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August 13, 2001

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

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

Dear Ms. Dickson:

The Pennsylvania State University is a Carnegie Class I research institution that received and expended over \$240 million in federal grants and contracts during the fiscal year July 1, 2000 through June 30, 2001. Included in that figure is over \$75 million of research conducted by the University's Applied Research Laboratory in support of the Office of Naval Research, much of it for advanced technology essential for national defense. During the fiscal year ended June 30, 2001, the University also received and expended over \$100 million of combined funds from DHHS, NIH, NSF and NASA. Penn State's long tradition of fostering interdisciplinary research ensures that research advances made at the University are developed and shared in a timely manner. The University encourages and supports the transfer of ideas and technologies to benefit all aspects of life and society.

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. 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, Carnegie I institutions like Penn State 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 information arising from research conducted at Penn State has the potential to be treated in a way that could be damaging to the government-university research partnership by discouraging the sharing of qualified research information and thereby denying the public the ultimate benefit of the information. We hope to highlight the areas of greatest concern in this letter and urge OMB to consider our arguments for revising the guidance prior to final publication. We share the same basic concerns voiced in the letter submitted under separate cover by The Council on Governmental Relations (COGR) and will reiterate those same concerns.

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Background: Types and Nature of Scientific Information and Processes

A brief overview of the types of 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:

1. 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.
2. 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.
3. 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. OMB should encourage agency guidelines to provide for appropriate disclaimers or qualifiers when the agency chooses to disseminate such "preliminary" or "in progress" information.
4. Publications subjected to peer review which have already met the scientific community's traditional and effective criteria of objectivity, reproducibility, clarity of presentation and integrity of data. Many research-supporting agencies currently rely on the intensive peer review process prior to funding of research projects and for scrutiny of ongoing projects prior to renewal. 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 adopt traditional scientific standards as an exclusive basis for disseminating peer-reviewed information.

Specific Issues

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

We agree 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 that is not specifically addressed in the statute, OMB validly recognizes the

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potential for the delay of dissemination and considerable cost increases resulting from independent analysis. 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.”

2. 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 and 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. 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.

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. 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.

3. 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.

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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.

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, we recommend 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.

Summary

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. We are especially concerned that the proposed opportunity for independent analysis of underlying data could have serious adverse impacts on research. Absent assurance that their intellectual property will be protected; our most

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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, Penn State requests 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,



Kenneth S. Babe
Corporate Controller