

Staying Ahead

with Saul Ewing

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Life Sciences Law

OIG Issues Draft Compliance Guidance For Recipients of Public Health Service Research Awards

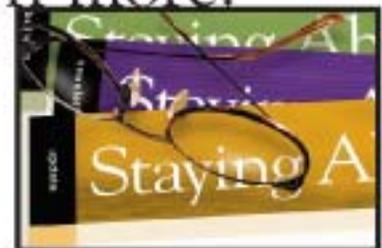
What happened?

The United States Office of Inspector General recently released a draft Compliance Program Guidance for Recipients of Public Health Service Research Awards that outlines key risk areas and compliance recommendations for institutions that receive federally funded research grants.

What does it mean?

The issuance of the guidance and the identification of key risk areas for noncompliance suggest that OIG may now be targeting research institutions receiving federal research funds to ensure that the use of those funds does not violate anti-fraud laws.

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In order to help research organizations that receive federal funding comply with federal laws relating to healthcare fraud and abuse, the Office of Inspector General (“OIG”) issued a draft Guidance that provides recommendations for compliance programs. The draft is open for comment by the industry. In the Guidance, OIG identifies several potential problem areas that could arise in the context of recipients of PHS research money. These areas are: time and effort reporting; properly allocating charges to award projects; and reporting financial support from other sources. OIG has recently pursued several cases targeting these key risk areas in high-profile research institutions.

For example, the Mayo Foundation, the parent organization of Mayo Clinic, recently paid a \$6.5 million settlement to the United States government to resolve a whistleblower lawsuit in which the United States alleged that the Mayo Foundation falsely reported spending related to research grants. Included in the allegations were claims that the Mayo Foundation violated grant reporting regulations by “shifting” the costs it reported for each grant. The government claimed that the Mayo Foundation transferred some expenses incurred for grants on which it had overspent and instead reported them as expenses incurred for other grants on which it had under-spent. The result, according to the federal government, was that the Mayo Foundation received more federal research grant money than the Mayo Foundation was “entitled to receive.” Further, the government also determined that the Mayo Foundation’s accounting system for the money spent and costs incurred related to the federal grants was inadequate to meet the recordkeeping standards required—to monitor these charges and be able to identify the wrongly transferred charges.

Similarly, Northwestern University paid \$5.5 million to settle a case in which the United States alleged that it had falsely reported its Institutional Base Salary for its clinical faculty members by including both the salary paid by the university, and also money that was paid by a separate, private clinical practice plan. The government also alleged that in Northwestern’s application for federal grant money, the university overstated the research time that would be devoted to the grant and that Northwestern failed to comply with the rules requiring that researchers devote a specific amount of time to the grant, as well as failed to comply with the requirement to report the total effort devoted to the grant, broken down and accounted for by research activity.

Other recent settlements involving research institutions receiving federal funds include a \$3.25 million settlement paid by Harvard University and a \$2.6 million settlement paid by Johns Hopkins University. Among the issues in the Harvard settlement were the government’s claims that various salary and equipment expenses were charged to the grants, even though such expenses did not relate to research sponsored by the grants. The Johns Hopkins settlement arose from claims that the University overstated the time expected to be spent for grant-related research, and engaged in improper

accounting procedures, improper estimating of employee costs and effort spent on research funded by the grant.

While the federal government has aggressively enforced federal laws against fraud and abuse in the healthcare system with respect to Medicare or Medicaid reimbursements, these recent settlements involving the research institutions appear to reflect the government’s commitment to enforcing anti-fraud laws in other healthcare-related settings. These settlements also indicate that OIG and the Department of Justice have decided to aggressively pursue the enforcement of claims of fraud with respect to government-sponsored research grants.

As a result of the government’s increased activity in pursuing fraud allegations against institutions that receive federal research grants, it is advisable for these institutions to implement an active strategy to help ensure that their organizations comply with the rules of the federal government. The key risk areas identified in the Compliance Guidance are consistent with the focus of the government’s audits, investigations, and the source of the eventual allegations in the previous cases. Being especially vigilant about compliance with these areas, therefore, is likely to help protect institutions who receive federal research grant money from allegations of fraud in obtaining, using, or reporting these grants.

Research institutions should also be attentive about complying with the federal rules regarding research grants because of the potentially enormous monetary incentive to individual “whistleblowers” who initiate these claims. Under federal anti-fraud laws such as the False Claims Act, an individual person who learns of and reports fraudulent practices can bring a claim on behalf of the United States, and if the claim is settled, is entitled to a portion of a settlement that the government receives. For example, the Mayo Clinic, Northwestern University, and Johns Hopkins cases were all brought as *qui tam* actions, and in each case, the individual who brought the action received a portion of the settlement paid to the government.

The federal government’s recent pursuit of research institutions that engage in fraudulent practices in connection with federal grant money, the large amounts of recent settlements paid to resolve these allegations, and the enormous incentives for individuals to report fraudulent practices are all reasons that research institutions should develop and implement effective strategies for compliance with the regulations associated with federal research grants. The key risk areas identified in the Guidance are a start to forming an effective compliance strategy. Each institution should also consider the individual features and needs of the organization, and tailor its compliance program accordingly.

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