Advising Committees on the Reckless Standard
ARIO, September 25, 2018
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Is This Fraud, or Is It Just Confusion?
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False Claims Act:

“[T]he terms ‘knowing’ and ‘knowingly’ mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729(b)
“Forty years ago Jimi Hendrix trilled his plaintive query: ‘Is this love, baby, or is it [just] confusion?’ JIMI HENDRIX, Love or Confusion, on ARE YOU EXPERIENCED (Reprise Records 1967). In this False Claims Act case, we face a similar question involving a mortgage subsidy program initiated in that era: Is this fraud, or is it just confusion?”

1. Case study
2. What is reckless?
3. When to discuss recklessness with your committees?
4. How to discuss recklessness with your committees?
Case Study: Canadian Drug Trial
Says gifts rain on group

Pop star faces 2 drug charges

Pop star Jimi Hendrix, on trial for possessing narcotics, said yesterday fans shower him and his group with gifts ranging from teddy bears to jewelry as they move from city to city singing and playing.

A general sessions jury is trying Hendrix, 27, on charges of possessing heroin and hashish last May 3 at Toronto International Airport. The previous night Hendrix performed in Detroit, and on May 1 had played in Los Angeles.

He told his counsel, John O'Driscoll, that he was discharged from the U.S. Army in 1962, played a guitar with various bands until 1965, and then formed a group, the Jimi Hendrix Experience, in England.

Hendrix appeared for his trial in a blue blazer, flared grey trousers with buttons down the sides, an open shirt and an Ascot tie. On his left wrist he wore a turquoise bracelet, and on the index finger of his left hand a matching ring.
“According to sources at the scene, the Mounties – who were waiting for Hendrix to step off his plane from Detroit – were at first unable to make any positive identification of the substance; nevertheless, they kept the stunned Hendrix detained while they called a mobile police laboratory unit to the airport.”

“Then James Marshall Hendrix took the stand. Twenty-seven years old. Lives in New York. Born in Seattle. Did 18 months in the Army. Discharged for back injury. Professional musician. Four gold records. Jimi then proceeded to tell the court about how generous his fans are. He receives countless gifts: scarves, jewelry, clothes, teddy bears, oil paintings, anything at all. Most of the time he is too busy to look at them and he just tosses them in his bags.”

“Malone countered: ‘You are charged with a serious offense, and your evidence is you don't really know how it got there, or who put it there’, to which Hendrix responded: ‘Yes.’”
What is reckless?
What is reckless?

One definition:

Conscious disregard of a substantial and unjustifiable risk
When to discuss recklessness with your committees?
When to discuss recklessness with your committees?

Committees at Columbia

- Standing Committee on the Conduct of Research
- Inquiry Committees
- Investigation Committees
Inquiry?

When to discuss recklessness with your committees?
When to discuss recklessness with your committees?

Investigation

- At initial meeting?
- When reviewing documents?
- Before witness interviews?
- Only when asked?
How to discuss recklessness with your committees?
1. Regulation
2. Institutional policy
3. ARIO
4. Agency findings, decisions, reports
§ 93.104 Requirements for findings of research misconduct.
A finding of research misconduct made under this part requires that—
(a) There be a significant departure from accepted practices of the relevant research community; and
(b) The misconduct be committed intentionally, knowingly, or recklessly;
(c) The allegation be proven by a preponderance of the evidence.

“Negligence” doesn’t count.
§ 93.103 Research misconduct.
Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
(a) Fabrication is making up data or results and recording or reporting them.
(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
(c) Plagiarism is the appropriation or another person’s ideas, processes, results, or words without giving appropriate credit.
(d) Research misconduct does not include honest error or differences of opinion.
“The determination of whether the alleged misconduct is intentional, knowing, or reckless, including consideration of evidence of honest error or difference of opinion, should be made at the investigation stage, following a complete review of the evidence.”

1. Honest error → defense to intentional, knowing, or reckless misconduct
2. Not for inquiry phase
§ 93.313 Institutional investigation report.
The final institutional investigation report must be in writing and include:..... (f) Statement of findings. For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so—

(1) Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard

“in reckless disregard” of what?
• the truth?
• the consequences of his/her actions?
• resulting harm?
• accepted practices?
• the integrity of the research?
• the regulation?
§ 93.408 Mitigating and aggravating factors in HHS administrative actions.... (a) Knowing, intentional, or reckless. Were the respondent’s actions knowing or intentional or was the conduct reckless? ...
Does your misconduct policy define “reckless”?
ARIO 2015/2016 (Blumenthal/Klein):
The accused was consciously aware of a substantial risk that his/her conduct in proposing, performing, reviewing, or reporting research could result in FFP;

and

In the face of the known risk, the accused failed to exercise the level of care that a researcher of ordinary prudence in the relevant research community would exercise under such circumstances
ARIO 2017 (Garfinkel/Barnes):
Permitting, tolerating or causing conditions in experimentation, documentation, analysis, or preparation of publications that a reasonable scholar would understand to have a high probability of resulting in falsified or fabricated data or plagiarism.
ARIO 2017 (Garfinkel/Barnes):
Factors supporting a finding of recklessness:
• Widespread perception in the field that the specific conditions pose high risk for f/f/p
• Repeated or sustained nature of the permitting, tolerating and/or causing of the conditions
• Lack of controls that otherwise are typical of labs and research efforts in the field
• Lack of attentiveness to or use of well-recognized oversight mechanisms and practices
ARIO 2017 (Garfinkel/Barnes):
Factors supporting a finding of recklessness:
• Length of time over which the specific conditions pertained
• Lack of attentiveness in face of previous allegations or concerns of f/f/p
• Context of the lab and its staff – e.g., past records or investigations of possible f/f/p make it more likely that the behavior was intentional, knowing or reckless
ARIO 2017 (Garfinkel):
Requires evidence to prove that R was aware that conduct or behavior created a risk for F/F/P and ignored the risk
• Who made the figures? Who assembled/submitted the papers?
• Testimony - lab procedures from current & former lab members?
• Do the manipulations change the results?
• Does PI have papers/applications over many years?
• Did R/PI ever have to correct any papers previously?
• Is PI senior with many grant awards and many papers? Should PI know correct lab practices?
ARIO 2018:

- ORI
- NSF
“Even if 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.... [H]e did not ensure that his papers and grant applications were without fabrication and falsification when he submitted them.... [H]e caused the journal articles to be published and submitted the grant applications without regard for 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, at a minimum, acted recklessly and without regard for the truth of the information he reported.”

“Li Wang, Ph.D., University of Connecticut: Based on an assessment by UConn, an admission by Respondent and additional documents providing clarifying information, and analysis conducted by ORI in its oversight review, ORI found that Dr. Li Wang, Professor of Physiology and Neurobiology, UConn, engaged in research misconduct by recklessly including false data in [unfunded grant applications].... In addition to making an admission, Respondent cooperated fully with UConn and ORI, has expressed remorse for her actions, and took full responsibility for her reckless behavior.”

“Can you commit research misconduct if you fail to detect false data from another scientist? The answer is yes....”

Richard Goldstein, “Are You Liable for Misconduct by Scientific Collaborators?” Retraction Watch, 8/13/18
“The ruling is ‘thorough and careful,’ and ORI is ‘pleased with the judge’s thoughtful decision and believes the research community is likely to find it useful and educational,’ the [HHS] spokesperson said....

Noting that the ruling ‘provides an example of reckless research misconduct and a judge’s thoughts on how to define the terms,’ the HHS spokesperson said the decision ‘will be helpful to ORI in deciding how to approach future cases. Each case is unique and should not be generalized.’”

HCCA Report on Research Compliance, September 2018
Former ORI Deputy: ‘Reckless’ Ruling Disappointing, Troubling; Impact Unclear

HCCA Report on Research Compliance, September 2018
“ORI argues that recklessly should mean that the respondent either knew or should have known that there is an increased risk that materials are false, fabricated, or plagiarized, but the research uses the materials anyway....”

ORI v. Kreipke (2017) (p. 11)
“....Respondent distills from various authorities the definition that one acts recklessly in the context of research misconduct when one acts or fails to act, knowing there was a substantially or unjustifiably high risk that research used was false, fabricated, or plagiarized, and despite knowledge of the risk, used the research anyway.”

ORI v. Kreipke (2017) (p. 13)
“Recklessly means one acts without proper caution despite a known risk for harm. In the context of research misconduct, I conclude that ORI must show by a preponderance of the evidence, that Respondent:

• [Acted intentionally or knowingly, or]
• Used materials without exercising proper care or caution and disregarding or showing indifference to the risk that the materials were false, fabricated or plagiarized thereby causing harm to the integrity of the research process or waste of public funds, the basis for regulating research misconduct stated in 42 C.F.R. § 93.100.”

ORI v. Kreipke (2017) (p. 14)
“JUDGE SICKENDICK: So if you choose to - - if you choose to present data in whatever form, whether it's an image, a table or whatever, what I'm hearing you say is you don't feel like you had any responsibility to verify the accuracy of the data before sending that off to NIH as part of the consideration for the submittal, to approve a grant? Is that - - is that what you want me to think you said?

RESPONDENT: Well, what I'm saying is, is that while I am responsible as the principal investigator, ... at the end of the day, I take it on good faith that my collaborators have already gone through the validation process. I don't think that it's common practice for a scientist that receives data from a collaborator, to ask them, to show them, to validate the data.”
1. “Recklessly means one acts without proper caution despite a known risk for harm.”

2. “[Reckless means he] [u]sed materials without exercising proper care or caution and disregarding or showing indifference to the risk that the materials were false, fabricated or plagiarized thereby causing harm to the integrity of the research process or waste of public funds, the basis for regulating research misconduct stated in 42 C.F.R. § 93.100.”
The opinion applies an **OBJECTIVE** test.

“The Secretary has imposed upon institutions and researchers a heavy responsibility to protect PHS funds and ensure the integrity of PHS research. Grant applications seek PHS funding, often significant amounts, and based on all the testimony it is clear that researchers rely upon the research of their predecessors. False information in grant applications may result in expenditure of PHS funds or mislead other researchers as to the results of PHS funded research....” (p. 83)
The opinion applies an **OBJECTIVE** test.

“Therefore, including data, images, and other materials without validation of the accuracy of the information constitutes failure to exercise proper care or caution and disregard or indifference to the risk for potential false information, and a violation of the responsibility institutions and researchers accept to protect PHS funds and the integrity of PHS research.” (p. 83)

“The Kreipke Page 83 Test”
The opinion applies a **SUBJECTIVE** test.

“Based on his knowledge of the state of his laboratory and personnel situations, it was reckless for Respondent to simply assume that materials placed in his grants, articles, and posters were reliable.” (p. 84)

“The Kreipke Page 84 Test”
Recklessness and Risk

The Experience indulge in their favourite rock’n’roll recreation: Risk.
Recklessness and Known Risk

1. “Respondent knew that in 2008, Ted Petrov, his original mentor, had been terminated for personal reasons. All of Petrov’s computers and laboratory notebooks were sequestered by WSU at that time. Respondent also knew that many image were done originally in 2007 or 2008 when Petrov headed the laboratory.”

2. “Respondent was aware of disorganization and lack of record keeping when he joined the laboratory and for which he became a leader.”

3. “Respondent was aware that virtually everyone that worked in the laboratory had access to all the computers and laboratory notebooks.”
4. “Respondent told the WSU Investigation that in 2010, one of his ‘first missions’ was to hire a laboratory administrator, and that is when they started doing oversight in the laboratory.”

5. “Respondent also knew that Reynolds, who was hostile to Respondent, had access to the computers and laboratory notebooks.”
“Based on his knowledge of the state of his laboratory and personnel situations, it was reckless for Respondent to simply assume that materials placed in his grants, articles, and posters were reliable.”
Future studies could also look at the other MPC mental states not analyzed here, namely Purposeful and Negligent. Although we have shown here that a recklessness mental state could be distinguished from a knowing mental state, to confirm that recklessness is a mental state on its own future studies should see whether recklessness can be distinguished from Negligence using brain data alone.
So which is it?

- **Subjective standard?** “Based on his knowledge of the state of his laboratory and personnel situations, it was reckless for Respondent to simply assume that materials placed in his grants, articles, and posters were reliable.”

- **Objective standard?** “[I]ncluding data, images, and other materials without validation of the accuracy of the information constitutes failure to exercise proper care or caution and disregard or indifference to the risk for potential false information, and a violation of the responsibility institutions and researchers accept to protect PHS funds and the integrity of PHS research.”
Reckless Plagiarism

PI Plagiarized Portions of His Proposed Research Work

A PI from a New York university copied a portion of another scholar’s research goals into a declined NSF proposal and copied a substantial portion of the methodology into a second declined NSF proposal. The university’s investigation concluded that, although the PI’s act was a significant departure from accepted practices, the PI did not commit research misconduct because he acted with careless intent.... Our review of the university’s report found that the university incorrectly interpreted the reckless standard of intent, determining erroneously that recklessness requires a conscious or purposeful element. Our investigation concluded that the PI acted recklessly and thus committed research misconduct....

Assistant Professor Recklessly Plagiarizes in NSF Proposal

An assistant professor in Alabama submitted an NSF proposal in which most of the first page, as well as a few other paragraphs, were apparently copied from other sources. She stated she copied and pasted text from her source documents without any notation into the same computer document where she was also composing original text for the proposal—over months of composition, this practice led to her inability to distinguish copied from original text. The university determined that she recklessly plagiarized and terminated her employment. We agreed with the university’s conclusions and recommended that NSF require certifications for one year.

“Don't be reckless with other people’s hearts. Don’t put up with people who are reckless with yours.”

- Jimi Hendrix