



Noncompliance or Research Misconduct? Definitions and Policies for Researchers

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Office of Accountability and Compliance
Research Integrity Office
UMB

August 21, 2025



Noncompliance versus Research Misconduct

Noncompliance

Deviation from an approved protocol, contract, agreement, or federal regulation

- Research and protocol breach
- Financial issues
- Privacy violations

HRPO, IRB,
OAWA, IACUC,
IBC

Research Misconduct

Fabrication,
Falsification, or
Plagiarism (FFP)

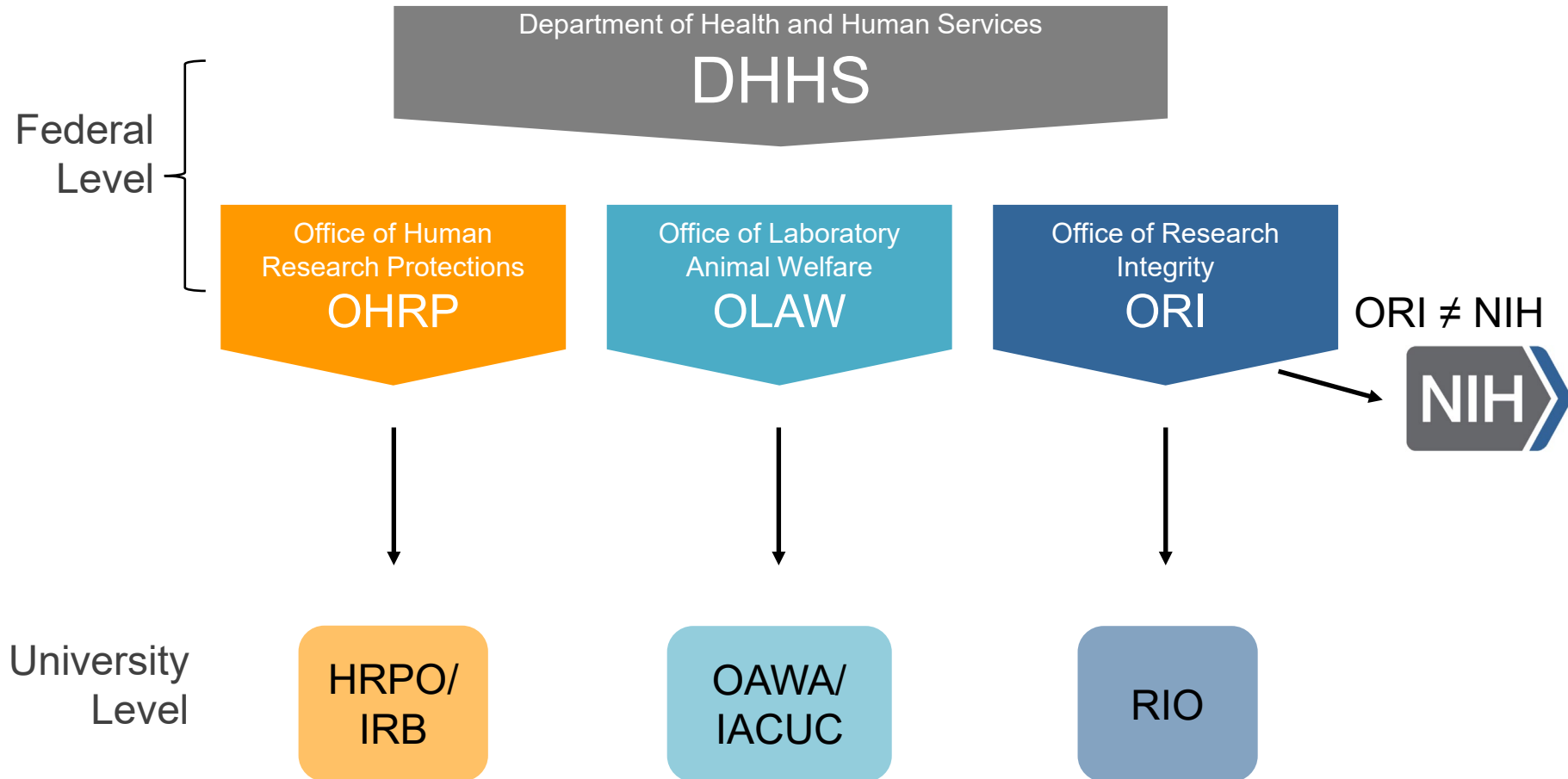
- In proposing, performing, or reviewing research, or in reporting research results

42 CFR § 93.103

RIO



Research oversight





Office of Accountability and Compliance (OAC at UMB)

Office of Accountability and Compliance

620 W. Lexington St.
5th Floor
Baltimore, MD 21201
410-706-2281

Susan Buskirk, DM, MS, CCEP

Chief Accountability Officer
Vice President

oac@umaryland.edu

HRPO/
IRB

OAWA/
IACUC

RIO

COI

Title IX



HRPO/IRB

Human Research Protections Office Institutional Review Board

- Risks to subjects are minimized
- Selection of subjects is equitable
- Obtain and document informed consent
- Prior approval for any protocol deviation
- Protection of privacy of subject and confidentiality of data



hrpo@umaryland.edu



OAWA/
IACUC

Office of Animal Welfare Assurance Institutional Animal Care and Use Committee

- Review and approve all animal use research proposals
- Review the institution's animal care program
- Inspect (at least twice a year) the institution animal facility
- Receive and review concerns raised about the care and use of animals



iacuc@umaryland.edu



RIO

Research Integrity Office

- Promote research integrity on campus
- Provide education and guidance on the Responsible Conduct of Research (RCR)
- Investigate allegations of research misconduct



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Further defining Research Misconduct FFP

Fabrication

Making up data or results and recording or reporting them

Falsification

Manipulating research materials, equipment, or processes, or changing or omitting data/results such that the research is not accurately represented in the research record

Plagiarism

Appropriation of another person's ideas, processes, results, or words without giving appropriate credit

Does NOT include honest errors or differences in opinion



Examples of Noncompliance and Research Misconduct

Noncompliance

- Not obtaining informed consent from participants in accordance with approved IRB
- Performing procedures on animals not approved by IACUC
- Failure to follow established safety protocols in the lab
- Performing research under an expired protocol

Research Misconduct

- Creating and reporting data from experiments that were never conducted
- Intentionally removing data to create stronger support for a hypothesis
- Knowingly using text from another author's work without proper citation



POP QUIZ! Noncompliance or Research Misconduct?

A participant was involved in a research study, and it was discovered that some of the documented visits did not occur. The data were recorded in the research record.

Research Misconduct issue

A PI forged a signature on an IRB protocol.

Noncompliance issue



Part of the Research Record

What is false?

Is it part of research?

Where is it reported as false in the research record?

§93.222 Research.

Research means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

§93.224 Research record.

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding.



Basic Science Research Misconduct

Fabrication

- Creating images
- Making up data from an experiment that did not occur

Falsification

- Substitution of data for a different experimental condition
- Altering data to fit a hypothesis
- Selectively eliminating data



Clinical Research Misconduct

Fabrication

- Making up data, test results
- Creating records of a patient interview that did not happen
- Making up appointments and inserting them into medical chart record
- Preparing records for deceased subjects

Falsification

- Substitution of one subject's record or samples for another subject
- Altering eligibility dates, times, test results, etc.
- Selectively eliminating data
- Intentionally not reporting IRB approved protocol deviations in publications and grant applications



Social/Behavioral Research Misconduct

Fabrication

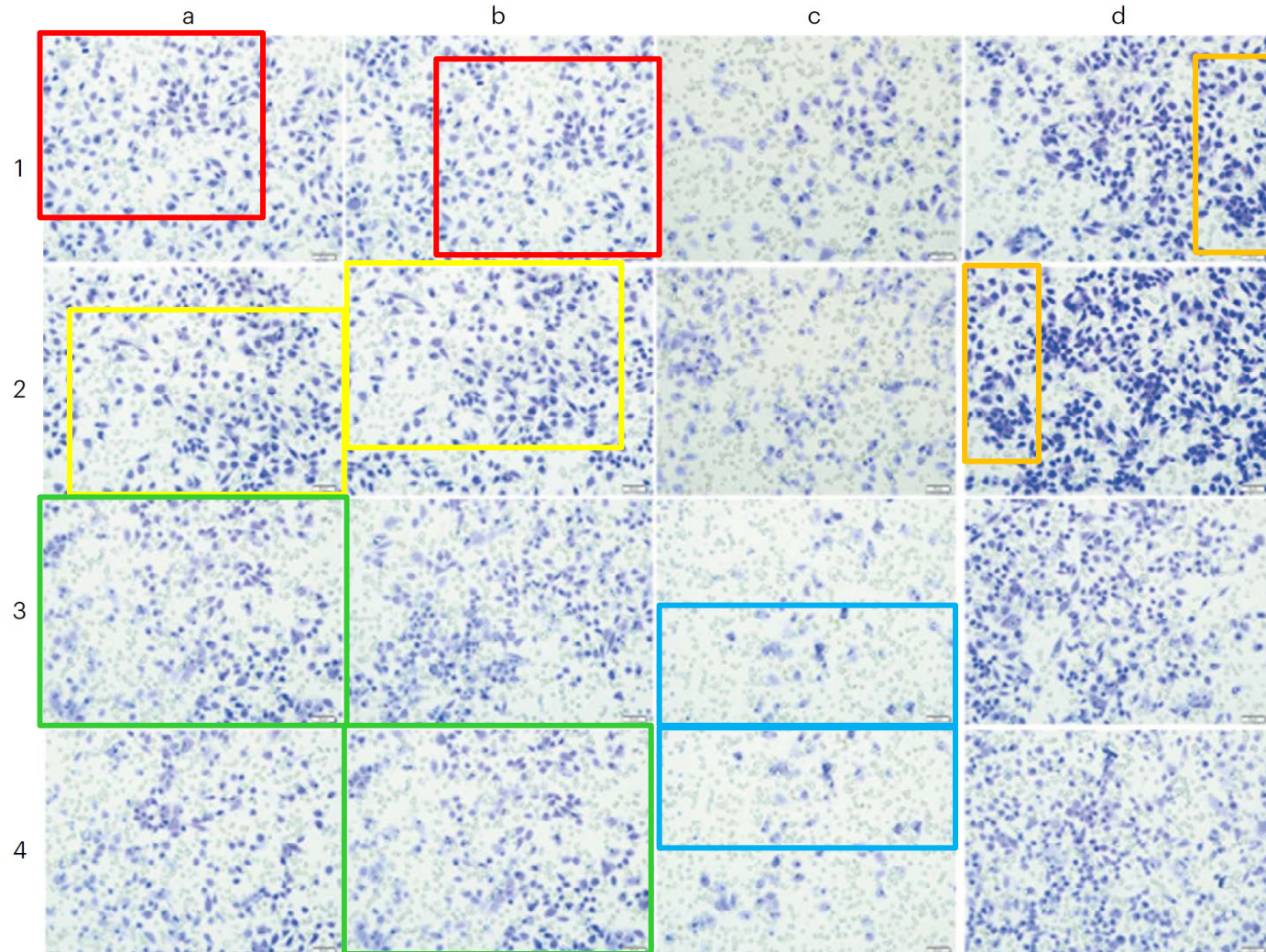
- Inventing survey and questionnaire responses
- Making up interview transcripts or notes
- Preparing records for an observational session that did not occur

Falsification

- Substitution of one subject's record or samples for another subject
- Altering eligibility dates, times, test results, etc.
- Manipulating demographic data to create more representation
- Altering the coding of qualitative data



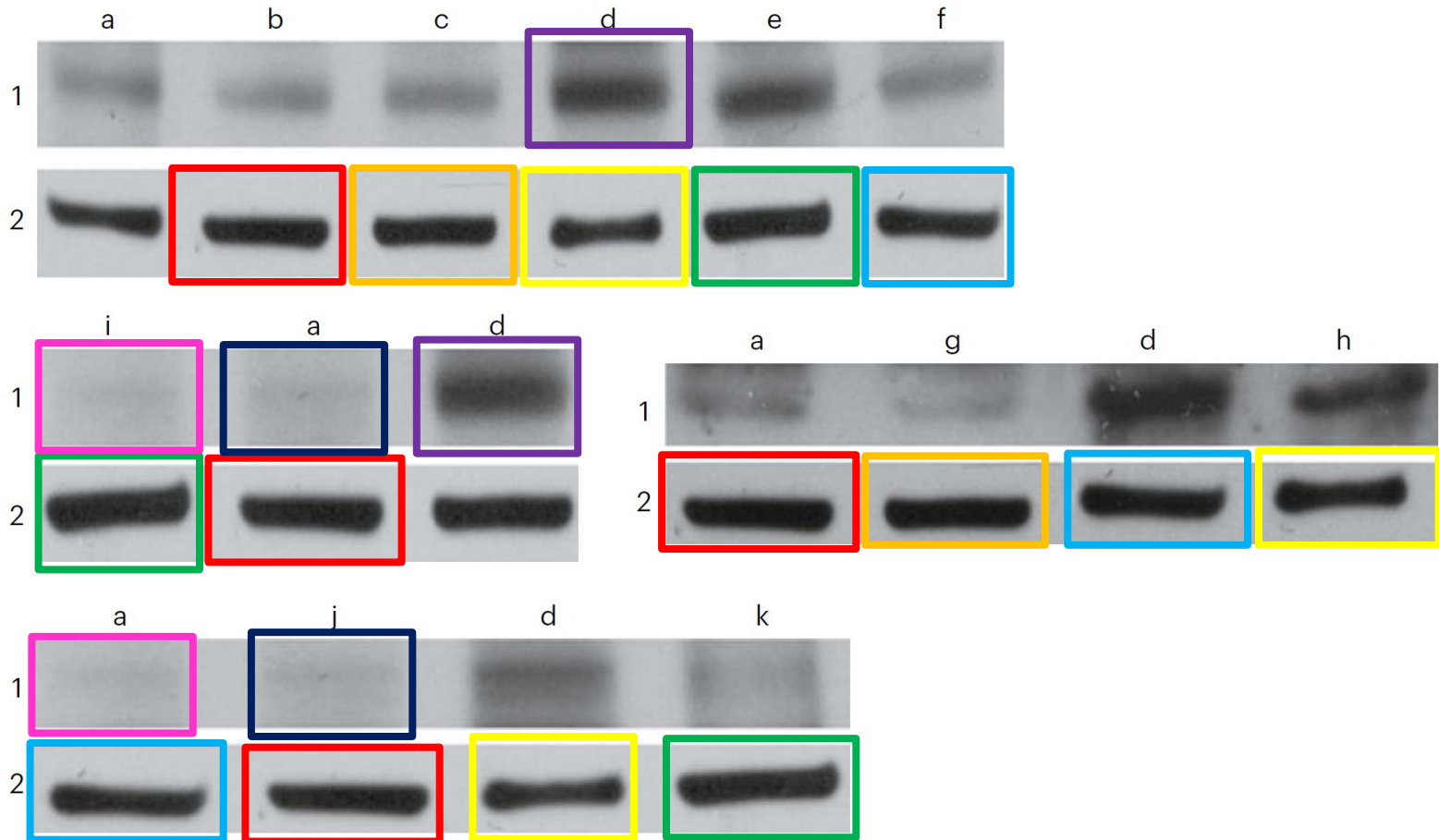
Image duplication



SOURCE: S. GENGET AL. PLOS ONE 9, E91566 (2014); RETRACTION 14, E0214018 (2019).



Image duplication

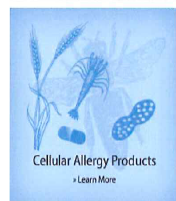


SOURCE: Y. TAN ET AL. PLOS ONE 9, E102195 (2014); RETRACTION 14, E0220600 (2019).



Changing raw data

GLP-1 (Active 7-36) ELISA



Focus

Clinical
Research

Application

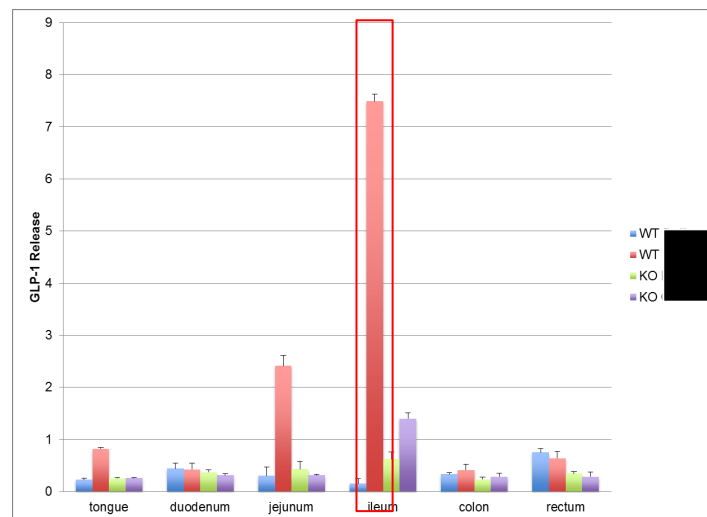
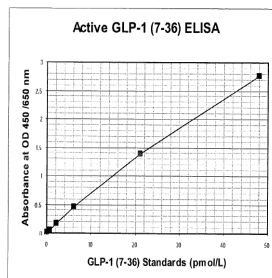
Immunossays
Flow Cytometry
HPLC/LC-MS

Therapeutic Areas

Allergy & Infectious Disease
Bone Metabolism
CVD & Oxidative Stress

[Buy Now](#) [Price](#) [SHARE](#)

Catalog Number: 43-GP1HU-E01
Description: GLP-1 (Active 7-36) ELISA
Sample Types: EDTA Plasma, Plasma
Sample Sizes: 100 μ L
Available Sizes: 96 Wells
Range: 0.64 - 48 pmol/L
Incubation: Overnight
Protocol: [GLP-1 \(Active 7-36\) ELISA](#)
Material Safety Data Sheet: [GLP-1 \(Active 7-36\) ELISA](#)
Regulatory Status: Research Use Only. Not for Use in Diagnostic Procedures.
Product Distribution: Available Worldwide



Sample #:

Raw Data

Excel

	A	B	C	D
Raw Data	1.696	1.226	0.364	1.677
Excel	7.696	7.226	7.364	7.677



Changing raw data

- Anil Potti, MD: ORI March 2016 Case Summary
 - Fabricated enrolled patients
 - Falsified data for lung cancer study
 - Switched cancer recurrence phenotype
 - Altered data sets to improve the accuracy of predictors for response to treatments
- Suspended 3 clinical trials
- Lawsuit filed by patients
- Multiple paper retractions



Research Misconduct in the news



Exterior of Dana-Farber Cancer Institute

(CNN) — The Dana-Farber Cancer Institute is moving to retract six studies after allegations of data manipulation.



ty to clinical trial



Stanford president's research under investigation for scientific misconduct, University admits mistakes'



The New York Times

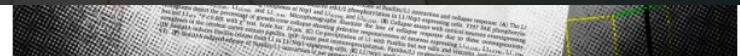
PICTURE IMPERFECT

Scores of papers by Eliezer Masliah, prominent neuroscientist and top NIH official, fall under suspicion

26 SEP 2024 • 9:00 AM ET • BY CHARLES PILLER



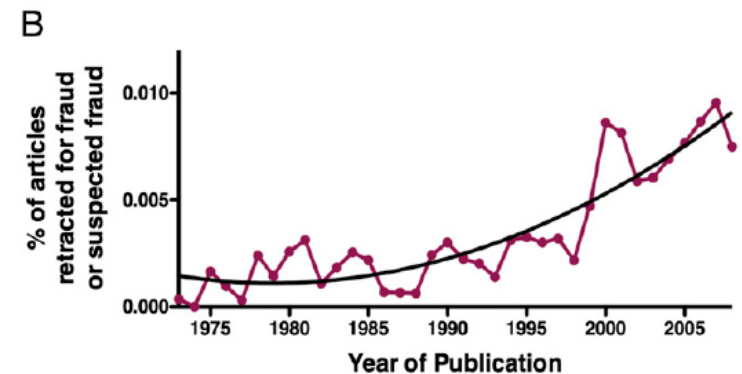
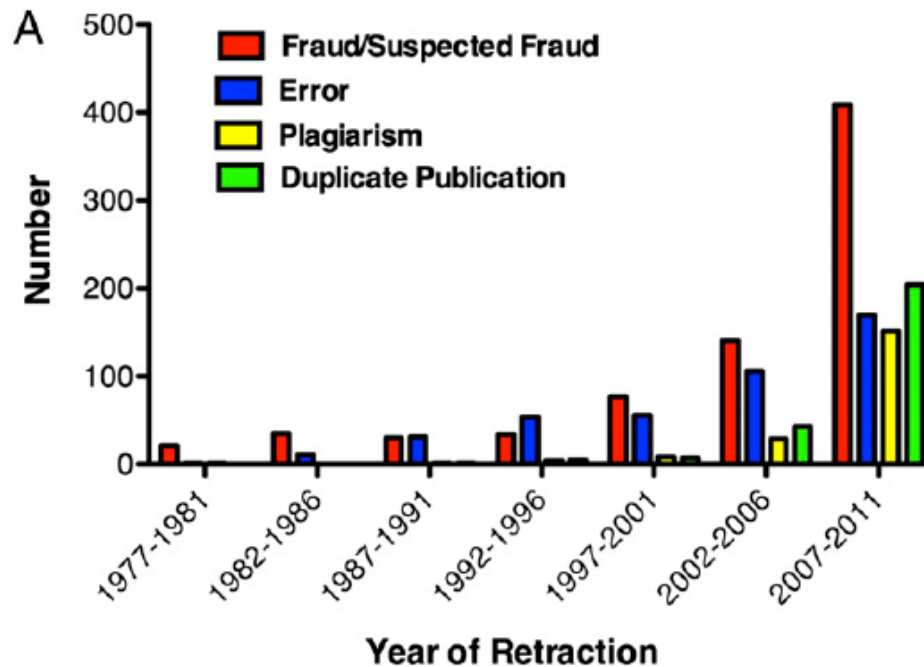
Haruko Obokata, a researcher at the Riken Center for Developmental Biology, at a news conference in Osaka, Japan, in April. After having two articles published in the journal Nature, she was accused of fabricating data and of plagiarism. Kinomasa Mayama/European Preprint Agency



(Graphic: MICHELLE FU/The Stanford Daily)



Misconduct accounts for the majority of retractions





Retractions numbers increasing



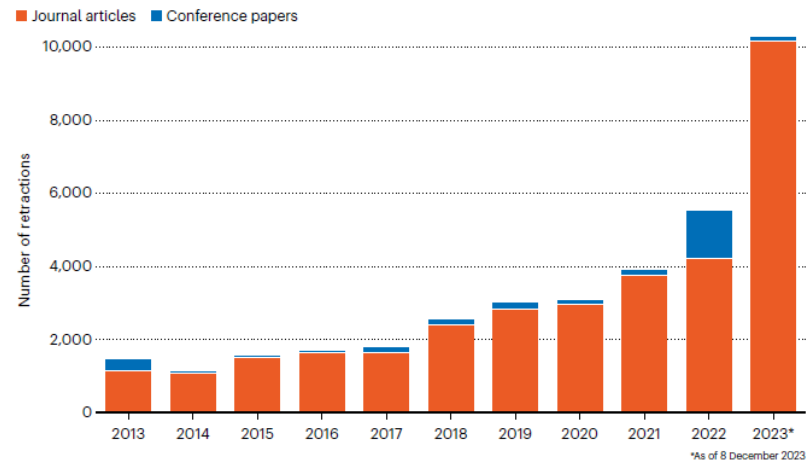
Retractions are skyrocketing as publishers work to remove sham articles from the literature.

MORE THAN 10,000 RESEARCH PAPERS WERE RETRACTED IN 2023—A NEW RECORD

The number of articles being retracted rose sharply this year. Integrity experts say that this is only the tip of the iceberg.

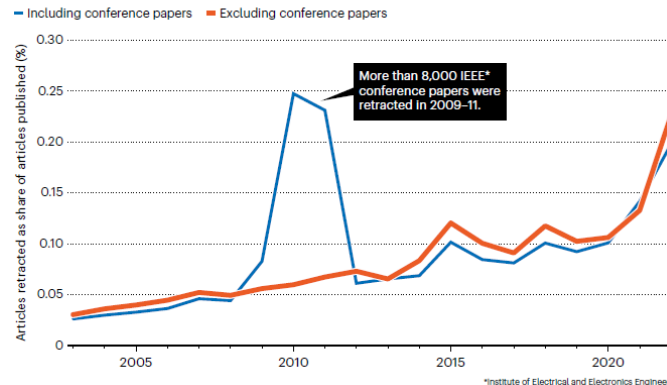
A BUMPER YEAR FOR RETRACTIONS

Retraction notices in 2023 have passed 10,000, largely because of more than 8,000 retractions by Hindawi.



RIISING RETRACTION RATES

The ratio of retracted papers to articles published has risen to above 0.2%.





Requirements for a finding of Research Misconduct

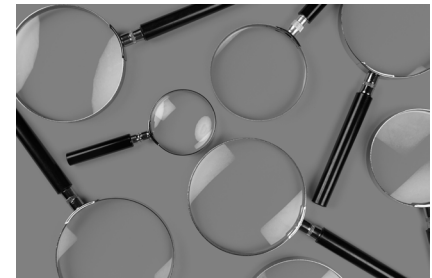
Fabrication

Falsification

Plagiarism

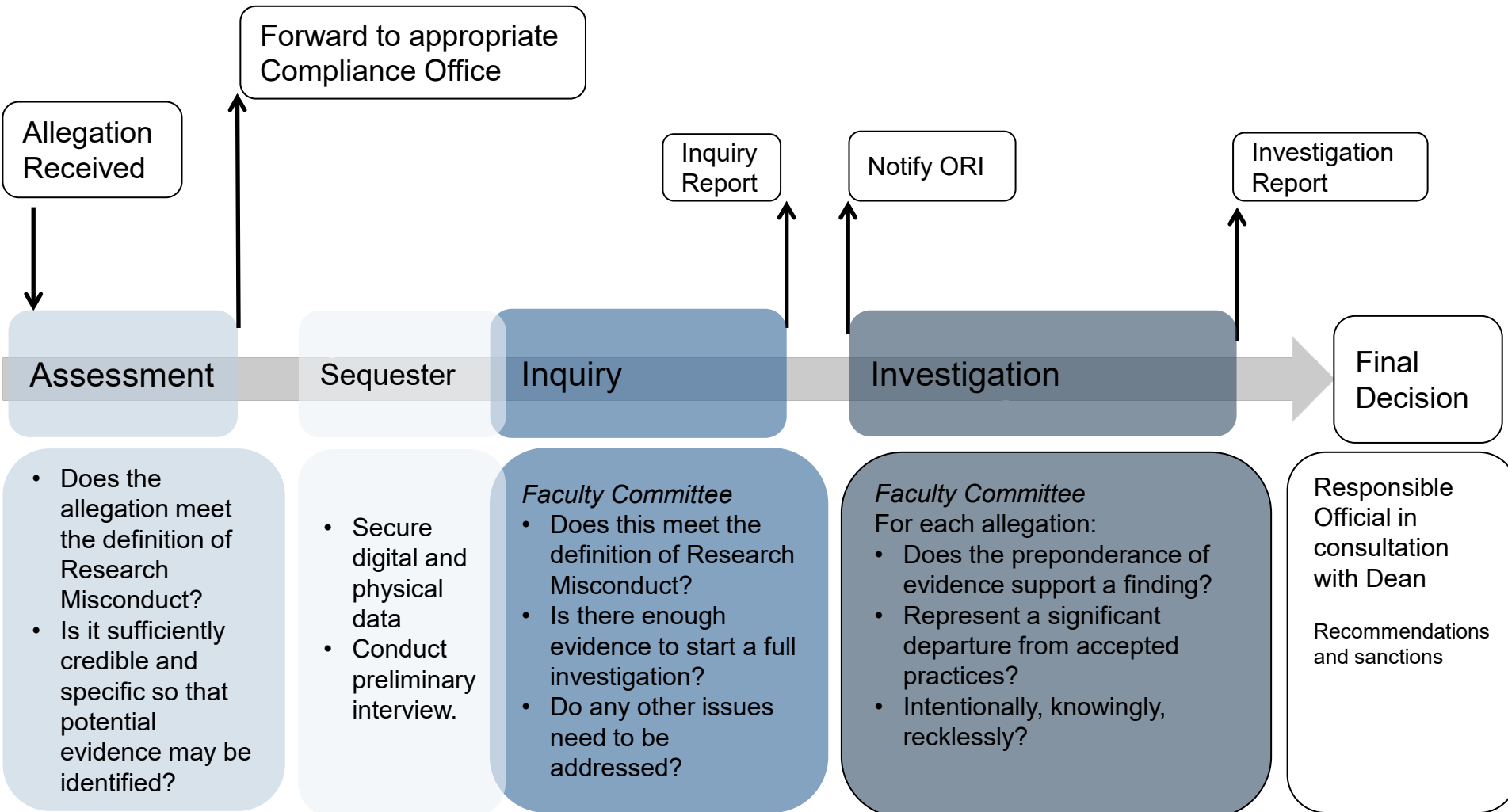
Does NOT include honest errors or differences in opinion

1. There be a significant departure from accepted practices of the relevant research community; and
2. The misconduct be committed intentionally, knowingly, or recklessly; and
3. The allegation be proven by a preponderance of the evidence.





Investigation of Research Misconduct





Potential actions and sanctions

Noncompliance

- Special training
- Research oversight committee
- Suspension of protocols and research
- Termination of position (multiple violations)
- Corrections or retractions

*Investigations follow due process
in each office*

Research Misconduct

- Corrections
 - Retractions
 - Special training
 - Research oversight committee
 - Termination of position
 - Suspension of clinical trials
 - Prohibited from serving in an advisory capacity
 - Funding withheld
 - Funding barred for X number of years
 - Money returned by institution
- } cases of honest error

Correct the scientific record!



UMB OAC RIO

Report Misconduct:

- Hotline 866-594-5220
- <http://www.ethicspoint.com>
- Email oac@umaryland.edu
- In person

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620 W. Lexington St., 5th floor
Baltimore, MD 21201

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UMB Research Ombuds



UMB Research Ombuds (RO)

Bruce K. Krueger, PhD

Professor of Pharmacology & Physiology and Psychiatry



The RO will

- help faculty, trainees and staff examine options for reporting concerns about research misconduct or determine if a violation of research misconduct policy has occurred
- answer questions from individuals against whom research misconduct allegations have been made.
- function independently from official UMB processes for investigating and resolving allegations of research misconduct (i.e., the Research Integrity Office).
- hold all communications in strict confidence and not disclose confidential communications unless given permission to do so.

The RO can be contacted at bkrueger@som.umaryland.edu