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NEWSLETTER

Threat of False Claims Act Suits Undermines Attempts to Focus Universities on Mission Rather than Administrative Compliance

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Government Contracts Issue Update

When it comes to doling out federal taxpayer funds for research grants, the Government has a strong interest in preventing waste, fraud, and abuse. In its zeal to protect the public fisc, however, the Government can tip the balance towards inefficient and unnecessary oversight at the expense of focusing resources on the actual research. Additionally, this balancing act often has multiple actors within the Government, with different agendas on either side of the equation.

This article analyzes recommendations by the U.S. Government Accountability Office (GAO) encouraging funding agencies to continue their efforts to reduce the administrative burdens and costs imposed on research universities that receive federal grant awards. It also highlights the upswing in False Claims Act (FCA) suits against universities involving federal research grants. Ultimately, these competing interests—more efficient administration versus more aggressive enforcement—send mixed signals to grant recipients that any administrative flexibility offered by the funding agencies could be offset by increased exposure to enforcement actions, potentially undermining the gains of various streamlining initiatives.

I. GAO Identifies Need to Ease the Burden on Grant Recipient Compliance

In June 2016, GAO issued a report highlighting opportunities to streamline administrative burdens imposed on federal research grant recipients. GAO-16-573, Federal Research Grants: Opportunities

Authors

Brian Walsh
Partner
202.719.7469
bwalsh@wiley.law

George E. Petel
Of Counsel
202.719.3759
gpetel@wiley.law

Practice Areas

Government Contracts

Remain for Agencies to Streamline Administrative Requirements (June 2016). On September 29, 2016, the GAO issued written testimony summarizing the report for a hearing of the House of Representatives Subcommittee on Research and Technology of the Committee on Science, Space, and Technology. In accordance with Executive Order No. 13563 and in response to decades-long complaints from the research grant community, the Office of Management and Budget (OMB) and research funding agencies have undertaken efforts to reduce the administrative workloads and costs faced by universities. These efforts include government-wide standardization, delaying some pre-award requirements until after preliminary funding decisions have been made, and permitting more flexibility for universities to assess and manage risks related to some requirements. GAO's findings show that these initiatives have had only limited results. GAO recommended increased efforts, particularly in these three areas, to further reduce burdens on universities and enable them to better allocate limited administrative oversight resources to those areas that pose the greatest risk of improper use of government funds.

GAO noted that there were at least nine distinct categories of administrative requirements, beyond proposal writing and submission, imposed on grant recipients during the competitively awarded federal research grant life cycle. Various stakeholder organizations have raised concerns about the burden of these requirements, with at least one such organization finding that principal investigators were spending, on average, 42 percent of their time on administrative tasks rather than performing active research. Another study identified financial management, the grant proposal process, progress reporting, and personnel management as the most frequently cited areas of high administrative workload.

Efforts to reduce this burden, however, face the competing goal of ensuring that grant funds are properly spent. For example, the primary effort at standardizing grantee administrative requirements was the issuance of OMB's "super-circular," the *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* (Uniform Guidance). This guidance consolidated a number of OMB's prior circulars in an attempt to provide consistency among grant recipients, reduce the administrative burden, and reduce waste, fraud, and abuse by strengthening federal oversight. The funding agencies have implemented the guidance through various agency-specific regulations, agency guidance, and in the terms and conditions of individual grant awards, creating a patchwork of compliance obligations from one agency to the next. Because of the competing goals of the Uniform Guidance, grant recipients continue to cite increasing compliance costs as the additional requirements outweigh the streamlining efforts, especially when those streamlining efforts are undercut by significant variations in implementation across different agencies. These increased costs fall mostly on the universities because of a compliance cost reimbursement cap included in the Uniform Guidance.

A. GAO Identifies Common Factors Driving Administrative Burden

During its review, GAO conducted interviews with officials at six research universities to identify common factors that add to their administrative workload and costs. Three common factors GAO discovered were variations among agency implementation of the Uniform Guidance; detailed pre-award requirements; and increased prescriptiveness of certain requirements. These burdens fell on both the universities' administrative staffs as well as on the researchers themselves.

Variations in the implementation of the Uniform Guidance substantially increased costs. Especially for larger universities that receive grants from different funding agencies, variations in the implementation of the Uniform Guidance often require multiple processes, requiring researchers and administrative staff to spend time learning each agency's unique requirements, processes, and systems. The universities reviewed by GAO all reported significant investment in electronic systems to attempt to comply with these variations, especially at the pre-award stage where any minor noncompliance can often result in a rejected grant application.

Detailed pre-award requirements were another area of significant concern to university officials, particularly when the likelihood of selecting a proposal for funding is relatively low. Researchers, including principal investigators, reported that responding to proposals and the submission process contributed the most to their administrative workload. The burden is especially high when the details of a research project requested by the funding agency are still unknown, resulting in inefficient estimating and updating processes.

Lastly, the increased prescriptiveness of certain requirements through the implementation of the Uniform Guidance has forced universities to implement new and updated systems. For example, new purchasing system requirements, including more detailed competition requirements for purchases above the micro-purchase threshold, forced the universities to update their electronic purchasing systems to handle to the increased number of transactions. Prescriptive subrecipient monitoring was also identified by the universities as a significant burden, particularly where the Uniform Guidance provides no risk threshold for when grant recipients are required to prescriptively monitor subrecipient compliance and the subrecipients's resolution of audit deficiencies. GAO reported OMB's opinion, that some of this burden is based on an erroneous interpretation of the requirements by the universities. GAO noted that audit findings by the Health and Human Services (HHS) and NSF Offices of Inspectors General were often based on differences in how auditors, agencies, and universities interpreted requirements. The universities expressed concern that they must conservatively interpret the requirements in the way that they expect aggressive Offices of Inspectors General would, or else risk findings that unallowable or questionable costs were charged to the grant. This conservative position leads universities to defensively conduct more thorough reviews and audits than are necessary under the guidance.

B. Recommendations to Reduce the Administrative Burden

GAO also identified steps funding agencies have taken to address the compliance burden, but many of these efforts focus on post-award administrative reporting burdens rather than the more significant pre-award burdens. The steps identified include:

- A pilot program designed to continue the coordination between agencies to standardize financial and other reporting by grant recipients.
- The Office of Science and Technology Policy Research Business Models (OSTP RBM) working group is expanding a centralized portal where researchers can assemble biographical information required for proposal submissions, and there have been some efforts to standardize terms and conditions. This portal, however, has not been adopted outside NIH and NSF.

- Some agencies have established different pre-award phases, allowing grant applicants to submit initial proposal documents sufficient to allow the agency to make an initial funding determination, sparing the applicants from preparing and submitting unnecessary documents when there is no chance of award. For example, requirements related to budgeting, full biographical sketches, data management plans, and researcher mentoring and developing plans have been postponed until later in the pre-award phase. Despite these efforts, even the agencies that have adopted this approach have not extended it to all grant solicitations, and regulatory changes would be needed to further extend this effort.
- The Uniform Guidance requires the use of OMB-approved government-wide standardized forms for the reporting of financial and performance information from grantees. The Uniform Guidance also provides grant recipients some flexibility in meeting certain requirements, including:
    - "Expanded authorities" under the Uniform Guidance allow funding agencies to waive certain prior approvals necessary before recipients can make changes to project budgets.
    - Changes related to documenting personnel expenses, including the streamlining of the payroll certification process, resulted in an 80 percent reduction in the number of forms principal investigators were required to review.
    - Allowing the use of fixed-amount grant awards reduces recipients' cost accounting burden.
    - A change in the accounting for administrative support staff provided greater flexibility to assign staff to specific projects, freeing researchers to engage in more active research rather than complying with the administrative requirements.

On the other hand, other administrative requirements, such as the imposition of the mico-purchase threshold and subrecipient oversight requirements, limit grant recipients' flexibility. These limits unnecessarily force grantees to shift resources to the oversight of low-risk areas such as micro-purchases, historically unproblematic subrecipients, and insignificant financial conflicts of interests. GAO recommended that agencies update their regulations to set more flexible risk tolerance levels and to better evaluate the effectiveness of their risk response actions.

The GAO report was especially critical of the Government for not addressing variations between agencies. GAO criticized OMB and RBM for not doing more to limit the funding agencies' variations. RBM's response stated that without allowing for such variation, the agencies would simply not adopt RBM's proposals for standardized terms and conditions and processes. GAO conceded that these problems were in part driven by differences in statutory mandates by Congress, but stressed that even within those restraints, the agencies have more opportunities to standardize than they are engaging in at present.

II. False Claims Act Suits Are on the Rise in Grant-Funded Research Arena.

At the same time the administrative burdens on universities and other grant recipients are changing, *qui tam* whistleblowers, Inspectors General, and the Department of Justice are increasing their efforts targeting these recipients for false claims actions based on fraud, waste, and abuse, as the following cases demonstrate.

U.S. *ex rel.* Feldman v. van Gorp, 697 F.3d 78 (2nd Cir. 2012): *False statements in doctoral fellowship program application*. This FCA suit was initiated by a former Cornell University fellow who filed a *qui tam* suit alleging that a Cornell professor of psychiatry and Cornell University Medical College made false statements in both an initial grant application and all renewal applications for grant funding. The government funding at issue was from the T32 grant program, which is run by the NIH. Compliance with T32 grant funding requires recipient pre- and post-doctoral programs to train fellows "with the primary objective of developing or extending their research skills and knowledge in preparation for a research career." The defendants sought T32 funding for a fellowship program which would study neuropsychology and HIV/AIDS. As part of the application, defendants identified core curriculum courses fellows would take, named specific faculty members serving as key personnel, and explained that fellows would work with persons with HIV. In each annual renewal application, defendants largely reiterated this information and did not report significant changes.

The nature of the relator's false statements in this FCA suit was that Cornell did not provide the curriculum, resources, faculty members, or training as described in the grant application, nor did Cornell identify changes to the program in its renewal applications to correct NIH's understanding of how the funding was being used.

After the relator prevailed, defendants appealed to the Second Circuit Court of Appeals arguing that damages had been improperly calculated and asking the Second Circuit to consider how to measure damages in a FCA case where a contract between the Government and defendants did not produce a tangible benefit to the Government. The Second Circuit reasoned that "the Government bargained for something qualitatively, but not quantifiably, different from what it received." Using this reasoning, the Second Circuit held that the appropriate measure of damages was the full amount the Government paid based on materially false statements by defendants—which ***amounted to the entire amount of the grant***. Because defendants had to submit yearly renewal applications—which contained false statements—the Court determined that these annual false statements materially influenced NIH's decisions to renew Cornell's T32 grant.

U.S. ex rel. Feldman demonstrates how protracted a FCA suit can become: the defendants applied for the grant funding at issue in 1997; the relator filed a *qui tam* suit in 2003 (two years after having left the program); the complaint was unsealed in 2007 when the Department of Justice declined to intervene; discovery was completed in 2009; and defendants eventually appealed to the Second Circuit, which issued a decision in 2012. It took 15 years to ultimately resolve this FCA suit involving grant funding for pre- and post-doctoral training at Cornell University Medical College.

United States *ex rel.* Melissa Theis v. Northwestern University, et al., N.D. Ill., No. 09 C 1943: *False statements in NIH claim submissions for grant expenditures.* The relator, the individual defendant, and the Government reached a settlement in this *qui tam* suit, in which the Department of Justice intervened.

Northwestern University received grant funding from NIH for which the defendant served as the Principal Investigator for at least five grant awards. The relator, a purchasing coordinator for Northwestern's medical school, alleged that the Principal Investigator authorized and directed the spending of grand funds on goods

and services that did not meet the NIH and OMB guidelines for grant funds. The allegations involved improper submissions of claims to NIH for grant expenditures, including professional and consulting services, airfare, conference registration fees, food, hotel, travel, and other expenditures for the personal benefit of the defendant and his family and friends, incurred in connection with grants as to which the defendant was the Principal Investigator. In settling the FCA suit against him, the defendant agreed to pay $475,000.

United States *ex rel.* Rose v. Stephens Inst., N.D. Cal., No. 09-cv-5966: *False statements in certifying compliance with grant requirement.* In this suit the defendant, Academy of Art University, allegedly fraudulently obtained funds from the Department of Education, by falsely alleging compliance with Title IV of the Higher Education Act (HEA). The HEA requires fund recipients to enter a Program Participation Agreement (PPA), which requires the recipient to comply with certain regulations. The *qui tam* relators, four admissions representatives, alleged that Academy of Art University had been and was continuing to violate the PPA incentive compensation ban, which prohibits payment of any commission or bonus based directly or indirectly on an employee's success in securing enrollments or financial aid. The case against AAU is proceeding under an implied false certification theory, and ultimately the court will decide whether AAU paid compensation solely on the basis of enrollment success, and in doing so, made an impliedly false certification to the Department of Education. Notably, the relators prevailed against defendant's motion for summary judgment, with the court applying the recent Supreme Court FCA case *Universal Health Servs., Inc. v. United States ex rel. Escobar*. The case is pending in the Northern District of California.

United States v. Columbia University, S.D.N.Y., 13 Civ. 5028: *False statement in billing for grant overhead costs.* Columbia and the Department of Justice reached a $9.5 million settlement involving the FCA case against Columbia University. Columbia's FCA trouble arose out of its use of NIH grant money, specifically how Columbia billed for its facilities and administrative (F&A) indirect costs. NIH places restrictions on how much F&A costs a grant recipient could charge, one of which relates to whether research is conducted "on-campus" or "off-campus." Columbia improperly collected the full F&A rate—allowed only for "on-campus" research—for research conducted "off-campus."

United States ex rel. Thomas v. Duke University, et al., W.D. Va., No. 4:13-cv-00017: *False statements in scientific research potentially used to obtain funding.* A recently unsealed *qui tam* complaint against Duke University and a Duke University scientist centers on research misconduct as a basis for a false claim, which is a fairly new concept in the realm of FCA litigation. The *qui tam* suit was brought by a former Duke biologist who participated in a review of the scientist's data after the scientist separately pled guilty to embezzling money from Duke University. The review led to more than a dozen scientific papers being retracted. The relator alleges that during his participation in the review of the data, he learned that researchers and staff members knew the defendant "doctored" almost all of the experiments in which she participated. The relator claims that Duke is liable for a false claim because Duke received approximately 50 grants totaling $82.8 million from agencies, including NIH and the Environmental Protection Agency (EPA), which either directly arose from the research misconduct or where the misconduct influenced the award of the grant to Duke. The case is ongoing in the Western District of Virginia.

III. Trying to Streamline Compliance While FCA Threats Loom Large.

It is easy to see why universities may be wary of accepting the responsibilities associated with federal research funding, given the compliance requirements and the increase in FCA litigation relating to grant funds. The threat of a looming *qui tam* suit coupled with the growing, changing compliance environments is likely to cause universities to do far more policing and far less research. After all, a trebled damage award and potentially decade-long lawsuit presents a greater threat to a university's finances and public reputation than fewer published research papers. This is unfortunate, since it is clear that GAO recognizes that universities should not be saddled with unnecessary compliance costs—both dollar costs and the cost of taking researchers away from their work in the name of administrative paperwork—in exchange for receiving funding to conduct research.

The diverse range of fraud and abuse in the university research space that gave rise to the cases summarized in Section II illustrates how even streamlined administrative compliance will not eliminate universities' focus on monitoring and oversight of grant funds, perhaps to the detriment of progress on research. While agencies have been working to streamline administrative compliance, all the myriad ways a false claim can be generated in the university research space are likely to keep universities feeling the burden of complying with federal funding requirements. However, this should not discourage or dissuade GAO and funding agencies from continuing to attempt to achieve meaningful progress in lessening the administrative compliance burden placed on universities. Indeed, perhaps lessening the administrative burden on universities will allow universities to shift that effort to monitoring true fraud and abuse while still allowing universities to accomplish their research initiatives.

For more information, please contact a Wiley Rein attorney.