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SPECIAL ALERT

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OIG Publishes Draft Compliance Guidance for Recipients of PHS Research Awards

On November 28, 2005, the HHS Office of Inspector General ("OIG") published a draft compliance guidance for recipients of research awards from the National Institutes of Health and other components of the U.S. Public Health Service.[1] The draft guidance follows several cases brought under the False Claims Act against universities, research institutions, and researchers involving improper use of grant funds. It also marks the first time that the OIG has published compliance guidance for entities that are not involved in furnishing items or services covered under the Medicare or Medicaid program. The OIG will accept comments on the draft until **January 30, 2006**.

Briefly, recipients of research awards are required to comply with a wide range of terms and conditions that include financial reports to the granting agency. Without appropriate compliance procedures in place, the award recipient may have costs disallowed; in more serious cases, the recipient may be exposed to liability under the federal False Claims Act ("the Act"). The Act imposes monetary penalties and damages on any entity for a range of conduct involving government funds including, but not limited to, submitting a false or fraudulent claim for payment by the federal government, or knowingly making a false record or statement to avoid or conceal an obligation to repay monies to the federal government.[2] As the process for obtaining research grant awards and administering those awards involves numerous certifications of compliance with a broad range of laws and policies, any one material misrepresentation could result in liability under the Act.

Although many research institutions have developed their own compliance policies for handling federal grants and contracts to ensure that claimed costs are allowable, this is the first time that one of the key enforcement agencies has published compliance advice on this topic. The OIG's stated intent for publishing this draft was to communicate its suggestions for research institutions to establish internal controls to ensure that they follow applicable rules and program requirements, especially OMB Circular A-21, which sets out cost principles for colleges and universities, and OMB Circular A-122, which applies to non-profit organizations.[3]

[1] 70 Fed. Reg. 71312 (2005). The date for submitting comments was extended by the OIG to January 30, 2006. 70 Fed. Reg. 73015 (2005).

[2] 31 U.S.C. § 3729.

[3] 70 Fed. Reg. at 71313.

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The OIG's draft notice highlights three important risk areas for recipients of NIH grants that can trigger administrative, civil, or criminal liability. The first area is accurate time and effort reporting. A failure to account properly for the time spent by researchers on a project can result in overcharges to the government and potential liability under the False Claims Act.[4] Second, institutions should ensure that when research projects are funded by multiple sources, their internal systems should track the sources of federal funding to avoid improper transfers of costs. The OIG emphasized that such improper allocation of costs and charges are not simple accounting errors, but can result in civil or criminal liability.[5] Third, the OIG focused on incomplete or inaccurate reporting of research funding from other sources. This poses a significant risk to research institutions and individuals under the Act. For example, each applicant for all competing PHS research awards must disclose all sources of funding for the research and also must sign a certification on the PHS-398 form that the information in that form is "true, complete, and accurate". Any knowing misrepresentation could result in an investigation or liability under the Act.

As with providers, suppliers, and manufacturers, some of the goals of a compliance program are to identify and remedy unlawful conduct as early as possible, to put safeguards in place that will allow the entity to respond to government audits or investigations, and to minimize any liability to the government when a violation has occurred.[6] The draft OIG guidance covers the same seven elements of an effective compliance program that have been discussed in its previous compliance guidances. They are the following:

- Developing written policies and procedures;
- Designating a compliance officer and other appropriate bodies;
- Developing and implementing effective training and education programs;
- Developing and maintaining effective lines of communication;
- Enforcing standards through well-publicized disciplinary guidelines;
- Using audits and other evaluation techniques to monitor compliance; and
- Developing procedures to respond to detected offenses and initiating corrective action.

In addition to these seven elements, the OIG has added an additional element addressing the definition of roles and responsibilities for oversight of research awards. The OIG's reasoning reflects an understanding that within some large institutions, it is not always clear where the responsibilities of investigators end

[4] *See*, e.g., *United States ex rel. Schwiderski v. Northwestern University, et al.*, No. 02 C 5287 (N.D. Ill. 2000).

[5] 70 Fed. Reg. at 71316.

[6] 70 Fed. Reg. at 71314.

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and those of departmental or administrative personnel begin. By defining these responsibilities and communicating them to all of the individuals involved in conducting or supporting research, the OIG hopes that this will help minimize the possibility of lapses in compliance.

We recommend that all research institutions and researchers who receive federal financial support from granting agencies such as NIH or other components of the Public Health Service take full advantage of this comment opportunity to educate the government regarding the details of the award administration process. The more input that the OIG receives from affected parties, the greater the likelihood that the OIG's final guidance will reflect the actual experiences of award recipients. We are prepared to assist clients with the preparation of such comments or recommendations. Once again, the current thirty-day comment period runs through **January 30, 2006**.

* * *

If you would like additional information regarding this topic or assistance in preparing Comments on the Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards, please contact Robert Wanerman at 202/861-1885 or rwanerman@ebglaw.com in the firm's Washington, D.C. office or the Epstein Becker & Green attorney who regularly handles your legal matters. For further information about Epstein Becker & Green's Health Care & Life Sciences Practice, or to see back issues of Special Alerts, please visit our website at www.ebglaw.com.

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