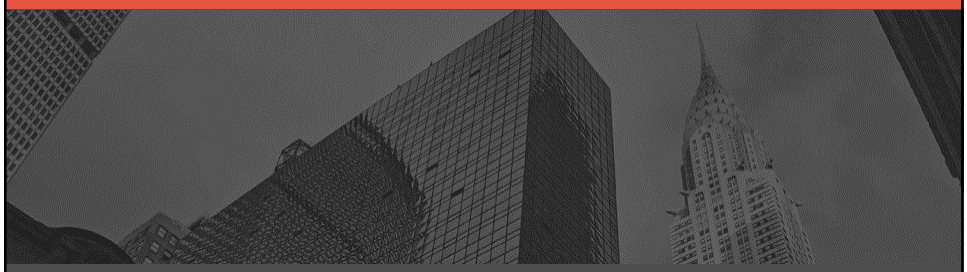
MS STRATEGIC SOLUTIONS

MOSES SINGER



2023 ENFORCEMENT IN RESEARCH

SPEAKERS:
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WHAT IS RESEARCH MISCONDUCT?

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REESEARCH MISCONDUCT & FRAUD

What Is It?

- *Research misconduct* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- *Research Fraud* means the use of intentional deception (e.g., a material misrepresentation of fact) concerning research to obtain money.
- Can occur at any level of industry and with any participants.
- Parallels to "traditional" healthcare fraud:
  1. Claims for services or supplies that were never provided;
  2. Falsifying medical records to support unperformed services or services to ineligible subjects;
  3. Duplicate subjects/duplicate claim submissions.

Why Is It Of Concern?

- Bad data contaminating a study (data falsification or fabrication).
- Systemic harm — maintain integrity of medicine and healthcare.
- Reputational harm to confidence in medical advances.
- Patient harm.
- Financial harm (e.g., grants, and adverse impacts on product or service revenues).

 OIG Fraud Enforcement cases: https://oig.hhs.gov/Fraud/enforcement/cmp/cmp-ae.asp.

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RESEARCH MISCONDUCT & FRAUD

Who Should be Concerned About Enforcement Actions?

- Clinical and Bench researchers
- Medical and research clinic owners and executives
- CROs, labs, and other third parties
- Sponsors
- Those who participate in federally-funded research
- Academic research organizations

5 OIG Fraud Enforcement cases: https://oig.hhs.gov/Fraud/enforcement/cmp/cmp-ae.asp.

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REGULATORY ENFORCEMENT FOCUS & KEY COMPLIANCE RISKS

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PRIMARY REGULATIONS OVERSEEING CLINICAL RESEARCH ENFORCEMENT

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COMMON COMPLIANCE RISKS

- CMP Violations
- Non-Compliance with the Investigational Plan
- Federal Exclusion or Debarment
- False Claims Act
- Falsification of Data

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FDA ENFORCEMENT

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FDA LATEST REGULATORY ENFORCEMENT FOCUS AREAS

- Decentralized Clinical Trials & Hybrid DCTs
- Management of Electronic Systems
- Failure to Comply with Applicable Regulations
- Failure to Submit Required Clinical Trial Results Information to ClinicalTrials.Gov

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FDA WARNING LETTERS

Clinical Investigators Disqualifications

- FDA may allege a Clinical Investigator has violated applicable regulations.
- FDA may then initiate Clinical Investigator disqualification proceedings.

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FDA WARNING LETTERS

Antonio E. Blanco, M.D./Vista Health Research, LLC

- Sept. 26, 2023 Warning Letter
- Issued by CDER
- CDER inspection was conducted as part of FDA's Bioresearch Monitoring Program.
- Alleged failure to ensure that the investigation was conducted according to the investigational plan (21 CFR 312.60).
- See here for warning letter: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/antonio-e-blanco-mdvista-health-research-llc-668519-09262023.

Luis Javier Pena-Hernandez, M.D., FCCP

- Sept. 20, 2023 Warning Letter
- Issued by CDER
- Alleged failure to ensure that the investigation was conducted according to the investigational plan (21 CFR 312.60), specifically the inclusion/exclusion requirement.
- Alleged failure to ensure that IRB complies with the 21 CFR part 56 requirements for initial and continuing review and approval of the proposed clinical trial (21 CFR 312.66).
- See here for warning letter: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/luis-javier-pena-hernandez-md-fccp-668217-09202023.

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FDA WARNING LETTERS

Angela M. Stupi, M.d.

- Aug. 8, 2023 Warning Letter
- Issued by CDER, and inspection conducted as part of FDA's Bioresearch Monitoring Program
- Alleged failure to adhere to the FD&C Act and applicable regulations in 21 CFR part 312.
- The investigational plans for Protocols required Investigator to determine whether subjects met inclusion or exclusion criteria before enrollment in the studies. Protocol (b)(4) required Investigator to administer the study drug in specific body locations as specified in the protocol. Investigator failed to adhere to these requirements
- See here for warning letter: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/angela-m-stupi-md-665471-08082023.

Mobeen Mazhar, M.D.

- May 31, 2023 Warning Letter
- Issued by CDER
- The investigational plan for Protocol required the Investigator to ensure that subjects met prescreening laboratory criteria to be eligible for study screening. The protocol also required Investigator to ensure that subjects met all eligibility requirements before enrollment and beginning the single-blind, two-week, placebo run-in portion of the study, and before randomization to receive study drug or placebo during the double-blind treatment portion of the study. Additionally, the protocol required Investigator to report adverse events of special interest (AESI) to the sponsor no more than 24 hours after learning of the event. Investigator failed to adhere to these requirements.
- See here for warning letter: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/vasyl-melnyk-md-623671-12212021.

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FDA WARNING LETTERS

Robert J. Hayashi, M.D./Washington University School of Medicine, Department of Pediatrics

- Mar. 14, Warning Letter
- Issued by CDER
- The Clinical Investigator failed to adhere to the investigational plan (21 CFR 312.60) which required the Investigator to ensure that subjects meet certain treatment eligibility criteria before each treatment cycle. Investigator admittedly deviated from these requirements which subjected to trial subjects to increased risk of neurotoxicity(e.g., seizures and encephalopathies).
- See here for warning letter: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/robert-j-hayashi-mdwashington-university-school-medicine-department-pediatrics-654873-03142023.

Tyrone L. McCall, M.D./Cornea Associates of Texas

- Mar. 22, 2023 Warning Letter
- The Clinical Investigator failed to submit an Investigational New Drug application for the conduct of a clinical investigation with an IND subject to 21 CFR 312.2(a).
- The sponsor, Cornea Associates failed to submit, and to have in effect, an IND before initiating the clinical investigation in human subjects, without having the clinical investigation qualified for an IND exemption under 21 CFR 312.2.
- See here for warning letter: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/tyrone-l-mccall-mdcornea-associates-texas-651261-03222023.

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OIG ENFORCEMENT

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OIG ENFORCEMENT

Illinois Institute of Technology Agreed to Pay $51,000 for Alleged CMP Violations

- February 28, 2023
- Illinois Institute of Technology (IIT) agreed to pay $51,907,50.
- Alleged violation of CMP Law: Former IIT employee stole gift cards that were meant to be dispensed to research study participants.
- OIG alleged that IIT submitted false claims for the cost of gift cards to two HHS funded awards that were awarded by the National Institutes of Health and the Administration for Community Living.

Illinois Institute of Technology Agreed to Pay $51,000 for Allegedly Violating the Civil Monetary Penalties Law by Submitting False Claims to NIH and ACL Grants, https://oig.hhs.gov/fraud/enforcement/illinois-institute-of-technology-agreed-to-pay-51000-for-allegedly-violating-the-civil-monetary-penalties-law-by-submitting-false-claims-to-nih-and-acl-grants/ (Feb. 28, 2023)

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OIG WORKPLAN ITEMS

Announced/ Revised	Report No.	Agency	Title	Summary
Sept. 2023	WA-23-0033 (W-00-23-35901)	CMS	Audit of Round 2021 of the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program	CMS administers a competitive bidding program under which prices for selected durable medical equipment, prosthetics, orthotics, and supplies furnished in specified areas are determined through a competitive bidding process. Federal law requires OIG to assess the process used by CMS to conduct the competitive bidding and subsequent pricing determinations under the first two rounds. Federal law also permits OIG to continue to verify such calculations for subsequent rounds (Medicare Improvements for Patients and Providers Act of 2008, § 154(a)(1)(A)(iv), adding subparagraph 42 U.S.C. § 1395w-3(a)(1)(E)). We will review the process used by CMS to conduct competitive bidding and to make subsequent pricing determinations during round 2021 of the competitive bidding program. Expected to be issued in 2024.
Sept. 2023	WA-23-0037 (W-00-23-35903)	CMS	Audits of Medicare Part C Unlinked Chart Review Diagnosis Codes	Payments to Medicare Advantage (MA) organizations are risk-adjusted on the basis of each enrollee's health status (SSA § 1853(a)). MA organizations are required to submit risk adjustment data to CMS according to CMS instructions (42 CFR § 422.310(b)). CMS allows MA organizations to conduct chart reviews of enrollee medical record documentation to identify diagnosis codes that providers either: (1) did not originally provide the MA organization or (2) provided the MA organization in error. For some chart reviews known as unlinked chart reviews, CMS does not require that the MA organization identify the specific date of service for previously unidentified diagnosis codes. CMS also allows MA organizations to submit chart review results to CMS for inclusion in calculating each enrollee's risk score. Miscoded diagnoses may cause CMS to pay MA organizations improper amounts. For these audits, we will focus on enrollees who had diagnoses identified from unlinked chart reviews that resulted in increased risk-adjusted payments from CMS to MA organizations. For these enrollees, we will determine whether all of the diagnosis codes that the MA organizations submitted to CMS for use in CMS's risk adjustment program, including the diagnosis codes submitted via unlinked chart reviews, complied with Federal requirements Expected to be issued in 2026.

17 OIG Active Work Plan Items, https://https://oig.hhs.gov/reports-and-publications/workplan/active-item-table.asp.

OIG AUDIT REPORT ON AWARDS AND SUBAWARDS MONITORING

The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies

- OIG initiated the audit due to concerns regarding the NIH's grant awards to EcoHealth Alliance, NIH's monitoring of EcoHealth, and EcoHealth's use of grant funds—including EcoHealth's monitoring of subawards to a **foreign entity**.
- OIG Objectives: to determine whether (1) NIH monitored grants to EcoHealth IAW Federal requirements and (2) EcoHealth used/managed its NIH grant funds IAW Federal requirements.
- Audit covered 3 NIH awards to EcoHealth **totaling approx. $8 Million**, which includes $1.8 Million subawards to 8 subrecipients, including ***the Wuhan Institute of Virology***).

18 The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies, https://oig.hhs.gov/oas/reports/region5/52100025.asp (Jan. 25, 2023).

OIG AUDIT REPORT ON AWARDS AND SUBAWARDS MONITORING

The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies (cont.)

- OIG Recommendations NIH ensure that EcoHealth:
  - 1. Accurately and in a timely manner report award and subaward information;
  - 2. Ensure that administrative actions are appropriately performed;
  - 3. Implement enhanced monitoring, documentation, and reporting requirements for recipients with foreign subrecipients;
  - 4. Assess whether NIAID staff are following policy to err on the side of inclusion when determining whether to refer research that may involve ePPP for further review;
  - 5. Consider whether it is appropriate to refer WIV to HHS for debarment; ensure any future NIH grant awards to EcoHealth address the deficiencies noted in the report; and
  - 6. Resolve costs identified as unallowable as well as possibly unreimbursed costs

19 The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies, https://oig.hhs.gov/oas/reports/region5/52100025.asp (Jan. 25, 2023).

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DOJ ENFORCEMENT

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DOJ ENFORCEMENT

Research fraud, including clinical trial fraud, remains a priority for the Department of Justice ("DOJ").

- In July 2022, the DOJ, together with OIG, published the 2021 Health Care Fraud and Abuse Control ("HCFAC") Program Report, indicating that clinical trial fraud involving possible falsification of study documents and/or fraudulent study subject enrollments have been increasing.
- DOJ works collaboratively with its agency partners, such as FDA and HHS-OIG, on research fraud and clinical trial fraud-related matters and investigations.
- Clinical trial fraud is one of several areas of focus for the DOJ Consumer Protection Branch, which works in coordination with U.S. Attorney's Offices throughout the United States.

21 Study Coordinator Charged in Scheme to Falsify Clinical Trial Data, https://www.justice.gov/opa/pr/study-coordinator-charged-scheme-falsify-clinical-trial-data (May 11, 2021).

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DOJ ENFORCEMENT FOCUS AREAS

DOJ research fraud enforcement focus areas:

1) Intentionally falsifying or fabricating clinical trial data for profit
2) Creating a risk of harm to research subjects and/or vulnerable patient populations
3) Conducting "clandestine" clinical trials – studies which lack the required oversight from FDA and IRBs
4) Submitting false claims for reimbursement (e.g., False Claims Act violations) related to medical research
5) Use of fraudulent data to obtain research funds (e.g., grant fraud)
6) Failure to disclose ties to foreign governments
7) Falsified or fabricated generic drug studies

22 Miami Medical Clinic Owner and Pharmacist Convicted for Clinical Trial Fraud Scheme, https://www.justice.gov/opa/pr/miami-medical-clinic-owner-and-pharmacist-convicted-clinical-trial-fraud-scheme (Sept. 7, 2023).

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DOJ ENFORCEMENT

Case Study: Miami Medical Clinic Owner and Pharmacist Convicted for Clinical Trial Fraud Scheme

- On Sept. 5, Miguel Angel Montalvo Villa (53) and Ivette Maria Portela Martinez (53)—both of Miami, were each convicted of one count of conspiracy to commit wire fraud and one count of wire fraud.
- From September 2015 through March 2018, Montalvo and Portela conspired to falsify clinical trial data for profit while working at AMB Research Center Inc. (AMB), a medical clinic located in Miami, Florida.
- As part of the conspiracy, Montalvo also submitted falsified and fraudulent invoices, totaling $277,920.70, in order for AMB to receive payments for purportedly conducting a clinical trial.
- Montalvo and Portela falsified hundreds of pages of documents and entered that false information into clinical trial databases, to make it appear as though the purported subjects had the disease in question and were fully participating in the clinical trial, when in fact they were not.

23 Miami Medical Clinic Owner and Pharmacist Convicted for Clinical Trial Fraud Scheme, https://www.justice.gov/opa/pr/miami-medical-clinic-owner-and-pharmacist-convicted-clinical-trial-fraud-scheme (Sept. 7, 2023).

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DOJ ENFORCEMENT

The potential scope of criminal liability for research misconduct is broad.

- Title 18 of the United States Code criminalizes wire and mail fraud, conspiracy, obstruction of an agency proceedings, false statements, and much, much, more.
- The Federal Food, Drug & Cosmetic Act (FDCA) imposes misdemeanor strict liability on individuals and organizations who violate the FDCA.
- The Park Doctrine—also known as the Responsible Corporate Officer Doctrine—imposes strict vicarious criminal liability upon responsible corporate officers for misdemeanor FDCA violations.

24 Miami Medical Clinic Owner and Pharmacist Convicted for Clinical Trial Fraud Scheme, https://www.justice.gov/opa/pr/miami-medical-clinic-owner-and-pharmacist-convicted-clinical-trial-fraud-scheme (Sept. 7, 2023).

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DOJ ENFORCEMENT

Clinical Trial Fraud & Enforcement under the False Claims Act

- Companies that falsify clinical trial data, make false statements to the FDA, omit relevant data in applications for FDA approval (data falsification or fabrication), or otherwise misrepresent the safety or efficacy of treatments in clinical trials, can face liability under the **False Claims Act**.
- The FCA allows whistleblowers to bring *qui tam* actions on behalf of the government to report fraud and misconduct in federal government contracts and programs. If money is recovered for the government in a *qui tam* case, the whistleblower may be entitled to a share, up to 30%, of the recovery from the case.

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DOJ ENFORCEMENT

False Claims Act liability could be based on many different aspects and phases of research.

- For example, False Claims Act liability could be based on:
  - Misrepresentations in seeking federal research dollars
  - Personal misuse of grant funds
  - Falsifying research data paid for with grant funds
  - Improperly billing for clinical research costs
  - Using falsified or fabricated data in applications submitted to the FDA
  - The FDA approving and, through government-funded insurance and healthcare (e.g., Medicare), the government paying for drugs or devices that do not do what they have been represented to do.

United States Settles Kickback Allegations with BioTek reMEDys Inc., Chaitanya Gadde and Dr. David Tabby, https://www.justice.gov/opa/pr/united-states-settles-kickback-allegations-biotek-remedys-inc-chaitanya-gadde-and-dr-david (Oct. 2, 2023).

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DOJ ENFORCEMENT

- In 2019 Duke University paid $112 million to resolve False Claims Act liability based on research misconduct.
  - In that case, the government alleged that a research technician falsified or fabricated data and research results for over a decade, causing the National Institutes of Health and Environmental Protection Agency to disburse grant funds to Duke.
  - "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/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related
- Enforcement risk is not just to pharmaceutical manufacturers or individual researchers: Risk extends throughout the healthcare system, including to universities and hospitals when their researchers falsify data.

27 Two Jacksonville Compounding Pharmacies and Their Owner Agree to Pay at Least $7.4 Million to Resolve False Claims Act Allegations, https://www.justice.gov/opa/pr/two-jacksonville-compounding-pharmacies-and-their-owner-agree-pay-least-74-million-resolve (June 15, 2023).

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ORI ENFORCEMENT

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CASES WITH RESEARCH MISCONDUCT BY ORI

2023: William M. Armstead, Ph.D

University of Pennsylvania: ORI found that William M. Armstead, Ph.D. (Respondent), who was a Research Associate Professor of Anesthesiology and Critical Care, Department of Anesthesiology and Critical Care, Perelman School of Medicine, UPENN, engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds.

- ORI found that Respondent engaged in research misconduct by knowingly and intentionally falsifying and/or fabricating fifty-one (51) figures and the methods, data, results, and conclusions reporting on the effects of various vasoactive agents on the neurologic response to traumatic brain injury in piglets of different ages and genders in the following five (5) published papers, one (1) unpublished manuscript, one (1) review article, three (3) posters, three (3) grant applications submitted for PHS funds, and four (4) NIH grant progress reports.
- The Respondent agreed:
  - Exclusion (for 7 years) from contracting or subcontracting with any agency of the U.S. Government and from eligibility for or involvement in "covered transactions" under 2 CFR Parts 180 and 376;
  - Exclusion from serving in any advisory or consultant capacity to PHS.
  - Correction or retraction of the falsified data in the germane publications.

29 ORI Case Summary, https://ori.hhs.gov/content/case-summary-armstead-william-m.

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CASES WITH RESEARCH MISCONDUCT BY ORI

2023: Andrew Dannenberg, M.D.

Weill Cornell Medical College: ORI found that Andrew Dannenberg, M.D. (Respondent)—a Professor of Medicine, Department of Medicine, WCMC, engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds.

- ORI found that Respondent engaged in research misconduct by recklessly reporting falsified and/or fabricated data in the following twelve (12) published papers.
- Specifically, Respondent recklessly reported falsified and/or fabricated Western blot image data that were reused, with or without manipulation to conceal their similarities, and falsely relabeled as data representing different experiments or proteins in sixty (60) figure panels included in twelve (12) published papers.
- The Respondent agreed to have his research supervised for 7 years. The agreed upon supervision plan would require Respondent to, among others, to have a committee review primary data for Respondent's laboratory on a quarterly basis and submit a report to ORI every 6 months and for the committee to conduct advance review of each application for PHS funds.

30 ORI Case Summary, https://ori.hhs.gov/content/case-summary-dannenberg-Andrew.

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CASES WITH RESEARCH MISCONDUCT BY ORI

2023: Ivana Frech, Ph.D.

University of Utah: ORI found that Ivana French, Ph.D. (formerly Ivana De Domenico), former Assistant Professor, Department of Internal Medicine, UU School of Medicine, engaged in research misconduct under 42 C.F.R. Part 93 in research supported by U.S. Public Health Service (PHS) funds.

- ORI found that Respondent intentionally, knowingly, or recklessly falsified and/or fabricated western blot and autoradiogram images related to mechanisms of cellular iron regulation by reusing, relabeling, and manipulating images to falsely report data in eight (8) figures included in the following three (3) PHS-supported published papers.
- Respondent is subject to administrative actions including:
  - **Debarred** (for 3 years) from participating in "covered transactions" as defined in 42 CFR § 180.200 and procurement transactions covered under the Federal Acquisition Regulation.
  - Prohibited from serving in any advisory capacity to PHS.
  - Applicable publications by Respondent will be retracted or corrected.

 ORI Case Summary: https://ori.hhs.gov/content/case-summary-de-domenico-ivana.

CASES WITH RESEARCH MISCONDUCT BY ORI

2023: Johnny J. He, Ph.D.

Rosalind Franklin University of Medicine and Science: ORI found that Johnny J. He, Ph.D. (Respondent), who is a Professor, Department of Microbiology and Immunology, RFUMS, engaged in research misconduct in research reported in grant applications submitted for U.S. Public Health Service (PHS) funds. Respondent falsified, fabricated, and plagiarized research data and text.

- ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying, fabricating, and plagiarizing experimental data and text that described the research from one (1) pre-print and four (4) published papers and represented the data and/or ideas as his own under different experimental conditions in four (4) NIH grant applications and in one research record.
- Under the Voluntary Settlement Agreement, Respondent agreed to:
  - 3 years of research supervision
  - Have a committee of senior faculty members at RFUMS review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at 6-month intervals.
  - Excluded from serving in any advisory or consultant capacity to PHS.

 ORI Case Summary, https://ori.hhs.gov/content/case-summary-he-johnny-j.

CASES WITH RESEARCH MISCONDUCT BY ORI

2023: Surangi (Suranji) Jayawardena, Ph.D.

University of Alabama in Huntsville: ORI found that Surangi (Suranji) Jayawardena, Ph.D. (Respondent), who was an Assistant Professor of Chemistry, UAH, engaged in research misconduct in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically, Respondent intentionally, knowingly, or recklessly falsified and/or fabricated the following image data by reusing data from the same source and falsely relabeling the data as representing different experimental conditions with antibiotic particles or bacteria.

- Additionally, Respondent reported falsely relabeled images to represent different bacterial experimental conditions, when such conditions were not experimented.
- Under the Voluntary Settlement Agreement, Respondent agreed to have his research supervised for 4 years, subjected to supervision plan that included a committee of senior faculty members at the institution that would provide oversight and guidance for four years, and review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at 6-months intervals.

33 ORI Case Summary, https://ori.hhs.gov/content/case-summary-jayawardena-suranji.

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CASES WITH RESEARCH MISCONDUCT BY ORI

2023: Yiorgos (Georgios) I. Laliotis, M.D.

Stuart G. Jarrett, Ph.D., University of Kentucky: RI found that Yiorgos (Georgios) I. Laliotis, M.D. (Respondent), who was a Postdoctoral Fellow, Department of CanceOr Biology and Genetics, College of Medicine, OSU, and Postdoctoral Fellow, Department of Oncology, JHU, engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Cancer Institute (NCI), National Institutes of Health (NIH) grants.

- ORI found that Respondent engaged in research misconduct by intentionally and knowingly falsifying and/or fabricating data, methods, results, and conclusions by representing a fabricated Exon 2 splice variant of U2AF2, which would translate as a Serine-Arginine-Rich deficient U2AF65 isoform, leading to the repression of lung adenocarcinomas and by enhancing the role of splicing in mutant PIK3CA breast cancer cell lines in the following three (3) published papers, two (2) NIH grant applications, and two (2) unpublished manuscripts.
- Respondent is subject to 3-years research supervision plan.
- During the Supervision Period, Respondent will ensure that any institution employing him submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported and not plagiarized in the application, report, manuscript, or abstract.

34 ORI Case Summary: https://ori.hhs.gov/content/case-summary-laliotis-yiorgos-georgios-i.

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CASES WITH RESEARCH MISCONDUCT BY ORI

2023: Carlo Spirli, Ph.D.

Ritankar Majumdar, Ph.D., National Institutes of Health: ORI found that Carlo Spirli, Ph.D. (Respondent), who was an Assistant Professor of Medicine, Department of Digestive Diseases, YU, engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH) grants.

- ORI found that Respondent engaged in research misconduct by knowingly, intentionally, or recklessly falsifying and/or fabricating data included in the following four (4) published papers, two (2) presentations, and three (3) grant applications submitted for PHS funds.
- Respondent knowingly, intentionally, or recklessly falsified and/or fabricated Western blot image data for cholangiopathies in a murine model of Congenital Hepatic Fibrosis (CHF) by reusing blot images, with or without manipulating them to conceal their similarities, and falsely relabeling them as data representing different experiments or proteins and falsifying quantitative data in associated graphs purportedly derived from those images in twenty-one (21) figures included in four (4) papers, two (2) presentations, and three (3) grant applications.
- Under the Voluntary Exclusion Agreement, Respondent agreed to:
  - Exclusion from any contracting or subcontracting with any agency of the U.S. government for "Covered Transactions" under 21 CFR Part 180 and 376 for a period of 4 years.
  - Exclusion from serving as a consultant or advisor to PHS.
  - Correction and retraction of his publications.

35 ORI Case Summary, https://ori.hhs.gov/content/case-summary-spirli-carlo.

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CASES WITH RESEARCH MISCONDUCT BY ORI

2023: Kotha Subbaramaiah, Ph.D.

Weill Cornell Medical College: ORI found that Kotha Subbaramaiah, Ph.D. (Respondent), who was a Professor of Biochemistry Research in Medicine, Department of Medicine, WCMC, engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds.

- ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying and/or fabricating data included in the following twelve (12) published papers.
- Under the Voluntary Exclusion Agreement, the Respondent is excluded for 7 years from any contracting or subcontracting with any U.S. agency and from eligibility for or involvement in non-procurement programs of the U.S.

36 ORI Case Summary, https://ori.hhs.gov/content/case-summary-subbaramaiah-kotha.

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BEST PRACTICES FOR MANAGING CLINICAL TRIAL RISKS

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KEY TAKEAWAYS

- Thoroughly vet persons and entities whom you work/contract with.
- Consider data reporting mechanisms
- Look for outlier data during course of clinical trial
- Be transparent with FDA and other regulators
- Self-disclose for IRBs, Sponsors, the OHRP, and FDA, as applicable

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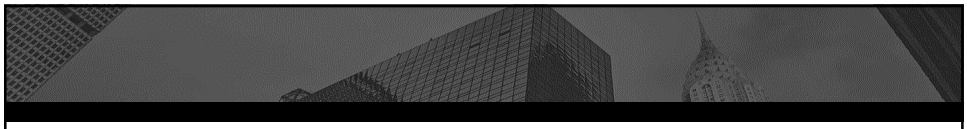

Thank you for your attention!

Questions?

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