

Compliance Today – May 2018 Scientific research misconduct vs. fraud: How to tell the difference

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For years, misconduct in scientific research was policed primarily by the Office of Research Integrity (ORI) at the U.S. Department of Health and Human Services.^[1] After a lengthy and confidential review, an institution suspected of producing false or fraudulent research was either cleared of the charges or required to issue retractions and pay back any federal grants that had been tainted by misconduct.

In recent years, two new players have entered the field: The Department of Justice (DOJ) and private whistleblowers. Driven partly by a University of Iowa scandal that caught the attention of Sen. Charles Grassley, the DOJ has become more aggressive in pursuing False Claims Act (FCA) cases against research institutions where researchers have been accused of misconduct.^[2] Private whistleblowers, sometimes financed by law firms specializing in such qui tam litigation, are also bringing suits, galvanized by the treble damages offered under the FCA and bounties of up to 30% of anything the government recovers.

Duke University currently is facing more than \$600 million in potential damages in an FCA suit brought by a former lab technician who alleges another researcher's false experimental data was incorporated into grant requests and progress reports involved in more than \$200 million in grants.^[3] A federal judge in North Carolina allowed the case to proceed to discovery in April 2017, despite Duke's arguments the plaintiff, known as a relator, failed to identify any grant applications or other claims containing falsified data. Because it failed to "foster an environment conducive to responsible research," the plaintiff argues, Duke is liable.

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