

**COLUMBIA UNIVERSITY**

IN THE CITY OF NEW YORK

EXECUTIVE VIC PROVOST

August 13, 2001

**By Facsimile and Mail**

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

Dear Ms. Dickson

I write on behalf of Columbia University in response to the Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, which were published on June 28, 2001 in the Federal Register. OMB has sought comments as to whether these proposed guidelines strike the appropriate balance between setting rigorous standards for ensuring a high level of quality of information that is disseminated by Federal agencies and not imposing undue burdens and obstacles that could inhibit or unduly delay the dissemination of information that could be of benefit to the public.

Evaluating the proposed guidelines from the vantage point of a research institution strongly committed to the highest possible standards for quality and integrity of research, we believe that some clarification and modification of the proposed guidelines are needed in order to reach the appropriate balance sought by the OMB. We are concerned that implementation of the proposed guidelines in their present form could have unintended and damaging consequences for research conducted at and disseminated by academic institutions like Columbia.

At the outset, we also note that we are uncertain as to how these proposed guidelines, and the manner in which they are implemented by individual agencies, will apply to research and academic institutions. While there are no direct requirements imposed on research institutions, the dissemination by agencies of information arising from research conducted at research and academic institutions could have direct consequences for such institutions and our comments are designed to suggest ways in which OMB can ensure that those consequences are not damaging to the research partnership in which the government and research institutions are engaged.

Our comments focus on the following major concerns that we have: the lack of clarity in the definitions; the need for greater emphasis on the adequacy of current journal and peer review practices in evaluating the quality and integrity of information; and the need for adequate safeguards against abuse of the administrative complaint mechanisms set forth in the guidelines. We have other concerns as well, such as the potential administrative costs and burdens, not just for Federal agencies, but also for research institutions and researchers, that could result from implementation of the guidelines, and in that connection, request that OMB consider the comments submitted by the Council on Governmental Relations, the Association of American Universities and the Association of the American Institute of Biological Sciences.

### Definitions

The guidelines do not provide adequate definitions for the terms "quality", "utility", "objectivity" and "integrity", and what definitions are provided raise some troublesome questions. For example, the guidelines state that the utility of information is supposed to be evaluated by ascertaining whether it is useful to all users of the information, including the public. This is not an appropriate standard by which to evaluate scientific research, as its potential usefulness, particularly that of basic research, may not be known when it is first developed. The process of determining its utility may be one that goes on for years. Moreover, the utility of the results of scientific research may be apparent to experts in the field, but not to the general public, or it may be apparent to some members of the public but not others.

Similarly, the proposed guidelines do not adequately define the term "integrity". All research conducted under the auspices of a Federal agency is already subject to research misconduct regulations, the purpose of which is to ensure the integrity of research. Those regulations, among other things, establish procedures for the investigation of allegations of scientific misconduct. It should not be necessary to require agencies to use a different measure of integrity for purposes of these proposed guidelines, nor to create a separate mechanism for investigating potential scientific misconduct. The use of separate standards or procedures in the context of these guidelines would add significant costs to, and unduly delay, the dissemination of research information, and we question whether there is any basis for concluding that separate standards and procedures under these proposed guidelines would result in a higher level of integrity than that which is already required to be met under existing scientific misconduct regulations.

Another issue arising from the difficult attempt of the proposed guidelines to define a level of quality, utility, objectivity and integrity that information should meet before it is disseminated is the added requirement imposed on scientific research information that the results of such information be "substantially reproducible upon

independent analysis of the underlying data". There are a number of problems with the imposition of this additional requirement. For example, as noted in comments submitted by the American Institute of Biological Sciences, independent analysis would require access to all of the experimental and observational data, something which reviewers rarely have, and it also raises the issue of the competency and skills of the reviewer. The requirement of re-analysis of all of the data would also impose substantial additional costs and delays in dissemination. Moreover, as set forth more fully below, there should be no need for independent analysis when scientific research information is already subject to a rigorous peer review process.

We also request that OMB give further consideration to the definition of "dissemination". The kinds of information provided to an agency by a research institution include not only completed research papers and final research results, but also grant applications which may contain preliminary research data, progress reports, or other research information that is not intended for public dissemination. These categories of information should be excluded from information that is considered "disseminated" under the proposed guidelines, even if any such information does get reported or cited in an agency publication of some kind.

#### The peer review process

In describing the underlying principles for the proposed guidelines, OMB states that agencies are encouraged to rely, to the extent possible, upon existing processes for evaluating information dissemination activities. The goal of ensuring and maximizing the overall quality and integrity of information disseminated by an agency is much the same goal of the journal and other external peer review processes that are used in the scientific research community to evaluate research results. Those processes already subject scientific research information to rigorous standards for quality, integrity and objectivity of research. Many government agencies that support research already rely on the peer review process in evaluating projects to fund and/or renew and in connection with information to be disseminated by the agencies.

We recommend that the proposed guidelines expressly recognize that agencies which now employ the peer review process in assessing research projects and research results or which establish comparable peer review processes, meet the standards of quality set forth in the guidelines. We fear that the imposition of a different set of standards would inject a level of uncertainty in the research community that could have a chilling effect on the conduct and dissemination of research.

### Safeguards against abuse of the complaint mechanism

We believe that further guidance is needed in connection with the provision requiring agencies to establish "administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the OMB guidelines." We strongly recommend that safeguards be incorporated into the guidelines to prevent the abuse and misuse of such mechanisms by individuals and companies or other organizations who are not acting in good faith. Such safeguards should include establishing objective criteria for defining "affected person", and placing the burden of proof on the affected person, so that his or her allegations are subject to the same rigorous standards of quality and integrity as is the research information being challenged. Moreover, just as researchers at academic institutions like Columbia are required to disclose any conflicts of interest in connection with the reporting of research results, so too should the affected person be required to disclose any conflicts of interest.

Our concern regarding potential abuse of the complaint mechanism is related to the lack of clarity in the definition of "dissemination" for purposes of the complaint procedures. As noted above, information provided to an agency by a research institution that is not intended to constitute completed research findings, e.g., preliminary data, progress reports, and the like, should not be subject to the complaint procedures.

### Conclusion

We believe that further work needs to be done to ensure that a standard of excellence in information disseminated by Federal agencies is achieved without the imposition of significant administrative costs and burdens that would undermine the achievement of that standard by substantially delaying and inhibiting the free flow of research information and results that could be of great benefit to the government, the scientific community and the general public. We urge that, in evaluating the proposed guidelines and the letters that have been submitted in response to the request for comments, OMB make specific efforts to avoid the imposition of additional costs and burdens on academic institutions and the scientific community.

Thank you for this opportunity to comment on these proposed guidelines.

Sincerely,



Michael Crow  
Executive Vice Provost