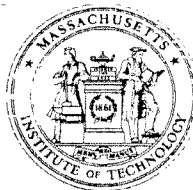


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August 6, 2001

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

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

Dear Ms. Dickson

The Massachusetts Institute of Technology appreciates the opportunity to comment on the proposed guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by federal agencies. We recognize that these guidelines have been developed in response to the adoption of P.L. 106-554, section 515(a).

The Massachusetts Institute of Technology remains committed to the principles of quality, objectivity, utility, and integrity in the information its researchers develop in the course of their academic and research activities. The draft regulations, however, pose challenges to universities and, in some instances, extend beyond the requirements of the law. Of significant concern are the definitions and concepts articulated by OMB in its discussion of "quality, utility, objectivity, and integrity." We hope the following comments will be useful to OMB as it considers how to implement the requirements of the public law.

We are seriously concerned about the use of the term scientific data. The statute does not refer to scientific data; rather it refers to information, government information, information dissemination product, and dissemination. It is, we believe, important to recognize that federal sponsoring agencies utilize multiple forms of expert, merit-based or peer review of research performed under their sponsorship. Nothing should interfere

or restrict or constrain the concept of expert, merit-based, peer review as the primary engine that ensures the accuracy, validity, and viability of research outcomes (scientific data). We believe OMB should direct federal agencies which support research activities to accept peer review as the quality standard.

In addition, we recommend that OMB use the entire definition of “information” in 5 CFR 1320.3(h) including the general exemptions [5CFR 1320.3(h)(1)-(7)]. This definition assures consistency between the Paperwork Reduction Act and these proposed guidelines and offers additional protections for some, limited types of scientific data and help address concerns with privacy.

The OMB suggested mandate that the results of research must be “substantially reproducible upon independent analysis of the underlying data” and “must be useful to all users, including the public” is troublesome. The issue of reproducibility, as we and others have commented in the past, raises complex questions and, unless carefully managed, could seriously impede the progress of fundamental research itself. The usefulness of data statement is also troublesome. Although we clearly recognize there must be mechanisms to allow appropriate access to data, we are concerned how this would actually be done, especially as the language speaks to “all users.” We urge OMB to consider language which establishes standards for persons directly affected by the information to initiate claims, with a requirement that such persons be required to demonstrate how they are specifically affected by the information. Otherwise, we fear the system could be dramatically impacted by frivolous requests for data access, analysis, reproducibility, and corrective procedures. Also, we are quite concerned that the more risk averse an agency is the less likely they will be to disseminate information. We believe that OMB should conduct a careful risk/benefit analysis of this because of, as a minimum, the potential chilling effect the lack of dissemination might have on the community.

Institutions and individuals who perform fundamental research now have certain expectations with respect to privacy and the confidentiality of proprietary data. Care must be taken to ensure that the same guarantees of confidentiality that currently exist be included in the implementation of these regulations. If these guarantees of confidentiality are omitted, unauthorized and premature release of underlying scientific data will occur with adverse financial effects for institutions and perhaps sponsors of research as well as damaging impacts on open and unfettered scientific inquiry.


In addition to these general concerns regarding the definitional items (objectivity, utility, quality, and integrity) and the issue of data reproducibility and dissemination, we are further concerned that the latitude given to federal agencies to implement these regulations is excessive. We strongly urge OMB and the agencies to reject all administrative burdens beyond those specifically mandated in the law.

A final concern relates to the financial consequences of these policies. It isn't clear, for example, whether the individual doing the initial research would be the one

required to replicate the study and who would provide the funding for that work? Additionally, there is no statement in the regulations mandating that any implementation is only prospectively and not retrospective. This should be clearly addressed.

We appreciate the opportunity to comment and are available for additional discussion.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie T. Norris". The signature is fluid and cursive, with the first name "Julie" and last name "Norris" clearly legible.

Julie T. Norris

Cc Dr. R. Brown
Mr. J. Curry
Dr. P. Clay
Mr. J. Crowley