Enforcement in Research

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Overview of Law and Enforcement in Research

Academic Medical Centers, Small Business & Physicians

- Protection of PHI, HIPAA, and GDPR
- Clinical trial requirements & billing
- IRB requirements
- Research Integrity
- Physician Compensation
- Allocation/billing of research costs
- Research contracts
- Human subject protection
- Conflicts of Interest

Fraud and Abuse

- Certifications and Liability
- Anti-Kick Back Statute
- False Claims Act
- Exclusion / Debarment
- OIG Civil Monetary Penalty Law
- Office of Research Integrity Authority

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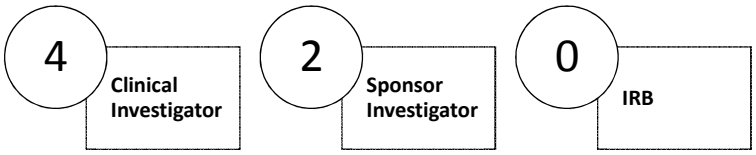
Steiner, John et al., *Clinical Research law and compliance handbook (2006)*

FDA Enforcement

2017 FDA Warning Letters



All issued by the Center for Drug Evaluation and Research

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126500.pdf

2017 FDA Clinical Investigator Warning Letters

Cassandra E. Curtis, M.D. 01/27/2017

- Failed to ensure that the investigation was conducted according to the investigational plan.
- Failed to maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation.
- Failed to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects.

Adolfo Kaplan, M.D. 04/20/2017

- Failed to ensure that the investigation was conducted according to the investigational plan.

Laveeza (nmi) Bhatti, M.D. 08/04/2017

- Failed to ensure that the investigation was conducted according to the investigational plan.
- Failed to retain records required to be maintained under 21 CFR Part 312 for a period of two years following the date a marketing application is approved for the drug for the indication for which the drug is being investigated; or, if no application is filed or if the application is not approved for such indication, until two years after the investigation is discontinued.

Sohail M. Khan, M.D. 10/10/2017

- Failed to retain records required to be maintained under 21 CFR Part 312 for a period of two years following the date a marketing application is approved for the drug for the indication for which the drug is being investigated; or, if no application is filed or if the application is not approved for such indication, until two years after the investigation is discontinued.

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2017 FDA Sponsor-Investigator Warning Letters

Merrill D Benson, M.D. 03/20/2017

- Failed to ensure that the investigation was conducted according to the investigational plan [21 CFR 312.60].

Kang Zhang, M.D., PhD. 01/05/2017

- Failed to ensure that the investigation was conducted according to the investigational plan [21 CFR 312.60].
- You failed to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects [21 CFR 312.62(a)].

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OIG Enforcement

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Civil Monetary Penalties Law

21st Century Cures Act

- Penalties for Violations of Grants, Contracts and Other Agreements [Section 5003].
- The Act adds several new violations to the list for which penalties are available under the Civil Monetary Penalties law. The newly added violations include: misrepresentations of "specified claims" under an HHS grant or contract; misrepresentations in a document required to receive or retain funds under an HHS grant or contract; misrepresenting a material "obligation" to transmit funds under an HHS grant; and failing, upon reasonable request, to grant timely access for audits or other statutory functions involving such grants or contracts.

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Civil Monetary Penalties Law

Latest Enforcement of New Authority

09-05-2018

California Biotechnology Company Settles Case Involving False Grant Claims On September 5, 2018, Sonata Biosciences, Inc. (Sonata), Auburn, California, entered into a $37,716.30 settlement agreement with OIG. The settlement agreement resolves allegations that Sonata knowingly presented to the Department of Health and Human Services (HHS) two specified claims under an HHS grant that Sonata knew or should have known were false or fraudulent. Specifically, OIG alleged that Sonata drew down $37,384.74 from a National Institutes of Health Small Business Innovation Research Grant for costs unrelated to the grant.

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HHS OIG Highlights

Announced/Revised	Report No.	Agency	Title	Summary	Impact
Apr-14	https://www.sbir.gov/tutorials/fraud-waste-abuse/	HHS SBIR-STTR	Vulnerabilities in the HHS Small Business Innovation Research Program Fraud, Waste and Abuse Training	The training provides detailed information on what represents fraud, waste, and abuse (FWA) under government programs and funding agreements like SBIR - STTR. The most common mistakes that lead to FWA problems are discussed, as well as the penalties. During the application process, examples of fraud include submitting plagiarized proposals and submitting proposals to multiple agencies for duplicative research. Within the proposal, false information about the company, the principal investigator, and/or the research to be conducted can constitute fraud. Using SBIR/STTR funds for personal use or any use other than those activities specified in the proposal and award during the SBIR performance period can lead to fraud investigations. Example of matters follow later in the presentation	Demonstrates HHS & OIG focus on SBIR – STTR fraud – as also demonstrated in support for DOJ actions against perpetrators of fraud involving these programs.
Dec-17	DHHS/OIG/OCIG Grantee Self-Disclosures 330 Independence Avenue, Room 5527 Washington, DC 20201	OIG	Self- Disclosures	HHS grantees or sub-recipients may voluntarily disclose evidence of potential violations of Federal criminal law involving fraud, bribery, or gratuity violations, potentially affecting the Federal award. 45 C.F.R. 75.113 notes mandatory disclosures of criminal offenses that non-Federal entities must make with respect to HHS grants. Recipients submitting disclosures in connection with this requirement should include the subject reference line "Mandatory Grant Disclosure." Recipients choosing to disclose conduct that may not fit squarely within the scope of offenses described in 45 C.F.R. 75.113, should include the following subject reference line in the submission: "Voluntary Grant Disclosure."	Indication that HHS OIG is making an effort to follow up on grantee required self-disclosures which may be related to research grants. Mandatory disclosures are required under 45 CFR § 75.113.

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OIG Active Work Plan Items

Announced /Revised	Report No.	Agency	Title	Summary	Impact
Dec-17	W-00-18-35804	CMS	Review of CMS Systems Used to Pay Medicare Advantage Organizations	Medicare Advantage (MA) organizations submit to CMS diagnoses on their beneficiaries; in turn, CMS categorizes certain diagnoses into groups of clinically related diseases called hierarchical condition categories (HCC). For instances in which a diagnosis maps to a HCC, CMS increases the risk-adjusted payment. CMS has designed its Medicare Part C systems to capture the necessary data in order to make these increased payments to MA organizations. As CMS transitions to a new data system to make these payments, OIG will conduct analysis to inform both use of current systems and the transition to a new system. We will review the continuity of data maintained on current Medicare Part C systems. Specifically, we will review instances in which CMS made an increased payment to an MA organization for a HCC and determine whether CMS's systems properly contained a requisite diagnosis code that mapped to that HCC.	Could impact reimbursement for SOC items/services for beneficiaries enrolled in Medicare Advantage programs
Dec-17	OEI-03-16-00420; OEI-03-17-00410	CMS	Data Briefs Regarding Financial Relationships Reported to the Open Payments Program	The Physician Payments Sunshine Act (from the Patient Protection and Affordable Care Act § 6002) requires that manufacturers disclose to the Centers for Medicare & Medicaid Services payments made to physicians and teaching hospitals. Manufacturers and group purchasing organizations must also report ownership and investment interests held by physicians. We will analyze 2015 data extracted from the Open Payments website to determine the number and nature of financial interests. We will also determine how much Medicare paid for drugs and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) ordered by physicians who had financial relationships with manufacturers and group purchasing organizations. We will determine the volume and total dollar amount associated with drugs and DMEPOS ordered by these physicians in Medicare Parts B and D for 2015.	Indication that CMS is finally acting on the financial relationship disclosure requirements set forth in the Affordable Care Act Sunshine provisions. It is important for providers organizations to know whether PI disclosures comport with Sponsor/Manufacture published payment lists.

OIG Active Work Plan Items (continued)

Announced/ Revised	Report No.	Agency	Title	Summary	Impact
Dec-17	W-00-16-35745; W-00-18-35745	CMS	Payment Credits for Replaced Medical Devices That Were Implanted	Certain medical devices are implanted during inpatient or outpatient procedures. Such devices may require replacement because of defects, recalls, mechanical complication, and other factors. Under certain circumstances, Federal regulations require reductions in Medicare payments for inpatient, outpatient, and ambulatory surgical center (ASC) claims for the replacement of implanted devices due to recalls or failures (42 CFR §§ 412.89, 419.45, and 416.179). Prior OIG reviews have determined that Medicare administrative contractors made improper payments to hospitals for inpatient and outpatient claims for replaced medical devices. We will determine whether Medicare payments for replaced medical devices were made in accord with Medicare requirements.	May impact payments received for category B medical devices that have been explanted and/or replaced
Jun-17	W-00-17-59422; A-04-17-04059	NIH	NIH Compliance with Federal Requirements for Indirect Cost Rate Setting	In fiscal year 2016, HHS awarded contracts to commercial organizations totaling over $5.9 billion. Indirect costs make up a significant portion of award costs. The National Institutes of Health (NIH) Division of Financial Advisory Services (DFAS) is the cognizant Federal agency responsible for negotiating and establishing indirect cost rates for commercial organizations that receive the preponderance of their Federal contract awards from HHS. We will determine whether DFAS established indirect cost rates for applicable commercial organizations in accordance with Federal requirements.	Indirect Cost Rate calculations are under scrutiny. Ensure that your organizations methodology is sound and document your negotiations with the NIH.

Civil Enforcement

Recent DOJ Cases

9/2018--Texas A&M Research Foundation Pays $750,000 to Settle Claims Alleging Improper Charges to Federal Grants

The Texas A&M Research Foundation (TAMRF), without admitting fault, agreed to pay the United States $750,000 to resolve claims that the Foundation submitted improper charges to federal grants. In a statement, A&M said that "there were a few instances where mistakes were made."

The settlement is the result of an investigation that began after a *qui tam*, or whistleblower, lawsuit was filed under seal on June 6, 2013. The whistleblowers are employed by TAMRF and alleged that during their employment they witnessed TAMRF allow personnel to ignore federal restrictions and permitted the overcharging of salaries, which inflated grant expenses. The whistleblowers also alleged TAMRF engaged in cost shifting; allowed academic employees to wrongfully receive longevity pay; violated salary caps; and improperly charged grants for expenses not incurred or not covered.

The United States also concluded that TAMRF improperly charged various federal grants for expenses not properly allocable to them, including salaries and wages for individuals not working on the grants and supplies and equipment unrelated to the grants. TAMRF also improperly charged various federal grants for unallowable costs such as travel expenses unrelated to the objectives of the grants or for unaffiliated parties not working on the grants.

https://www.justice.gov/usao/pressreleases

Recent DOJ Cases

9/2018--LoTEC Inc. (d/b/a Vesta Sciences)

The settlement resolves allegations uncovered by the Office of Inspector General of the National Science Foundation that LoTEC Inc. (d/b/a Vesta Sciences) transferred proceeds of the awards to an undisclosed related company, loaned award funds to other related companies and to LoTEC's principal, certified that the principal investigator for the awards was primarily employed by LoTEC when she was not, and failed to properly account for hours worked under the awards.

U.S. Attorney Carpenito said. "The government relies on small businesses to research and innovate. But the government also relies on SBIR Program recipients to engage in open communications, to make clear disclosures, and to keep accurate records so that awarding agencies can oversee these important research projects."

The California ceramic materials company will pay $175,000 to resolve allegations that it committed multiple False Claims Act violations relating to awards by the National Science Foundation and the U.S. Army under the Small Business Innovation Research (SBIR) Program.

Recent DOJ Cases

9/2018--Advanced Thermal Technologies and CEO Agree to Pay $100,000 for Failing to Account for Federal Research Funds

Advanced Thermal Technologies, LLC (ATT), and its President and Chief Operating Officer, James W. Connell, of Upton, Mass., agreed today to pay $100,000 to resolve allegations that they failed to account for a portion of federal research grants they received and that they used a portion of the funds unlawfully.

The government's complaint alleges that on multiple occasions from 2007 to 2016, Connell personally certified to NSF and DOE that: (1) ATT maintained an adequate financial system to account for the award funds as required by regulations, (2) ATT would comply with the award terms and conditions, and (3) ATT spent the award funds and performed the research in accordance with the terms and conditions. The complaint alleges that these certifications were often false because ATT and Connell failed to prepare and maintain documentation substantiating that they used the funds for the awarded research projects, and, on occasion, that they claimed and received funds for NSF projects that were already completed.

Recent DOJ Cases

3/2018 - University of Pittsburgh Professor Pays $132,000 and Agrees to Exclusion to Resolve Allegations of False Claims for Federal Research Grants

Christian Schunn, Ph.D., a professor at the University of Pittsburgh since 2001, has agreed to pay the United States $132,027 to resolve allegations that he violated the False Claims Act by submitting false documents to the National Science Foundation (NSF) in order to obtain federal grants to fund his research

The settlement resolves allegations that from 2006 through 2016, Schunn created false IRB approvals and submitted them to NSF in connection with multiple proposals for NSF funding totaling more than $2.3 million. Following Schunn's submission of each false IRB approval, NSF awarded funding to the University of Pittsburgh with Schunn as Principal Investigator, and award funds were drawn down. Schunn then allegedly made, or caused others to make, false claims for payment by certifying that the drawdowns were being made in accordance with the terms and conditions of the awards, when in fact, no proper IRB approval had been in place. The United States contends that Schunn also made false certifications in connection with annual and project reports associated with these awards.

Recent DOJ Cases

5/2018 – MassTech, Inc. Settles SBIR Fraud Lawsuit with Government for $1.9 Million

MassTech agreed to pay $1.9 to settle allegations that the company falsely certified itself as a small business in order to receive Small Business Innovation Research Awards.

In order to qualify, a company must have fewer than 500 total employees.

The U.S. Attorney for the District of Maryland pursued the fraud. The National Science Foundation investigated the false certifications based on allegations that the company was never eligible to receive grants it awarded. NASA and HHS also participated in the investigation.

According to the settlement agreement, the United States alleged that MassTech, Arnold Lee, and Richard Lee falsely represented to NSF, NASA, and HHS that MassTech was an eligible small business concern at the time of the SBIR application as well as throughout the lifecycle of the award. As a result, NSF, NASA, and HHS approved and funded SBIR awards to MassTech that MassTech otherwise would not have received. MassTech, Arnold Lee, and Richard Lee denied the United States' allegations.

Recent DOJ Cases

2/2018 - **University of North Texas Health Science Center to Pay $13 Million to Settle Claims Related to Federal Grants**

- UNTHSC has agreed to pay the United States $13,073,000.00 to settle claims that it inaccurately measured, tracked and paid researchers for effort spent on certain NIH-sponsored research grants.

4/2017 - **Partners Healthcare and Brigham and Women's Hospital Agree to Pay $10 Million to Resolve Research Fraud Allegations**

- Partners HealthCare System and one of its hospitals, Brigham and Women's Hospital (collectively, BWH), have agreed to pay $10 million to resolve allegations that a BWH stem cell research laboratory run by Dr. Piero Anversa fraudulently obtained grant funding from the National Institutes of Health (NIH). BWH disclosed these allegations to the government.

2/2017 - **Jackson State University Agrees to Pay $1.17 Million to Settle False Claims Act Allegations**

- JSU has agreed to pay the United States $1.17 million to settle allegations that JSU mismanaged National Science Foundation (NSF) Grants, announced U.S. Attorney Gregory K. Davis and Allison Lerner, Inspector General at the National Science Foundation.

https://www.justice.gov/usao/pressreleases

Criminal Enforcement

Recent DOJ Cases

2/2018 - **46-year-old Bin "Ben" Wen pleaded guilty to conspiracy to commit wire fraud, and 45-year-old Peng "Jessica" Zhang, pleaded guilty to conspiracy to defraud the United States and agreed to forfeit nearly $5 million in assets from their research fraud criminal activity.**

- Between June 2010 and December 2015, the defendants participated in a scheme to defraud agencies of federal research funds which were awarded to companies controlled by Wen and Zhang.
- They submitted approximately 13 applications to the National Science Foundation (NSF) totaling more than $2.6 million, 10 applications to the U.S. Department of Energy (DOE), totaling more than $5 million, and four applications to the U.S. Department of Agriculture (USDA), totaling approximately $650,000.
- Wen and Zhang submitted false and fraudulent information in Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR). A substantial amount of the fraudulently obtained money went toward the personal use and benefit of the defendants.

http://www.weny.com/story/37416489/owners-of-former-horseheads-businesses-plead-guilty-to-government-fraud

Recent DOJ Cases

3/2018 - **CFO of New Haven Biotech Firm Charged with Embezzling Nearly $1 Million**

- Upon further review of payroll and other financial records, firm's CEO discovered that, for several years, CFO had been writing checks to himself that were disguised as bonuses, that he had been giving himself unauthorized additional salary payments, that he had been using the firm credit card for personal expenditures, and that he had used the firm's funds to make unauthorized donations to an organization that CFO personally supported. A subsequent forensic audit revealed that, between 2012 and 2016, CFO had embezzled approximately $950,000 from the firm.

12/2017 -**Former Hershey Medical Center Research Technologist Sentenced For Making False Statements About Cancer Tests**

- According to United States Attorney David J. Freed, Benko, a former Research Technologist at the Hershey Medical Center in Hershey, Pennsylvania, was indicted in July 2015, and charged with one count of health care fraud and two counts of making false statements in health care matters. Benko performed DNA gene mutation tests (known as Epidermal Growth Factor Receptor (EGFR), KRAS gene mutation (KRAS), and BRAF gene mutation (BRAF) assays) for 124 advanced stage cancer patients at the Hershey Medical Center in 2013 and 2014. These genetic tests help physicians diagnose a patient's particular type of cancer so specifically tailored treatments can be administered to the patient.

https://www.justice.gov/usao/pressreleases

Recent DOJ Cases

11/2017 - **Yiheng Percival Zhang Charged with Seven Felonies in Relation to Federal Grants**
The former Virginia Tech professor is charged with one count of conspiring to defraud the United States, three counts of making false statements within the jurisdiction of the United States, and three counts of making false claims to the United States.

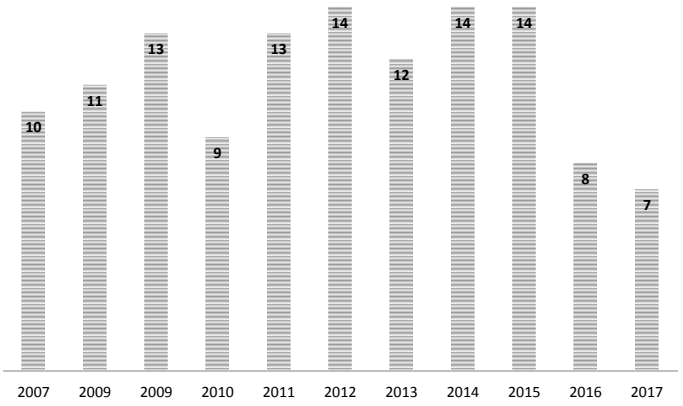
8/2017 - **Former Deputy Executive Director of USAID Contractor Sentenced for Theft of Grant Funds**
Eugene Sickle, the former deputy executive director of a South African research institute, was sentenced today to seven months of incarceration and ordered to pay $206,250 in restitution for a scheme in which he stole grant funds originating with the U.S. Agency for International Development (USAID).

5/2017 - **Dr. Jian Dong Sentenced to Seventy Months for Grant Fraud**
Dr. Jian Yun Dong, aka John Dong, was sentenced to seventy months imprisonment for multiple fraud-based convictions and ordered to pay over three million dollars in restitution.

https://www.justice.gov/usao/pressreleases

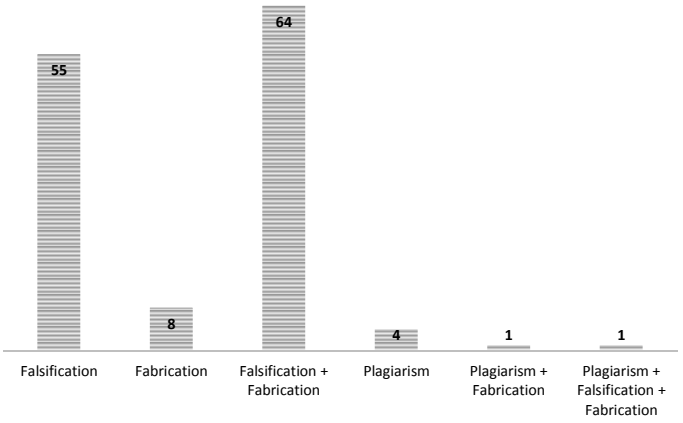
ORI Enforcement

Cases with Research Misconduct by ORI



https://ori.hhs.gov/case_summary

Types of Misconduct



Cases with Research Misconduct by ORI

2018 :

Shiladitya Sen, The Ohio State University

- In June 2016, Ohio State revoked Sen's doctorate in chemistry, which he received in 2013.
- Colleagues noted that "these problems occurred despite blinding of the identities of all samples … as well as regular examination of the melting data by multiple authors throughout the course of this work."
- ORI found that Mr. Shiladitya Sen, former graduate student, OSU, engaged in research misconduct in research supported by National Institute of General Medical Sciences (NIGMS), NIH, grant R01 GM083114. ORI found that Respondent engaged in research misconduct by knowingly and intentionally falsifying and/or fabricating data reported in the following published paper, his Ph.D. thesis, a poster presentation, and his mentor's grant applications submitted to NIGMS, NIH.
- Mr. Sen entered into a Voluntary **Exclusion Agreement for a period of three (3) years.**

Cases with Research Misconduct by ORI

2018 :

Bhagavathi Narayanan, Ph.D., New York University

- Retraction Watch Wrote: Narayanan said that at the time the work was done, over a decade ago, there were no rules that you had to keep the data. When we asked Narayanan about her work, she told us "of course science papers have mistakes." In regards to the comments on PubPeer, she added:
  - It's discrimination, [it's] jealousy, it is targeting somebody. Most of the PubPeer comments were meritless. They just want to hurt the people…This is not a pleasant experience to share…This is, at the expense of someones dead body, eating the other person's flesh.
- ORI found that Dr. Narayanan, former Research Associate Professor, Department of Environmental Medicine, NYU, engaged in research misconduct in research supported by NCI grants. Dr. Narayanan engaged in research misconduct by knowingly and intentionally falsifying and/or fabricating data reported in the following three (3) published papers and seven (7) grant applications submitted to NIH.
- Dr. Narayanan entered into a Voluntary **Exclusion Agreement for a period of three (3) years.**

Cases with Research Misconduct by ORI

2018 :

H.M. Krishna Murthy, Ph.D. University of Alabama at Birmingham

- In 2009, a university announced a prominent researcher in the field of protein crystallography had likely fabricated nearly a dozen protein structures. Nine years later, the U.S. Office of Research Integrity (ORI) has upheld the results — and announced a relatively long sanction, by the agency's standards.
- Dr. Murthy former Research Associate Professor, Department of Vision Sciences committed research misconduct in research supported by NIAID, NHLBI, and NIDDK grants. Dr. Murthy intentionally, knowingly, or recklessly engaged in research misconduct by falsifying and/or fabricating X-ray crystallographic data and that he intentionally, knowingly, or recklessly falsified and/or fabricated the PDB coordinate files.
- Dr. Murthy disputed these findings before an ALJ. The ALJ granted summary judgment on January 19, 2018 and sustained ORI's proposal to impose a ten-year debarment. On April 2, 2018, the HHS Debarring Official issued a final notice of **ten year debarment**.
- **The investigation took 9 years of ORI work resolve.**
- **The University dedicated a massive amount of time and effort to the inquiry and investigation**.

Cases with Research Misconduct by ORI

2018 :

Christian Kreipke, Ph.D., Wayne State University: Press Attention & Cross Complaints

- In 2010, Christian Kreipke was a rising star in the world of neuroscience research. He was a tenure-track professor at Wayne State University's School of Medicine, and a health scientist with the Veterans Administration (VA). His research focused on traumatic brain injuries. Kreipke was fired for research misconduct and filed a False Claims Act suit alleging grant fraud at Wayne State. The government declined to intervene. The suit was dismissed. Kriepke petitioned for certiorari. The Supreme Court Denied. The ORI matter continued and found Kriepke committed research misconduct.
- Dr. Kreipke disputed the findings. An agreed with ORI findings that he recklessly caused or permitted twenty-three (23) instances of research misconduct in his three (3) grant applications, two (2) articles on which he was the first listed author, and two (2) posters on which he was the first listed author. **The ALJ held that appropriate administrative actions included a five-year debarment.**
- On July 13, 2018, the HHS Debarring Official issued a final notice of debarment for a period of 5 years.

Cases with Research Misconduct by ORI

2018 :

Gareth John, Ph.D., Icahn School of Medicine at Mount Sinai – Press Attention

- Mount Sinai multiple sclerosis researcher admits to misconduct
- ORI found that Respondent engaged in research misconduct by knowingly and intentionally falsifying data reported in Development 141(12):2414-28, 2014 Jun (hereafter referred to as "Development 2014").
- Dr. John admitted, cooperated fully and expressed remorse for his actions.
- Dr. John entered into a **Voluntary Settlement Agreement** to have restricted research rights. He agreed to have his research supervised for a year, to not serve on committees including peer review committees at the U.S. National Institutes of Health for the same amount of time, and to follow up with Development to ensure they make the corrections he requested.

Cases with Research Misconduct by ORI

2018 :

Maria Cristina Miron Elqutub, University of Texas MD Anderson Cancer Center – Press Attention

- "MD Anderson research assistant subbed in her blood for study participants" – Houston Chronicle
- ORI found that Respondent engaged in research misconduct by intentionally and knowingly falsifying and/or fabricating data that were included in the following two (2) published papers and two (2) grant progress reports submitted to NIDCR. Specifically, ORI found that Respondent engaged in research misconduct by recording dates and providing her own blood samples to cause these samples to be falsely labeled as samples from ninety-eight (98) study subjects in a cancer genetics study involving human blood samples.
- Ms. Elqutub entered into a **Voluntary Settlement Agreement to have restricted research rights for 3 years**. As part of the ORI finding, Elqutub agreed to have her research supervised for three years and for any institution employing her that seeks federal funding to submit certification that any data she provides is legitimate.

Cases with Research Misconduct by ORI

2018 :

Brandi M. Baughman, Ph.D., University of North Carolina at Chapel Hill

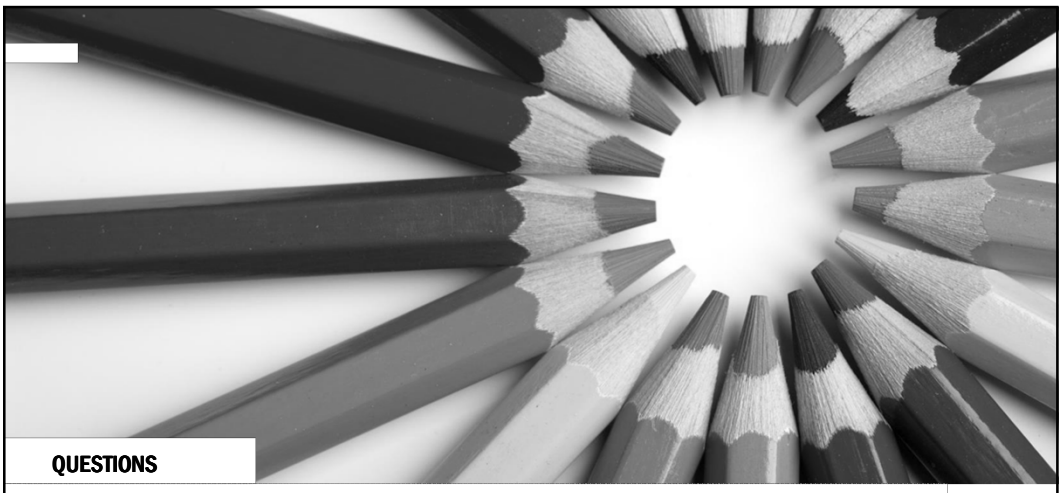
- Based on an assessment conducted by UNC, Respondent's admission, and analysis conducted by ORI in its oversight review, ORI found that Dr. Baughman, postdoctoral fellow in the Center for Integrative Chemical Biology and Drug Discovery, Division of Chemical Biology NIGMS.
- Dr. Baughman falsely reused and relabeled 14 individual Western blot images from an unrelated experiment conducted in September 2013 showing pulldown with biotin-UNC1215 using 0401 and HeLa overexpressed FL L3MBTL3 lysates (hereafter referred to as the "9/13 experiment") to falsely represent Western blot analysis of GFP.Flag co-IP experiments in GFP-WT lysates in Figure 3 of the Manuscript and a supplementary analysis of co-IPs with FullL-D274A in Figure 6 of ASC 2016.
- Dr. Baughman entered into a Voluntary Exclusion Agreement for a period of 2 years.

Cases with Research Misconduct by ORI

2018 :

Colleen T. Skau, Ph.D., National Institutes of Health

- Based on **Dr. Skau's admission**, an assessment conducted by the National Institutes of Health (NIH), and analysis conducted by ORI in its oversight review, ORI found that Dr. Colleen T. Skau, former postdoctoral fellow in the Cell Biology and Physiology Center, National Heart, Lung, and Blood Institute (NHLBI), NIH, engaged in research misconduct in research supported by NHLBI, NIH.
- ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly reporting falsified and/or fabricated data and/or falsifying and/or fabricating data in the following two (2) papers:
  - Cell 167(6):1571-1585, 2016
  - Proceedings of the National Academy of Sciences 112(19):E2447-E2456, 2015
- Dr. Skau entered into a **Voluntary Settlement Agreement** and agreed to have her research restricted for 3 years, subject to supervision and other requirements.



QUESTIONS

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