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Ensuring that rules and regulations are met

an interview with
Lynda S. Hilliard

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FEATURES

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COLUMNS

DEPARTMENTS

by Michael Tuteur and Torrey Young

Scientific research misconduct vs. fraud: How to tell the difference

» The Office of Research Integrity (ORI) has a regulatory framework for research misconduct matters.

» Following ORI regulatory requirements does not shield research institutions from False Claims Act (FCA) liability.

» Understanding when research misconduct creates FCA liability is the first step in protecting a research institution.

» Research misconduct can create FCA liability if the misconduct results in false information submitted in an application that was material to the government's decision to fund the research.

» Research institutions may need to conduct parallel investigations to comply with ORI requirements and to mitigate potential FCA liability.

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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.

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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.

These new threats force research institutions to confront vexing questions: When does

research cross the line from sloppy or even deliberately false, to a potential FCA violation? And how early must administrators and lawyers intervene to prevent the former from becoming the latter?

Under the traditional ORI process, investigations are delegated to the institution itself, which relies on "fact finders"—typically scientific experts—to determine whether misconduct has occurred. The primary goal is to remove bad science from the published literature. Helping the government recover federal grant money is secondary.

Because the ORI process can take several years or more, it can expose an institution to hefty FCA fines if misconduct is proven at the end. Every dollar the institution accepts after the initial referral to ORI could be subject to treble damages unless the institution halts federal funding immediately. And while the ORI process is predominately a scientific inquiry, an FCA investigation is primarily a legal one, with an emphasis on non-scientific concerns such as the preservation of evidence and due process. So at the initiation of an FCA investigation, administrators may face the terrible Hobson's choice of either giving researchers the benefit of the doubt through a confidential and scientifically-driven investigation, or cutting off funding immediately, potentially spelling the end of a lab and its workers.

Unfortunately, there are no firm rules to distinguish scientific misconduct from deliberate fraud, but experience suggests some basic principles. The National Institutes of Health defines research misconduct[4] as:

- **Fabrication**—Making up data or results and reporting them.
- **Falsification**—Manipulating research materials, equipment, or processes, or omitting data so that the research isn't accurately represented in the record.
- **Plagiarism**—Appropriating another person's ideas, processes, results, or words without appropriate credit.

Importantly, research misconduct does *not* include honest error or differences of opinion. Experts involved in ORI investigations must perform meticulous analyses of the research, first to determine whether it includes false data and then whether that data was falsified deliberately or through carelessness, sloppy technique, or merely the inevitable errors that occur when scientists are operating at the cutting edge. Plagiarism is always a serious violation that requires immediate action, although it may not have any implications under the FCA.

How does the FCA define a violation? In theory, any incorrect statement made to the government when requesting payment for goods or services can give rise to an FCA penalty, but the U.S. Supreme Court has narrowed that to statements that are *material* to obtaining payment. In *Universal Health Services v. U.S. ex rel. Escobar*, the high court stated the FCA is not "an all-purpose antifraud statute" and isn't intended to punish "garden-variety breaches of contract or regulatory violations."[5]

In the context of medical research, that means errors and even negligence probably don't rise to the level of an FCA violation. Some labs are incredibly sloppy, and that's inexcusable on a professional level. But, the FCA comes to bear only if the institution knowingly allows false information to be included in a federal grant proposal or some other request for payment. A postdoc who runs off the rails and plagiarizes or Photoshops microscope images to get the results she wants may not implicate FCA if her misconduct was discovered and wasn't incorporated in grant proposals. A principal

investigator who knowingly or recklessly uses tainted research to obtain federal funds may be putting the institution in grave danger.

Thanks to online publications like Retraction Watch and so-called "Clare Francis" letters from anonymous tipsters, scientific institutions today may receive warnings about suspect research.[6] The challenge is to identify when scientific error or misconduct is serious enough to begin a parallel inquiry into possible FCA violations. The questions to ask include:

- Is there reason to believe there was fabrication or plagiarism?
- Is there reason to believe it was deliberate, or at least reckless?
- Is the tainted research out in the world in the form of a publication or grant proposal?
- What is the relationship to federal funding?

This last question is the most important one, because it could be the deciding factor between allowing the ORI investigation to proceed to a conclusion, or calling in the lawyers to prepare for a potential subpoena from the DOJ. Because *qui tam* suits are filed under seal while the government decides whether to join the action, institutions must consider the possibility of an FCA violation and potential mitigating actions—including halting the flow of federal funds and returning moneys already received—to avoid greater costs later.

1. 42 CFR Part 93 (Public Health Service Policies on Research Misconduct; Final Rule)
2. Sara Reardon: "US vaccine researcher sentenced to prison for fraud," *Nature*, July 1, 2015. Available at http://go.nature.com/2G49ZOJ
3. *U.S. ex rel. Thomas v. Duke University*, Case No. 4:13-cv-17 (W.D. Va. March 28, 2017).
4. 42 CFR 93.103 (Research misconduct)
5. *Universal Health Services v. United States ex rel. Escobar*, 136 S.Ct. 1989 (2016).
6. See "Clare Francis scores a bullseye: *Journal of Cell Biology* paper retracted for image manipulation" *Retraction Watch*. Available at https://bit.ly/2G2YI12