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2022-2023 Research Year-in-Review

June, 2023

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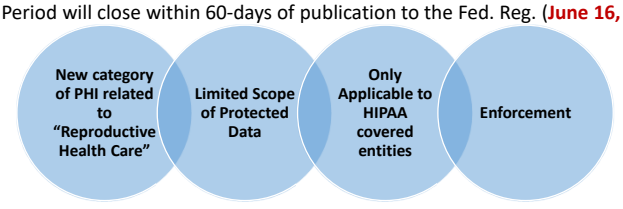
OCR Update

HIPAA and Reproductive Health

Notice of Proposed Rulemaking on the HIPAA Privacy Rule and Reproductive Health Care

- **Release Date:** April 12, 2023
- **Background:** NPRM follows in the aftermath of the Supreme Court's decision in Dobbs v. Jackson Women's Health Organization which overturned its ruling in Roe v. Wade. After the Dobbs decision, President Biden signed Executive Order 14076, directing HHS to consider taking action to further protect sensitive reproductive health care information and patient-provider confidentiality.
- **Purpose:** HHS-OCR issued an NPRM to strengthen the HIPAA Privacy Rule protections by prohibiting the use or disclosure of PHI to identify, investigate, prosecute, or sue patients, providers and others involved in the provision of legal reproductive health care, including abortion.
- Comment Period will close within 60-days of publication to the Fed. Reg. (**June 16, 2023**).



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HIPAA Privacy Rule to Support Reproductive Health Privacy, https://public-inspection.federalregister.gov/2023-07517.pdf. HHS, HIPAA Privacy Rule NPRM to Support Reproductive Health Care privacy Fact Sheet, https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/hipaa-reproductive-health-fact-sheet/index.html.

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FDA Updates

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FDA Updates

FDA Increases Regulatory Focus on Artificial Intelligence and Machine Learning

FDA's Working Definition of AI/ML

- A branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions, and making predictions.
- ML is considered a subset of AI that allows models to be developed by training algorithms through analysis of data, without models being explicitly programed.

Why is FDA looking to regulate AI/ML?

- FDA recognizes the increased use of AI/ML throughout the drug development life cycle and across a range of therapeutic areas.
- FDA has received significant drug and biologic application submissions using AI/ML components.
- AI/ML applications are increasingly integrated in Real-World Data analytics and Digital Health Technologies—areas where FDA is actively engaged

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Final Guidance on Clinical Decision Support Software, https://www.fda.gov/media/109618/download (Sept. 28, 2022).

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FDA Updates

FDA 2022 Regulatory Guidance on AI/M

Final Guidance on Clinical Decision Support Software

- Issued: September 28, 2022.
- The Final Guidance clarifies the scope of the FDA's oversight of clinical decision support (CDS) software intended for use by health care professionals.
- It also eliminates FDA's prior approach of leveraging risk factors to guide the agency's willingness to exercise enforcement discretion over some categories of products that qualify as medical devices.

Non-device CDS

Not acquire, process, or analyze medical images, signals, or patterns

Display, analyze, or print medical information about a patient or other medical information (e.g., clinical practice guidelines)

Support or provide recommendations to a healthcare professional (HCP) about prevention, diagnosis, or treatment of a disease or condition AND

Enable independent review of its recommendations so that the HCP need not rely primarily on the software's recommendations to make a clinical decision about a patient

Device CDS

CDS product that does not meet ***ALL FOUR*** of the non-device CDS criteria

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FDA Updates

FDA 2023 Regulatory Guidance on AI/ML

Draft Guidance on Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

- Issued: April 3, 2023
- Comment Period: 90 days (closes on July 3, 2023)
- The Draft Guidance reflects FDA's intent to strike a balance between the use of ML technologies and patient safety. FDA seeks to provide the least burdensome approach to support iterative improvement through modifications to ML-enabled device software functions (ML-DSF).
- The guidance applies to automatic or manual modifications of ML-DSFs that would normally require a premarket approval supplement, a *de novo* submission, or a 510(k)—new premarket notification.

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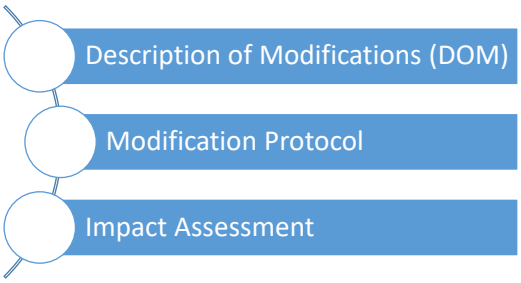
FDA Updates

FDA 2023 Regulatory Guidance on AI/ML

Draft Guidance on Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions (cont.)

- The FDA proposes the use of a Predetermined Change of Control Plan (PCCP) to be used in marketing submissions for ML-DSFs to streamline the implementation of modifications after the device has been authorized for commercialization.
- Section 3308 of the Food and Drug Omnibus Reform Act of 2023 grants the FDA express authority to approve PCCPs for devices requiring premarket approval or notification. The PCCP should include three (3) components:



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FDA Updates

FDA and Diversity in Clinical Trial

Guidance on Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry; Availability

- Release Date: April 13, 2022
- The FDA released this April 2022 guidance to provide recommendations to sponsors developing medical products on the approach for developing a Race and Ethnicity Diversity Plan to enroll adequate numbers of participants in clinical trials from underrepresented racial and ethnic populations in the United States.

2023 Omnibus Spending Bill—The Food and Drug Omnibus Reform Act of 2022 (Public Law 117-328)

- Enacted Dec. 2022.
- The bill requires diversity action plans for the clinical trials used by the FDA to decide whether drugs are safe and effective, reflecting the principles outlined in the FDA's April 2022 draft guidance.
- FDORA requires diversity action plans to include:
  1. sponsor's enrollment goals,
  2. rationale for the goals, and
  3. an explanation of how the sponsor intends to meet the goals.

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FDA Proposes Individual Risk Assessment for Blood Donations, While Continuing to Safeguard U.S. Blood Supply, https://www.fda.gov/news-events/press-announcements/fda-proposes-individual-risk-assessment-blood-donations-while-continuing-safeguard-us-blood-supply.

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FDA Updates

FDA Proposes Individual Risk Assessment for Blood Donations, While Continuing to Safeguard U.S. Blood Supply

- Released Date: Jan. 27, 2023

- The FDA is proposing a new "gender-inclusive" change from time-based deferrals to assessing blood donor eligibility using gender-inclusive, individual risk-based questions to reduce the risk of transfusion-transmitted HIV. This proposal is in line with policies in place in countries like the United Kingdom and Canada.

- The draft recommendations propose:
  1. The time-based deferrals for men who have sex with men (MSM) and women who have sex with MSM would be eliminated.
  2. The current donor history questionnaire would be revised to ask all prospective donors about new or multiple sexual partners in the past three months.
  3. Prospective donors who report having a new sexual partner, or more than one sexual partner in the past 3 months, would then be asked about a history of anal sex.
  4. All prospective donors who report having a new sexual partner or more than one sexual partner and had anal sex in the past three months would be deferred from donation.
  5. Under this proposal, a prospective donor who does not report having new or multiple sexual partners, and anal sex in the past three months, may be eligible to donate, provided all other eligibility criteria are met.

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FDA Proposes Individual Risk Assessment for Blood Donations, While Continuing to Safeguard U.S. Blood Supply, https://www.fda.gov/news-events/press-announcements/fda-proposes-individual-risk-assessment-blood-donations-while-continuing-safeguard-us-blood-supply.

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FDA Updates

Clinical Investigator Administrative Actions – Disqualification (FDA-2010-D-0265)

- Released Date: Dec. 1, 2022

- The FDA release this draft guidance for IRBs, clinical investigators, and sponsors, to receive comments on revised recommendations for evaluating donor eligibility using individual risk-based questions. FDA recommends that you make corresponding revisions to your donor educational materials, donor history questionnaires and accompanying materials, along with revisions to your donor requalification and product management procedures.

- This guidance, when finalized, will supersede the guidance entitled, "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products" dated April 2020, updated August 2020 (April 2020 guidance).

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Clinical Investigator Administrative Actions – Disqualification, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-investigator-administrative-actions-disqualification.

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FDA Updates

Tissue Agnostic Drug Development in Oncology (FDA-2022-D-0286)

- Released Date: Oct. 17, 2022.
- The FDA released this guidance to provide recommendations to sponsors regarding considerations for tissue agnostic drug development in oncology. For the purpose of this guidance, the term tissue agnostic oncology drug refers to a drug that targets a specific molecular alteration(s) (a kind of biomarker) across multiple cancer types as defined, for example by organ, tissue, or tumor type. A tissue agnostic oncology drug can therefore be used to treat multiple types of cancer (e.g., colorectal, thyroid, and breast cancers) with the targeted molecular alteration (e.g., either the same targeted molecular alteration or targeted molecular alterations affecting a single pathway).
- This guidance describes the development of tissue agnostic drugs, scientific considerations in determining when tissue agnostic oncology drug development may be appropriate, and, if appropriate, issues to be addressed during such development.

Tissue Agnostic Drug Development in Oncology, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tissue-agnostic-drug-development-oncology.

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FDA Updates

Characterizing, Collecting, and Reporting Immune-Mediated Adverse Reactions in Cancer Immunotherapeutic Clinical Trials (FDA-2022-D-1744)

- Released Date: Oct. 17, 2022
- This guidance is intended for sponsors of cancer immunotherapeutic drugs that modulate the endogenous immune system and may disrupt immunologic tolerance to normal organs and tissues. Examples of such cancer immunotherapeutic drugs include monoclonal antibodies, anticancer vaccines, and cytokines. Adoptively transferred cell-based cancer immunotherapeutics that target a tumor-associated antigen (TAA) and directly exert an anticancer effect (e.g., a TAA-directed genetically modified T-cell immunotherapy) are outside the scope of this guidance.
- This guidance provides recommendations regarding the data that should be collected and evaluated to assess whether adverse events qualify as imARs and the data on imARs that should be included in a new drug application (NDA) or biologics license application (BLA) for a cancer immunotherapeutic drug.

Characterizing, Collecting, and Reporting Immune-Mediated Adverse Reactions in Cancer Immunotherapeutic Clinical Trials, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/characterizing-collecting-and-reporting-immune-mediated-adverse-reactions-cancer-immunotherapeutic.

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FDA Updates

Acute Myeloid Leukemia: Developing Drugs and Biological Products for Treatment (FDA-2020-D-1298)

- Released Date: Oct. 17, 2022
- The FDA released this guidance is to assist sponsors in the clinical development of drugs and biological products for the treatment of acute myeloid leukemia (AML).
- Specifically, this guidance addresses FDA's current thinking regarding the overall development program and clinical trial designs for the development of drugs to support an indication of treatment of AML, including indications limited to an individual phase of treatment (e.g., maintenance, transplantation preparative regimen, etc.).

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Acute Myeloid Leukemia: Developing Drugs and Biological Products for Treatment, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acute-myeloid-leukemia-developing-drugs-and-biological-products-treatment-0.

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FDA Updates

Ethical Considerations for Clinical Investigations of Medical Products Involving Children (FDA-2022-D-0738)

- Released Date: Sept. 26, 2022
- Clinical investigations in children are essential for obtaining data on the safety and effectiveness of drugs, biological products, and medical devices in children and to protect children from the risks associated with exposure to medical products that may be unsafe or ineffective. Children are a vulnerable population who cannot consent for themselves and who therefore are afforded additional safeguards when participating in a clinical investigation. Such safeguards are an essential requirement for the initiation and conduct of pediatric investigations as part of a medical product development program.
- This guidance describes the FDA's current thinking regarding ethical considerations for clinical investigations of medical products in children.

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Ethical Considerations for Clinical Investigations of Medical Products Involving Children, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ethical-considerations-clinical-investigations-medical-products-involving-children.

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FDA Updates

Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products

- Release Date: Sept. 8, 2022
- The FDA issued the this guidance to facilitate FDA's internal tracking of submissions to the Agency that include real-world data (RWD) and real-world evidence (RWE).
- This guidance encourages sponsors and applicants to identify in their submission cover letters certain uses of RWD/RWE. This guidance does not address FDA's substantive review of the RWD/RWE submitted as part of the Agency's standard review process.
- This guidance applies to submissions for investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) that contain RWD/RWE intended to support a regulatory decision regarding product safety and/or effectiveness.

Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submitting-documents-using-real-world-data-and-real-world-evidence-fda-drug-and-biological-products.

NIH Updates

NIH Updates

NIH Policy Updates regarding Data Management

Reminder: NIH Policy for Data Management and Sharing effective on January 25, 2023 (NOT-OD-23-053)

- Release Date: Jan. 25, 2023
- The effective date of the DMS Policy is January 25, 2023 for competing grant applications submitted to NIH for the January 25, 2023 and subsequent receipt dates; proposals for contracts submitted to NIH on or after January 25, 2023; NIH Intramural Research Projects conducted on or after January 25, 2023; and other funding agreements (e.g., Other Transactions) executed on or after January 25, 2023, unless otherwise stipulated by NIH.
- Ultimately, the new DMS Policy promotes transparency and accountability in research by setting a minimum set of expectations for data management and sharing. This means that other NIH policies or NIH Institutes, Centers, Offices, or programs may build upon these expectations, for instance, by specifying scientific data to share, relevant standards, repository timelines, and/or shorter data sharing timelines for meeting programmatic needs, the DMS Policy sets a consistent baseline across NIH.

Reminder: NIH Policy for Data Management and Sharing effective on January 25, 2023, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-053.html.

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NIH Updates

NIH Policy Updates regarding Data Management (cont..)

Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/Alaska Native Participant Data (NOT-OD-22-214)

- Release Date: Sept. 21, 2022
- This Supplemental Information to the NIH Policy for Data Management and Sharing (DMS Policy) describes considerations and best practices for the responsible and respectful management and sharing of AI/AN participant data under the DMS Policy. This Supplemental Information was developed in response to Tribal Nations' input received through Tribal Consultation and public comments from AI/AN organizations and community members, researchers, institutions, data providers and users, research participants, infrastructure developers, and others to further promote culturally respectful and effective research partnerships.
- This Supplemental Information clarifies the considerations for researchers working with tribal nations, and best practices for researchers for data management and sharing of AI/AN Tribes.

Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/Alaska Native Participant Data, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-214.html.

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NIH Updates

NIH Policy Updates regarding Data Management (cont..)

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Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/Alaska Native Participant Data, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-214.html.

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NIH Updates

NIH Policy Updates regarding Data Management (cont..)

Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data (NOT-OD-22-213)

- Release Date: Sept. 21, 2022
- To advance efforts under its new Data Management and Sharing Policy (DMS Policy), NIH is providing supplemental information assisting researchers in addressing privacy considerations when sharing human research participant data. This information is not intended to provide a guide for compliance with regulatory requirements nor is it establishing binding rules for NIH awardees, but instead provides a set of principles, best practices, and points to consider for creating a robust framework for protecting the privacy of research participants when sharing data.
- This Supplemental Information provides the operational principles for protecting participant privacy when sharing scientific data, the best practices for protecting participant privacy, and considerations in choosing whether to designate scientific data for controlled access.

Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-213.html.

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NIH Updates

NIH Policy Update regarding Notification of Removal or Disciplinary Action Involving Program Directors/PIs or other Senior/Key Personnel

Updated Requirements for NIH Notification of Removal or Disciplinary Action Involving Program Directors/Principal Investigators or other Senior/Key Personnel (NOT-OD-22-129)

- Release Date: May 10, 2022.
- The purpose of this notice is to announce updated requirements for NIH notification when a Program Director/Principal Investigator (PD/PI) or other Senior/Key personnel on an NIH grant or cooperative agreement notice of award is removed or otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions.
- Effective 60 days from the publication of this Notice, NIH recipient institutions are required to notify NIH when individuals identified as PD/PI or other Senior/Key personnel in an NIH notice of award are removed from their position or are otherwise disciplined by the recipient institution due to concerns about harassment, bullying, retaliation or hostile working conditions.
    - Notification must be provided by the Authorized Organization Representative within 30 days of the removal or disciplinary action and must be submitted to NIH through a dedicated web form.
    - All required notifications must include, at a minimum, the name of the Authorized Organization Representative submitting the notification, the name of the individual of concern, a description of the concerns, the action(s) taken, and any anticipated impact on the NIH-funded award(s).

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Updated Requirements for NIH Notification of Removal or Disciplinary Action Involving Program Directors/Principal Investigators or other Senior/Key Personnel, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-129.html.

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NIH Updates

NIH launches intramural bioengineering center to foster technology collaboration across the agency

NIH-wide resource will champion diversity, equity, inclusion and accessibility (Jan. 25, 2023)

- The National Institute of Biomedical Imaging and Bioengineering (NIBIB) established the Center for Biomedical Engineering Technology Acceleration (BETA Center), a new intramural research program to solve a range of medicine's most pressing problems.
    - The BETA Center will serve the wider NIH intramural research program as a biotechnology resource and catalyst for NIH research discoveries.
- Focus areas of development: biomedical imaging, biosensing, engineered and synthetic biology, nanomaterials and biomaterials, artificial intelligence, modeling, computation and informatics.
- Fundamental objective of the BETA Center: to expand diversity, equity, inclusion and accessibility (DEIA) at NIBIB, building on the inherent interdisciplinary nature of biomedical engineering.

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NIH launches intramural bioengineering center to foster technology collaboration across the agency, https://www.nih.gov/news-events/news-releases/nih-launches-intramural-bioengineering-center-foster-technology-collaboration-across-agency.

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OHRP Updates

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OHRP Updates

OHRP's Priorities in 2023

Facts & Statistics

- HHS requested $6.412 million for OHRP for FY 2023.
- Currently operating with a 62% vacancy rate among staff (ORHP staff of 20, additional 12 positions "on hold").

Top Priorities in 2023

1. Staffing
2. Collaboration with the FDA "to harmonize the revised Common Rule with FDA's regulations"
3. Develop and issue policies and guidance on the 2018 Revised Common Rule
4. Modernizing compliance assessment procedures, and developing a new OHRP Human Research Complaints form to facilitate reporting of alleged noncompliance.
5. Developing "tools and capacities to incorporate equity considerations into guidance and policy initiatives, exploring options for language translation to further disseminate OHRP's educational and policy resources."
6. Developing "educational resources for the research community and the public, including new interactive training programs for the research community, hosting more webinars on the revised Common Rule, and adding new videos for research participants."
7. Improving databases and the use of technology.

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A Dialogue with OHRP, https://c53ac34983397363b9e2-fa85729df59db74d0fed9dc21ffea231.ssl.cf1.rackcdn.com/2190250-112639-002.pdf (Dec. 13, 2022).

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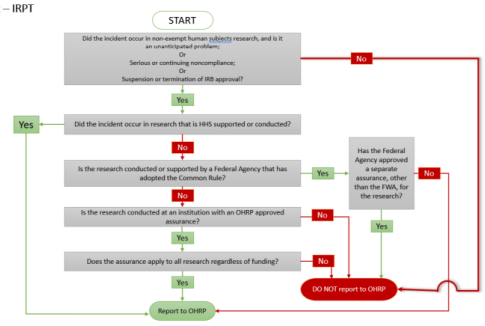
OHRP Updates

OHRP Guidance on Reporting Incidents to OHRP

Nov. 9, 2022 – OHRP releases the Guidance on Reporting Incident to OHRP

- OHRP published a new Guidance clarify the requirements for reporting incident to OHRP.
- Specifically, the Guidance clarifies that OHRP is not required for incidents that occur in non-federally supported resea conducted by institutions holding a Federalwide Assurance (FWA), where t institution does not "check the box" on FWA to apply the Common Rule and therefore does not submit to OHRP oversight for all of its research, includin research that is not federally supported.

Flow Chart – IRPT



OHRP Guidance on Reporting Incidents to OHRP (2022), https://www.hhs.gov/sites/default/files/guidance-on-reporting-incidents-to-ohrp-2022.pdf (Sept. 9, 2022).

OIG Updates

OIG Updates

OHRP Guidance on Reporting Incidents to OHRP

OIG expands its FAQ program as part of its Modernization Initiative.

- The expanded FAQ covers new topics:
  - AKS enforcement
  - CMP
  - General compliance

Some benefits and drawbacks of using the expanded FAQ over the traditional advisory opinion:

- Benefits
  - FAQ is quick
  - FAQ is free
  - FAQ is informal and allows stakeholders to receive reasonably tailored guidance
- Drawbacks
  - FAQ is non-binding
  - FAQ will likely have less precedential value in court
  - Information provided in FAQ could become public

Off. of Inspect. Gen., Frequently Asked Questions, https://oig.hhs.gov/faqs/.

OIG Updates

OIG Work Plan Items

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May 2023	W-00-23-59050	NIH	NIH Recipient Institutions' Reporting of Monetary Donations That Support Research	National Institutes of Health's National Institute of Environmental Health Sciences (NIEHS) provides Superfund Research Program funds for university-based multidisciplinary research on human health and environmental issues related to hazardous substances. Federal law and regulations require that OIG conduct an annual audit of the Institute's Superfund activities (Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. § 9611(k)). We will review payments, obligations, reimbursements, and other uses of Superfund money by NIEHS.

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

OIG Updates

OIG Work Plan Items

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Dec. 2022	OEI-03-22-00570	NIH	NIH Recipient Institutions' Reporting of Monetary Donations That Support Research	Recipient institutions that receive funding from the National Institutes of Health (NIH) play a key role in protecting the integrity and security of U.S. biomedical research, in part by identifying investigators' Other Support (which includes all resources made available to an investigator in support of and/or related to all of their research endeavors) and reporting this information to NIH during the grant award process. Recipient institutions' failure to comply with these reporting requirements hinders NIH's ability to conduct effective oversight. When an investigator receives a monetary donation where there is no expectation of anything in return (e.g., time commitment, services, specific research activities), NIH considers it a gift and does not require recipient institutions to report it as Other Support. However, NIH has not issued specific guidance to recipient institutions on how specific or explicit the donor's expectation must be for such funds to be considered Other Support, not a gift. Our evaluation will identify how recipient institutions determine whether monetary donations that support investigators' research are gifts or should be reported to NIH as Other Support. We also will determine the value of monetary donations that supported investigators' research in FY 2022. The Report is expected to be issued FY 2024.
Nov. 2022	WA-23-0001 (W-00-23-59475)	NIH	NIH Grant Closeout Process	The National Institutes of Health (NIH) invests approximately $41.7 billion annually in medical research and is the largest Federal funding source for health research and development. Prior OIG work identified issues regarding NIH's grant post-award closeout processes. A closeout of an award is the process by which NIH determines that all applicable administrative actions and all required work under an award have been completed by the recipient and NIH (45 CFR § 75.381). We will determine whether NIH closed its grants in accordance with Federal requirements and departmental guidance. We will also determine which actions NIH took to address noncompliance with closeout requirements. The Report is expected to be issued FY 2023.

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

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OIG Updates

OIG Work Plan Items (continued)

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Aug. 2022	WA-22-0010 (W-00-22-35889)	CMS	Toolkit for Identifying Adverse Events Through Medical Record Review	Laboratory tests are a critically important part of early detection, diagnosis, monitoring, and treatment of disease. During public health emergencies or disasters, CMS has the authority to provide regulatory flexibilities and waivers to ensure that Medicare beneficiaries continue to have access to needed health care. To help health care providers and suppliers prepare for these emergencies or disasters, CMS adopted a final rule (the Emergency Preparedness Rule) in September 2016. The rule required those providers and suppliers to: (1) plan adequately for both natural and manmade disasters; (2) coordinate with Federal, State, Tribal, and regional and local emergency preparedness systems; and (3) adequately prepare to meet the needs of patients during disasters and emergency situations. The rule covers 17 facility types (e.g., hospitals, hospices, and long-term care facilities) but does not cover clinical laboratories. Continued laboratory testing during a public health emergency as well as timely and reliable testing for novel infectious diseases are important for the health of Medicare beneficiaries. Effective testing for novel infectious diseases (including COVID-19) are essential in helping to slow the spread of these diseases by identifying those who are infected and enabling treatment or isolation if needed. We will conduct an audit to determine whether CMS's emergency preparedness for clinical laboratories could be improved. Specifically, we will look at CMS's emergency preparedness to ensure that: (1) beneficiaries maintain access to all types of laboratory tests, including laboratory tests for novel infectious diseases during a public health emergency, and (2) laboratories have the ability to develop and deliver timely and accurate testing for novel infectious diseases during a public health emergency.
Oct. 2022	W-00-23-57300	NIH	Recipients' Use of President's Emergency Plan for AIDS Relief Funds	CDC received more than $5.4 billion for FY 2019 through 2021 (about 97% of the funds received by HHS during the three FYs) to accelerate HIV treatment and prevention worldwide by using public health, innovation, and data-driven approaches to achieve the global goal of HIV/AIDS epidemic control. To date, HHS-OIG has conducted 21 audits of recipients in 8 countries on 2 continents (Africa and Asia). In previous audits of foreign PEPFAR recipients, OIG identified unallowable expenditures, inadequate accounting systems, and internal cont.rol weaknesses. We will determine whether selected foreign or domestic recipients: (1) managed and expended PEPFAR funds in accordance with award requirements, and (2) have controls to mitigate potential risk to the PEPFAR program.

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

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OIG Updates

OIG Work Plan Items (continued)

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Aug. 2022 COMPLETED	OEI-09-22-00400	NIH	Medicare Payments for Clinical Diagnostic Laboratory Tests in 2021	Medicare is the largest payer of clinical laboratory services in the United States. Medicare Part B covers most lab tests and pays 100 percent of allowable charges. The Protecting Access to Medicare Act of 2014 (PAMA) requires CMS to set payment rates for lab tests using current charges in the private health care market, under Title XVIII of the Social Security Act (Pub. L. No. 113-93 § 216(c)(2)(A)). On January 1, 2018, CMS began paying for lab tests under the new system mandated by PAMA. PAMA requires OIG to publicly release an annual analysis of the top 25 laboratory tests by expenditures. In accordance with the Act, we will publicly release an analysis of the top 25 laboratory tests by expenditures for 2021.

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

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DOJ Updates

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DOJ Updates

DOJ Continues to Eye Clinical Researchers

- The DOJ continues to investigate certain issues related to clinical research—particularly the universities and hospitals employing them.
  - Clinical trial fraud as a top priority—discussed further later.
  - Grant fraud (e.g., Fresenius Medical Care settlement)

Clinical Trial Fraud

- Remains a top priority for DOJ scrutiny of researchers (discussed further later)

Grant Fraud

- Ex: Settlement of civil fraud lawsuit against Former Hunter College Professor And Hunter College

Failure to Disclose Ties to Foreign Governments

- Cases against researchers who obtained federal grants but who also did not disclose relationships with Chinese universities.
- Ex: *U.S. v. Minqing Xiao* (S.D. Ill. Apr. 21, 2021) (indictment)

DOJ Updates

Settlement of Civil Fraud Lawsuit Against Former Hunter College Professor and Hunter College (NY)

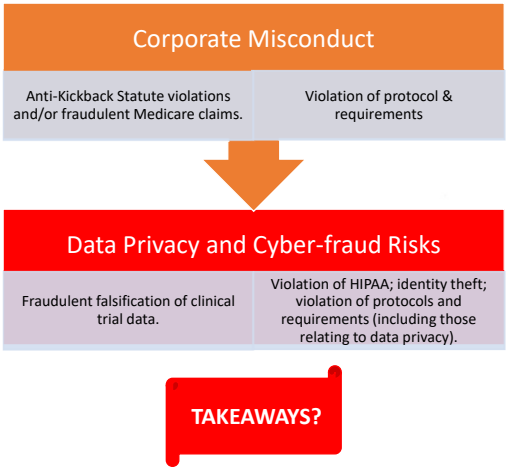
- U.S. Attorney for S.D.N.Y. announced that the U.S. had filed and settled a civil fraud lawsuit against Hunter College in New York and a former Hunter psychology professor (Prof. Jeffrey T. Parsons-Hietikko). Who served as Director of Hunter College's Center for HIV Education Studies (CHEST).
- In the case, U.S. alleged, from January 1, 2010 through May 17, 2018:
  - Professor Parsons improperly invoiced personal expenses to NIH funds, including expenses related to scuba diving trips, international flights for his family, a tropical birthday celebration, and travel for his work as a private consultant;
  - Hunter College used NIH funds to pay Professor Parsons over $90,000 in retention bonuses without disclosing these payments to NIH;
  - Prof. Parsons and Hunter College submitted false timekeeping records that misrepresented the time that CHEST staff spent working on NIH grant-related projects.
- Settlement:
  - Defendants agreed to pay $375,000 (Prof Parsons) and $200,000 (Hunter College) to the U.S. and made detailed factual admissions regarding their conduct.

U.S. Attorney Announces Settlement of Civil Fraud Lawsuit Against Former Hunter College Professor and Hunter College for Fraudulently using Federal Research Funds, https://www.justice.gov/usao-sdny/pr/us-attorney-announces-settlement-civil-fraud-lawsuit-against-former-hunter-college (Jan. 30, 2023).

DOJ Updates

DOJ's Renewed Focus on Clinical Trial Enforcement

- In April 2022, the U.S. Department of Justice (DOJ) Civil Division's Consumer Protection Branch (CPB) published its first-ever "Recent Highlights" report.
- DOJ-CPB's enforcement focus regarding clinical trial fraud in two (2) areas:
  - Corporate misconduct in health care and medical device companies
  - Data privacy and cyber-fraud risks
- DOJ announced Nationwide Coordinated Law Enforcement Action to Combat Health Care-Related COVID-19 Fraud



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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).

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DOJ Updates

Facts & Statistics of DOJ's Health Care Fraud

On April 20, 2022, DOJ announced a Nationwide Coordinated Law Enforcement Action to Combat Health Care Fraud in relation to COVID-19.

Example COVID-19 Health Care Fraud subject to DOJ's enforcement scrutiny:
- Offering COVID-19 test to induce patients to provide personal identifying information, saliva, or blood sample and use the information and samples to submit false and fraudulent Medicare claims.

Examples of Clinical Trial Fraud subject to DOJ's enforcement scrutiny:
- Falsification of clinical study participant data (including fraudulent enrollment and falsification of participant records).
- False representation to FDA inspector.
- Fraudulent testing for duplicative or unnecessary services.

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DOJ Health Care Fraud Unit: Facts & Statistics, https://www.justice.gov/criminal-fraud/facts-statistics.
DOJ COVID-19 Health Care Fraud Enforcement Action: https://www.justice.gov/criminal-fraud/health-care-fraud-unit/covid-19-health-care-fraud-enforcement-action.

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DOJ Updates

Recent DOJ Enforcement Cases Against Falsified Clinical Trial Data

Jan. 2023 – Florida Woman Sentenced to Prison for False Statement to Investigator Related to Pediatric Asthma Drug Study

- A clinical research coordinator of a Miami-based clinical trial firm (Unlimited Medical Research), was previously found guilty of falsification of clinical trial data, and was subsequently found guilty of making false statement to an FDA regulatory investigator about her role in the fraudulent clinical trial at UMR.
- UMR conducted a clinical trial designed to investigate the safety of an asthma medication in children, and UMR principal investigator, research coordinator, and other staff falsified medical records to make it appear as though pediatric subjects made scheduled visits to UMR, received physical exams from a clinical investigator, and took study drugs as required, when in fact these events had not occurred.
- Each of the coordinator's co-conspirators from UMR previously pleaded guilty and were sentenced between 30 months and 3 years in prison for their roles in the falsification of clinical trial data. The coordinator was sentenced to 36 months in prison and 3 years of supervised release.

Florida Woman Sentenced to Prison for False Statement to Investigator Related to Pediatric Asthma Drug Study, https://www.justice.gov/opa/pr/florida-woman-sentenced-prison-false-statement-investigator-related-pediatric-asthma-drug (Jan. 13, 2023).

DOJ Updates

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

Oct. 2022 – Florida Medical Clinic Owners and Staff Charged with Falsification of Clinical Trial Data

- Members of a Miami-based medical clinic were indicted for conspiracy to commit wire fraud and one substantive count of wire fraud, giving false statement to an FDA investigator.
- The medical clinic conducted a clinical trial and knowingly enrolled subjects in a clinical trial even though those subjects failed to meet eligibility criteria, falsified subject laboratory results, falsified subject medical records, and falsely represented that subjects were taking the drug being studied when, in fact, they were not.
- Some of the medical clinic's members previously pleaded guilty and were sentenced to 30 to 46 months in prison for their roles in the scheme.

Two Florida Medical Study Coordinators Plead Guilty in Connection with Scheme to Falsify Clinical Trial Data, https://www.justice.gov/opa/pr/two-florida-medical-study-coordinators-plead-guilty-connection-scheme-falsify-clinical-trial (July 20, 2022); https://www.justice.gov/opa/pr/florida-medical-clinic-owners-and-staff-charged-falsifying-clinical-trial-data (Oct. 13, 2022).

DOJ Updates

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

Jan. 2022 – Florida Study Coordinator and Clinical Researchers Sentenced in Scheme to Falsify Clinical Drug Trial 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)

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DOJ Updates

Recent DOJ Enforcement Cases Against COVID-19 Health Care Frauds

DOJ Action reported Jan. 9, 2023

- DOJ Press Release No. 23-16
- A Florida doctor who served as the Medical Director or Authorizing Physician for over 50 sober homes, substance abuse treatment facilities, and clinical testing laboratories in the Palm Beach County area signed standing orders for expensive, medically unnecessary urine drug tests for patients at various addiction treatment facilities.
- The doctor profited by billing patients' private health insurance plans over $746 million and being paid approx. $127 million for medically duplicative, medically unnecessary, and expensive urine drug tests, blood tests, and other addiction treatments.

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Florida Doctor Sentenced for Substance Abuse Treatment Fraud Scheme, https://www.justice.gov/opa/pr/florida-doctor-sentenced-substance-abuse-treatment-fraud-scheme (Jan. 9, 2023).

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DOJ Updates

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

DOJ Action reported June 30, 2022

- DOJ Press Release No. 22-694
- MorseLife Health System Inc. agreed to pay the U.S. $1.75 million to resolve its potential liability under the False Claims Act for facilitating COVID-19 vaccinations for hundreds of individuals ineligible to participate in the Centers for Disease Control and Prevention's Pharmacy Partnership for Long-Term Care Program (LTC PPP), a program specifically designed to vaccinate long-term care facility (LTCF) residents and staff when doses of COVID-19 vaccine were in limited supply at the beginning of the CDC COVID-19 Vaccination Program.
- The DOJ reports that Morselife allegedly invited members of its various boards of directors and their family members to provide COVID-19 vaccination and testing services at MorseLife facilities when these individuals were not eligible for those services under the CDC COVID-19 Vaccination Program.

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MorseLife Nursing Home Health System Agrees to Pay $1.75 Million to Settle False Claims Act Allegations for Facilitating COVID-19 Vaccinations of Ineligible Donors and Prospective Donors, https://www.justice.gov/opa/pr/morselife-nursing-home-health-system-agrees-pay-175-million-settle-false-claims-act (June 30, 2022).

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DOJ Updates

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

DOJ Actions focusing Violations of AKS and Physician Self-Referral Law

- DOJ Press Release No. 22-752
- BioReference Health LLC, formerly known as BioReference Laboratories, Inc., (BioReference), and OPKO Health, Inc. (OPKO) have agreed to pay $9.85 million to resolve alleged violations of the False Claims Act arising from BioReference's payment of above-market rents to physician landlords for office space in order to induce referrals from those physicians to BioReference.
- BioReference and OPKO have agreed to pay $9.85 million to resolve allegations that, between January 2013 and March 2021, BioReference made lease payments to physicians and physician groups for the rental of office space for amounts that exceeded fair market value, in violation of the Physician Self-Referral Law and the Anti-Kickback Statute.

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BioReference Laboratories and Parent Company Agree to Pay $9.85 Million to Resolve False Claims Act Allegations of Illegal Payments to Referring Physicians, https://www.justice.gov/opa/pr/bioreference-laboratories-and-parent-company-agree-pay-985-million-resolve-false-claims-act.

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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 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

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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 defendants-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)

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ORI Updates

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ORI Updates

Cases with Research Misconduct by ORI

May 2023: Johnny J. He, Ph.D..—Data Falsification

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.

- 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.
- Dr. He entered into a Voluntary Settlement Agreement and agreed to:
  - Supervision of his research for three (3) years beginning on April 17, 2023; and
  - Obligated to certain set of requirements for his research supervision plan.

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

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ORI Updates

Cases with Research Misconduct by ORI

Carlo Spirli, Ph.D..– Data Falsification/ Fabrication

Yale University: 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).

- 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.
- Specifically, 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. In the absence of reliable image and numerical data, the figures, statistical analyses, and related text also are false.
- The Respondent agreed to voluntarily exclude himself for four (4) years from any contracting or subcontracting with U.S. federal agency and from eligibility for or involvement in nonprocurement or procurement transactions under 2 C.F.R. Parts 180 and 376; from serving in any advisory or consultant capacity to PHS; and to correct or retract certain papers of the falsified data.

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

ORI Updates

Cases with Research Misconduct by ORI

Dec. 2022: Alice C. Chang, Ph.D.. – Data Falsification/ Fabrication

Purdue University: ORI found that Dr. Alice C. Chang, Ph.D.. (formerly named Chun-Ju Chang), an Associate Professor of Basic Medical Sciences College of Veterinary Medicine, PU, 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).

- ORI found that Respondent engaged in research misconduct by knowingly, intentionally, or recklessly falsifying and/or fabricating data included in sixteen (16) grant applications submitted for PHS funds.
- Specifically, ORI found that the Respondent knowingly, intentionally, or recklessly falsified and/or fabricated data from the same mouse models or cell lines by reusing the data, with or without manipulation, to represent unrelated experiments from different mouse models or cell lines with different treatments in three hundred eighty-four (384) figure panels in sixteen (16) grant applications.
- The Respondent agreed to voluntarily exclude herself for a period of ten (10) years from any contracting or subcontracting with any agency of the U.S. Government and from eligibility for or involvement in nonprocurement or procurement transactions under the Debarment Regulations (2 CFR Parts 180 and 376), and from serving in any advisory or consultant capacity to PHS.

ORI Case Summary, https://ori.hhs.gov/content/case-summary-chang-alice-c.

ORI Updates

Cases with Research Misconduct by ORI

Nov. 2022: Douglas D. Taylor, Ph.D..– Data Falsification/ Fabrication

University of Louisville School of Medicine: ORI found that Dr. Douglas D. Taylor, Ph.D.. (Respondent), a former Professor and Vice Chair for Research, Department of Obstetrics & Gynecology, UL, 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 used falsely labeled images to falsely report oncological research data in figures, and in one finding, intentionally, knowingly, or recklessly plagiarized, reused, and falsely labeled an image to falsely report data in a figure across
- The Respondent has been debarred from participating in any nonprocurement or procurement transaction under 2 CFR § 180.200 and the Federal Acquisition Regulation (48 C.F.R Chap. 1); prohibited from serving in any advisory capacity to PHS; the HHS will notify all pertinent journals of ORI's findings regarding the Respondent's publications and the need for retraction or correction of two of the Respondent's publications.

ORI Case Summary, https://ori.hhs.gov/content/case-summary-taylor-douglas-d.

ORI Updates

Cases with Research Misconduct by ORI

Nov. 2022: Romina Mizrahi, M.D., Ph.D.. – Data Falsification/ Fabrication

Centre for Addiction and Mental Health and University of Toronto: ORI found that Dr. Romina Mizrahi, M.D., Ph.D.. (Respondent), who was a Clinician Scientist, Positron Emission Tomography Centre, CAMH, and an Associate Professor, Department of Psychology, University of Toronto, engaged in research misconduct in research reported in a grant application submitted for U.S. Public Health Service funds.

- ORI found that Respondent knowingly, intentionally, or recklessly falsified the Positron Emission Tomography (PET) data of the binding of radiopharmaceutical [^{11}C]NOP-1A (NOP) in brain regions between the patient group and healthy volunteer (HV) group
- The Respondent entered into a Voluntary Settlement Agreement and agreed to have the Respondent's research be supervised for one (1) year, and to submit a plan of supervision of the Respondent's duties to ORI for approval in the event of an application for PHS support for a research project the Respondent will participate.
- During the one year supervision period, any institution employing the Respondent and the Respondent participates in any PHS-supported research at the institution, must submit a certification to ORI that the data provided by Respondent are based on actual experiments and are legitimately derived, and that are not plagiarized in the application, report, manuscript, or abstract.
- The Respondent also agreed to voluntarily exclude herself from serving in any advisory or consultant capacity to PHS.

ORI Case Summary, https://ori.hhs.gov/content/case-summary-mizrahi-Romina.

ORI Updates

Cases with Research Misconduct by ORI

Sept. 2022: Ritankar Majumdar, Ph.D.. – Data Falsification/ Fabrication

National Institutes of Health: ORI found that Dr. Ritankar Majumdar, Ph.D.. (Respondent), who was a postdoctoral fellow in the intramural program of the Laboratory of Cellular and Molecular Biology (CMB), Center for Cancer Research (CCR), National Cancer Institute (NCI), NIH, 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 or recklessly falsifying and/or fabricating data in, for example, electron microscopic (EM) image data for the formation of multivesicular bodies (MVBs) in migrating primary neutrophils following chemoattractant activation.
- ORI specifically found that the Respondent knowingly or recklessly falsifying and/or fabricating data in one (1) published paper, one (1) manuscript, three (3) PHS grant applications, and fifteen (15) presentations.
- The Respondent entered into a Voluntary Settlement Agreement to have his research supervised for three (3) years; to submit plan for supervision of Respondent's duties to ORI for approval prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity in PHS-supported research.
- During the Supervision Period, Respondent must 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

ORI Case Summary, https://ori.hhs.gov/content/case-summary-majumdar-ritankar.

ORI Updates

Cases with Research Misconduct by ORI

Aug. 2022: Stuart G. Jarrett, Ph.D.. – Data Falsification/ Fabrication

University of Kentucky: ORI found that Dr. Stuart G. Jarrett, Ph.D.. (Respondent), former research-track assistant professor, Department of Toxicology and Cancer Biology and Markey Cancer Center, University of Kentucky (UK) College 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 histological image data related to mechanisms of melanoma protection by reusing, relabeling, and manipulating images or using blank panels to falsely report data in twenty-eight (28) figures included in four (4) PHS-supported published papers, one (1) funded PHS grant application, and two (2) unfunded PHS grant applications.
- ORI specifically found that these acts constitute a significant departure from accepted practices of the relevant research community.
- ORI took the following administrative actions against the Respondent:
  - Debarment of the Respondent from participating in "covered transactions" under 2 C.F.R. § 180.200 and procurement transactions under Federal Acquisition Regulation (45 C.F.R. Chap. 1).
  - Prohibition against serving in any advisory capacity to PHS.
  - Notify relevant journal for the retraction of Respondent's publication in the Journal of Molecular Cell.

ORI Case Summary, https://ori.hhs.gov/content/case-summary-jarrett-stuart-g.

ORI Updates

Cases with Research Misconduct by ORI

Aug. 2022: Deepak Kaushal, Ph.D. – Data Falsification/ Fabrication

Texas Biomedical Research Institute: ORI found that Deepak Kaushal, Ph.D.. (Respondent), Professor and Director, Southwest National Primate Research Center, Host Pathogen Interactions Program, TBRI, 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, and/or recklessly falsifying and fabricating the experimental methodology to demonstrate results obtained under different experimental conditions that were included in the following one (1) published paper and two (2) grant applications submitted for PHS funds.
- The Respondent entered into a Voluntary Settlement Agreement to have his research supervised for one (1) years; to submit plan for supervision of Respondent's duties to ORI for approval prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity in PHS-supported research.
- Prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity in PHS-supported research, Respondent will submit a plan for supervision of Respondent's duties to ORI for approval. The supervision plan must be designed to ensure the integrity of Respondent's research. Respondent will not participate in any PHS-supported research until such a supervision plan is approved by ORI.

ORI Case Summary, https://ori.hhs.gov/content/case-summary-majumdar-ritankar.

ORI Updates

Cases with Research Misconduct by ORI

Aug. 2022: Janina Jiang, M.D., Ph.D.. – Data Falsification/ Fabrication

UCLA: ORI found that Dr. Janina Jiang, M.D., Ph.D.. (Respondent), former Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of Medicine, University of California, Los Angeles (UCLA) engaged in research misconduct in research included in grant applications submitted for U.S. Public Health Service (PHS) funds.

- ORI found that Respondent engaged in research misconduct by knowingly and recklessly falsifying and/or fabricating flow cytometry data that were included in the following eleven (11) grant applications submitted for PHS funds.
- ORI specifically found that the Respondent knowingly and recklessly falsified and/or fabricated flow cytometry data to represent interferon-γ (IFN-γ) expression in immune cells of mice administered with human recombinant vaults such that the represented data were incompatible with the raw experimental data.
- The Respondent entered into a Voluntary Settlement Agreement:
  - Have her research supervised for three (3) years
  - Submit plan for supervision of Respondent's duties to ORI for approval prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity in PHS-supported research.
  - Ensure that any institution employing her 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.

ORI Case Summary, https://ori.hhs.gov/content/case-summary-jiang-Janina.

Sources

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- FDA, Regulatory Information, https://www.fda.gov/regulatory-information.
- FDA Artificial Intelligence and Machine Learning (AI/ML) for Drug Development, https://www.fda.gov/science-research/science-and-research-special-topics/artificial-intelligence-and-machine-learning-aiml-drug-development.
- 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.
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- 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.