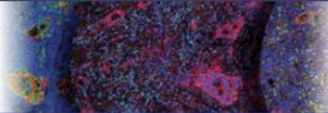


HMS Research Administrators Open Forum
June 2019

Overview of False Claims, Inauthentic Data & the Duke University Case

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Duke University settles research misconduct lawsuit for \$112.5 million

By Science News Staff | Mar. 25, 2019, 1:50 PM

Duke University will pay \$112.5 million to the U.S. government to settle a lawsuit brought by a former employee who alleged that the university included falsified data in applications and reports for federal grants worth nearly \$200 million. The university will also take several steps "to improve the quality and integrity of research conducted on campus," including the creation of a new advisory panel that will provide recommendations to the president, the Durham, North Carolina, institution said in a **statement released today**.

<https://www.sciencemag.org/news/2019/03/duke-university-settles-research-misconduct-lawsuit-1125-million>

Why is this case of interest?

- Large private nonprofit academic institution
- Large biomedical research enterprise
- Large gov't grant portfolio

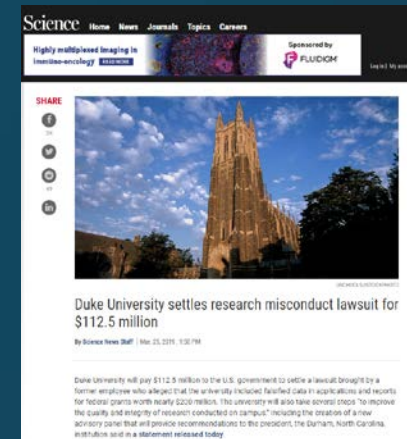
Duke #16 in terms of NIH funding in 2019:
\$163,511,427 through 356 awards

#9 Massachusetts General Hospital
\$203,238,495 through 418 awards

#17 BWH
\$140,799,840 through 249 awards

#37 Harvard Medical School
\$79,798,644 through 152 awards

“[one of] the largest FCA suits ever to focus on research misconduct in academia...and... could "open the floodgates" to other whistleblowing cases.”



<https://www.sciencemag.org/news/2019/03/duke-university-settles-research-misconduct-lawsuit-1125-million>

Elements of false claims to familiarize ourselves with regarding Duke case

False Claims Act (FCA, also known as the “Lincoln Law”, signed March 2, 1862)
18 U.S.C. §§ 3729 -3733

Earliest conventions:

- Concerned that suppliers of goods to the Union Army during the Civil War were defrauding the Army (enacted in 1863)

What is a claim?

- Demand for money or property made directly to the government, contractor, grantee, or other recipient if money is spent on the government’s behalf and the government provides the government money demanded (e.g., a federal grant application and associated supporting documentation are claims for \$ to support research and an award is government provided \$)

What’s a “whistleblower”?

- Provisions of the FCA (*qui tam*) allow for an individual to file suit on behalf of the government and for money or property made directly to the government, contractor, grantee, or other recipient if money is spent on the government’s behalf and the government provides the government money demanded (e.g., a federal grant application and associated supporting documentation are claims for \$ to support research and an award is government provided \$)

FCA and academic research

What might lead to a finding of a "false claim"?

- When expenses charged to a grant do not comply (e.g., are the expenses allowable, allocable, reasonable and consistent?)
 - Yale University Settlement 2008 (\$7.6M)
- When activities executed are not within the scope of the original application/progress reports
 - Cornell Medical College 2012 (\$855K)
- When the underlying data supporting the grant (application/progress reports etc.) are fraudulent
 - Duke University Settlement 2019 (\$112.5M)

Elements of false claims to familiarize ourselves with regarding Duke case

Fraudulent (“inauthentic”) data and ultimate FCA liability

Data:

1. Inauthentic (fraudulent) = “not in fact what it is said to be”

The bar or standard: civil (not criminal) “more likely than not”

2. Material = “the quality of being relevant or significant”

The bar or standard: means “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property”

Knowledge:

3. [A person] must have submitted, or caused the submission of, the false claim (or made a false statement or record) with knowledge of the falsity

(a) actual knowledge,

(b) deliberate ignorance of the truth or falsity of the information, or

(c) reckless disregard of the truth or falsity of the information

The False Claims Act: A Primer

https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf

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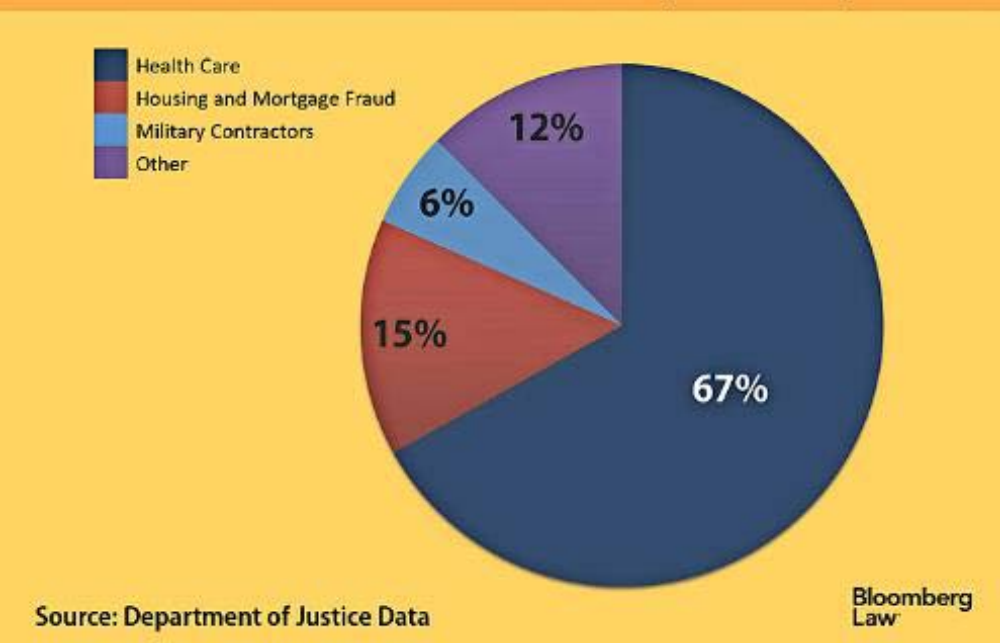
- Provisions of the FCA (*qui tam*) allow for an individual to file suit on behalf of the government (anyone can do this, they are known as the “relator”)
- The government investigates and can decide to intervene or not (more often not: ***approximately 80% time***)
- Relator can proceed with action if government does not intervene (not common, happened in Duke case)

What's the big deal?

Big \$\$\$

- In FY 2018, FCA settlements and judgements were estimated at \$2.8 billion (recoveries since 1986 total more than \$59 billion)
 - ~\$2.5billion (90%!) in health care fraud recoveries (eclipsed 2017: 67% related to health care)
 - pharmaceutical and medical device and drug manufacturers represented the majority of recoveries (nearly \$1B came from just 2 settlements)
 - Medicare, Medicaid, billing, kickbacks

The False Claims Act: Recoveries by Industry (2017)



The False Claims Act in 2017. The Year in Review and What to Watch in 2018. Mark A. Rush, David I. Kelch, and Isaac T. Smith.

- \$2.1billion (of the \$2.8) were the result of qui tam recoveries under the FCA
- While FCA settlements and judgments concerning academic institutions have typically represented a smaller piece of the overall FCA assessments, their relative impact and resonance within academic institutions (both \$, policy and practice) has been building

What's the big deal?

Duke Settlement

Big \$ and Big Impact in the Academic arena

Damages and Penalties

- *A civil penalty of between \$5,000 and \$10,000 for each false claim (those amounts are adjusted from time to time; the current amounts are \$5,500 to \$11,000) and treble the amount of the government's damages*
 - *Scope of Duke funding considered was \$200M covering more than 60 grants between 2006-2013 (**may have been on the hook for \$600M**)*
 - *Settlement (of allegations regarding falsified or fabricated data or statements in thirty (30) grants, recovery of \$112.5)*

WhistleBlower provisions

- *Individuals coming forward with evidence of false claims may receive up to 30% of recoveries*
 - *Relator could have received **recoveries of \$200M***
 - *Settlement (Relator will receive \$33,750,000)*

Scientific Record

- *Suit alleges fraudulent research in 38 publications between 2007 and 2013*
 - *To date, 17 retractions (earliest May 2013)*

What's the real deal?

Institutional Responsibility

<https://today.duke.edu/2019/03/message-duke-community-about-research-misconduct-case>

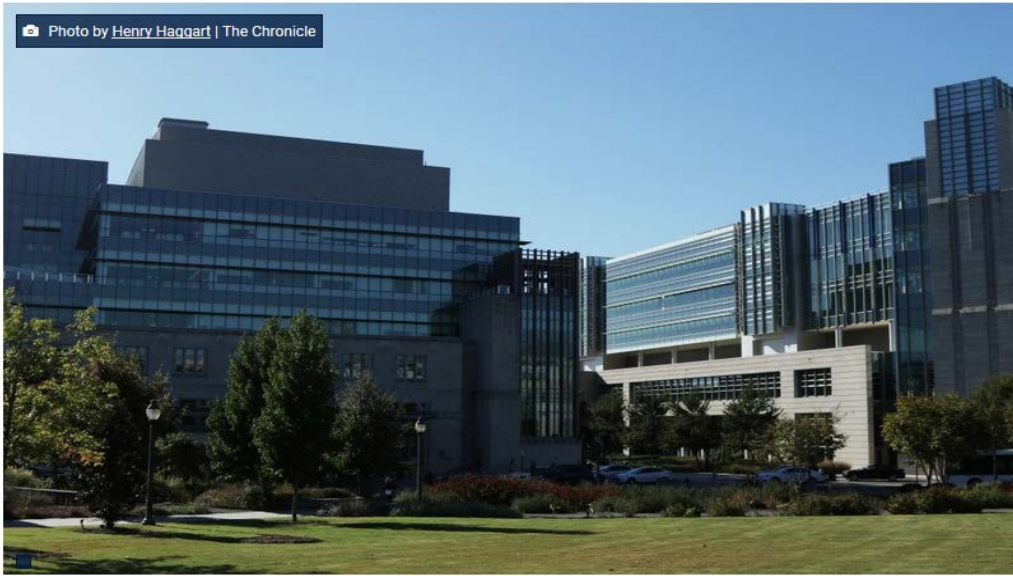


- Creation of “Office for Scientific Integrity”
- Appointment of an Advisory Panel on Research Integrity and Excellence (external)
 - Ann M. Arvin (Stanford University)
 - Edward M. Stolper (Caltech)
 - Barry S. Coller (Rockefeller University)
- Implementation of a new data management tool (LabArchives)
- Educational efforts such as mandatory research integrity training for all School of Medicine faculty and staff involved in research
- Advisory Panel will provide recommendations to Duke university leadership for improving the structure and function of research administration, with a focus on promoting research integrity, **by June 30, 2019**

What's the real deal?

Institutional Responsibility

Photo by Henry Haggart | The Chronicle



NIH places new regulations on Duke research in wake of prior misconduct cases

By Nathan Luzum | 03/28/2018

The National Institutes of Health issued additional regulations for researchers at Duke after high-profile research misconduct cases have surfaced at the University in recent years.

The guidelines, which take effect April 1, will require Duke researchers applying for grants under \$250,000 per year to submit a detailed budget of their proposed costs. Researchers must also receive prior NIH approval when extending grant budget periods and carrying over unused funds into the next budget period. The new regulations, however, will not affect current research grants.

<https://www.dukechronicle.com/article/2018/03/duke-research-to-face-new-federal-regulations-in-wake-of-prior-misconduct-cases>

<http://www.sciencemag.org/news/2018/03/duke-s-mishandling-misconduct-prompts-new-us-government-grant-oversight>

For new grant applications from Duke, NIH to require:

- detailed budgets, even for smaller grants, and
- prior approval to carry over funds if renewed.

NIH will also require prior approval for modification to existing Duke grants.

What's the real deal?

Institutional Responsibility

ORI RM assessment ongoing:

➤ Additional sanctions? PHS/HHS may take administrative actions against respondents including (not limited to)

- Debarment/supervision from eligibility to receive Federal funds for grants and contracts,
- prohibition from service on PHS advisory committees, peer review committees, or as consultants,
- submission of a correction/retraction of a published articles by respondent.

Can apply to institution as well in addition to:

- directing HHS to handle research misconduct proceedings for PHS-funded research
- publishing information about the institution's noncompliance on ORI's website
- If actions determined to constitute a substantial or recurrent failure to comply, ORI may also revoke the institution's assurance, thereby suspending PHS awards to that institution.

➤ Additional retractions?

Currently 17 (may be more coming)

The screenshot shows the ORI Research Integrity website. At the top, it says "U.S. Department of Health & Human Services" and "THE OFFICE OF RESEARCH INTEGRITY". There is a "Contact Us" link. Below the navigation bar, the page is titled "Case Summaries". A disclaimer states: "This page contains cases in which administrative actions were imposed due to findings of research misconduct. The list only includes those who CURRENTLY have an imposed administrative actions against them. It does NOT include the names of individuals whose administrative actions periods have expired." The cases are listed by year:

- 2019**
 - Case Summary: Cruikshank, William W.
 - Case Summary: Fox, Edward J.
- 2018**
 - Case Summary: Baughman, Brandi M.
 - Case Summary: Elqutub, Maria Cristina Miron
 - Case Summary: Kadam, Rajendra
 - Case Summary: Kreipke, Christian
 - Case Summary: Murthy, Krishna H.M.
 - Case Summary: Narayanan, Bhagavathi
 - Case Summary: Rajamani, Uthra
 - Case Summary: Ramadugu, Venkata Sudheer Kumar
 - Case Summary: Santhanam, Srikanth
 - Case Summary: Sen, Shiladitya
 - Case Summary: Skau, Colleen T.
 - Case Summary: Srivastava, Rakesh
 - Case Summary: Wang, Li
- 2017**
 - Case Summary: Baughman, Brandi
 - Case Summary: Chegini, Nasser
 - Case Summary: Chetram, Mahandransuth Anand
 - Case Summary: El-Remessy, Azza
 - Case Summary: Endo, Matthew
 - Case Summary: Mirohandani, Alec
 - Case Summary: Sauer, Frank
- 2016**
 - Case Summary: Cullinane, Andrew R.
 - Case Summary: Li, Zhiyu
 - Case Summary: Malhotra, Ricky
 - Case Summary: Pastorino, John G.
- 2015**
 - Case Summary: Potti, Anil

Local Discussions – what can (do) we do?

Not this...

Ostriches may feel safe



but, they don't live longer!

Local Discussions – what can (do) we do?

Do what we continue to do – address concerns thoughtfully and responsibly

Preliminary Assessments

Did the alleged misconduct occur in the review, proposing or performance of research?

- If so, did these data find their way into a grant? Review of grant applications and progress reports for active federal grant funding to determine if data are included
- Publication of data? look to see if federal grant funding cited as the sponsor/support for the data

1. Data authenticity assessment
2. Materiality Assessment
3. Financial Review (Expenses associated with materially inauthentic data? Suspend active spending? What needs to be reported and to whom and when?)

Local Discussions – what can (do) we do?

Do what we continue to do – support our community

- Partners in academic research success in our community
 - Document, Document, Document (Data, Data, Data)

 - DMWG (Data Management Working Group)
 - Countway Library
 - ORA
 - and many more....

- Ask Questions
 - ARI
 - Ombuds Office
 - OGC
 - IT and data security
 - Sponsored Programs and/or Technology Development offices (DUAs)
 - University Anonymous Hotline

Acknowledgements

HMS Office for Academic and Research Integrity (ARI) Team

Gretchen Brodnicki, J.D.

Jennifer Ryan, J.D.

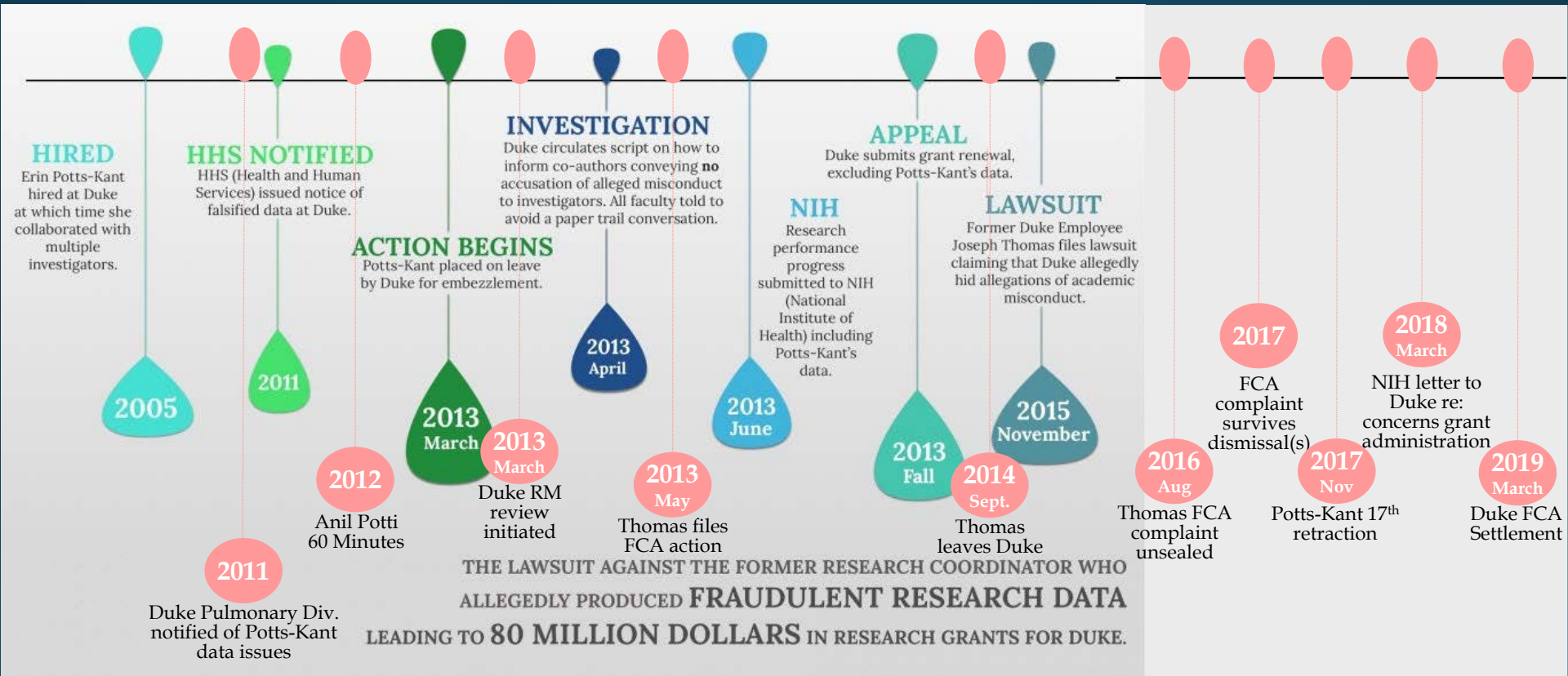
Daniel Wainstock, Ph.D.

Blake Talbot, M.P.H.

Disclosures:
Maidstone Consulting Group, LLC

Anatomy of Duke FCA allegations

<https://www.dukechronicle.com/article/2016/09/experts-address-research-fabrication-lawsuit-against-duke-note-litigation-could-be-protracted>



Some of this information is alleged in the lawsuit and some information is known

References and additional resources

Duke University Agrees to Pay U.S. \$112.5 Million to Settle False Claims Act Allegations Related to Scientific Research Misconduct

(DOJ – OPA)

<https://www.justice.gov/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related>

Duke University settles research misconduct lawsuit for \$112.5 million

<https://www.sciencemag.org/news/2019/03/duke-university-settles-research-misconduct-lawsuit-1125-million>

The False Claims Act: A Primer

https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf

The False Claims Act in 2017. The Year in Review and What to Watch in 2018.

http://www.klgates.com/files/Publication/8acb73b9-d504-4a32-b345-a5f4655b4fdf/Presentation/PublicationAttachment/70bf6328-87f3-4dff-bdff-4cb2794f098f/False_Claims_Act_in_2017.pdf

Justice Department Recovers Over \$3.7 Billion From False Claims Act Cases in Fiscal Year 2017

<https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017>

Justice Department Recovers Over \$2.8 Billion from False Claims Act Cases in Fiscal Year 2018

<https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018>

Gibson Dunn: 2018 Year-End False Claims Act Update

<https://www.gibsondunn.com/2018-year-end-false-claims-act-update/>

Top 50 NIH-Funded Institutions of 2019

<https://www.genengnews.com/a-lists/top-50-nih-funded-institutions-of-2019/>

MDNC docket US ex rel Thomas v Duke

<https://www.courtlistener.com/docket/5239044/the-united-states-of-america-v-duke-university/>

The False Claims Act What Every Administrator Needs to Know (Rochester University ORPA)

http://www.rochester.edu/orpa/_assets/pdf/tool_112013RARA_RR_FalseClaims.pdf

(“Cornell FCA case”)

<https://www.leagle.com/decision/infc020120905067>

[https://cornellsun.com/2012/10/21/after-court-says-weill-cornell-medical-](https://cornellsun.com/2012/10/21/after-court-says-weill-cornell-medical-college%E2%80%88defrauded-government-university%E2%80%88pays-1-6-million/)

[college%E2%80%88defrauded-government-university%E2%80%88pays-1-6-million/](https://cornellsun.com/2012/10/21/after-court-says-weill-cornell-medical-college%E2%80%88defrauded-government-university%E2%80%88pays-1-6-million/)

(“Yale case”)

<https://oig.nasa.gov/docs/pr2009-B.pdf>

<https://news.yale.edu/2008/12/23/yale-and-federal-government-reach-settlement-agreement-research-grant-accounting>

Experts address research fabrication lawsuit against Duke, note litigation could be lengthy

<https://www.dukechronicle.com/article/2016/09/experts-address-research-fabrication-lawsuit-against-duke-note-litigation-could-be-protracted>

Duke admits faked data “potentially affected” grant applications

<http://retractionwatch.com/2017/06/29/duke-admits-faked-data-potentially-affected-grant-applications/>

Duke Today: Message to Duke community about research misconduct case

<https://today.duke.edu/2019/03/message-duke-community-about-research-misconduct-case>

NIH regulations on Duke research in wake of prior misconduct cases

<https://www.dukechronicle.com/article/2018/03/duke-research-to-face-new-federal-regulations-in-wake-of-prior-misconduct-cases>

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<https://www.the-scientist.com/news-opinion/nih-suspends-duke-university-grants-amid-misconduct-allegations-65923>

https://img.medscapestatic.com/article/913/283/NIH_letter_to_Duke.pdf

Erin Potts-Kant Retraction list (to date)

<http://retractiondatabase.org/RetractionSearch.aspx#?auth%3dPotts-Kant%252c%2bErin%2bNicole>