the PRA, which defines the practical utility of information as "the actual, not merely the theoretical or potential, usefulness to the agency." We recommend that this measure of utility be the sole criterion.

In view of all these consideration, we strongly urge OMB to clarify that to the extent an agency disseminates the results of scientific research, the determination of utility and the selection of material not be delegated solely to the agency's chief information officer. Scientific judgment must be recognized and mandated as an essential component of dissemination decisions.

Claims by Affected Persons

The proposed guidance does not provide a definition of "affected person." Because the statute grants affected persons not only access to information but also an opportunity to have information corrected, agencies and the scientists upon whose research the agency information is based, may be inundated with or harassed by claims for correction. We believe it is essential that objective criteria be established for determining who is an affected person. Among those criteria should be a direct, measurable impact with significant personal consequences. We suggest that the most obvious demonstrable impact on a person would be if the material was not merely information, but information used in agency rulemaking.

OMB should also direct agencies to take into account that requests for the correction of information may be motivated by bad faith. This type of guidance is contained in comparable legislation, e.g., "whistleblower protection" statutes, and should be incorporated into this guidance.

We mentioned earlier that some of the scientific research information provided by universities to federal agencies is preliminary in nature. We want to reinforce our point that such material should not be considered information subject to challenges. Any necessary correction or verification will be a part of the ongoing research process.

4. Opinion

We recognize that "opinion" is a part of the definition used in Circular A-130 (6.j) and in a slightly different manner in 5 CFR 1320 and, therefore, has been included in the proposed guidance.

OMB has not addressed the role of opinion in the scientific information covered by these guidelines. OMB needs to clarify the standards to which "opinion" would have to be subjected in order to meet these statutory expectations, and to gain legitimacy and credibility in official information distribution. OMB should direct the agencies that an opinion by a recognized expert cannot be the basis for a claim for correction by an affected person.

In addition to this clarification, COGR recommends that OMB use the entire definition of "information" in 5 CFR 1320.3(h) including the general exemptions [5 CFR 1320.3(h)(1)-(7)]. This definition assures consistency between the PRA and these proposed guidelines. It offers additional protections for some limited types of scientific data and helps to address concerns with regard to protection of privacy.

5. Cost

We believe that the OMB guidelines do not provide sufficient discussion to guide agencies in anticipating the cost of independent analysis of underlying data and to balance those considerations against the cost of depriving the public of information from which it may derive multiple benefits.

Further, lacking in OMB's guidance is a discussion of the cost that may result from abuse of the new agency information processes as a result of claims from affected persons. OMB should consider guidance on how agencies may protect themselves and the public in that regard.

We support OMB's basic guidance that agencies may continue to rely on existing administrative mechanisms if they satisfy the standards in the guidelines.

Conclusion:

In formulating its response to the proposed guidance, COGR has been guided by important underlying principles that govern the universities' role as the primary performers of basic research and our long-standing relationship with the federal government. We are concerned that guidance for maximizing standards of excellence, which the university research community has adopted and to which it is committed in conducting research, have not yet been formulated by OMB with sufficient care. COGR is especially concerned that the proposed opportunity for independent analysis of underlying data could have serious adverse impacts on

research. Without the assurance that private personal information will be protected, it will be impossible to recruit human participants into medical research. Absent assurance that their intellectual property will be protected; our most creative and productive scientists may no longer want to participate in the government-university partnership.

We are also very concerned about the impacts of costs and delays in publication that could result from this guidance. Therefore, we specifically urge OMB to state explicitly that the statute cannot be interpreted by agencies to place additional burdens on the scientific community, either directly or by requiring procedures that would result in substantial delays for publication or that would impose a process that would divert funds from research support.

For all the reasons discussed above, Michigan State University supports the COGR request that OMB revise its proposed guidance in accordance with our comments and republish the revised guidance as a draft for public comment.

We appreciate the opportunity to comment on these proposed guidelines. Please let us know if additional information would be helpful.

Sincerely,

A handwritten signature in black ink, appearing to read "David E. Wright". The signature is fluid and cursive, with a large initial "D" and "W".

David E. Wright
Assistant Vice President for
Research Ethics and Standards