

Duke Will Repay Federal Government \$112 Million To Settle Faulty Research Case

By Administrator

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Duke University will pay \$112.5 million to the United States Government to settle Thomas v. Duke, a lawsuit alleging that a research technician improperly falsified and fabricated data from 2006 to 2013 to obtain research funding from the National Institutes of Health (NIH) and other federal agencies, the university announced Monday. Duke discovered the possible research misconduct in 2013 after the technician was fired for embezzling money from the university, which also occurred over the same period. The payment to the government includes both reimbursement for grants received as a result of the falsified and fabricated data and associated penalties. The Thomas v. Duke suit was filed by a former Duke employee under the False Claims Act, a federal law that allows people not affiliated with the government to file actions on behalf of the government against persons and companies that defraud the government. Persons filing under the act can receive a portion of damages.

“We expect Duke researchers to adhere always to the highest standards of integrity, and virtually all of them do that with great dedication,” said President Vincent E. Price. “When individuals fail to uphold those standards, and those who are aware of possible wrongdoing fail to report it, as happened in this case, we must accept responsibility, acknowledge that our processes for identifying and preventing misconduct did not work, and take steps to improve.”

Thomas v. Duke was filed under seal in federal court in 2014 -- after the research technician was discovered to have embezzled federal grant funds that had been awarded to the university, but before Duke understood the extent of her research misconduct. Duke reported this to the appropriate agencies and repaid the embezzled funds along with all grant-funded compensation and benefits that had been paid to the technician. The technician eventually pled guilty to two counts of forgery and paid restitution to Duke.

The university then launched a formal scientific misconduct investigation of the technician’s experiments. Those experiments involved measuring the lung function of laboratory mice using highly specialized equipment and were not connected to human subject or clinical research.

Following a detailed, three-year review of more than 50 potentially compromised research grants, Duke concluded that the technician had falsified or fabricated data that had been included in grant and payment requests submitted to the NIH and other agencies over the period of her employment. Duke also retracted scientific publications that relied on the data.

In response to the settlement, Duke immediately will implement a series of key steps to build

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on the university's already wide-ranging efforts to improve the quality and integrity of research conducted on campus, including:

The appointment of a new Advisory Panel on Research Integrity and Excellence chaired by Ann M. Arvin, professor of pediatrics and microbiology and former vice provost and dean of research at Stanford University, and including Edward M. Stolper, William E. Leonhard Professor of Geology and former provost of Caltech, and Barry S. Coller, David Rockefeller Professor, physician in chief and vice president for medical affairs at Rockefeller University. The advisory panel will provide recommendations to President Price and university leadership for improving the structure and function of research administration, with a focus on promoting research integrity, by June 30, 2019;

The establishment of a new, integrated leadership structure for research to provide clear and consistent policy guidance, oversight and accountability for all research at Duke University and Duke Health;

A new initiative to promote values and a culture of excellence and accountability at Duke;

The creation of an Executive Oversight Committee, chaired by Chancellor for Health Affairs A. Eugene Washington and including senior leadership and faculty, and a related Faculty Advisory Committee to oversee the ongoing implementation of Duke's research excellence initiative.

These steps build on significant work already completed to improve research integrity at Duke over the past decade.

Even before the Thomas v. Duke case came to light, the university significantly expanded its research education, training, oversight and accountability efforts. These improvements, including, some informed by this case, include:

Required science and accountability plans for all School of Medicine units;

Mandatory Responsible Conduct of Research training for all School of Medicine faculty and staff involved in research, with campus-wide implementation underway, as well as town hall meetings on relevant research integrity topics;

The appointment of Geeta Swamy as associate vice provost and vice dean for scientific integrity. Swamy leads the Office of Scientific Integrity, which includes the Advancing Scientific Integrity, Services and Training (ASIST) initiative, and oversees conflicts of interest, research misconduct, a new institutional research incident response team and the Clinical Quality Management Program;

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Significant improvements in clinical research oversight, including the establishment of clinical research units, and creation of the Duke Office of Clinical Research and the Duke Translational Medicine Quality Framework;

Continued implementation of the Research Administration Continuous Improvement initiative.

“Through these efforts, many of which have been underway for several years, we aim to promote and adhere to the highest standards of research excellence and integrity,” Price added. “We continue to have great confidence in the high quality of Duke faculty and their research. This settlement, which results primarily from willful misconduct that took place in one laboratory, but which affected the work of many more researchers, should not diminish the life-changing and life-saving work that takes place at every day at Duke. Our difficulties in ferreting out and ending such misconduct remind us that important work remains to be done.”