

AAMC Association of American Medical Colleges
AAU Association of American Universities
COGR Council on Governmental Relations
NASULGC National Association of State Universities and Land-Grant Colleges

January 30, 2006

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

Subject: OIG-1026-CPG: Compliance Program Guidance for Recipients of PHS Research Awards

Dear Mr. Stern:

As associations representing the nation's research universities and their affiliated academic medical centers, teaching hospitals, research institutes, and research faculty and staff, we recommend that the Inspector General withdraw the proposed Compliance Program Guidance for Recipients of PHS Research Awards in its current form. The detailed description of the compliance program and discussion of compliance risk areas will not accomplish the objective of enhancing compliance. It is too limited in scope and focus to result in the most effective compliance approaches. PHS research awardees share the belief that an effective compliance program helps ensure good stewardship of Federal funds. They are already striving to meet the goals of improving grants management and ensuring responsible conduct based on guidance developed by the research community itself, tailored to meet the complex compliance challenges inherent in the research enterprise.

This recommendation represents the views of the Association of American Medical Colleges (AAMC), the Association of American Universities (AAU), the Council on Governmental Relations (COGR), and the National Association of State Universities and Land-Grant Colleges (NASULGC). AAMC is a non-profit organization representing all 125 allopathic medical schools in the United States, about 400 major teaching hospitals and health systems, and 94 academic and professional societies representing nearly 110,000 faculty members. The AAU is an organization of public and private research universities devoted to maintaining a strong system of academic research and education, and consists of 60 U.S. universities and 2 Canadian universities. COGR is an association of 167 research intensive universities, affiliated hospitals and research institutes in the United States that concerns itself with the influence of government regulations, policies, and practices on the performance of research conducted at colleges and universities. NASULGC, with roots back to 1887, is the nation's oldest nonprofit higher education association with 214 members from all 50 states, the District of Columbia, and the U.S. territories. NASULGC's mission is to support high-quality public education and to enhance the ability of its members to carry out their land-grant heritage in learning, discovery, and engagement with society at large.

General Comments

Research institutions recognize the importance of a comprehensive compliance program for the management of research and research-related activities, and we agree with the general framework and principles of the proposed basic elements of the Compliance Program Guidance (CPG). Research institutions are developing or have already developed integrated systems of policies, procedures, training, reporting and assessment to achieve full compliance with regulations from multiple federal sponsors. The OIG recognizes the value of an integrated compliance approach and, acknowledging the diversity in sponsorship and regulatory complexity, points to the existing body of literature and expertise in the various areas of research compliance. Despite this recognition and acknowledgement, the CPG proposes an inflexible and prescriptive approach that is inappropriate in most research settings and precludes implementation of the most effective compliance system tailored to individual institutional needs and culture. It is too narrowly defined and prescriptive, and it does not address the challenges of an integrated compliance program.

A primary concern is that this guidance will become *de facto* regulation in areas where we currently have greater flexibility to achieve compliance with Federal regulations. Although the OIG states that the guidance “should not be viewed as mandatory,” the draft guidance is replete with phrases that “strongly encourage” implementation, define when an approach is “structured appropriately,” or identify the “optimal” or “ideal” strategies. What is ideal in one setting may be ineffective in another. Yet, with such language, institutions are left with the choice of structuring their compliance programs precisely as the OIG “strongly encourages,” or bearing the burden of demonstrating to auditors why they have “failed” to adopt the OIG’s “regulatory” CPG. This level of detail reads like an oblique way of setting standards that are contrary to the existing regulatory flexibility provided by the agencies that have direct oversight over federal grant recipients.

OMB Guidance on Guidance

Presumably, the concern about the impact of such overreaching federal guidance documents led the White House Office of Management and Budget (OMB) in November 2005 to issue draft policies and procedures for agencies to develop, issue and use guidance documents. See <http://www.whitehouse.gov/omb/inforeg/regpo.html>. In this proposed bulletin for Good Guidance Practices, OMB states that:

“The purpose of GGP [Good Guidance Practices] is to ensure that agency guidance documents are: developed with appropriate review and public participation, accessible and transparent to the public, of high quality, and not improperly treated as binding requirements.”

Not only does the draft CPG fail to achieve these goals, but its prescriptive detail and use of “mandatory language” such as “should” and “must” contradicts the OMB guidance.

Risk Areas

We are profoundly concerned with the description of Risk Areas included in the discussion of compliance guidance and strongly recommend that a re-proposed CPG eliminate this discussion. A document that focuses on three areas of financial risk does not begin to address the full spectrum of a comprehensive research compliance program. Discussions of current concerns are more appropriate in the OIG’s Annual Work Plan or, if they reflect broader concerns across Federal agencies, in the OMB Circular A-133 annual Compliance Supplement.

Singling out three risk areas, all dealing with the financial aspects of the compliance spectrum, is not helpful and will not serve the intended purpose of enhancing the overall compliance environment. When these risk areas are combined with the highly prescriptive level of detail “strongly encouraged” for particular elements of an adequate compliance program, the ominous tone of the “Risk Areas” discussion suggests the imposition of strict audit standards, despite clear regulatory guidance that allows flexibility in addressing the subject matter.

A good example of this mixed message occurs in the subsection entitled “Time and Effort Reporting”. The draft CPG indicates that “accurate reporting” is critical and that there is a need for “effective timekeeping systems.” The draft opines that one reason that time and effort is a critical risk area is that researchers have multiple responsibilities “that must be accurately measured and monitored.” There is no such requirement in the regulatory standard that is found in OMB Circular A-21. A-21 explicitly recognizes that in an academic setting, duties are inextricably intermingled and acknowledges that academic employment is a context in which “precise assessment is not always feasible nor is it expected. Reliance is placed on estimates in which a degree of tolerance is appropriate.” Effort reporting is thus not “timekeeping,” as the OIG draft purports.

Further, the draft CPG suggests examples of situations that are characterized as “clearly improper” when in fact it is our understanding that they are acceptable. The draft CPG describes one such “clearly improper” practice as researchers who in separate applications for funding report “to three awarding agencies that they intend to spend 50 percent of their time on each of the three awards.” Without an understanding of how the grants award process works, this might appear to mean that the researcher is requesting funding for 150% of his/her time. Yet because funding from external sources is highly uncertain, this is exactly what institutions and their researchers are allowed to do (and must do in times when funding is so uncertain, and multiple applications are necessary for research to proceed) provided there is disclosure to the potential research sponsor. If all three awards are funded, then the researcher and his or her institution will, with the permission of the funding agency, adjust the time commitments and requested funding.

The second risk area identified is the proper allocation of charges to award projects. Here the draft correctly notes that accounting systems must separate the amount of funding from each funding source in the event of multiple awards for a single research area. However, the draft is inconsistent with A-21 when it ignores the freedom to use other allocation standards, including proportionality on a reasonable basis in addition to relative benefit.

Singling out the third risk area noted in the draft CPG, that is, the reporting of financial support from other sources, is not appropriate. Long an emphasis of compliance education within the university community, accurate and complete reporting is essential, including where Medicare and other health insurers are involved. But singling out this area from other equally essential compliance risks faced by universities, academic medical centers, and research institutes distorts its importance.

Sufficient Research Compliance Guidance Already Exists

We do not believe the OIG should attempt to create this type of detailed guidance for PHS research awardees. On the contrary, we believe that the OIG should rely on existing guidance and standards developed by the research community itself and direct its guidance to general program characteristics or elements. Rather than publish a document that is incomplete and at odds with the current regulations with which research institutions must comply, the OIG should recognize that there already exist highly detailed documents, developed by

associations and individuals with the appropriate expertise, that are considered by research institutions to provide a blueprint for their research compliance programs.

The precedent for endorsing guidance developed by the stakeholders lies in the OIG's Compliance Program Guidance for Pharmaceutical Manufacturers. This CPG references the PhRMA Code on Interactions with Healthcare Professionals and says that, while compliance with the code "will not protect a manufacturer as a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements." Accepting an already existing code as the basis for the finding of a good faith effort to comply—though not as a guarantee of compliance—should be extended to the research arena.

The OIG should consider accepting the "Principles for Managing Externally Funded Research Programs: A Guide to Effective Management Practices (2005)" developed by COGR as a general tool for achieving honest and responsible conduct of research. The Guide is available on the web at www.cogr.edu. As with the PhRMA Code, the OIG could acknowledge that compliance with the COGR Guide would "substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal" requirements.

The goal of COGR's Guide is to assist research institutions in reviewing their management systems and internal controls to ensure compliance. The Guide is structured around the framework of a comprehensive compliance system that calls for an institutional commitment to compliance as a systemic enterprise rather than discrete practices in response to specific regulations. Thus, while the detailed practices may take different forms in meeting financial, administrative, or performance requirements, all these activities reflect a culture of compliance.

The principles and practices were developed by a working group of senior research administrators drawing on the specialized expertise of research institutions across the country. First published in April 1989, COGR released a fifth, fully revised edition in 2005. Like the CPG, the COGR Guide begins with a call for an institutional program of compliance that includes written policies and procedures, defined roles and responsibilities, knowledgeable leadership, broad-based education and training, a program of incentives and enforcement to encourage compliance, and on-going assessment and modification of the program.

As a complement to COGR's broad-based Guide, the research community through its associations has developed voluntary guidelines and standards to advance full compliance with a range of Federal requirements, notably the AAU and AAMC guidelines for managing financial conflicts of interest and the creation in 2001 of the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Over 250 research institutions have committed to AAHRPP accreditation and 33 programs covering 97 research entities currently hold accreditation. AAU, AAMC, and NASULGC joined four other non-profit organizations and associations to establish this voluntary, educationally focused, peer-driven program not only to ensure compliance, but to help institutions reach performance standards that surpass the threshold of state and federal requirements.

Summary

Compliance in the research arena is a complex, multifaceted, ongoing challenge. Research institutions have taken an operational approach to achieving compliance with policies and regulations from as many as 27 different federal grant-making agencies and departments. The overarching message that universities, academic

health centers and research institutes are sending their research faculties and staff is that compliance involves the complete environment for research – everything from human subject protection through the intricacies of cost accounting. The OIG’s centralized oversight and management approach that focuses on investigation and enforcement is not in tune with current, proven-effective strategies used in research institutions for meeting compliance.

To issue the CPG in the proposed form will reduce clarity about what is expected of research institutions and place undue emphasis on a single solution or strategy and a limited number of risk areas. The OIG should re-propose the CPG in draft form and emphasize a flexible approach to compliance performance standards and principles that recognize institutional diversity and permit institutions to design compliance systems that are most effective for them. The COGR Guide should be deemed a way to demonstrate a good faith effort. Moreover, the OIG must make unequivocally clear that effective research compliance can be achieved by a variety of different approaches and that there is no single approach that is the standard for the research community.

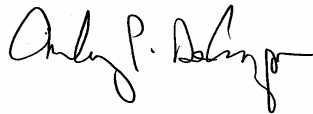
Thank you for the opportunity to comment on the proposed Compliance Program Guidance for Recipients of PHS Research Awards.



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