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## Research Division

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August 10, 2001

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

Re:

Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies

Dear Ms. Dickson:

By this letter, Virginia Tech wishes to join collectively with the Association of American Universities, the National Association of State Universities and Land Grant Colleges, the Council on Governmental Affairs, and other scientific and educational societies and institutions to express the need for a revision of the proposed guidelines, and republication for comment after the suggestions from the scientific and educational communities have been thoroughly considered.

In attempting to address the breadth of data and information disseminated by federal agencies, the proposed guidelines probably should not be too specific in their tenor. However, in their attempt to address scientific and statistical data and information concerns, the proposed guidelines run afoul of the current, and in our opinion, strong system of research and reporting that already exists between investigators and their federal sponsors.

OMB proposes, "... When the issues of reproducibility and transparency of the information are relevant for assessing the information's usefulness from the public's perspective, the agency must take care to ensure that reproducibility and transparency have been taken into account." This statement is ambiguous, and circular in its formation. Perhaps herein the proposed guidelines are attempting to ensure that agencies review and revise their current procedures to ensure that the agencies' policies themselves do not stand as barriers to independent attempts at reproduction of the information. Perhaps the guidelines are pointing to the need for clear identification of sources of the information being disseminated by the agency.

Neither of these readings is particularly troublesome for scientific investigators. However, some may read this part of the proposed regulation as creating an obligation on the part of the subject agency to fund and conduct studies aimed at ascertaining the reliability and validity of the information being disseminated. The question then arises, if the agency's validation study is disseminated (perhaps to put the original information in context), then who validates the agency's validation study? If OMB desires to create the obligation on the part of federal agencies to fund and conduct these types of studies, it would be best for the guidelines to simply state that desire. We disagree with this approach; but we certainly do wish for clarity in this statement. We believe this lack of clarity in the proposed guidelines raises significant opportunity costs in the efficient delivery of vital scientific and statistical findings to the public.

Non-classified scientific and statistical studies conducted by federal agency-funded investigators are commonly subject to both pre- and post-screening by sophisticated investigators who play a central role in assuring quality findings. The majority of federal agency funding to scientific and statistical investigators is awarded through a competitive peer-review system, wherein roughly one-in-five applications receive an

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award. Investigators work closely with their program officers throughout the research process, often submitting periodic reports of progress and findings. The results are then disseminated in agency sponsored and independent forums, including symposia, conferences, the common media, and most notably the many discipline-specific and interdisciplinary peer-reviewed journals. These journals and forums further subject the findings to critical review.

In Sction V.B. ii of the proposed OMB guidance, agencies are told, "... In the context of scientific and statistical information, the results must be substantially reproducible upon independent analysis of the underlying data." Also that, "... The information [must be] obtained using sound statistical methods, and error sources affecting data quality (must be) disclosed to users." Further, "... [the agency must certify] whether the information has been protected from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification."

This section of the proposed guidelines could be interpreted to mean that agencies should learn toward disseminating only that scientific information that is sourced to peer-reviewed journals and studies, and if periodic work products are disseminated, that they would somehow have to be branded of a lesser quality. While we support without reservation the strength of the peet review system, federal agencies frequently, and in our opinion, rightly disseminate and refer to the many periodic and special reports and "deliverables" incidental to federally funded investigations which can be equally valuable, and frequently are available in a more timely fashion.

In Sction II.2 the proposed guidelines state, "...[agencies must] establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with these OMB guidelines." Inasmuch as this section refers to scientific and statistical data used in conducting scientific investigations, there is a particularly disastrous opportunity for an increased, and likely unfounded, burden on research performers. Should these proposed guidelines be interpreted to require correction of disparate and diverse scientific databases and subsequent submittal of revised findings, the research enterprise would stall and the public would loose access to valuable information. A particularly troublesome ambiguity in this section is the lack of definition for the term "person."

If "person" is defined as a single human individual or a class of single human individuals, then corrections may be in greater priority. However if the definition of "person" includes corporate entities, the possibility for burdens imposed by litigation and threats of litigation becomes explosive, particularly for agencies like the Environmental Protection Agency that frequently relies upon scientific and statistical data as a partial basis for establishing governmental regulations and definitions. The inclusion of corporate entities in the definition of person for this purpose should be carefully considered, and we are skeptical of the value of their inclusion for this purpose.

We write to oppose the proposed guidelines on these and additional grounds identified by our associates in the scientific and educational societies, and request the revised proposal be published for further comment prior to enactment.

Leonard K. Peters Vice Provost for Research