



FEDERAL DEMONSTRATION PARTNERSHIP

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Washington, DC 20001

Nancy J. Wray
Chair

January 27, 2006

Richard B. Stern,
Office of Counsel to the Inspector General
Office of Inspector General,
Department of Health and Human
Services, Attention: OIG-1026-CPG,
Room 5246, Cohen Building, 330
Independence Avenue, SW.,
Washington, DC 20201

RE: Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards

Dear Mr. Stern:

On behalf of the Federal Demonstration Partnership, I am happy to provide comments to the November 28, 2005 Federal Register Notice of the HHS Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards. The Federal Demonstration Partnership is a unique organization because the membership comes from the research community (98 Institutions) and the government (10 Federal Agencies). At the January 2006 meeting, we held an open forum to collect comments from the membership regarding the Draft Guidance which I have summarized for you below.

The members agree that Institutions need comprehensive compliance programs that serve the entire research enterprise. The Draft Compliance Guidance only focuses on PHS research and research related awards. Most Institutions have policies and processes that cover not only PHS, but other sponsors as well. Focusing on only one Agency will set up the possibility of conflicting guidance depending on the source. In addition, the members commented on the prescriptive nature of the guide which will be interpreted not as a guide, but become the de facto standard and any deviation will be considered in non compliance. As a case in point, Institutions stated that their external audit firms were already using this guide as requirement. Much concern was raised about the excessive detail outlined for the organizational structure for a compliance program including the appropriate budget amount. A compliance program has to work within the unique Institutions structure and budget. Some may set up programs within the schools of their Institution, while others have a centralized program. Therefore the members feel strongly that it is inappropriate for the Guidance document to dictate an organizational structure. Overall, the members do not feel that the Draft Compliance Document meets the standards of the OMB's guidance on guidance.

The Members commented that while the principles stated in the guide were common sense, there were many technical inaccuracies. The statements concerning Time and Effort reporting needs to be written to be in compliance with A-21 section J.10, Compensation for personnel services. Members took exception to the references concerning discipline of faculty. Institutions have Misconduct Policies in addition to other ethical policies to govern the behavior of faculty. Infractions are normally

The FDP is a cooperative initiative of U.S. research institutions, federal agencies, and professional organizations to enhance research productivity.

confidential and the matters are resolved. Public disclosure is not always the best method for enforcement of the regulations.

In closing, the members strongly encourage you to withdraw the Draft Compliance Guidance Document and work with the other Federal Agencies to develop a Compliance Guide across all agencies. We would be happy to discuss this further and invite you to attend our May 22/23rd meeting.

Sincerely,

A handwritten signature in black ink, appearing to read "Nancy J. Wray". The signature is written in a cursive, flowing style with a large initial "N".

Nancy J. Wray
Chair