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Proposed OMB Guidelines COGR Comment

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OMB Issues Final Peer Review Guidelines for Agencies

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OMB Issues Final Peer Review Guidelines for Agencies

COGR has reported on the more than year-long effort of the Office for Information and Regulatory Affairs (OIRA) to issue guidelines for the Peer Review of influential scientific information under the Information Quality Act. The final Bulletin for Peer Review was issued by OIRA on December 15, 2004 and is available on its web site at:

<http://www.whitehouse.gov/omb/infoereg/infopoltech.html>.

This Bulletin provides guidelines for enhancing the quality of scientific information used by the Federal agencies. These guidelines do not have a direct effect on universities. The guidelines may have an impact on university scientists but only if their publications or research results are endorsed by an agency as fact or the agency's view or if the research is incorporated into a scientific assessment prepared to support a specific agency action.

In such cases, scientists may be asked to provide access to the underlying data used in publications or reports. To temper the impact of these information quality guidelines and to qualify for the general exclusion from the information quality provisions for government-funded scientists, it will be more important than ever that investigators include the clear, standard disclaimer on all publications and presentations of federally supported research results – “The findings and conclusion in this report are those of the author(s) and do not necessarily represent the views of the funding agency.”

The other area that scholars will want to be alert to is the public disclosure of the peer review panel. In all cases of agency-sponsored peer review, the names of the panelists and their affiliation will be made available to the public. Attribution of comments or critiques by individual panelists is not required, or expected, but the final report of the panel will be made available to the public.

The final OMB Guidelines are an addition to or clarification of the Information Quality Act guidelines issued by OMB in February 2002. The Peer Review guidelines set minimum standards for when peer review by an agency is required and the types of review to be used based on the nature of the information and the circumstances of its use. COGR commented on the earliest version of the Bulletin issued in September 2003. Based on the comments from COGR and other associations and individuals, OMB issued a revised version in April 2004 for comment.

The June 2004 meeting Agenda described the revisions OMB offered for comment in April. We noted that OMB clearly considered the concerns of the agencies and the public including COGR in crafting the April revision. In commenting on the September 2003 version, COGR questioned the Bulletin's vague description of the scope of review, the overly prescriptive nature of the required peer review process including the selection of peer reviewers, and the

cumbersome processes for public participation and reporting. OMB addressed these concerns by focusing on influential scientific information and accepting prior peer review as in the case for publication in a journal if the agency determines the prior peer review to have been adequate. In response to one of the most contentious issues, the exclusion of scientists who have received funds from the agency, the April version and the final version supports convening panels with the greatest expertise that reflect the breadth and diversity of scientific perspectives. COGR did not submit a formal comment on the April version of the Guidelines.

In this final December version, OMB has made some minor and, one could argue, major changes that may make it more difficult for agencies to rely on prior peer review before disseminating influential scientific information; may bring additional information as used in agency-developed scientific assessments under peer review; and, without question, will increase the administrative burden on the agencies.

In the April version, OMB set the novelty and complexity of the science or scientific approach to be the standards for determining the need for a peer review and the adequacy of any prior review of influential scientific information. In this final version, OMB has added the importance of the information to decision making, the extent of the prior review and the expected costs and benefits to the standards for initiating a review and determining the appropriate mechanism, e.g., letter reviews or convening a panel.

It is in the required peer review of highly influential scientific assessments – an evaluation of a body of scientific knowledge that synthesizes information and, generally, applies professional judgment to bridge uncertainties – that OMB seems to broaden the applicability of the guidelines. In the earlier version, the more rigorous peer review was required for scientific assessments that could have “clear and substantial impact on important public policies or private sector decisions with a potential effect of more than \$500 million in any year or involve[ed] precedent setting, novel, and complex approaches.” This final version requires peer review for scientific assessments that could have “a potential impact of more than \$500 million in any year or is novel, controversial, or precedent-setting.” OMB shifts the requirements from standards that set the monetary impact bar at a clear and substantial threshold and built the scientific standard on the cumulative measures of precedent-setting, novel, and complex. Now the monetary applicability has been broadened to the potential impact of \$500 million – easily reached as OMB notes in programs that include a substantial first-year capital investment – and covers all novel or potentially controversial science under the requirements for a peer review. It will be more difficult for agencies to rely on prior review and the more cautious approach to meet the test of novelty, controversy or precedent setting will be to conduct peer review on any scientific assessments that changes current requirements.

The National Academy of Sciences (NAS) in its processes and its reports gets a very strong endorsement under the new guidelines. As an alternative to conducting its own peer review, agencies can rely on NAS report findings, conclusions and recommendations that are presumed to have been adequately peer reviewed. In those cases of scientific assessments prepared by or for an agency, the agency can commission NAS to peer review the assessment. Agencies are directed to “adopt or adapt” the NAS processes for selecting panel members and resolving potential conflicts of interest. An agency will likely want to weigh the costs and benefits of commissioning an NAS assessment against the costs of conducting their own reviews.

All of this and the new annual reports and more complex annual peer review planning process will increase the administrative burden on the agencies.

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