Office of Inspector General Releases Draft Compliance Program Guidance for Recipients of Federal Research Awards

On November 28, 2005, the Department of Health and Human Services Office of Inspector General ("OIG") published for public comment draft Compliance Program Guidance for recipients of research awards from federal Public Health Service ("PHS") agencies funding biomedical and behavioral research (70 Fed. Reg. 71,312). Comments on the draft compliance guidance are due by December 28, 2005.

The draft compliance guidance is especially timely in light of numerous recent federal enforcement actions and audits finding deficiencies and fraud relating to administration, accounting, time and effort reporting and third party billing under federal research awards. The draft guidance focuses specifically on grant compliance and administration issues, but the principles outlined in the document can and should be applied to other institutional compliance efforts.

Compliance Risk Areas

In the guidance document, OIG identifies three key potential compliance risk areas for recipients of PHS research awards: (1) time and effort reporting, (2) properly allocating charges to award projects, and (3) reporting of financial support from other sources.

Time and Effort Reporting

Noting the large portion of research costs that is allocated to compensation for the personal services of researchers, OIG emphasizes that the portion of the researchers' compensation on a particular project must be properly documented and reported. OIG highlights three specific areas of compliance scrutiny that an effective institutional compliance program should address: "commitment of effort" reporting, after-the-fact reporting of payroll distribution, and treatment of "institutional base salary" in calculating allocation of employee activity to research awards. Ropes & Gray attorneys have recently published an article on this subject that provides further background and recommendations for compliance efforts with respect to time and effort reporting.

Properly Allocating Charges to Award Projects

Cautioning that improper allocation of charges to various research award sources is not merely an "accounting problem," but rather draws limited federal research funds away from their intended sources, OIG directs research institutions to implement compliance steps to improve charge-allocation systems.

Reporting Financial Support from Other Sources

Reiterating the importance of properly identifying sources of grant funding to assist in identification of federal award priorities, OIG reminds research institutions that reporting of other sources of financial support is a required element of PHS award applications.

Compliance Program Elements

The draft guidance recognizes that research institutions may already have implemented compliance programs addressing research more broadly or other regulated activities and that efficiencies may be achieved through integration of compliance activities. Consistent with the foregoing, the draft compliance guidance retains the emphasis of prior OIG compliance guidance documents on the establishment of effective internal controls and procedures to promote adherence to relevant laws, regulations, and other requirements. Specifically, the draft compliance guidance describes eight fundamental elements to a comprehensive compliance program:

1. Implementing written policies, procedures and standards of conduct;
2. Designating a compliance officer and compliance committee;
3. Conducting effective training and education;
4. Developing effective lines of communication;
5. Conducting internal monitoring and auditing;
6. Enforcing standards through well-publicized disciplinary guidelines;
7. Responding promptly to detected offenses and developing corrective action; and
8. Defining clear roles and responsibilities and ensuring effective oversight.

These elements are generally familiar concepts in developing effective health care compliance programs. However, the eighth element -- defining roles and responsibilities and assigning oversight responsibility -- has not in prior OIG compliance guidance documents been explicitly articulated as a separate fundamental component to an effective compliance program. Institutional recipients of biomedical and behavioral research grants often face particular challenges in effectively overseeing grants administration and defining clear roles and responsibilities because many key aspects of grants administration (e.g., time and effort reporting and charge allocation) are decentralized in most academic environments. This eighth element is therefore a new charge to research institutions' compliance efforts. Moreover, because this element is consistent with past comments by OIG about the design and implementation of effective compliance programs, OIG may begin to expect clear definitions of roles and responsibilities and effective oversight in other contexts as well.

Ropes & Gray continues to be at the forefront of working on these and many other grant administration and research compliance issues. Ropes & Gray attorneys also have deep experience in developing effective compliance programs in universities, hospitals, and academic medical centers and have recently published an article on this subject.