


Enforcement in Research

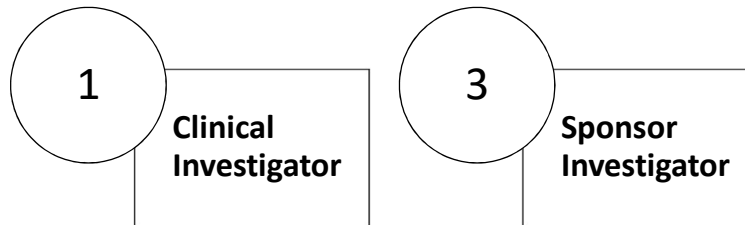
September 16th, 2019



FDA Enforcement



2018-2019 FDA Warning Letters



All issued by the Center for Drug Evaluation and Research



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

3

3

2018-2019 FDA Clinical Investigator Warning Letters

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.

Paddock Laboratories, LLC 06/15/2018

- Failed to comply with the milestone dates in the timetable for completion of a postmarketing requirement for Testosterone Gel 1%, under NDA 203098

Oeyama-Moto-Medical Group Foundation, LLC

05/21/2018

- Failed to assure that there was a Quality Assurance Unit (QAU), which monitors each nonclinical lab study to ensure conformance with GLP regulations
- Failed to establish standard operating procedures (SOPs) which insure the quality and integrity of the data generated
- Failed to assure all experimental data was accurately recorded and verified

Lymol Medical Corp 01/08/2019

- Failed to comply with the milestone date in the timetable for completion of a postmarketing requirement for Sterile Talc Powder under NDA 21388



4

4

OIG Enforcement

5

OIG Active Work Plan Items

Announced/ Revised	Report No.	Agency	Title	Summary	Impact
Jun-19	OEI-09-19-00350	CMS	Overtured Denials in Medicaid Managed Care	Managed care organizations (MCOs) contract with State Medicaid agencies to provide beneficiaries with Medicaid services. MCOs must cover services in at least the same amount, duration, and scope that would be covered under Medicaid fee-for-service. However, capitated payment models in managed care may create an incentive for MCOs to inappropriately limit or deny access to covered services to increase profits. We will review the extent to which selected MCOs' denied services and payments were overturned upon appeal. We will also review any concerns about the selected MCOs' performance related to denials and appeals that were identified through State oversight and monitoring efforts.	Denials and limited covered services will be under scrutiny. Ensure that your organizations methodology for denials is sound and well documented.
Jun-19	OEI-06-18-00400	CMS	Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries - 10-Year Update	OIG has conducted studies about adverse events (patient harm) in various healthcare settings since 2008, with 15 reports released or in process through 2019. The series includes a congressionally-mandated study released in 2010 that found that 27 percent of Medicare beneficiaries experienced adverse events or temporary harm events while hospitalized in 2008. The current study will replicate the methodology used in the prior work for a sample of Medicare beneficiaries admitted to acute-care hospitals in 2018. We will measure the incidence of adverse events and temporary harm events, the extent to which the harms were preventable given better care, and the associated costs to Medicare. We will compare the 2018 results with the prior study results to assess progress in reducing harm at the 10-year mark, and identify differences in harm rates, types, contributing factors, preventability, and costs.	Adverse events and adverse event reporting will be under scrutiny. Ensure that your organizations methodology for adverse events is sound and well documented.

6

OIG Active Work Plan Items (continued)

Announced /Revised	Report No.	Agency	Title	Summary	Impact
Jun-19	OEI-09-18-00260	CMS	Inappropriate Denial of Services and Payment in Medicare Advantage	Capitated payment models are based on payment per person rather than payment per service provided. A central concern about the capitated payment model used in Medicare Advantage is the incentive to inappropriately deny access to, or reimbursement for, health care services in an attempt to increase profits for managed care plans. We will conduct medical record reviews to determine the extent to which beneficiaries and providers were denied preauthorization or payment for medically necessary services covered by Medicare. To the extent possible, we will determine the reasons for any inappropriate denials and the types of services involved.	Denials and limited covered services will be under scrutiny. Ensure that your organizations methodology for denials is sound and well documented.
Jun-19	W-00-19-40005	Office of	Reviews of Non-Federal Audit Audits Services	In accordance with the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS awards at 45 CFR Part 75, State, local, and Indian tribal governments; colleges and universities; and nonprofit organizations receiving Federal awards are required to have annual organization-wide audits of all Federal funds that they receive. OIG reviews the audits and reports to ensure they meet applicable standards, identifies any follow-up work needed, and identifies issues that may require management attention. OIG also provides upfront technical assistance to non-Federal auditors to ensure they understand Federal audit requirements and to promote effective audit work. We analyze and record electronically the audit findings reported by non-Federal auditors for use by HHS managers. Our reviews inform HHS managers about the management of Federal programs and identify significant areas of internal control weaknesses, noncompliance with laws and regulations, and questioned costs that require formal resolution by Federal officials. We will continue to review the quality of audits conducted by non-Federal auditors, such as public accounting firms and State auditors, in accordance with the uniform grant guidance.	Ensure that annual audits are executed by auditors who understand the regulations of uniform grant guidance.

DOJ Enforcement

Recent DOJ Cases

9/2019 - Couple Who Worked at Local Research Institute for 10 Years Charged with Stealing Trade Secrets, Wire Fraud

A former Dublin, Ohio couple has been charged with crimes connected to stealing exosome-related trade secrets concerning the research, identification and treatment of a range of pediatric medical conditions.

According to the indictment, Yu Zhou, 49, and Li Chen, 46, currently of San Diego, Calif., conspired to, attempted to and did steal scientific trade secrets related to exosomes and exosome isolation from Nationwide Children's Hospital's Research Institute for their own personal financial gain.

"Nationwide Children's Hospital devoted years of work and its own money to researching exosomes in order to promote honorable medical advances," U.S. Attorney Glassman said. "The hospital's Research Institute took reasonable measures to keep its trade secrets secret. I commend the cooperation of Nationwide Children's throughout this investigation."



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

9

9

Recent DOJ Cases

9/2019 - Stony Brook University Professor Indicted for Stealing Over \$200,000 in Cancer Research Funds

Geoffrey Girnun, an Associate Professor in the Department of Pathology and Director of Cancer Metabolomics at the Renaissance School of Medicine at Stony Brook University ("SBU") was charged in a seven-count indictment unsealed today with theft of state and federal government funds, wire fraud and money laundering. Girnun allegedly submitted fraudulent invoices for research equipment to SBU from sham companies he created to conceal his theft of funds from cancer-related research grants issued by the National Institutes of Health ("NIH") and SBU.

According to the indictment, in or about 2013 and 2017, Girnun formed shell companies Atlas Metabolomics, LLC ("Atlas") and Emphyrean Biosciences, LLC ("Emphyrean"), which purportedly provided research items and equipment for the defendant's cancer-related research projects. Girnun then submitted fraudulent electronic invoices to SBU for payment to the companies for equipment, goods and services that were never received or provided.

SBU used NIH and SBU grant funds to pay the shell companies over \$200,000. Girnun transferred the NIH and SBU grant funds into his personal bank accounts and used the funds for personal expenses, including payments toward the mortgage on his home.



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

10

10

Recent DOJ Cases

8/2019 - Physicians and Cardiac Center Agree to Pay Total of more than \$1.1 Million to Resolve Allegations that They Received Kickbacks from Northwest Medical Testing Company

Three doctors and one medical practice entered into settlements with the U.S. Department of Justice to resolve allegations that they referred patients for genetic testing in exchange for kickbacks from a Seattle-area testing company, announced U.S. Attorney Brian T. Moran. The physicians, Dr. Gregory Sampognaro of Monroe, Louisiana, Dr. Warren Strickland and Dr. Isabella Strickland of Huntsville, Alabama and a cardiac center, Cardiology P.C. of Birmingham, Alabama, have agreed to pay a total of more than \$1.1 million to resolve the allegations.

According to the settlement agreements, between 2012 and 2013 the doctors and cardiac center were alleged to have accepted payments from now-defunct testing company Natural Molecular Testing Corporation (NMTc) in return for ordering genetic tests from NMTc, which NMTc then billed to Medicare. The scheme was alleged to be in violation of the Anti-Kickback Statute and the civil False Claims Act.



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

11

11

Recent DOJ Cases

4/2019 - Duke University Agrees to Pay U.S. \$112.5 Million to Settle False Claims Act Allegations Related to Scientific Research Misconduct

Duke University has agreed to pay the government \$112.5 million to resolve allegations that it violated the False Claims Act by submitting applications and progress reports that contained falsified research on federal grants to the National Institutes of Health (NIH) and to the Environmental Protection Agency (EPA), the Justice Department announced today.

"Duke knowingly, the government contended, falsified data to claim millions of grant dollars from the National Institutes of Health," said Maureen R. Dixon, Special Agent in Charge, Office of Inspector General for the U.S. Department of Health and Human Services. "OIG and our law enforcement partners will continue to hold such grantees fully accountable regardless of the length or complexity of the investigations."

The settlement resolves allegations that between 2006 and 2018, Duke knowingly submitted and caused to be submitted claims to the NIH and to the EPA that contained falsified or fabricated data or statements in thirty (30) grants, causing the NIH and EPA to pay out grants funds they otherwise would not have. Specifically, the United States contends that the results of certain research related to mice conducted by a Duke research technician in its Airway Physiology Laboratory, as well as statements based on those research results, were falsified and/or fabricated.



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

12

12

Recent DOJ Cases

- 3/2019 - Former University of New Hampshire Employee Sentenced for Stealing Government Funds
- According to court documents and statements made in court, Zhang was a former Research Associate Professor at the University of New Hampshire's Institute for the Study of Earth, Oceans and Space (EOS). Zhang was authorized to use a credit card provided by UNH to pay for expenses covered by federal research grants that were awarded to UNH by the National Aeronautics and Space Administration (NASA).
- 2/2019 - University to Pay \$1.5 Million to Settle False Claims Act Allegations
- Scott C. Blader, United States Attorney for the Western District of Wisconsin, announced that the Board of Regents of the University of Wisconsin System, acting through the University of Wisconsin-Madison ("University"), agreed to pay \$1.5 million to the United States to settle the claims that it violated the False Claims Act by failing to properly account for rebates and credits to reduce costs allocable to federal grants and awards ("Federal Awards").
- 2/2019 - Former Virginia Tech Professor Found Guilty of Grant Fraud, False Statements, Obstruction
- According to evidence presented at trial, Yiheng Percival Zhang, who at the time of the offenses was a biological systems engineering professor at Virginia Tech, founded Cell-Free Bioinnovations, Inc. ("CFB"), a research firm located in Blacksburg, Virginia. CFB relied exclusively on federal grants for funding its research activities. Zhang began working as a paid researcher for the Tianjin Institute of Industrial Biotechnology, Chinese Academy of Sciences by, at least, 2014. In 2015, Zhang caused fraudulent grant proposals to be submitted to the NSF. Evidence presented at trial indicated grant funds obtained would be used for research Zhang knew had already been done in China. Zhang intended to use the grant funds for other CFB projects rather than for the projects for which the funds were requested. To obstruct the investigation, Zhang submitted falsified timesheets to government investigators.



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

13

13

Recent DOJ Cases

- 1/2019 - UT Health Science Center Pays More than \$2.3 Million to Resolve Allegations
- The University of Texas Health Science Center (UTHSC) at Houston has paid \$2,396,769.76 to resolve allegations that its Human Genetics Center misappropriated grant funds the National Institutes of Health (NIH) provided for research related to the impact of genomic variation on individual health and the health of families and populations, announced U.S. Attorney Ryan K. Patrick. A component of UTHealth, UTHSCH is one of the largest research institutions in the United States.
- 11/2018 - Richland-Based Research Laboratory and Its Owner Indicted for Allegedly Falsifying Opioid Addiction Drug Research Trials
- The Indictment charges that the defendants enrolled ineligible study subjects and forged physician signatures and falsified medical records and other documentation designed to make it appear as though a licensed physician had determined that the subjects were eligible for the study. The Indictment further charges that the defendants falsified records and study data designed to make it appear as though subjects were participating in the study and were receiving the experimental treatment when they were not, in order to falsely bill for the study and obtain over a quarter of a million dollars from the drug company that was sponsoring the study.
- 2/2018 - University of North Texas Health Science Center to Pay \$13 Million to Settle Claims Related to Federal Grants
- The University of North Texas Health Science Center (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, announced U.S. Attorney Erin Nealy Cox of the Northern District of Texas.



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

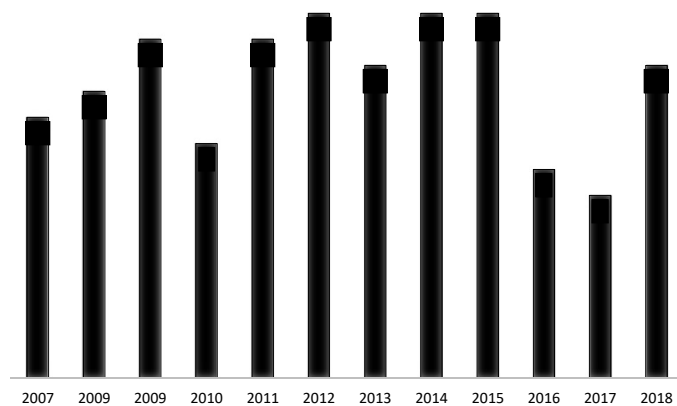
14

14

ORI Enforcement

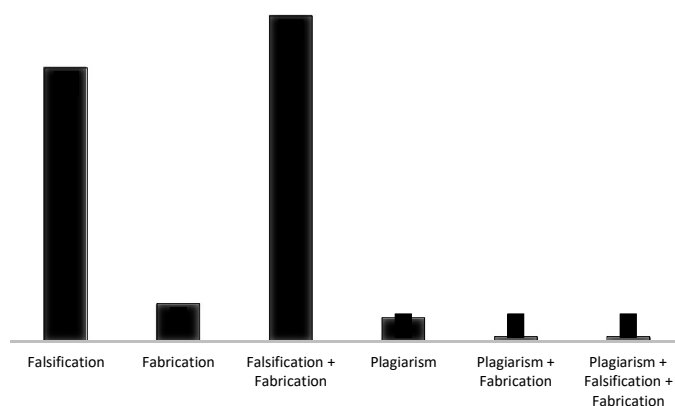
15

Cases with Research Misconduct by ORI



16

Types of Misconduct 2007 - 2018



17

Cases with Research Misconduct by ORI

2019 :

- Dr. Rahul Agrawal, National Institutes of Health:** Based on Respondent's admission, an assessment conducted by the National Institutes of Health (NIH), and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, ORI found that:
- Dr. Rahul Agrawal (Respondent), former visiting fellow at the Center for Cancer Research, Laboratory of Pathology, Cancer Molecular Pathology Section, National Cancer Institute (NCI), NIH, engaged in research misconduct in research supported by the Intramural Research Program of NCI, NIH.
 - ORI found that Respondent engaged in research misconduct by intentionally, knowingly, and/or recklessly falsifying and/or fabricating data in the unpublished research record by the alteration, reuse, and/or relabeling of quantitative real-time polymerase chain reaction (qRT-PCR) data and colony forming cell (CFC) and focus formation (FF) assay images to represent experiments that measured microRNA expression levels and the effect of long intergenic non-protein coding (LINC) RNAs in human cancer cell lines that were not conducted.
 - ORI found that Respondent knowingly, intentionally, and/or recklessly falsified and/or fabricated: qRT-PCR data in fifty-nine (59) Excel files by:
 - conceiving Cycle Threshold (CT) values and PCR machine run identification numbers and run dates for fifty-nine (59) experiments that were not conducted
 - inserting falsified and/or fabricated CT values in fifty-four (54) files that originated from one (1) Excel template with a single file creation date to represent distinct experimental runs with different experimental dates in exported Excel files from the PCR machine
 - utilizing an earlier PCR machine calibration date in four (4) Excel files to represent experiments completed at a later date
 - Dr. Agrawal entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed: to have his research supervised for a period of one (1) year beginning on August 8, 2019; Respondent agreed that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research.

18

Cases with Research Misconduct by ORI

2019 :

- William W. Cruikshank, Ph.D., Boston University School of Medicine:** Based on an investigation conducted by Boston University (BU) and analysis conducted by the Office of Research Integrity (ORI) in its oversight review, ORI found that William W. Cruikshank, Ph.D. (Respondent), former Professor of Medicine, Pulmonary Center, BU School of Medicine engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grant R01 CA122737-01A2.
- ORI found that Respondent engaged in research misconduct by knowingly, intentionally, and/or recklessly falsifying and/or fabricating data included in the following published paper, an earlier version of the submitted manuscript, a seminar presentation, and two grant applications submitted to NCI, NIH:
 - *J. Clin. Invest.* 2011;121:4838-49 (hereafter referred to as "JCI 2011"). Retracted in *J. Clin. Invest.* 2014;124(11):5085.
 - Manuscript submitted to *J. Clin. Invest.* (hereafter referred to as the "JCI manuscript").
 - Cruikshank, W. "A New Look at T Cell Cancers: A Case Study of Translational Research." Presented at the Clinical Research Training (CREST) Seminar Series on 09/08/09 (hereafter referred to as the "CREST Presentation").
 - R01 CA122737-01A1 and R01 CA122737-01A2
 - Respondent knowingly, intentionally, and recklessly falsified and/or fabricated Western blot data for protein expression in primary CD4+ T cells from patients with advanced T-cell acute lymphocytic leukemia (T-ALL) or cutaneous T-cell lymphomas (CTCL), by copying blot band images from unrelated sources, manipulating to disguise their origin, and combining multiple images to generate new figures to falsely represent results using sixty-four (64) such band images in the following sixteen (16) figures and related text included in one (1) manuscript, one (1) published paper, two (2) grant applications, and a seminar presentation.
 - Dr. Cruikshank entered into a Voluntary Exclusion Agreement (Agreement) and voluntarily agreed for a period of five (5) years, beginning on May 13, 2019: (1) to exclude himself from any contracting or subcontracting with any agency of the United States Government and (2) to exclude himself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.



https://ori.hhs.gov/case_summary

19

19

Cases with Research Misconduct by ORI

2019 :

- Edward J. Fox, Ph.D., University of Washington:** Based on Respondent's admission, an inquiry conducted by the University of Washington (UW), and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, ORI found that Edward J. Fox, Ph.D. (Respondent), former Acting Assistant Professor in the Department of Pathology, UW, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grants R01 CA193649, R01 CA160674, P01 CA77852, and R01 CA102029.
- ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly:
 - fabricating data and analyses in a manuscript submitted to *Nature*,^[1] which was subsequently voluntarily withdrawn. These fabricated data and analyses also appear in Figure 1 of grant progress report R01 CA193649-02.^[2] Respondent stated during the inquiry that two abstracts that appear in *Cancer Research*^[3] are based on the fabricated data and analyses.
 - fabricating or falsifying data and analyses in the preliminary results section of grant application R01 CA193649-01A1, section C.1.a(iv).
 - presented data-based explanations that are fabricated or falsified because some of them were based on the fabricated or falsified data
 - Respondent and ORI desire to close this matter without further expense of time and other resources and thus have entered into a Voluntary Settlement Agreement (Agreement). With respect to grant application R01 CA193649-01A1, Respondent acknowledges that his research records were poorly maintained and lacked the documentation necessary to support the reported preliminary results.
 - Dr. Fox entered into an Agreement and voluntarily agreed:
 - to have his research supervised for a period of one (1) year beginning on March 18, 2019; Respondent agreed that prior to submission of an application for U.S. Public Health Service (PHS) support for a research project



https://ori.hhs.gov/case_summary

20

20

Cases with Research Misconduct by ORI

2018 :

Rajendra Kadam, University of Colorado, Denver

- Findings of research misconduct have been made on the part of Rajendra Kadam, former Ph.D. student in pharmaceutical sciences, University of Colorado, Denver (UCD) (Respondent). Mr. Kadam engaged in research misconduct in research supported by National Eye Institute (NEI), National Institutes of Health (NIH), grants R01 EY018940, R01 EY017533, R24 EY017045, and RC1 EY020361.
- Mr. Kadam entered into a Voluntary Exclusion Agreement (Agreement) and voluntarily agreed:
 - to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to HHS' Implementation (2 C.F.R. Part 376) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 C.F.R. Part 180 (collectively the "Debarment Regulations") for a period of three (3) years beginning on November 13, 2018
 - to exclude himself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years beginning on November 13, 2018; and
 - as a condition of the Agreement, to request that the following paper be retracted:
 - Mol. Vis. 19:1198-1210, 2013

21

Cases with Research Misconduct by ORI

2018 :

Venkata Sudheer Kumar Ramadugu, Ph.D., University of Michigan

- Findings of research misconduct have been made on the part of Venkata Sudheer Kumar Ramadugu, Ph.D. (Respondent), former postdoctoral scientist in the Department of Chemistry, University of Michigan (UM). Dr. Ramadugu engaged in research misconduct in research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant R01 GM084018 and National Institute on Aging (NIA), NIH, R01 AG048934.
- Dr. Ramadugu entered into a Voluntary Exclusion Agreement (Agreement) and voluntarily agreed for a period of five (5) years, beginning on December 8, 2018:
 - because he also made a false statement in his first admission that no other data were affected in his papers, to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to HHS' Implementation (2 C.F.R. Part 376) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 C.F.R. Part 180 (collectively the "Debarment Regulations"); and
 - to exclude himself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

22

Cases with Research Misconduct by ORI

2018 :

Uthra Rajamani, Ph.D., Cedars-Sinai Medical Center: Findings of research misconduct have been made against Uthra Rajamani, Ph.D. (Respondent), former project scientist in the Induced Pluripotent Stem Cell Core Facility, Cedars-Sinai Medical Center (CSMC). Dr. Rajamani engaged in research misconduct in research supported by National Center for Advancing Translational Science (NCATS), National Institutes of Health (NIH), grant UL1 TR000124.

- Dr. Rajamani entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed:
 - to have her research supervised for a period of one (1) year beginning on November 27, 2018; Respondent agrees that prior to submission of an application for U.S. Public Health Service (PHS) support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research
 - that for a period of one (1) year beginning on November 27, 2018, any institution employing her shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved
 - that if no supervisory plan is provided to ORI, Respondent will provide certification to ORI at the conclusion of the supervision period that she has not engaged in, applied for, or had her name included on any application, proposal, or other request for PHS funds without prior notification to ORI
 - to exclude herself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of one (1) year beginning on November 27, 2018
 - that as a condition of the Agreement, Respondent will request that *Nature Communications* 8(219):1-15, 2017 be retracted



https://ori.hhs.gov/case_summary

23

23

Cases with Research Misconduct by ORI

2018 :

Srikanth Santhanam, Ph.D., Washington University in St. Louis: Based on the respondent's voluntary admission and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, ORI found that Srikanth Santhanam, Ph.D. (Respondent), staff scientist in the Division of Gastroenterology, Department of Internal Medicine, Washington University in St. Louis (WUSTL), engaged in research misconduct in research supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH)

- ORI found that Respondent engaged in research misconduct by falsifying data that were included in a manuscript and a revision submitted to Cancer Research, entitled "IDO1 and kynurenine pathway metabolites activate PI3K-Akt signaling in the neoplastic colon epithelium to promote cancer cell proliferation and inhibit apoptosis".
- ORI found that Respondent intentionally, knowingly, and/or recklessly falsely labeled figures in both the original submission and the revised submission of the manuscript
- Dr. Santhanam entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed:
 - to have his research supervised for a period of two (2) years beginning on December 14, 2018; Respondent agreed that prior to submission of an application for U.S. Public Health Service (PHS) support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research
 - at for a period of two (2) years beginning on December 14, 2018, any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved
 - that if no supervisory plan is provided to ORI, Respondent will provide certification to ORI at the conclusion of the supervision period that he has not engaged in, applied for
 - exclude himself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of two (2) years beginning on December 14, 2018.



https://ori.hhs.gov/case_summary

24

24

Cases with Research Misconduct by ORI

2018 :

Rakesh Srivastava, Ph.D., University of Kansas Medical Center

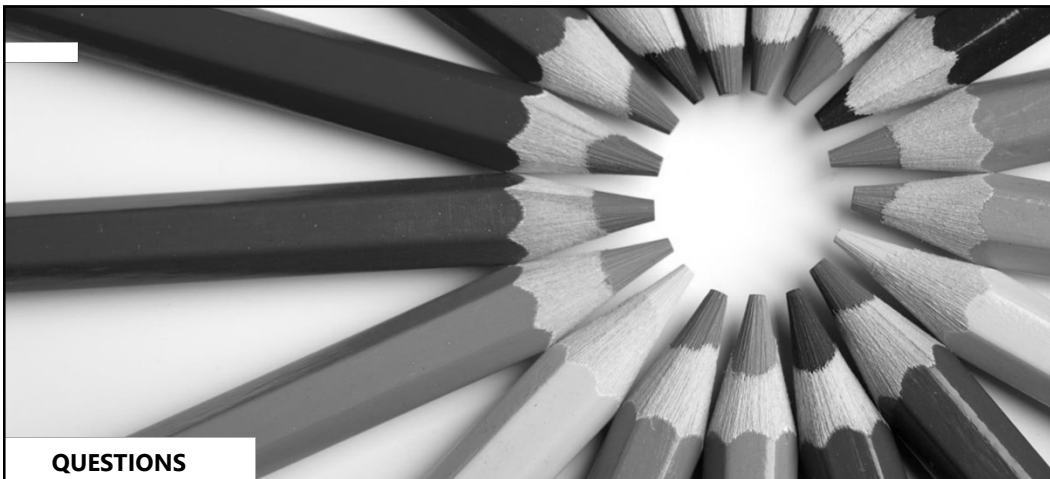
- Notice is hereby given that on October 22, 2018, the U.S. Department of Health and Human Services (HHS) Debarring Official, on behalf of the Secretary of HHS, issued a final notice of debarment based on an Administrative Law Judge's (ALJ's) finding of research misconduct against Rakesh Srivastava, Ph.D., former Eminent Scholar and Professor, University of Kansas Medical Center. Dr. Srivastava engaged in research misconduct in research proposed or reported in grant application 1 R01 CA175776-01, submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), on June 5, 2012.
- ORI issued a charge letter, and Dr. Srivastava (Respondent) subsequently requested a hearing before an ALJ of the Departmental Appeals Board to dispute the findings. ORI moved for summary judgment. On September 5, 2018, the ALJ granted summary judgment in favor of ORI and issued his recommended decision, finding that Respondent intentionally committed research misconduct by submitting to NIH a grant application that included plagiarized words
- The ALJ held that appropriate administrative actions included a two-year debarment from any contracting or subcontracting with any agency of the United States and from eligibility for or involvement in nonprocurement programs of the United States referred to as "covered transactions." 2 C.F.R. parts 180 and 376. The ALJ held it was an appropriate administrative action to also impose a two-year prohibition from serving in any capacity to the U.S. Public Health Service (PHS), including but not limited to, service on any PHS advisory committee, board, or peer review committee, or as a consultant.
- Thus, the research misconduct finding set forth above became effective, and the following administrative actions have been implemented for a period of two (2) years, beginning on: October 22, 2018
 - Dr. Srivastava is debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to HHS' Implementation
 - Dr. Srivastava is prohibited from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant



https://ori.hhs.gov/case_summary

25

25



QUESTIONS

F. Lisa Murtha: lisa.murtha@ankura.com Or (215) 801-7824
Tobin Boenig: trboenig@utmb.com Or (409) 747-8705



26

26