

August 10, 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, published in the *Federal
Register* June 28, 2001.

Dear Ms. Dickson

We have reviewed the referenced proposed guidelines and offer the following comments. We agree with the underlying premise that federal agencies should, to the best of their ability, ensure the quality, objectivity, utility, and integrity of information they disseminate. In addition, we strongly support OMB's recommendation that agencies rely on existing processes and procedures as much as possible in order to do this. It is our belief, however, that these processes and procedures already exist, and that adding yet another layer of bureaucracy may make release of government information even more cumbersome.

The proposed guidelines contain a number of areas of concern to the higher education community. The first has to do with the applicability of this new requirement to research performed by federally funded university faculty. Public Law 106-554 does not include specific reference to scientific research information, and we therefore strongly suggest that paragraph V.ii.a. be removed from your proposed guidelines. If you elect to retain this paragraph, we recommend that clarification be provided: who will perform the independent analysis, who will pay for it, what safeguards will be put in place to ensure that the analysts are objective and have scientific credibility. We believe that the requirement for independent analysis should not apply to peer-reviewed data, for obvious reasons. For non peer-reviewed data, agencies should be directed to develop specific criteria for independent analysis that take into account cost effectiveness and the negative impact of delaying information dissemination. We believe that allowing for independent analysis of underlying data could have serious adverse effects on university research. Without an explicit assurance that private personal information will be protected, it will dramatically hamper the recruitment of human participants into medical research. Without an explicit assurance that intellectual property will be protected, many of our best and brightest faculty researchers may elect to forgo federal funding.

We are also concerned about potential claims by “affected” persons. “Affected” person is a term that is ambiguous and needs to be defined. Criteria for determining who qualifies as an “affected” person must be established and should include a requirement that there be a clear, measurable impact with significant personal consequences. Because the guidance requires that “administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency,” it is possible that this could be used to discredit a line of research and facilitate the harassment of researchers by “affected” persons who may not like the results. In order to eliminate, or at least minimize, the possible influx of frivolous challenges by “affected” persons, they should be required to provide specific feedback from a qualified scientist that the results are questionable.

We are also concerned about the requirement that disseminated information be “substantially reproducible.” Novel basic research undertaken by university researchers by its very nature generates original results. Technical proposals and progress reports based on these results are provided to describe progress to date and to articulate proposed lines of research. Original research results are published in scientific journals with the expectation that others will attempt to reproduce them and possibly challenge them. If this guidance (66 FR 34489) is applicable to university research, this particular requirement will interfere with the publication of research results and add significant delays to the release of scientific discoveries.

As a member of the Association of American Universities and the Council on Governmental Relations, we support the comments provided by these organizations, as well as those contained in this response. Thank you for the opportunity to provide feedback.

Sincerely,

Lydia Villa-Komaroff
Vice President for Research
Northwestern University