



CASE WESTERN RESERVE UNIVERSITY

August 10, 2001

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

RE: Comments on "Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated By Federal Agencies"

Dear Ms. Dickson

This letter is Case Western Reserve University's (CWRU) formal response on the proposed guidelines as noted above, that were published in the *Federal Register* on June 28, 2001. We appreciate the opportunity to comment.

We agree that federal agencies should ensure that information provided by the federal government is as reliable as possible. In our opinion, existing agency procedures in place provide adequate assurances in that regard, particularly in the area of release of scientific information. Therefore, we appreciate that the OMB's notice states that agencies are encouraged "to rely, to the extent possible, upon existing agency processes for evaluating information dissemination activities rather than require the creation of new and potentially duplicative or contradictory processes." However, CWRU is concerned with several items included in the proposed guidelines.

- 1. Agency Responsibilities 2 – "Establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply..."*

Comment: CWRU is concerned that the statute will provide an opportunity for interested parties seeking to review, with intent of discrediting, the scientific basis for any position taken by the government. We do not believe that OMB should establish procedures that could facilitate harassment of scientists who may be investigating questions of economic or social importance, simply because an individual may dislike the conclusions reached through those investigations.

Recommendation: "affected persons" should not be permitted to challenge the substance of information without showing that a qualified scientist has found fault with its quality or integrity.

- 2. Paragraph V. 1. A. – "Whether the information is useful to all users of the information, including the public."*

Comment: The University believes that the Paperwork Reduction Act addresses this objective adequately. There is a concern that this test may provide another avenue for interested parties to impede release by the government of material to which they object on political or economic grounds by challenging its "usefulness" to an ill-defined "public". No single "public" exists and information useful to some members of the public may not be of value to others. A long-standing role of a research university is to assist the public in obtaining information and answering questions on a broad set of issues. Therefore, we

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support release of information in the government's possession subject to appropriate protections for national security, confidentiality, privacy, and proprietary value.

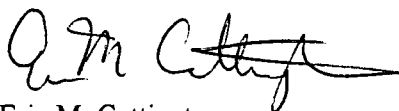
3. *Paragraph V.ii.a. – “With respect to scientific research information, the results must be substantially reproducible upon independent analysis of the underlying data.”*
- a. The statement suggests that data which was the basis of a study's conclusion would have to be disclosed so that anyone (qualified or not) could attempt to reproduce it. Our concern is that scientific data is generally not “reproducible” in a simple, straightforward way because it is generated in a particular setting with specific equipment, using techniques that only an individual properly skilled and trained could successfully apply. Further, the University's position historically has been that raw data does not belong to the sponsor of the research. A sponsor may have or be given the right to inspect a researcher's notebooks and to make copies, but we only allow the sponsor to own the report, not the underlying data. Another issue is whether public disclosure would make it impossible to protect valuable intellectual property and to force the university to disclose a sponsor's confidential information. This is of considerable concern when a research initiative is a university-government-industry partnership, where private industry participation would be severely handicapped.
- b. Another concern is that original research results are necessarily published before they have been replicated. These results may be challenged later, which is part of the scientific process. The “substantially reproducible” standard may interfere with publication of research results and delay important scientific discoveries from being publicized.

Recommendation: Delete paragraph V.ii.a. If the paragraph remains, we strongly suggest clarification of the term, “underlying data,” so that it is defined in a manner consistent with other existing federal policies and guidelines.

In general, CWRU finds the notice confusing, raising questions that merit serious review. We encourage OMB to provide leadership on this matter by requesting that Congress extend the September 30 deadline for promulgating the final guideline. The additional time will allow a more deliberate process, resulting in a satisfactory guideline that is in the best interests of the scientific research community and the public good.

Thank you for the opportunity to comment.

Sincerely,



Eric M. Cottington
Associate Vice President for Research

CC:
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