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August 13, 2001

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

Dear Ms. Dickson,

On behalf of the 900+ researchers and the Directors of Kaiser Permanente's National Research Council, we are writing to provide comment on the proposed guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (Section 515, 66 FR34489; June 28, 2001). Kaiser Permanente researchers engage in a full spectrum of medical research from epidemiology, to Health Services Research, to clinical trials. We constantly seek to find information that will improve the health of our members and communities and utilize the unique resource that our 8 million plus membership affords us. Our accountability back to our members is to protect their confidentiality and to not overly burden them with the demands of the research.

We share the expressed concerns raised by other professional societies and groups such as the AAU, the AAMC and the FASEB over the vague terminology in Section 515 and the suggestion that Federal agencies should seek ways to validate the conclusions of peer-reviewed research which is currently the gold standard and bedrock of scientific investigation. In addition, we have two other concerns.

First, a substantial number of Federal agencies provide grants that support biomedical research studies. Although disparate in subject matter, such research studies share commonalities with regard to how research integrity, quality, and objectivity are ensured. For example, Federally funded research is conducted under the authority of Institutional Review Boards, which ensure that the rights of research subjects are protected. In addition, the researchers and the organizations within which researchers perform research sometimes utilize information that is of a proprietary nature to the researchers or the organizations of which they are a part. Missing from the OMB guidelines to agencies is any reference to the importance of safeguarding the rights of research participants and the researchers in connection with such activity. We believe that the guidelines should be modified to include an explicit reference to confidentiality, so that the guidelines provide a more balanced guide to the considerations which agencies should use in devising their administrative mechanisms.

Secondly, Kaiser Permanente believes that the issues common to biomedical research are sufficiently great, and the advantages of having a common approach to the administrative mechanisms sufficiently important, that the guidelines should permit those agencies which



sponsor biomedical research to convene a multi-agency task force. The purpose of such a task force would be to devise a single mechanism for ensuring quality, integrity, and objectivity of information and a single mechanism for allowing citizen review of such information. These mechanisms would apply across the agencies participating in the multi-agency task force. Having such a common approach could yield a great efficiency for both the agencies and researchers. An example how such a common approach can work is the "Common Rule" which many Federal agencies involved in research use to govern the review of research for the purpose of human subjects' protection.

Thank you for hearing our concerns. We stand ready to assist the OMB in any way possible.

Sincerely,

Jed Weissberg MD
Associate Executive Director
The Permanente Federation

and

Mary L. Durham PhD.
Chair- Kaiser Permanente National Research Council
Director-Kaiser Permanente Center for Health Research
And Vice President, Research
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