

# PURDUE UNIVERSITY

August 10, 2001

VICE PRESIDENT FOR RESEARCH AND  
DEAN OF THE GRADUATE SCHOOL

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:

Thank you for the opportunity to provide formal comment on the above referenced Proposed Guideline (66 FR 34489). The following comments are submitted on behalf of Purdue University, a research-intensive institution of higher education located in West Lafayette, IN. Purdue University shares the Office of Management and Budget's goal of promoting policies that support the conduct of research at the highest standards. Our comments are offered in the spirit of fostering sound and informed decision-making on issues critical to the research and education community.

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 statement 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 a research-intensive university. We note OMB's reliance on the Paperwork Reduction Act (PRA) and OMB Circular A-130 and we understand that these requirements are imposed on agencies and not directly on recipients of federal support, with a few exceptions. However, research universities such as Purdue generate much of the information that is critical to federal agencies and the material they distribute. Under the proposed guidelines, some agency dissemination of information, which arises from research conducted at universities, may be treated in a manner that discourages the sharing of research information, and that may potentially reduce the ultimate benefit of the information to the public. Such treatment could be quite damaging to the government-university research partnership. With this comment letter, Purdue University highlights issues of concern and urges OMB to consider our arguments for a revision of the guidance to agencies prior to final publication.

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Background : Types and Nature of Scientific Information and Processes

We do not claim to understand the full scope of agency information subject to the proposed guidance. However, at the outset, we believe 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 three ways. The most obvious of these is information produced under contract with a Federal agency for a variety of purposes, including research, surveys, evaluations, 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 academic institution, but summarized and disseminated in an agency publication. While the agency has responsibility for the quality and utility of this summary information, OMB's policy and guidance should not suggest that an affected person could seek and obtain correction of the original underlying information.

An even more inadvertent, adverse impact would result when agencies publish 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 work provided to the agency is usually prior to publication and not intended for dissemination to the public. It often represents "preliminary" or "in progress" reporting that is not considered as established fact. Rather, it is likely to represent a best estimate, initial hypothesis, or interim conclusion. It is the nature of the scientific process that an experimental test of a preliminary hypothesis leads to refinement and further experimentation. A scientist's best understanding or explanation of a process or phenomenon today may be shown (by the same scientist or others) tomorrow to be clearly inadequate in the face of new data or a new paradigm. OMB should encourage agency guidelines to provide for appropriate disclaimers or qualifiers when the agency chooses to disseminate this type of information.

The scientific community traditionally and effectively employs objectivity, reproducibility, the clarity of presentation, and integrity of data as standards by which the community judges itself. 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. There is scrutiny of ongoing projects prior to renewal. The same standards are used ultimately in the assessment of programmatic productivity. Journals are strengthening their review prior to publication to assure that only the highest quality and 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 basis for accepting scientific information.

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### Specific Issues

#### 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, which is not specifically singled out in the statute, OMB directs federal agencies as follows:

*"with respect to scientific 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. It is our position that, in the case of peer-reviewed data and information, the burden should be placed on a complaining affected person to demonstrate that results are substantially different upon their independent analysis using methods generally accepted by the appropriate scientific community. For other, non-peer-reviewed information, we suggest that OMB direct agencies to develop useable criteria for independent analysis that take into consideration the nature of the scientific process (including the level of refinement and confidence that the author attributes to data in question), the cost effectiveness, and the adverse impact on the public likely to result from delays in information dissemination.

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 information, the peer review process meets the standard for accurate, clear, complete, and unbiased information."*

## 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. For scientific information, the potential utility is often unknown at the early stage, subject to further research and ongoing verification. The test for scientific research should therefore not be utility, but rather whether the information is complete and accurate in all material respects.

Scientists do not expect the government to publish their research results. Different expectations of utility separate the needs of the scientist from those of the citizen. Whenever agencies elect to use scientific information in their information dissemination, the guiding principle should be that

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information is presented in its proper context. The scientific community finds only limited utility in redacted, popularized material. Scientists expect that they themselves will publish their research data or that the agency will make unredacted 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.

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 for information outside of the area of scientific research information, the test for usefulness be tied to the agency's need to achieve its mission. In the PRA, the practical utility of information is defined 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 considerations, we strongly urge OMB to clarify that to the extent that 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.

### 3. Claims by Affected Persons

The proposed guidance does not offer 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 consequences.

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. 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.

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 information should not be subject to challenges. Correction or verification will be a part of the ongoing research process.

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#### 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 must clarify how an error or deficiency in "opinion" could 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 that are critical to ensure continued participation of human participants in research and protection of intellectual property that are essential to support and encourage entrepreneurship.

#### 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 crafting our response to the proposed guidance, Purdue University has been guided by important underlying principles that govern the university's role as the primary performer 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

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community has adopted and to which it is committed in conducting research, have not yet been formulated by OMB with sufficient care.

Lacking recognition of the nature of the scientific process and the importance of interim hypotheses and tentative conclusions, federally sponsored researchers may be hesitant to include their unproven insights in progress reports. 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 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 cited above, Purdue University 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,



Gary E. Isom, Ph.D.  
Vice President and Dean