

Compliance Today – November 2018 Investigating research misconduct: The legal process

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The alarming news about potential research misconduct can come in a variety of ways: a negative report in Retraction Watch,^[1] an anonymous “Clare Francis” letter,^[2] or a tip on the employee hotline. Regardless of the source, every institution must take each allegation seriously, especially if it involves research funded with federal dollars. Not only can a single allegation grow into a full-blown investigation regulated by the Health and Human Services Department’s Office of Research Integrity (ORI),^[3] but the Department of Justice (DOJ) might pursue its own probe seeking treble damages and penalties under the federal False Claims Act.^[4]

The important thing to remember is that once an allegation has been raised, the subsequent inquiry is a legal process — not just a scientific one. Institutions may have scientists who are qualified to evaluate the research, but they also must follow legally prescribed steps that will be crucial as the inquiry advances. Records must be sequestered, confidentiality must be respected, and everybody must act in good faith and document their actions. Although the underlying motivation of a misconduct investigation may be to identify bad research and correct the scientific record, the financial and reputational stakes are too high — for the institution and accused researcher alike — to neglect the legal rules and requirements that proceed alongside.

So how does a properly conducted research misconduct investigation unfold? It starts with an allegation, however it arrives. The next step, according to ORI regulations, is to determine if the allegation is “sufficiently credible and specific so that potential evidence of research misconduct may be identified.”^[5]

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