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OFFICE OF THE PROVOST AND SENIOR VICE PRESIDENT
ACADEMIC AFFAIRS

OFFICE OF THE PRESIDENT
1111 Franklin Street
Oakland, California 94607-5200

August 13, 2001

Brooke Dickson
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

Dear Ms. Dickson:

On behalf of the University of California, I am pleased to submit comments on the "Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies," published in the Federal Register on June 28, 2001 (66 FR 34489). The University strongly supports steps to ensure the quality of data and information disseminated by federal agencies. We applaud Congress's interests in this area and OMB's effort to implement the Congressional intent of Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (P.L. 106-554).

We have a number of concerns regarding OMB's translation of our shared goals and the objective of ensuring the quality of federal information into agency guidance, however. We urge OMB to devote particular attention to the application of the proposed guidelines to scientific information and research data, and to revise the guidelines substantially in these areas prior to final publication.

Most generally, we believe the proposed guidelines go beyond the statutory mandate of P.L. 106-554 in highlighting the application of these guidelines to scientific information. In fact, we believe that existing agency procedures to ensure the soundness of scientific information disseminated or utilized in the regulatory process function well. Despite this, the proposed guidelines introduce vague definitions of critical concepts and they ignore the essential role and function of peer review in ensuring the quality of scientific information. In these and other ways, the guidelines as written presage myriad, deleterious effects of the conduct, dissemination, and value of scientific research. For all of these reasons we advocate deletion of paragraph V.B.ii.(a) in its entirety.

More specifically, we are concerned with OMB's silence with respect to the role of the scientific, peer-review process in ensuring the quality of research data disseminated; and with overly simplistic treatments of the concepts of "reproducibility" and of "underlying data" in the scientific realm; with vague definitions of such concepts as "quality," "utility," "objectivity," and "integrity" as these terms apply to research results; and with the absence of safeguards against improper challenges to agencies' compliance with the guidelines by entities claiming to be "affected parties." The following sections of this letter explain in greater detail the foundation of our concerns.

Application to Scientific Research

1 The Process of Peer Review. Peer review is the process whereby technically qualified individuals familiar with a particular field of study review the soundness and sensitivity of the methods by which an investigator gains information about a particular phenomenon; the plausibility of claims

that certain data have been generated by certain methods and experimental designs; and the interpretation of results and conclusions reached in specific, empirical contexts. Functioning in this fashion, peer review has evolved as the proven best approach to verifying the reliability of information reported by scientists to their peers and to the public.

Although conclusions and interpretations from scientific research often are debatable, through the assurances afforded by peer review, such debate is protected from unfounded claims and unchecked bias. In those areas of science subject to peer review, therefore, we urge OMB to instruct all agencies to accept the peer review process as equivalent to prior validation of quality standards.

2. Reproducing Research Results. As suggested here, the body of knowledge deemed "scientific" entails an evolving set of information, hypotheses, and interpretations. A community of investigators arrives at this information empirically through repetition and extension, and it is protected from fundamental error by the process of peer review. By design, therefore, research results are verified and developed through additional research and subsequent study.

   In this view it is clear that certain information will prove to be unsubstantiated or incomplete at the time of first dissemination. With respect to scientific research, therefore, any imperative that states all information must be "substantially reproducible" prior to dissemination will hinder the very process by which valuable information is generated. In particular, progress reports and preliminary presentations of research results to colleagues cannot be held to the same standard as final, published materials. Accordingly, if section V.B.II.(a) remains in the revised guidelines, we urge that it make explicit the importance of sharing preliminary data and research reports.

3. Defining "Underlying Data." Prior to publication of research results, data are collected, encoded, modified and analyzed in accordance with prevailing standards within a field of study. Throughout this multi-stage process, the unit of analysis – the parameters of the information characterized by the term "data" – may vary. What constitutes the "underlying data" of a research publication or presentation is not fixed, therefore, and definitions within the OMB guidelines must be made precise.

   Generally, the standard for reproducibility within the scientific community is limited to *supportive data* (found in a research paper) and excludes such other information such as medical records, lab notebooks, phone logs, et cetera. Permitting access to underlying data raises serious privacy concerns, could jeopardize intellectual property, and could undermine medical research where any threat to confidentiality is unacceptable. We urge OMB to adopt a definition that is explicit and consistent with other key pieces of federal legislation, and existing guidelines. In particular, we urge OMB to make clear that the term "underlying data" excludes the daily work product of research scientists, including laboratory notebooks, medical records, and administrative records such as telephone logs.

Definitions: "Quality," "Utility," "Objectivity," "Integrity"

The proposed guidelines include definitions of "quality," "utility," "objectivity," and "integrity" that are vague and confusing. These ambiguous definitions may provide a basis for objection to research results by individuals and organizations whose views differ from an investigator's findings or from a federal agency's use of those findings. OMB's treatment of these terms collectively as components of the "usefulness" of information is particularly unclear, especially in the realm of scientific research.

For scientific information, the potential usefulness of information often is unknown at the time it is produced, published, or initially disseminated. Moreover, the usefulness of scientific information varies immensely depending on the audience, and no agency can meet a standard that suggests such

information be uniformly useful to all members of the public. Rather than "utility" as defined here, we concur with others in the academic community that the better test for the quality of scientific research is whether the information is accurate and complete in all material respects.

Claims by Affected Persons

The guidelines require "administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply" with the rules. OMB does not establish criteria of what constitutes an "affected person," nor does it lay out protections against challenges by claimants motivated by political, profit, or other personal interests. This raises the specter of harassment and possibly of litigation against scientists and agency personnel.

To safeguard against such impediments to the free flow of information and against excessive costs of accommodating frivolous requests for correction, OMB should establish a high standard for evaluating the merits of appeals for data correction. We suggest that the complainant be required to demonstrate credible technical expertise in the area and to disclose potential conflicts of interest, both financial and ideological.

Conclusions

The University of California is a strong advocate for high standards and policy to ensure the quality, integrity, and objectivity of scientific information. As this letter indicates, however, the proposed guidelines raise a multitude of concerns and questions regarding their applicability to research. Given the collective concerns detailed here, we suggest that Section V.B.ii.(a) be deleted entirely from the guidelines. If this section is retained, however, we propose the following as a possible substitute for the current language:

> *ii. a. With respect to scientific research information, the results must be substantially reproducible upon independent analysis of the ~~underlying data~~* ***supporting data, as is the case in the normal scientific review process. Research findings that have been published in a peer-reviewed scientific or technical journal, or that have undergone the normal scientific peer-review process are explicitly recognized as having met the requirements of these guidelines.***

In the past, the scientific and academic communities have worked effectively with OMB on many issues. The University hopes to continue to work with OMB to revise these guidelines in order to address the concerns raised by members of the academic and scientific communities. To that end, we note the short time frame between the date that comments are due to OMB (August 13, 2001), and Congress' mandate to implement guidelines by September 30, 2001. We encourage OMB to request an extension from Congress to the implementation deadline and to offer the public an opportunity to comment on the revised guidelines before they are considered final.

Sincerely,

Lawrence B. Coleman
Vice Provost for Research