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What is Recklessness in Scientific Research?: The Frank Sauer Case

David B Resnik, JD, PhD, NIEHS/NIH,

National Institutes of Health, National Institute of Environmental Health Sciences, 111 Alexander Drive, Box 12233 Mail Drop CU03, Research Triangle Park, 27709 United States
resnikd@niehs.nih.gov

Elise M. Smith, PhD, NIEHS/NIH,

National Institute of Environmental Health Sciences, Durham, 27709 United States

Stefanie H. Chen, PhD, NCSU, and

North Carolina State University, Raleigh, 27695 United States

Carlos Goller, PhD, NCSU

North Carolina State University, Raleigh, 27695 United States

Abstract

On May 22, 2017, administrative law Judge Leslie Rogall of the Department of Health and Human Services' Departmental Appeals Board, Civil Remedies Division, ruled in favor of the Office of Research Integrity (ORI) concerning its decision to charge former University of California at Riverside (UC-R) biochemistry professor Frank Sauer with research misconduct for fabricating or falsifying digital image data included in three papers and seven grant applications submitted to the National Institutes of Health (Office of Research Integrity v. Frank Sauer 2017). More specifically, Sauer was deemed responsible for manipulating, reusing, and falsely labeling images of autoradiograms and gels in his research in epigenetics. One month after this decision, ORI announced its final ruling concerning Sauer, which barred him from serving in any advisory capacity to the Public Health Services and required him to retract affected papers (Office of Research Integrity 2017). The case raises some interesting and important questions concerning research integrity because it focused on the legal issue of what constitutes recklessness in scientific research.

Keywords

Data management; Misconduct in research; Research ethics; Research integrity; Collaboration; Science policy

On December 6, 2000, the Office of Science and Technology announced a definition of research misconduct that applies to research funded by U.S. federal agencies. According to the definition, research misconduct is “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results [...] Research misconduct

does not include honest error or differences of opinion (Office of Science and Technology Policy 2000: 76263).” To make a finding of misconduct, an agency must prove by preponderance of evidence that the defendant’s conduct constituted “a significant departure from accepted practices of the relevant research community” and that the conduct was committed “intentionally, or knowingly, or recklessly (76263).” This last clause added a new dimension to federal misconduct policies because previous ones had not mentioned anything about recklessness in research (Steneck 1999, Resnik 2003).

On October 3, 2011, someone sent an anonymous email to officials at UC-R claiming that Sauer had fabricated and falsified data in eight papers over a 16-year span (Retraction Watch 2017). UC-R launched an investigation into the allegations against Sauer, most of which involved inappropriately splicing, reusing, labeling or manipulating digital image data pertaining to “controls or experimental results for in vitro interactions between RNA and proteins, co-immunoprecipitation (“co-IP”) assays, histone methytransferase (“HMT”) or kinase assays and related stained SDS-PAGE gels, and reverse transcription-polymerase chain reactions (“RT-PCR”) (ORI 2017).” The committee investigating Sauer found evidence of misconduct pertaining to 21/33 allegations and concluded that he alone was responsible for fabricating or falsifying the images. Although other individuals collaborated in his research, Sauer was the only author who’s work was consistently involved in fabrication and falsification (University of California at Riverside 2013). The Office of Inspector General at the National Science Foundation (NSF) conducted a separate investigation of Sauer and also concluded that he committed misconduct. On July 28, 2015, the agency informed Sauer that he would be barred from receiving NSF funding for five years (Office of Research Integrity v. Frank Sauer 2017).

On June 2, 2016, ORI sent a letter to Sauer charging him with misconduct in the federal grant applications and published papers, including a highly-cited article published in *Science* (Sanchez-Elsner et al. 2006). On July 8 Sauer contested findings brought by the ORI (in accordance with 42 C.F.R. § 93.501), and requested a hearing before an administrative law judge. ORI filed a motion for summary judgment and a statement of undisputed material facts and the respondent (Sauer) filed a cross-motion of summary judgment, a memorandum opposing ORI’s motion, and a statement of undisputed material facts (Office of Research Integrity v. Frank Sauer 2017). The respondent admitted that the images related to ORI’s allegations had been fabricated or falsified. These facts were not in dispute. Instead, the case focused on legal questions concerning the interpretation of the misconduct regulations and how to apply the regulations to the respondent’s conduct. The respondent challenged ORI’s motion for summary judgment on the grounds that he did not fabricate or falsify the images. Instead, the respondent claimed that someone else fabricated or falsified the images in order to sabotage his research (Office of Research Integrity v. Frank Sauer 2017). Since the respondent admitted that the images had been fabricated or falsified, the most important legal issue boiled down to whether the respondent acted intentionally, knowingly, or recklessly by publishing the images and using them in grant applications.

During his appeal, the respondent first suggested that the fabrications and falsifications were due to honest mistakes then later advanced two other possible explanations. First, he submitted an anonymous letter, written in German, in which the writer admits to fabricating

and falsifying images as revenge against Sauer for causing him to lose his job. He also submitted a letter, allegedly written Rune Dreser and notarized in Germany, claiming that Dreser fabricated and falsified the images to undermine genetic technology research conducted by German scientists. However, ORI submitted evidence that the notary seal and signature had been forged and questioned whether the anonymous saboteur or Dreser would have had access to the data (Office of Research Integrity v. Frank Sauer 2017).

Judge Rogall first asserted that the question of who fabricated or falsified the images was not material because:

Respondent has still committed research misconduct by *reporting* false and fabricated data when *he* submitted this information in grant applications and papers [...]. Even if the respondent believes that others somehow manipulated the data in his grant applications and publications, *he* ultimately *reported* that data, thereby adopting the data, and its flaws, as his own (Office of Research Integrity v. Frank Sauer 2017 at 14).

Judge Rogall held that the respondent was responsible for reporting the fabricated and falsified data because:

[H]e did not ensure that his papers and grant applications were without fabrication and falsification when he submitted them...he caused journal articles to be published and submitted the grant applications without regard to whether the content was true. Respondent's repeated publication and submission of applications containing utterly false information shows, at a minimum, indifference to the truth [...] Respondent[...] acted *recklessly* and without regard for the truth of the information he reported (Office of Research Integrity v. Frank Sauer 2017 at 15)

According to Judge Rogall, Sauer committed misconduct, even if one gives him the benefit of the doubt (consistent with a summary judgment) and assumes that he did not personally create the fabricated or falsified images, because he acted recklessly in reporting those images. After determining that ORI's proposed administrative sanctions were fair, Judge Rogall ruled in favor of the agency (Office of Research Integrity v. Frank Sauer 2017).

The most important legal and ethical issue in the case is: what constitutes "recklessness" in scientific research? The misconduct regulations do not define this term nor does Judge Rogall in her legal opinion. However, Rogall suggests that recklessness in research involves indifference to the truth, which is consistent with the actual malice standard for libel articulated by the US Supreme Court in *New York Times v. Sullivan* (1964). But what is indifference to the truth? Rogall suggests that Sauer demonstrated indifference by not ensuring that his papers and grant applications were without fabrication or falsification. While this proposal makes sense, it does not answer the important question of what one must do to ensure that a research document is without fabrication or falsification. Should one regularly review or audit data? Should one provide education and oversight for members of the research team? Should one ensure that the data are secure? Could failure to perform these tasks create potential liability for misconduct? Would a senior researcher be responsible for misconduct committed by a student if he or she did not adequately supervise the student?

Unfortunately, the recklessness standards used in the Sauer case does not provide clear answers to these questions and therefore fails to clearly and overtly distinguish between recklessness and negligence. As human beings, researchers sometimes make mistakes and fail to exhibit due care. While sloppiness should be avoided, they should not be equated with misconduct, which should be reserved for more serious ethical transgressions (Shamoo and Resnik 2015). When misconduct is committed by a student or other member a research team, there is a natural tendency to consider whether other members of the team could have prevented it through better supervision, education, or communication.

For example, when Seoul University researcher Woo Suk Hwang admitted to fabricating and falsifying digital images of cell lines in two papers published in *Science* in 2004 and 2005, University of Pittsburgh scientist Gerald Schatten also came under suspicion. Although a university committee found that Schatten did not commit misconduct, it said that he neglected his authorship responsibilities by not carefully reviewing the data and manuscript (Shamoo and Resnik 2015). From 1986–1996, Nobel Prize-winning molecular biologist David Baltimore was involved in a case in which Thereza Imanishi-Kari, a collaborator, was accused of misconduct. Although Baltimore was never charged with misconduct, his name became associated with the scandal, which had a negative impact on his career (Shamoo and Resnik 2015). In 1996, Francis Collins, who was Director of the Human Genome Project at that time, retracted two papers that contained fabricated and falsified data generated by a graduate student who was working with him (Dalton 1997). Collins (2006) later described the incident as his “darkest professional hour.”

Although the Sauer case relates to purported sabotage instead of problems associated with scientific teamwork, both scenarios involve quality control of scientific data, which can be challenging in large collaborations including researchers from different laboratories, institutions, disciplines, and countries. Very often, members of scientific teams contribute to the research by participating in experimental design or data analysis, but have no active involvement in data collection. Large projects may also include diverse datasets generated or acquired from different sources by different team members. Thus, it is frequently the case that researchers have ethical responsibilities related to data that they have not actually collected. Researchers who do not fulfill these responsibilities could be acting carelessly or recklessly, depending on the circumstances. It is incumbent on funding agencies, institutions, and researchers to develop ways of drawing the line between negligence and recklessness regarding responsibilities related to the quality control of data, so that scientists involved in collaborations will not be inappropriately charged with misconduct when fabrication or falsification is suspected.

To protect themselves from misconduct allegations, researchers should practice good data management (Shamoo and Resnik 2015). Although good data management practices can differ significantly based on the discipline of research and the complexity and use of data, some apply universally. For example, individuals should regularly perform data audits of their own labs to ensure that data collection and reporting is being handled properly (Loeb and Shamoo 1989, Shamoo 1989). Collaborators should ask for raw data to promote transparency in data processing and analysis. Having more than one individual to vouch for the integrity of data can also help to reduce bias, mistakes, and misconduct. Communication

and collegial oversight can allow collaborators to ensure the integrity of data collection, storage, processing, and analysis.

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