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2021-2022 Research Year-in-Review

June 8, 2022

Created by Kiyong Song, Associate

Presenter

F. Lisa Murtha
Partner
Tel: (212) 554 7585
Email: lmurtha@mosessinger.com

F. Lisa Murtha (Lisa) is a partner in the Healthcare and Privacy & Cybersecurity Practices of Moses & Singer, LLP based in the New York Office. Lisa has over 30 years of experience working as a healthcare and research attorney, a Chief Compliance Officer, and as a consultant where she served provider and life sciences organizations alike on a variety of research and healthcare legal and regulatory matters.

Prior to joining Moses & Singer, Lisa was a Senior Managing Director at Ankura where she was the Co-Chair of the Research and Compliance Practice. Lisa previously served as the leader of the research practice at FTI Consulting, where she provided compliance and operational services to research organizations. Before that, she was a partner at Dentons US LLP, where she provided legal services to research sponsors and research sites, including negotiations of clinical trial agreements, and investigations and settlements of allegations of scientific fraud.

Earlier in her career, Lisa worked as in-house counsel to two nationwide healthcare organizations, and also served as the chief compliance officer for both Pennsylvania Blue Shield and the University of Pennsylvania and its health system.

Lisa was a founding board member and officer of the Health Care Compliance Association and the Society of Corporate Compliance and Ethics. She is currently a faculty member of the Loyola (Beazley) School of Law. She previously taught research and health law courses for the Drexel (Kline) School of Law, Widener University Law School and Penn State University respectively.

Lisa's professional experience includes:

- Development of coverage analyses and assessments of research billing practices at more than 50 of the country's top research universities and health systems.
- Conducted internal investigations for pharmaceutical companies.
- Conducted investigations and provided expert witness testimony into allegations of research/misconduct at several research universities.
- Development and implementation of clinical trial offices at numerous universities and health systems.
- Investigations into conflict of interest allegations at several healthcare organizations.
- Provide interim CCO services for pharmaceutical and biotech companies.
- Investigations and assessments for human research protection programs at numerous research universities and hospitals.
- Assessment and process improvement consulting for the grants offices of several research universities.
- Investigations into allegations of federal grant fraud.
- Compliance program effectiveness assessments for numerous provider organizations.
- Coding and billing audits for several of the nation's top healthcare systems.

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FDA Updates

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FDA Updates

FDA Guidance on Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)

- Released on: November 15, 2021.
- The FDA revised its Coronavirus Disease-2019 Tests During the Public Health Emergency Policy, and this November 15, 2021 Guidance supersedes the guidance policy issued May 11, 2020.

FDA Updated Final Guidance on Conduct of Clinical Trials of Medical Product During the COVID-19 PHE (Revised, Final)

- Updated on: August 30, 2021.

The FDA has issued this guidance to provide general considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity for the duration of the COVID-19 public health emergency.

With the August 2021 update, the FDA included an appendix to this guidance that further explains those general considerations by providing answers to questions that the FDA received about conducting clinical trials during the COVID-19 PHE.

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FDA Updates

FDA Guidance on Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

- Issued on December 22, 2022.
- This draft guidance sets forth recommendations to sponsors, investigators, and other stakeholders on the use of digital health technologies (DHTs) to acquire data remotely from participants in clinical investigations evaluating medical products. DHTs may take the form of hardware and/or software and may be used to gather health-related information from study participants and transmit that information to study investigators and/or other authorized parties to evaluate the safety and effectiveness of medical products.
- This draft guidance also addresses some of the information that should be contained in an IND application or an IDE application for a clinical investigation in which the sponsor plans to use one or more DHTs or in a marketing application that includes such a clinical investigation

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Digital Health Technologies for Remote Data Acquisition in Clinical Investigations, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations

FDA Updates

FDA Guidance on Digital Health Technologies for Remote Data Acquisition in Clinical Investigations (cont.)

- The draft guidance noted that DHTs used in clinical investigations of medical products would usually be exempt from applicable requirements to obtain marketing authorization and other device requirements.
- It also outlines the considerations for study sponsors when using DHTs in the above fashion:
  - Technology Selection;
  - Verification and validation of the technology for clinical investigation use;
  - Usability of DHTs to collect data for trial endpoints;
  - Identification of risks associated with the DHTs used during clinical investigations;
  - Management of risks related to DHT use in clinical investigation.

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Digital Health Technologies for Remote Data Acquisition in Clinical Investigations, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations

FDA Updates

Investigator Responsibilities – Safety Reporting for Investigational Drugs and Devices

- Issued in September 2021
- This draft guidance assists clinical investigators to comply with the safety reporting requirements for IND studies under § 312.64(b) (21 CFR 312.64(b)) and IDE studies under § 812.150 (21 CFR 812.150).
- The draft guidance sets forth recommendations to help investigators identify:
  1. For drugs – identify safety information that is considered an unanticipated problem involving risks to human subjects or others, and therefore requires prompt reporting to IRBs under § 312.66 (21 CFR 312.66)
  2. For devices — Identify safety information that meets the requirements for reporting unanticipated adverse device effects (UADEs) to sponsors and IRBs under § 812.150(a)(1) (21 CFR 812.150(a)(1))

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Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency, https://www.fda.gov/media/136238/download.

FDA Updates

Responsibilities - Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies

- Issued in June 25, 2021.
- This draft guidance provides recommendations to help sponsors and sponsor-investigators comply with the expedited safety reporting requirements for human drug and biological products that are being investigated (1) under an investigational new drug application (IND) (21 CFR 312.32) or (2) as part of a bioavailability (BA) or bioequivalence (BE) study that is exempt from the IND requirements (21 CFR 312.64(b) and 320.31(d)(3)).
- The draft guidance defines terms used for safety reporting; makes recommendations on when and how to submit a safety report with focus on the analysis of aggregate safety data.

Institutional Review Board Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 PHE, https://www.fda.gov/media/138496/download.

FDA Updates

Clinical Pharmacology Considerations for Antibody-Drug Conjugates Guidance for Industry

- Issued in February 2022.
- This draft guidance provides recommendations to assist industry and other parties involved in the development of antibody-drug conjugates (ADCs) with a cytotoxic small molecule drug or payload. Specifically, this guidance addresses the FDA's current thinking regarding clinical pharmacology considerations and recommendations for ADC development programs, including bioanalytical methods, dosing strategies, dose- and exposure-response analysis, intrinsic factors, QTc assessments, immunogenicity, and drug-drug interactions (DDIs).
- The guidance outlines clinical pharmacology considerations of ADC development programs, including all pertinent laws and regs for biological products such as those governing product development, testing, and approval as outlined in Sec. 351 of the Public Health Service Act (42 U.S.C. 262).

Clinical Pharmacology Considerations for Antibody-Drug Conjugates Guidance for Industry, https://www.fda.gov/media/155997/download

FDA Updates

Bioavailability Studies Submitted in NDAs or INDs – General Considerations

- Issued in April 2022.
- This draft guidance provides recommendations to sponsors and applicants submitting bioavailability (BA) information for drug products in investigational new drug applications (INDs), new drug applications (NDAs), and NDA supplements. This guidance contains recommendations on how to meet the BA requirements set forth in 21 CFR part 320 as they apply to dosage forms intended for oral administration. These dosage forms include tablets, capsules, solutions, suspensions, conventional (e.g., immediate-release drug products) and modified-release (e.g., extended-release, delayed-release) drug products.
- The guidance provides recommendations on conducting BA studies during the investigational period for a drug intended to be submitted for approval in an NDA and bioequivalence (BE) studies during the post-approval period for certain changes to drug products with an approved NDA.

FDA BA Guidance, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bioavailability-studies-submitted-ndas-or-inds-general-considerations

FDA Updates

Clinical Pharmacology Considerations for Human Radiolabeled Mass Balance Studies

- Issued in May 2022; currently open to public comments until Aug. 4, 2022.
- This draft guidance provides the FDA's recommendations regarding clinical pharmacology considerations for conducting human radiolabeled mass balance studies of investigational drugs, including:
  1. deciding whether and when to conduct the study;
  2. designing the study; and
  3. reporting results.
- This guidance does not cover animal mass balance studies, safety testing of drug metabolites, or recommendations for selecting the radioactive dose.

Clinical Pharmacology Considerations for Human Radiolabeled Mass Balance Studies, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-pharmacology-considerations-human-radiolabeled-mass-balance-studies

FDA Updates

Notable 2021-2022 FDA Enforcement Action

Notice of Noncompliance – Ocugen, Inc.

- Issued on April 15, 2022.
- The FDA continues to issue warnings to companies for failure to submit clinical trial results. The FDA issued the Notice to Ocugen, a biotech company developing and commercializing novel gene therapies, biologicals, and vaccines, for potential failure to submit its Phase III clinical trial results for its Brimonidine Tartrate Nanoemulsion Eye Drops.
- The Notice required Ocugen to submit the required clinical trial results information in the manner and format specified at ClinicalTrials.gov within 30 calendar days from the receipt of the Notice, and informed Ocugen of FDA's ability to seek additional civil monetary penalties against it.
- Notice of Noncompliance (https://www.fda.gov/media/157774/download).

NIH Updates

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NIH Updates

NIH and FDA Partner for the Bespoke Gene Therapy Consortium (BGTC)

NIH and FDA, with 15 private organizations, Launches the Bespoke Gene Therapy Consortium (October 27, 2021)

- In October 2021, the FDA and NIH, together with 10 pharmaceutical companies and 5 non-profit organizations, partnered to accelerate development of gene therapies for Americans suffering from a rare disease through the newly launched Bespoke Gene Therapy Consortium (BGTC). The BGTC is a part of the NIH Accelerating Medicines Partnership (AMP) program and project-managed by the Foundation for the National Institutes of Health (FNIH), and aims to optimize and streamline the gene therapy development process to help fill the unmet medical needs of people with rare diseases.
- FDA, NIH, and 15 private organizations join forces to increase effective gene therapies for rare diseases: (https://www.nih.gov/news-events/news-releases/nih-establishes-new-childhood-asthma-clinical-research-network).

- The BGTC is establishing platforms and standards to speed the development and delivery of customized or "bespoke" gene therapies that could treat millions of people affected by rare diseases, including diseases too rare to be of commercial interest. The BGTC is the first AMP initiative focused on rare diseases and the sixth AMP initiative overall. It also is the first to focus on a therapeutic platform.
- The BGTC's goals are:
  1. to improve the understanding of the basic biology of the harmless adeno-associated virus (AAV), a common gene-delivery vehicle or vector;
  2. to improve the efficiency of both vector manufacturing and production quality control testing (by developing a standard and broadly applicable set of analytic tests that can be used to manufacture viral vectors);
  3. to improve the efficiency of both vector manufacturing and production quality control testing; and
  4. to develop strategies for streamlining the regulatory processes for FDA approval of safe and effective gene therapies, and they will develop standardized approaches to preclinical testing (e.g., toxicology studies).

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NIH Updates

Notable Public Meetings and Workshops Hosted by NIH

Workshop on Technology to Improve Maternal Health

- On January 18, 2022, the National Institute of Biomedical Imaging and Bioengineering (NIBIB), along with other NIH institutes, and the IMPROVE Initiative conducted a workshop to assess the state of the art in technology to improve maternal heath, identify technology gaps, and consider how new technologies can be used to improve maternal health and ultimately treat and/or prevent maternal morbidity and mortality.
- The IMPROVE Initiative supports research focused on reducing preventable causes of maternal deaths and improving health for women before, during, and after delivery. IMPROVE includes a special emphasis on health disparities and populations disproportionately affected, such as African American/Black women, American Indians/Alaskan Natives, Asian Pacific Islanders, Hispanics/Latinas, very young women and women of advanced maternal age, and people with disabilities.
- This workshop reviewed the diseases that affect maternal health at any time during the maternal health care continuum (from preconception to postpartum), the current state of art technology that can help assess risk, screen for, diagnose, treat, monitor, and follow-up on conditions and disease that affect maternal health.
- NIH Workshop Executive Summary (https://www.nibib.nih.gov/virtual-workshop-technology-to-improve-maternal-health/executive-summary)

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NIH Updates

Notable Public Meetings and Workshops Hosted by NIH (cont.)

2021 NIH Virtual Seminar on Program Funding & Grants Administration

- Hosted November 1–4, 2021; published online November 17, 2021.
- The NIH held its virtual seminar to inform administrator, researcher, early-stage investigators, and others working with NIH grants about the NIH grant processes, policies, and programs. As part of the seminar, the OHRP presented a two-part session explaining how to prepare a research proposal that addresses the regulatory requirements for review including the requirements for informed consent and helps investigators understand their responsibilities with respect to the IRB review and the protections of human research participants.
- In the first part of the OHRP's session, the OHRP personnel reviewed the Common Rule and its application; and discussed what investigators should heed about IRB review in the second part of the session.
- NIH Virtual Seminar on Grants Administration and Program Funding (https://grants.nih.gov/2021-nih-virtual-seminar.htm)

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OHRP Updates

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OHRP Updates

OHRP Guidance on Posting Requirement for the Exemption at 45 CFR 46.104(d)(5) of the 2018 Requirements

OHRP releases the Guidance (April 20, 2022)

- The April 20, 2022 Guidance describes the 45 CFR 46.104(d)(5) exemption for research projects conducted or supported by a Federal agency, its posting requirement, and how that requirement is implemented at the HHS.
- Specifically, the guidance explains that: (1) Regulations.gov [Docket ID: HHS-OPHS-2018-0025] is the posting site identified by HHS for the posting requirements under 45 CFR 46.104(d)(5); and (2) no human subjects may be involved in a study prior to the posting required by 45 CFR 46.104(d)(5)(i).

Regulations.gov
Your Voice in Federal Decision Making

Posting Requirement for the Exemption at 45 CFR 46.104(d)(5) of the 2018 Requirements (2022), https://www.hhs.gov/ohrp/regulations-and-policy/guidance/posting-requirement-for-the-exemption-at-45-cfr-46-104-d-5-of-2018-requirements/index.html

OHRP Updates

2021 OHRP Explanatory Workshop – "Review of Third-Party Research Risk: Is There a Role for IRBs"

OHRP held the Exploratory Workshop on September 24, 2021

- This OHRP Exploratory Workshop considered research risks that may impact third parties who are impacted by research but do not meet the definition under the Common Rule. In the Workshop, sessions addressed:
  1. Identification of third parties impacted by research and consideration of types of risk they might face in variety of studies;
  2. Whether researchers and the research community have a responsibility, moral or otherwise, to protect third parties and, if so, to what extent and in what capacity;
  3. Review of real-world examples for potential protections against risks to third parties; and
  4. The role of the IRBs for protecting third parties.

2021 ORHP Exploratory Workshop: Review of Third-Party Research Risk, https://www.hhs.gov/sites/default/files/2021-oew-summary-report.pdf

OIG Updates

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OIG Updates

OIG Work Plan Items

Announced/Revised	Report No.	Agency	Title	Summary
Feb. 2022	W-00-22-59469	CDC	Audit of CDC's COVID-19 Awards to Selected State Departments of Health	**In response to the COVID-19 pandemic in the United States, the Secretary of HHS declared a public health emergency on January 31, 2020. During 2020, Congress approved five COVID-19 appropriation bills. The CDC distributed funds from these appropriations through existing grants and cooperative agreements to provide support for core public health response activities, such as epidemiology, surveillance, laboratory capacity, infection control, mitigation, and communications. These distributions increased some States' normal annual award amounts by approximately three to four times. Prior OIG audits have identified potential risk areas related to influxes of appropriations to States. The objective will be to determine whether selected State Departments of Health used their CDC COVID-19 funding in accordance with award requirements.** **The Report is expected to be issued FY 2023.**
Dec. 2021	W-00-22-59466	NIH	Compliance With Federal Requirements for Other Transaction Agreements at the National Institutes of Health's National Heart, Lung, and Blood Institute	**The SBIR program helps small businesses participate in Federal research and development (R&D). Each year, every Federal agency with an extramural R&D budget that exceeds $100 million is required to allocate 3.2% of that extramural R&D budget to fund small businesses through the program. From FY 2016 through FY 2020, HHS obligated $4.6 billion in SBIR award funds, with funds from the NIH making up approximately 98 percent of total obligations.** **OIG has identified areas of potential risk regarding for-profit organizations receiving SBIR awards such as inappropriate or unsupported charges to Federal awards, deficiencies in internal controls related to financial management systems, and eligibility of organizations to participate in the SBIR program. Other OIGs as well as Congress have also raised concerns about risks of fraud, waste, and abuse in the SBIR program. We will determine whether selected SBIR awardees complied with Federal requirements. We may conduct additional audits of high-risk SBIR awardees following this review.** **The Report is expected to be issued in FY 2023.**

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

OIG Updates

OIG Work Plan Items (continued)

Announced/Revised	Report No.	Agency	Title	Summary
October 2021	OEI-06-21-00030	CMS, AHRQ	Toolkit for Identifying Adverse Events Through Medical Record Review	**OIG has found that patient harm is common among Medicare beneficiaries in a range of inpatient health care settings. Federal regulations require that hospitals and other health care facilities identify harm, such as adverse events, and work to reduce these events. We will use guidance materials and tools created for our prior studies of adverse events to develop a web-based toolkit for identifying and measuring adverse events to assist health care facilities, government agencies, and researchers in their efforts to improve care.** **OIG expects to release the Toolkit in FY 2022, and the OIG plans to share the resources that it developed and used in our adverse event studies to aid hospitals and other researchers in their own efforts to identify and monitor the incidence of adverse events. The toolkit will provide standard definitions for most event types, lists of triggers to flag patient harm, suggested guidance for reviewers, and considerations for clinical decision making.**
July 2021	OEI-01-21-00320	NIH	NIH's Oversight Processes To Ensure Diversity Among Human Subjects Enrolled in Clinical Trials	**Diversity in clinical research has been a topic of increasing concern for various federal agencies. Specifically, there is increased concern regarding underrepresentation of racial and ethnic minorities, women, and individuals of all ages in clinical trials, and the disparate impact of the COVID-19 pandemic on minority populations in the U.S.** **The NIH reviews annual progress reports that document grantees' progress toward NIH-approved enrollment plans, which may include a diversity and inclusion component.** **In this study report, expected to be issued FY 2023, will assess the describe how NIH monitors and ensures enrollment of racial and ethnic minorities, women, and individuals of all ages within the clinical trials it funds and the actions it takes in response to clinical trials that are not meeting approved enrollment plans. This study will also identify NIH's challenges and the steps it takes to address these challenges while monitoring and ensuring that its grantees meet their commitments to inclusive enrollment in their clinical trials.**

https://oig.hhs.gov/reports-and-publications/workplan/active-item-table.asp

OIG Updates

OIG Work Plan Items (continued)

Announced/Revised	Report No.	Agency	Title	Summary
June 2021	W-00-21-59461	Assistant Secretary for Preparedness and Response	National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected	**Approximately 80% of NIH funding goes to support research grants, including grants and subawards to support research conducted outside the United States. OIG has previously identified NIH's oversight of grants to foreign applicants as a potential risk to the Department meeting program goals and the appropriate use of Federal funds.** **NIH must manage and administer Federal awards to ensure that Federal funding is expended and associated programs are implemented in full accordance with statutory and public policy requirements. To do so, NIH must monitor grantee performance and grantee use of NIH funds.** **Grantees are responsible for complying with all requirements of the Federal award, including maintaining effective internal controls over the Federal award (45 CFR § 75.300 and § 75.305). Grantees that function as pass-through entities must monitor the activities of subrecipients, including foreign subrecipients, to ensure that subawards are used for authorized purposes in compliance with relevant laws and the terms and conditions of the subaward (45 CFR § 75.352). The OIG will review NIH's monitoring of selected grants, and grantee use and management of NIH grant funds in accordance with Federal requirements.**

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https://oig.hhs.gov/reports-and-publications/workplan/active-item-table.asp

DOJ Updates

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DOJ Updates

Trends in Recent DOJ Enforcement Cases

- In 2020, the DOJ, together with OIG, published the Health Care Fraud and Abuse Control (HCFAC) Program Report, reporting that clinical trial fraud involving possible falsification of study documents and/or fraudulent study subject enrollments have been increasing. Some investigations involve individuals suspected of falsifying and/or manipulating clinical trial data or conducting clinical trials without FDA oversight.
- Since, the **DOJ has stated that clinical trial fraud is an agency priority,** and industry sponsors of research, as well as researchers and research institutions, can expect more enforcement actions in the future. The DOJ's enforcement activities in 2021-2022 demonstrate its increased enforcement against health care fraud in general, including those relating to violations of anti-kickback statutes, wire fraud associated with fraudulent Medicare claims; but it also shows an increased enforcement focus relating to COVID-19 health care fraud and fraudulent falsification of clinical trial data.

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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).

DOJ Updates

Recent DOJ Enforcement Cases Against Falsified Clinical Trial Data

DOJ – Florida Study Coordinator and Clinical Researchers Sentenced in Scheme to Falsify Clinical Drug Trial Data: Jail time for falsifying research data!!

- The case was filed with the U.S. District Court for the Southern District of Florida (2021-2022).
- The Florida study coordinator—Tejeda worked for a clinical research firm based in Miami. According to the plea agreement, Tejeda admitted that he agreed with others to falsify data in medical records for clinical trials intended to evaluate various medical conditions, including opioid dependency, irritable bowel syndrome and diabetic nephropathy.
- The clinical researchers involved at the Miami clinical research firm—Navarro and Varona were sentenced to 46 months and 30 months in prison, respectively. Navarro served as the sub-investigator at the firm and Varona was the assistant study coordinator.
- Data falsification was made to appear as though the subjects were participating in the trial when, in fact, they were not.
- The Florida study coordinator is sentenced to 30 months in prison in connection with his participation in a conspiracy to falsify clinical drug trial data.

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Florida Study Coordinator Sentenced, https://www.justice.gov/opa/pr/florida-study-coordinator-sentenced-scheme-falsify-clinical-drug-trial-data (January 20, 2022)

DOJ Updates

Recent DOJ Enforcement Cases Against Falsified Clinical Trial Data (cont.)

A Clinical Trial Company co-owner admits to obstructing FDA inspection of a case involving fraudulent falsification of clinical drug trial data.

- Guilty plea reported Jan. 12, 2022
- On January 12, 2022, a Florida co-owner of a clinical trial company pleaded guilty to obstructing a 2017 regulatory inspection in connection with an alleged scheme to fraudulently falsify clinical drug trial data.
- The clinical trial company at issue was one of many companies hired to conduct a clinical trial designed to investigate the safety and efficacy of an asthma medication in children. The clinical trial company's other employees were tried and found guilty of healthcare fraud; and the co-owner admitted that she falsified clinical trial data despite having portrayed to the FDA otherwise.

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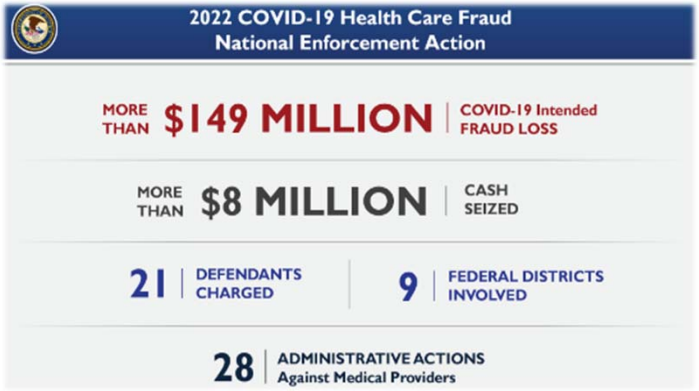
Florida Co-Owner of Clinical Trial Company Pleads Guilty to Obstructing FDA Inspection, https://www.justice.gov/opa/pr/florida-co-owner-clinical-trial-company-pleads-guilty-obstructing-fda-inspection.

DOJ Updates

Recent DOJ Enforcement Cases Against COVID-19 Health Care Frauds

DOJ Announces Nationwide Coordinated Law Enforcement Action to Combat Health Care-Related COVID-19 Fraud

- Released on April 20, 2022.



COVID-19 Healh Care Fraud Enforcement Action, https://www.justice.gov/criminal-fraud/health-care-fraud-unit/covid-19-health-care-fraud-enforcement-action

DOJ Updates

Recent DOJ Enforcement Cases Against COVID-19 Health Care Frauds (cont.)

DOJ Action in C.D. of Cal.

- Case No. 2:22-00154
- Two Californians—Shams and Navarro—were charged by indictment with conspiracy to commit health care fraud, conspiracy to pay and payment of illegal kickbacks and bribes, false statements to Medicare, and money laundering, for their roles in an alleged scheme to defraud Medicare of over $214 million for laboratory tests, including nearly $144 million in false and fraudulent claims during the COVID-19 health emergency for COVID-19 and respiratory pathogen tests that were submitted without regard to medical necessity.
- According to the DOJ's announcement, the defendants owned and controlled a clinical laboratory that performed and billed Medicare for urinalysis, routine blood work, and other tests, despite the fact that Shams had been excluded from all participation in Medicare for several decades. The indictment alleges that Shams and Navarro fraudulently concealed the role in the lab and his prior health care-related criminal convictions.

See U.S. v. Imran Shams & Lourdes Navarro (Case no. 2:22-00154), https://www.justice.gov/criminal-fraud/health-care-fraud-unit/court-documents

DOJ Updates

Recent DOJ Enforcement Cases Against COVID-19 Health Care Frauds (cont.)

DOJ Action in N.D. of Cal.

- Case No. 3:22-00155
- A Texas man was charged for conspiracy and alleged fraudulent scheme involving fake COVID-19 cures (a product known as "homeoprophylaxis immunizations") together with the naturopathic doctor for whom he worked as an officer manager. Both the doctor and the office manager also provided their patients with fake COVID-19 vaccination record cards.

DOJ Action in D.Md.

- Case No. 1:22-00146
- A Maryland owner and medical director of Drs ERGent Care, LLC was charged by indictment with three counts of health care fraud in connection with an alleged scheme to defraud the U.S. of more than $1.5M in claims billed in connection with COVID-19 testing.
- The defendant allegedly instructed the employees of Drs ERGent Care to submit Medicare claims and other insurance claims for "moderate-complexity office visits" for COVID-19 testing visits that took five minutes or less.

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See U.S. v. Jason Costanza (Case no. 3:22-00155) and U.S. v. Ron K. Elfenbein (Case No. 1:22-00146), https://www.justice.gov/criminal-fraud/health-care-fraud-unit/court-documents

DOJ Updates

Recent DOJ Enforcement Cases Against COVID-19 Health Care Frauds (cont.)

DOJ Action in NY and NJ

- Case No. 1:22-00146 (D.N.J.)
- Defendants were charged with conspiracy to violate the Federal AKS for their roles in an alleged scheme to defraud Medicare by paying illegal kickbacks and bribes of over $250,000 for lab tests for COVID-19 pathogen tests.
- The defendants owned and controlled a clinical lab in New Jersey that performed and billed Medicare for COVID-19 diagnostic testing. Some of the named defendants were marketers who supplied thousands of COVID-19 diagnostic tests to the defendant's-owned New Jersey clinical lab and received kickbacks and bribes from the lab owners.

DOJ Action in NY and NJ

- Case No. 4:22-00180 (E.D.N.Y.)
- The defendant-cardiologist owned and operated Advanced Cardiovascular Diagnostics PLLC, which allegedly submitted claims to Medicare and Medicaid for office visits that were not performed for patients who received COVID-19 tests performed at the clinic's mobile testing sites across Long Island, even when the defendant –cardiologist was not present in the state of New York. The defendant is charged by indictment with healthcare fraud for defrauding Medicare and Medicaid of over $1.3M in claims billed during the COVID-19 PHE.

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See U.S. v. Abid Syed, et al. (Case no. 2:22-12096) (D.N.J.) and U.S. v. Perry Frankel (Case No. 4:22-00180) (E.D.N.Y) , https://www.justice.gov/criminal-fraud/file/1321566/download (July 23, 2020)

ORI Updates

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ORI Updates

Cases with Research Misconduct by ORI

2022: Toni M. Brand, Ph.D.– Data Falsification/ Fabrication

University of Wisconsin-Madison and UCSF: ORI found that Dr. Toni M. Brand, who was a graduate student in the Department of Human Oncology, UWM, and subsequently a research fellow in the Department of Otolaryngology - Head and Neck Surgery, UCSF, 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, among others.

- ORI found that Respondent engaged in research misconduct by knowingly or recklessly falsifying or fabricating western blot data, by reusing and relabeling data to represent expression of proteins in control experiments measuring the purity of cytoplasmic and nuclear cell fractionation, measurements of proteins of interest, and measurements of the same protein under different experimental conditions or loading controls, included in twenty-four (24) figures in the following grant application submitted to NIDCR, NIH, her Ph.D. Thesis Dissertation, and seven (7) published papers.
- The Respondent agreed to have her research be supervised for four years under the agreed-upon supervision plan in which the Respondent will have other senior faculty members of her institution review her research and submit reports to ORI at 6 months intervals, and that the Respondent will have to include certifications to ORI on the primary data represented in her published papers and Thesis Dissertation.

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ORI Case Summary, https://ori.hhs.gov/content/case-summary-brand-toni-m.

ORI Updates

Cases with Research Misconduct by ORI

2022: Shuo Chen, Ph.D.

UC, Berkeley: ORI found that Shuo Chen, Ph.D. (Respondent), formerly a postdoctoral researcher, Department of Physics, University of California, Berkeley (UCB), engaged in research misconduct in research reported in a grant application submitted for U.S. Public Health Service (PHS) funds, specifically National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), grant application K99 NS116562-01. ORI found that Respondent engaged in research misconduct in falsifying data and methods by altering, reusing, and relabeling source two-photon microsocopy and electrophysiological data to represent images of mouse, among other data falsifications.

- The Respondent neither admitted nor denied ORI's findings of his research misconduct but entered into a Voluntary Settlement Agreement. Under the agreement, Chen has agreed to be subject to supervision of his research for only one (1) year, along with other typical reporting and certification requirements (e.g., a senior faculty member from the institution must review research work and submit a biannual report to the ORI).

ORI Case Summary, https://ori.hhs.gov/content/case-summary-chen-shuo.

ORI Updates

Cases with Research Misconduct by ORI

2022 : Daniel Leong, Ph.D. – Data Falsification/Fabrication

2022: Hui Bin Sun, Ph.D. – Data Falsification/Fabrication

Albert Einstein College of Medicine: ORI found that Daniel Leong, Ph.D. (Respondent), formerly a Research Technician, AECM, engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institutes of Health (NIH), grant R01 AR050968 and National Heart, Lung, and Blood Institute (NHLBI), NIH, grant P01 HL110900.

- Both the researchers were found to have fabricated data included in sixteen grant applications.
- Under the Voluntary Settlement Agreement, the researchers agreed to exclude themselves for four years from any contracting or subcontracting with any agency of the U.S. At the end of the four years, they will be subject to supervision of their research for another four years.

ORI Case Summary, https://ori.hhs.gov/content/case-summary-leong-daniel; https://ori.hhs.gov/content/case-summary-sun-hui-bin

ORI Updates

Cases with Research Misconduct by ORI

2021: Yibin Lin, Ph.D. – Data Falsification/Fabrication

University of Texas Health Science Center: ORI found that Yibin Lin, Ph.D. (Respondent), former postdoctoral fellow, McGovern Medical School, UTHealth, engaged in research misconduct in research supported by U.S Public Health Service (PHS) funds, specifically National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grant R01 AI125216.

- ORI found that Respondent knowingly and intentionally falsified, fabricated, and plagiarized the whole content of six (6) papers and eight (8) manuscripts, falsely created fictitious author names and affiliations without listing himself as an author to disguise himself from being the offender, and submitted them for publication in *bioRxiv* and *medRxiv*, open access preprint repositories, by falsely assembling random paragraphs of text, tables, and figures from previous publications and manuscripts to improve his citation metrics.
- Under the Voluntary Exclusion Agreement, the Respondent is excluded for 10 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.

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ORI Case Summary, https://ori.hhs.gov/content/case-summary-lin-yibin.

ORI Updates

Cases with Research Misconduct by ORI

2021 : Viravuth Yin, Ph.D.– Data Falsification/Fabrication

Mount Desert Island Biological Laboratory: ORI found that Viravuth Yin, Ph.D. (Respondent), former Associate Professor, MDIBL, engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grants P20 GM104318 and P20 GM103423.

- ORI found that Respondent engaged in research misconduct by knowingly, intentionally, and/or recklessly falsifying and/or fabricating data included in the following three (3) published papers and two (2) submitted manuscripts.
- The Respondent neither admits or denies ORI findings of research misconduct but entered into a Voluntary Settlement Agreement under which:
  - Respondent will have his research supervised for two years with senior faculty members of the institution reviewing his work and submitting biannual reports to ORI, submission of documents and certifications of his research's primary data, among other typical provisions of a Voluntary Settlement Agreement.

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ORI Case Summary, https://ori.hhs.gov/content/case-summary-yin-viravuth-p-.

Sources

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- FDA, Regulatory Information, https://www.fda.gov/regulatory-information.
- Nat'l Inst. Of Health, NIH Announces Restructured HIV Clinical Trials Networks, https://www.nih.gov/news-events/news-releases/nih-announces-restructured-hiv-clinical-trials-networks (Nov. 30, 2020)
- Off. Inspector Gen., Active Work Plan Items, https://oig.hhs.gov/reports-and-publications/workplan/active-item-table.asp.
- U.S. Dep't of Health and Human Serv., Guidance, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html.
- U.S. Dep't of Health and Human Serv., Enforcement Actions – Fraud, https://oig.hhs.gov/fraud/enforcement/?type=criminal-and-civil-actions,stipulated-penalties-and-material-breaches.
- U.S. Dep't of Just., 2022 COVID-19 Health Care Fraud Enforcement Action – Court Documents, https://www.justice.gov/criminal-fraud/health-care-fraud-unit/court-documents.
- U.S. Dep't of Just., Department Announces Nationwide Coordinated Law Enforcement Action to Combat COVID-19 Health Care Fraud, https://www.justice.gov/criminal-fraud/health-care-fraud-unit/case-summaries; see also, DOJ Press Release, https://www.justice.gov/opa/pr/justice-department-announces-nationwide-coordinated-law-enforcement-action-combat-health-care (April 20, 2022).
- Off. Res. Integrity (ORI), Case Summaries, https://ori.hhs.gov/content/case_summary.

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www.mosessinger.com

QUESTIONS?

F. Lisa Murtha lmurtha@mosessinger.com

Kiyong Song

Ksong@mosessinger.com

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www.mosessinger.com