



August 10, 2001

Ms. Brooke Dickson
Office of Information & Regulatory Affairs
Office of Management & Budget
Washington, DC 20503

Re: Proposed guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by federal agencies (66 FR 34489, June 28, 2001)

Dear Ms. Dickson

The American Psychological Association (APA) appreciates the opportunity to comment on the Office of Management and Budget (OMB) proposed guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by federal agencies. APA is the largest scientific and professional organization representing psychology in the United States and is the world's largest association of psychologists. APA's membership includes more than 155,000 researchers, educators, clinicians, consultants, and students. Through its divisions in 50 sub-fields of psychology and affiliations with 59 state, territorial, and Canadian provincial associations, APA works to advance psychology as a science, as a profession, and as a means of promoting human welfare.

APA supports OMB's efforts to improve the quality of data that are disseminated by federal agencies. However, in its current format the guidelines do little to enhance scientific research information that is generated and disseminated by federal agencies. In addition, these guidelines might serve to hinder scientific progress in at least four ways. First, they might unnecessarily increase the administrative burden on federal agencies. Second, they might gratuitously delay dissemination of vital research results. Third, they are vulnerable to misuse by individuals and groups with a non-scientific agenda. For example, the guidelines may provide ammunition for entities that are against the use of animals or of minors in research to further obstruct such research. Fourth, as the publisher of many of the leading journals in the field of psychology, APA is concerned that the guidelines do not acknowledge the rigor that is inherent in scientific research and publication and could unnecessarily delay timely publication of research results and thereby retard scientific progress. The crux of the problem, we believe, is the use of ambiguous, ill-defined, or undefined terminology. Below are specific comments and recommendations on behalf of APA.

Definitions

The terms “quality,” “utility,” “objectivity,” and “integrity” are not clearly defined in the proposed guidelines, thus making them open to subjective interpretation. In addition, the three aspects that, per the proposed guidelines, need to be addressed in order to meet these four criteria collectively are contentious. For instance the requirements that information both be presented in an accurate, clear, complete, and unbiased manner (a goal we of course endorse) and also be useful to *all* users including the public, is not only infeasible but next to impossible. Comprehension and “use” of highly specialized and technical scientific data requires more advanced understanding of the appropriate disciplines that may not always be accessible to the lay public. Furthermore, especially in basic research settings, the ultimate benefit or use to society, may not be readily evident early in the research process, but preliminary data, although of little, if any immediate “utility” to the general public, needs to be disseminated in order for the field to advance.

The subjectivity inherent in these proposed guidelines may render scientific data vulnerable to challenges on unscientific grounds. For instance, those whose political, religious, or moral views differ from the findings of research scientists may object to the quality of the data purely on those non-scientific grounds. Thus, APA urges OMB to explicitly state, in the definitions, that these guidelines and other guidelines subsequently issued by covered agencies cannot be used as a tool to challenge scientific findings or advances that may be objectionable on grounds other than their scientific merit. To circumvent this possibility, APA urges that OMB clearly specify in the guidelines that those who are authorized to challenge an agency’s compliance with these guidelines be required to demonstrate both a scientific basis for their challenge and the absence of a conflict of interest (e.g., commercial interest). Such a revision would ensure that these guidelines are truly in the best interest of the public rather than a lobbying or litigation tool.

Although it is apparent that the proposed guidelines cover intramural researchers in federal agencies, the relationship and impact, if any, of these guidelines on extramural researchers is undefined. The requirement that agencies present information (i) in an accurate, clear, complete, and unbiased manner, within the proper context, including other information, as needed and (ii) that they identify the sources of disseminated information thereby allowing the public to assess the objectivity of the sources would severely undermine the peer review process. Requiring extramural researchers to open their research data to public scrutiny, would, inhibit the early exchange of scientific data and results, and create an enormous administrative and regulatory burden. Thus, APA recommends that the guidelines explicitly state that the requirements do not extend to extramural researchers.

The proposed guidelines require that “the results must be substantially reproducible upon independent analysis of the underlying data.” This requirement is ambiguous since many of the key terms are undefined. These include *substantially reproducible*, the entity that would conduct the *independent analysis*, and finally, *underlying data*.

Substantially Reproducible – while acknowledging that confirming or disproving research findings is at the heart of the scientific process, and that high standards of data analyses are necessary, APA believes that the use of the phrase in the proposed guidelines is ambiguous. It also disregards the usual role of peer feedback, review and critique.

Independent Analysis -- There is no clear specification of who would be responsible for the independent analysis or how such analyses will be funded.

Underlying Data – in the absence of a definition, this term could be interpreted broadly to include the daily work product of research scientists, including lab notebooks, medical records, and administrative records such as telephone logs. Such information should be protected from public

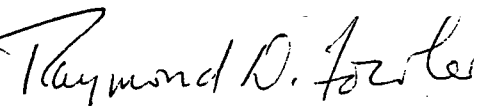
scrutiny (absent a legally authorized subpoena or statutory requirement) both to ensure the free thinking and exchange of ideas among scientists and to prevent a paralyzing administrative and regulatory burden on working scientists.

Reporting Requirements

The proposed guidelines state that agencies covered by these OMB guidelines will be statutorily required to report, on an annual basis, “the number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines...and how such complaints were resolved.” APA is concerned, however, that the number of complaints received, rather than the validity of the complaints received, is an inappropriate measure that could unfairly impact the reputation of an agency and/or its funded investigators. A large number of complaints on a scientific matter could simply reflect a controversial issue – or an organized advocacy effort – rather than the quality or validity of the data.

In conclusion, we welcome the opportunity to comment on these proposed guidelines, and trust that the comments will be useful in the deliberation process.

Sincerely yours,



Raymond C. Fowler
Chief Executive Officer



Merry Bullock, PhD
Acting Executive Director for Science