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# When Research Misconduct Violates the False Claims Act: Lessons From Duke's $112.5m Settlement

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On March 25, the U.S. Department of Justice (DOJ) announced that Duke University agreed to settle a False Claims Act *qui tam* action alleging widespread misconduct in federally funded research.

A former Duke researcher brought the whistleblower action, alleging that a Duke colleague knowingly submitted falsified research results to the National Institutes of Health (NIH) and the Environmental Protection Agency (EPA) in grant applications and progress reports to obtain tens of millions of dollars in federal grant funding. The whistleblower further alleged that, upon discovering the research fraud, Duke laboratory directors did not disclose the fraud to the government agencies and continued to submit the falsified data to support the university's research funding. The whistleblower will receive 30 percent of the settlement, or $33.75 million.

These unprecedented allegations of research misconduct rising to a level that violates the False Claims Act, and the sizeable settlement paid by Duke underscore the stakes of alleged noncompliance with the many requirements attached to receiving public research funding. While allegations of research misconduct in federally funded research have increased in recent years, lawsuits and enforcement actions alleging that this misconduct violates the False Claims Act have remained rare. With this high-profile settlement, and huge financial windfall earned by the whistleblower, the looming specter of increased False Claims Act actions should cause research institutions to be more attentive than ever to their research misconduct compliance and reporting obligations.

## The Allegations Against Duke University[1]

Generally speaking, the federal False Claims Act imposes civil and, in some instances, criminal liability on individuals or institutions that knowingly present false or fraudulent claims for payment to the government. Although not traditionally used to pursue alleged research fraud, the submission of false or fraudulent documentation to federal agencies that administer research grants can fall within the scope of the False Claims Act when that documentation includes false or fraudulent research data or otherwise violates applicable rules, policies or certifications.

Here, the whistleblower's allegations focused on the conduct of Erin Potts-Kant, the clinical research coordinator in Duke University's Airway Physiology Laboratory, and Dr. William Foster, a research professor in the Division of Pulmonary, Asthma, and Critical Care at Duke and a principal investigator of the Airway Physiology Laboratory. Potts-Kant was responsible for collecting and interpreting clinical data on the effects of pathogens, chemicals and environmental factors on the airways of laboratory mice, with the goal of treating human pulmonary diseases. Foster was the principal investigator who supervised Potts-Kant and bore ultimate responsibility for the

laboratory's research and for applying for and securing grant funding.

During Potts-Kant's almost eight-year tenure, Foster's laboratory secured more than $120 million in public grant funding from the NIH and EPA. These extensive research efforts culminated in Potts-Kant and Foster co-authoring more than 38 scientific papers and journals articles, all of which cited federal grant support.

In the *qui tam* complaint, however, the whistleblower alleged that Potts-Kant's research results supporting these publications were false and/or fabricated. Specifically, the whistleblower alleged that Potts-Kant deliberately manipulated the cited data or based it on experiments that she intentionally completed incorrectly. In some instances, the whistleblower alleged that there was no raw data at all to support Potts-Kant's results and that some of the experiments had never been conducted.

The whistleblower also argued that Duke bore False Claims Act liability because it included Potts-Kant's false and fabricated data in grant applications and progress reports it submitted to the NIH and EPA. The whistleblower alleged that faculty leadership at Duke learned of the extent of Potts-Kant's research misconduct in March 2013, but did not take appropriate steps to disclose Potts-Kant's fraud to the government, and also continued to include data obtained by Potts-Kant in grant applications.

Finally, the whistleblower alleged that, before learning about Potts-Kant's misconduct in March 2013, principal investigators in the Pulmonary Division received warnings of research misconduct by Potts-Kant in Foster's laboratory but did not take appropriate steps to investigate and address those warnings, as required by federal law and Duke's internal policies, and in accordance with Duke's obligations as a grant recipient.

**Key Takeaways for Research Institutions**

Duke's settlement of this whistleblower action with DOJ highlights the need for strict compliance and vigilant oversight of research activities by any institution that applies for and/or receives public grant money. Given the outcome here, it would not be surprising to see a spate of similar allegations and *qui tam* suits in the coming months and years. Federally funded research institutions would be wise to take the following steps to protect themselves from similar allegations and False Claims Act exposure.

1. ***Increased Oversight of Employees.*** Research institutions can face significant civil legal exposure for the misconduct of their employees — even if the conduct is isolated to a single researcher or department. Indeed, the Duke case may provide future whistleblowers with a roadmap for bridging the gap between employee and institution. The Duke whistleblower alleged that Potts-Kant acted within the scope of her employment and that any knowledge of her actions possessed by Foster and other principal investigators should be imputed to Duke. Given these stakes, research institutions should consider implementing policies and conducting training aimed at increasing oversight of individual employees. These efforts may deter rogue individuals from taking liberties with research results, and will also help institutions identify questionable research data before it is included in publications or grant proposals, thereby raising the potential for False Claims Act liability.

1. ***Increased Knowledge and Awareness of Certification Obligations.*** As the Duke case illustrates, the process by which institutions apply for and obtain federal research grants is rife with opportunities to make a false certification and thereby violate the False Claims Act. For example, to obtain federal research funds, institutions are repeatedly required to certify their ongoing compliance with numerous terms, conditions, laws

and policies during all stages of the public grant process — from application, to award, to progress reports, to close-out. A lack of understanding of, or appreciation for, the legal risks and compliance obligations that attach when an institution signs such certifications can trigger False Claims Act exposure, and increase the risk that an institution will be the subject of a whistleblower lawsuit and/or government enforcement action. Institutions must understand the consequences of their certifications, and should consider conducting training for principal investigators on the scope and meaning of these certifications, as well as implementing policies that require appropriate inquiries to confirm an institution's compliance with all requirements before any certification is submitted to the government.

1. ***Prompt and Thorough Investigations of Allegations of Misconduct.*** Federal law, not to mention granting agencies and grant applications, requires institutions to have a procedure for evaluating and, if necessary, investigating allegations of research misconduct. It is critical that institutions ensure their compliance with those obligations by taking appropriate investigatory action whenever they suspect or receive reasonable allegations of research misconduct, especially when the research is federally funded. Most institutional policies utilize the two-tiered investigation approach suggested by federal regulations. Because the first tier (*i.e.*, an "inquiry") can usually be completed quickly and with little disruption to the laboratory, institutions should err on the side of caution and look into most allegations or suspicions of research misconduct — even if only to clear the alleged perpetrator. Failure to investigate allegations of research misconduct that later turn out to be substantiated can open the door to additional liability for the institutions, especially if the failure to investigate resulted in the continued submission of false data to the government. As an extra measure of precaution, depending on the severity and extent of the alleged/suspected misconduct, institutions should consider engaging legal counsel to conduct a privileged investigation.

1. ***Evaluate and Mitigate False Claims Act Exposure.*** If an institution learns that research misconduct has occurred, it should quickly evaluate the scope of exposure and take appropriate remedial action. In the wake of the Duke settlement, this evaluation should include an analysis of potential False Claims Act liability when the falsified research implicates federal funds. An institution's failure to take appropriate action or inform the grant originator may result in separate and significant liability for concealing or avoiding an obligation to repay money to the government. Given this new but critical wrinkle in research misconduct cases, institutions should involve legal counsel early in the investigation and evaluation process and, at the very least, should consult legal counsel immediately upon learning that misconduct occurred in order to ascertain whether the misconduct could implicate the False Claims Act, and to determine what reports and remedial steps need to be taken to mitigate potential liability to the government or in a whistleblower suit.

It is incumbent on research institutions to appreciate and address the significant risks that are implicated by malfeasance committed by their employees in federally funded research. The Duke settlement presents, perhaps, an extreme example of how things can go wrong when fraud occurs, but the settlement illustrates that a research institution's liability under the False Claims Act is very real when there is falsification of federally funded research.

Given the severe penalties imposed by the False Claims Act, and the ability for whistleblowers to reap significant financial benefits by pursuing *qui tam* cases on behalf of the government, research institutions should learn from the Duke case and make every effort to protect themselves from future liability by taking appropriate preventive action and consulting with legal counsel the moment research fraud issues arise.

**Endnote**

[1] All details of the alleged conduct stem from the unproven allegations in the underlying *qui tam* complaint. *See* Am. Compl., *United States ex rel. Thomas v. Duke Univ.*, No. 1:17-cv-00276 (M.D.N.C. Nov. 13, 2015).