AuditCon

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Retracted! The Hidden Risks of Research Misconduct and What Auditors Need to Know

Meet your Presenters

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Why This Topic Matters

- Institutions have **too much to lose,** financially, reputationally, and strategically, not to treat research misconduct as a critical audit and compliance risk.
  - **Federal dollars dominate research funding:** Federal agencies (e.g., NIH and NSF) collectively award tens of billions annually, but agencies expect institutions to maintain strong internal controls under Uniform Guidance.
  - **Compliance failures can jeopardize future funding:** Even one misconduct case can trigger funding freezes, clawbacks, or heightened federal scrutiny.
  - **Reputation drives competitiveness:** Faculty recruitment, student enrollment, and industry partnerships all depend on an institution's credibility.
  - **"Publish or perish" pressures create vulnerabilities:** Faculty and labs are under constant pressure to produce, and without adequate controls, shortcuts or misconduct can go undetected.

Objectives

- Recognize emerging risks in research misconduct and understand how paper retractions, federal investigations, and whistleblower reports impact universities.
- Understand key regulations and compliance obligations, including OSTP, ORI and NSF research misconduct rules, and internal control and monitoring expectations under Uniform Guidance.
- Identify common red flags that indicate weaknesses in research integrity, such as lack of oversight in high-risk research areas, conflicts of interest, and data management deficiencies.
- Assess institutional controls related to research ethics, whistleblower protections, authorship disputes, and data falsification risks.
- Develop audit strategies to proactively evaluate and strengthen institutional frameworks for preventing, detecting, and responding to research misconduct.

Session Roadmap

- Risks and drivers of misconduct
- Regulatory frameworks
- Red flags and systemic weaknesses
- Institutional controls
- Audit strategies & takeaways
- Interactive case activity

Poll Question #1

How familiar are you with research misconduct risks?

- Very familiar
- Somewhat familiar
- Not familiar

Risks and Drivers of Misconduct

Setting the stage: the risk landscape

Defining Research Misconduct

Under the **Federal Research Misconduct Policy** (FFP) (adopted by agencies including NSF and NIH, and codified in 42 CFR Part 93):

Fabrication

- Making up data or results and recording or reporting them as if they were real.
- *Example: Inventing patient records or lab results.*

Falsification

- Manipulating research materials, equipment, processes, or data so the research is inaccurately represented.
- *Example: Adjusting images, deleting data points, or cherry-picking results to make findings look stronger.*

Plagiarism

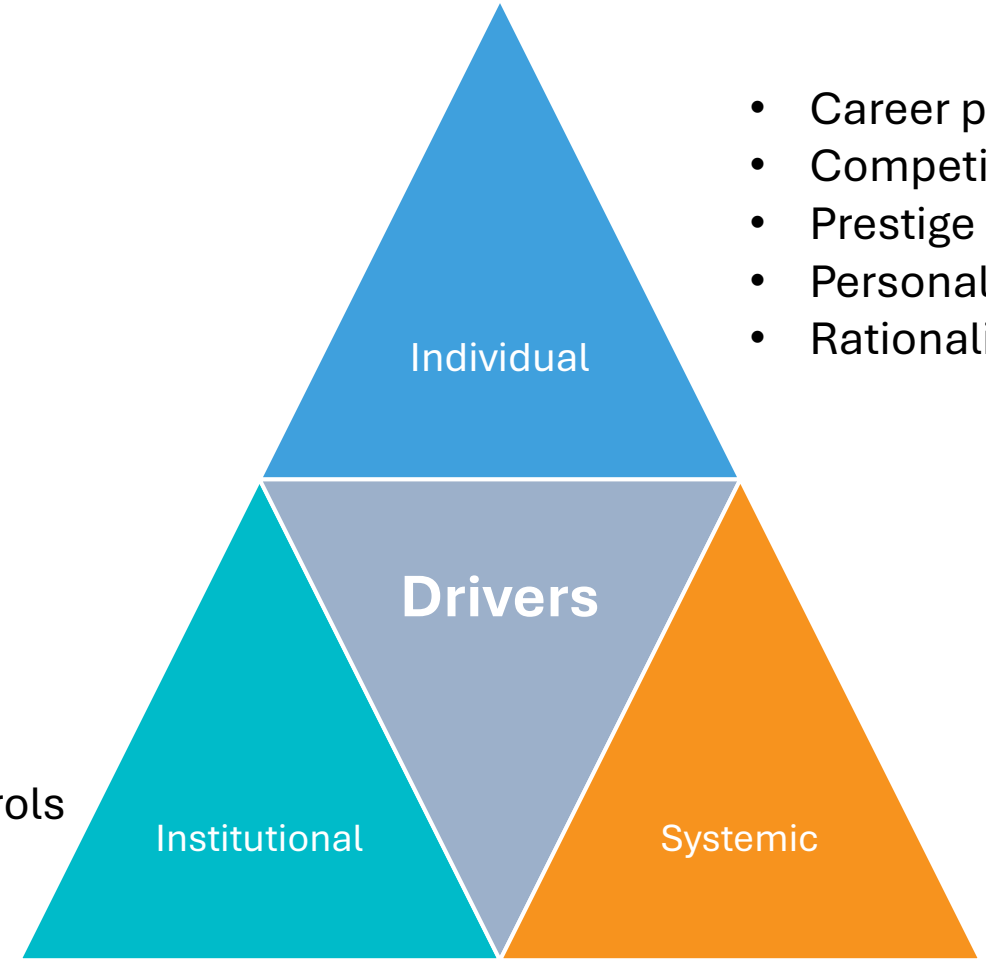
- Appropriating another person's ideas, processes, results, or words without giving appropriate credit.
- *Example: Copying text or reusing a colleague's experimental design without attribution.*

Beyond Misconduct – Other Integrity Breaches

- Many institutions also monitor or sanction other behaviors that may not rise to the federal definition but can be highly damaging:
  - Questionable research practices (QRPs)
  - Human subjects & Animal welfare violations
  - Financial & Conflict of interest (COI) misconduct
  - Peer review misconduct
  - Research mismanagement

Key Distinction
Research Misconduct (FFP): federally defined, requires investigation and reporting.
Other Integrity Breaches (QRPs, COI, IRB violations, etc.): may not be "misconduct" under federal rules but still pose compliance, reputational, and funding risks.

Why Misconduct Happens

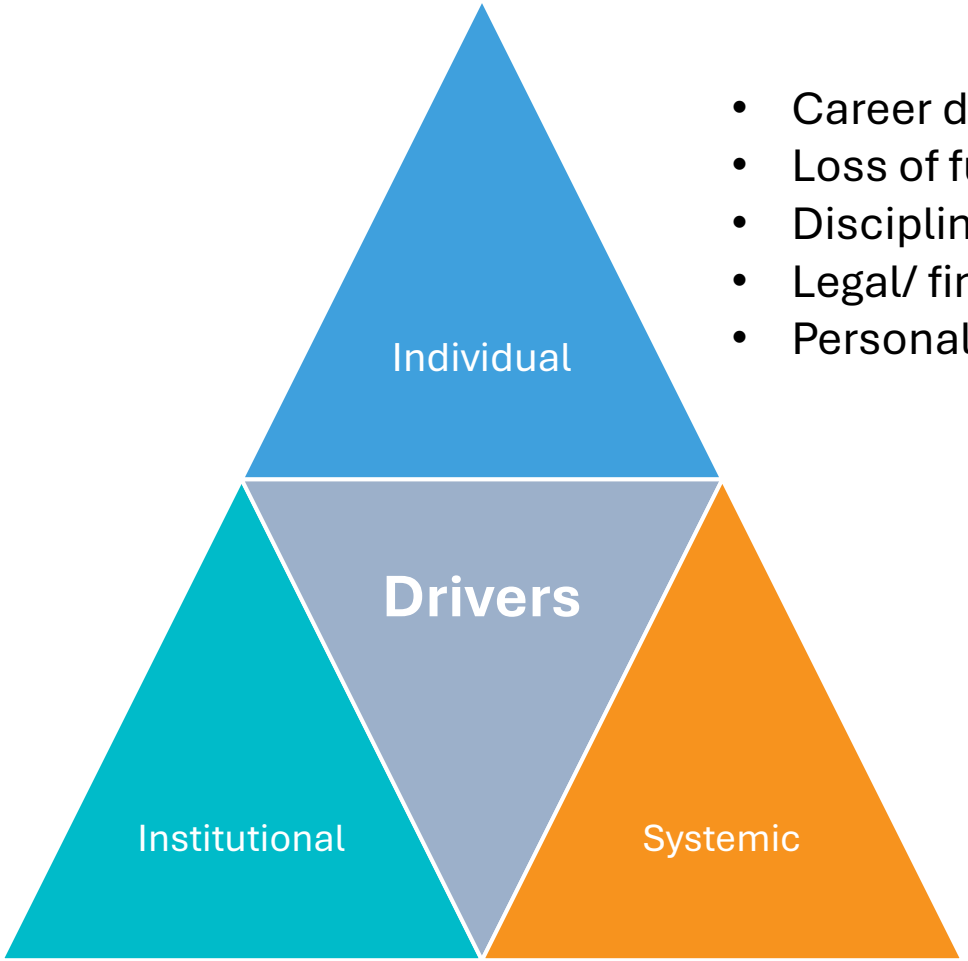


- Career pressure – publish or perish
- Competition for funding
- Prestige and recognition
- Personal financial gain
- Rationalization

- Funding dependence
- Culture
- Weak oversight/ limited controls
- Power dynamics
- Institutional reputation

- Hyper-competitive research ecosystem
- Publishing bias
- Evolving research areas
- Sponsor influence
- Metrics-driven accountability

Consequences of Misconduct



- Career damage
- Loss of funding eligibility
- Disciplinary action
- Legal/ financial liability
- Personal toll

- Financial impact
- Reputational hard
- Increased oversight burden
- Erosion of trust internally
- Legal/ compliance exposure

- Erosion of public trust in science
- Policy & regulatory backlash
- Funding landscape shifts
- Scientific progress delayed
- Equity & inclusion concerns

Poll Question #2

Which consequence would have the biggest impact on your institution?

- Loss of research funding
- Reputational harm
- Faculty/staff sanctions
- Federal investigation or penalties

Misconceptions & Trends

- Fraud in research is **not rare** and is growing rapidly.
- Certain subfields (especially in biomedical research) are disproportionately affected.
- Existing mechanisms (retractions, deindexing) are **not keeping pace** with the scale of fraudulent activity.
- The scientific enterprise is vulnerable to coordinated fraud, often facilitated by editors and brokers.

Proceedings of the National Academies of Science, 2025

Headlines

- Harvard University (2024)
  - Harvard Medical School neuroscientist Khalid Shah allegedly falsified data and plagiarized images across 21 research papers
- Dana-Farber Cancer Institute (2024)
  - Image duplications and manipulations in dozens of biomedical studies, prompting the retraction of six papers and corrections in 31 others, after biologist and blogger Sholto David publicly flagged serious concerns about the integrity of research from top scientists at the institute
- Stanford University (2023)
  - Marc Tessier-Lavigne resigned as President in July 2023 following an investigation that found flaws in multiple scientific papers he co-authored, including manipulated research data, though the inquiry concluded he did not personally engage in fraud.

Regulatory Frameworks

What rules must institutions follow?

Federal Research Misconduct Policy

- Office of Science Technology and Policy (2006)
  - Definition
    - Defines fabrication, falsification, plagiarism (FFP)
  - Key Requirements:
    - Establish procedures to **respond to allegations** of misconduct.
    - Conduct **thorough, competent, and objective investigations**.
    - Maintain **confidentiality** and protect **whistleblowers** and **respondents**.
    - Report findings to the relevant **federal agency**.
  - Administration Actions:
    - **Debarment** from future federal funding.
    - **Supervision or certification** of future research.
    - **Correction or retraction** of published literature.

Key Agency Application

- Federal Policies | ORI - The Office of Research Integrity
- DHHS Office of Research Integrity (ORI) Regulations (42 CFR Part 93)
  - Applies to Public Health Services (PHS) (e.g., National Institutes of Health) funding
  - Reporting and investigation obligations
- NSF Research Misconduct Rules (45 CFR 689)
  - Defines NSF-funded project responsibilities
  - Investigation and sanction processes – inquiry, investigation, interim actions
- OMB Uniform Guidance (2 CFR 200.303)
  - Requires effective internal controls
  - Prevent fraud, waste, abuse in federally funded research

Institutional Policies & Players

- Institutional compliance offices
- IRBs, research integrity committees
- Conflict of Interest/ Financial Conflict of Interest
- Training and data stewardship

Red Flags and Systemic Weaknesses

What you should be looking for

Common Red Flags

Red Flags

- Data Issues
- Authorship & Publication Concerns
- Conflict of Interest Risks
- Process/ Oversight Gap

Discovery

- Peer Review Process
- Whistleblower
- Journal & Retraction Watchdogs
- Internal Audits & Compliance Checks
- Replication Failures
- Data Forensics & Technology
- Federal Agencies
- Media & Public Watchdogs

Systemic Weaknesses

- Weak oversight and governance
- Cultural and incentive issues
- Resources constraints
- Data management & technology gaps
- Conflict of Interest & Sponsor pressure
- Fragmented accountability

Poll Question #3

Where do you think your institution is most vulnerable today?

- Oversight in high-risk research areas
- Data management and record-keeping
- Conflicts of interest
- Whistleblower protections

Institutional controls

How you can prevent and detect issues

Institutional Controls Framework

Governance and Oversight

- Research Compliance Office
- IRB and IACUC
- Provost/ Department Chairs/ Deans/Research Leadership

Policies and Procedures

- COI
- Research Misconduct
- Data Management and Retention
- Authorship and Publications Guidelines

Training and Awareness

- RCR/RECR
- Ongoing Awareness Campaigns

Monitoring and Detection

- Internal Audits and Spot Checks
- Whistleblower Hotlines
- Plagiarism Detection/ Data Forensic Tools
- Grant Compliance and Financial Oversight

Roles and Responsibilities

Control Area	Responsible Party
Governance and Oversight	Research compliance office, IRB/IACUC, department chairs, deans
Policies and Procedures	University leadership, legal counsel, compliance office, research integrity committees
Training and Awareness	Compliance office, HR, faculty mentors
Monitoring and Detection	Internal audit, compliance office, lab supervisors, external reviewers

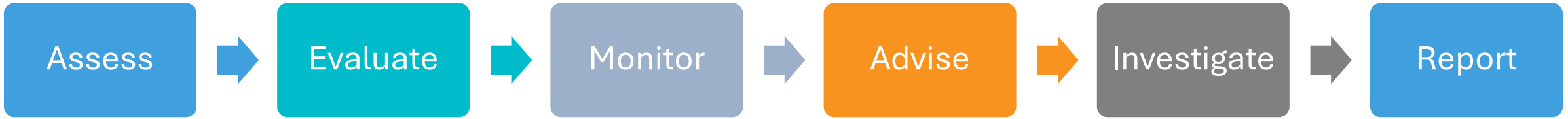
Whistleblower Protections

- Requirement:
  - Federal and agency policies broadly require institutions to protect individuals reporting research misconduct.
- Operationalization:
  - Cultural reinforcement
  - Formal written policies
  - Training and awareness
  - Monitoring and auditing
  - Confidential and written reporting channel
  - Investigative procedures
  - Remediation

Audit strategies & takeaways

Practical approaches to take back to campus

Internal Audit's Role



1. Risk Assessment

- Evaluate the **institutional exposure** to research misconduct, including high-risk research areas (clinical trials, high-dollar grants, emerging technologies).
- Identify **gaps in governance, controls, and compliance programs**.
- Assess whether the **tone at the top** and culture support ethical behavior.

2. Evaluating Policies & Controls

- Review **research misconduct policies**, whistleblower protections, and conflict-of-interest policies for adequacy and enforcement.
- Assess **data management practices**, including storage, retention, and access controls.
- Test **authorship and publication practices** for adherence to institutional guidelines.

Internal Audit's Role (cont.)

3. Monitoring & Testing

- Conduct **audits or spot checks** on high-risk labs, grants, or projects.
- Review **investigations of alleged misconduct** to ensure proper process and documentation.
- Evaluate **compliance with federal regulations** (ORI, NSF, Uniform Guidance).

4. Advisory / Consulting Role

- Act as a **trusted advisor** to research leadership and compliance offices.
- Recommend **strengthening controls** before misconduct occurs.
- Help **operationalize policies** and build awareness of red flags.

Internal Audit's Role (cont.)

5. Investigative Support

- Support research compliance or legal teams during internal investigations.
- Provide independent **review of processes, documentation, and findings**.
- Ensure audit evidence is preserved for regulatory or legal purposes.

6. Reporting & Strategic Insights

- Report findings to **Audit Committee, senior leadership, or Board**.
- Highlight trends, systemic weaknesses, and areas for improvement.
- Help the institution **prioritize resources** for mitigating research integrity risk.

Sample Audit Procedures

1. Planning & Risk Assessment

- **Understand the institutional landscape**: size, research portfolio, funding sources, regulatory environment.
- **Identify high-risk areas**: clinical trials, high-dollar grants, emerging research fields, labs with high publication pressure.
- **Review prior findings**: past audits, investigations, ORI/NSF notices, retractions, or media reports.
- **Develop objectives**: e.g., assess controls to prevent misconduct, evaluate whistleblower effectiveness, verify compliance with federal policies.

Sample Audit Procedures

2. Scoping

- Determine **engagement boundaries**: departments, labs, research centers, and grant types.
- Identify **regulatory focus areas**: ORI, NSF, NIH, Uniform Guidance, conflict-of-interest rules.
- Select **audit techniques**: document review, interviews, data analytics, site visits, control testing.

Sample Audit Procedures

3. Fieldwork / Execution

- **Policy & Procedure Review**
  - Evaluate research misconduct policies, COI management, whistleblower procedures, IRB/IACUC oversight.
- **Data & Documentation Testing**
  - Examine raw data access, retention, and integrity.
  - Assess lab notebooks, electronic records, and publication submissions.
- **Interviews / Observations**
  - Talk to researchers, lab managers, compliance officers, and administrative staff.
- **Whistleblower & Investigation Review**
  - Evaluate how allegations are reported, investigated, and resolved.
  - Verify protections against retaliation.
- **Control Testing**
  - Sample oversight mechanisms, approvals, and reconciliation of grant deliverables.

Sample Audit Procedures

4. Analysis & Evaluation

- Compare findings against:
  - Federal research misconduct definitions (FFP)
  - ORI / NSF / NIH requirements
  - Institutional policies and procedures
- Identify **control gaps, systemic weaknesses, and cultural risk indicators**.
- Evaluate **effectiveness of mitigation measures**.

Sample Audit Procedures

5. Reporting & Recommendations

- **Draft audit report** for Audit Committee and senior leadership.
- Include:
  - Key risks observed
  - Weaknesses in controls or compliance practices
  - Opportunities to strengthen culture, oversight, and monitoring
  - Suggested corrective actions, prioritization, and follow-up timelines
- Highlight **strategic insights**, not just compliance checklists.

Key Takeaways

- Misconduct is a growing but overlooked risk
- Understand the regulatory landscape
- Spot red flags and systemic weaknesses
- Serve as a key ally via Internal Audit and:
  - Strengthen institutional resilience
  - Improve oversight culture
  - Enhance trust in research integrity

Interactive case studies

Let's practice!

Interactive Activity

- Audit the Case: Spot the Risks
- Instructions: Review case scenario, identify risks, list controls, suggest audit steps

Case Scenario Example

- Dr. Lopez submits groundbreaking cancer study
- Data discrepancies, missing raw data
- Consulting ties to biotech company
- What are the red flags? What controls are weak?

Case Scenario 1: The Miracle Data

- Dr. Lopez submits a breakthrough cancer study
- Results unusually strong compared to prior studies
- Junior staff raise concerns about discrepancies
- Raw data missing; no backup exists
- Consulting income from biotech company
- Discussion: Red flags? Missing controls? Audit steps?

Case Scenario 2: Authorship Under Pressure

- Multi-institutional engineering project under pressure
- Senior administrator listed as co-author without contribution
- Graduate students concerned but silenced
- Data analysis on personal laptop; no secure repository
- Discussion: Where are the risks? What controls should exist?

Case Scenario 3: The Fast-Tracked Study

- NIH-funded clinical trial behind schedule
- Recruitment logs include participants who never consented
- PI defends practice as 'standard to keep sponsor happy'
- IRB chair approves expedited changes repeatedly
- Compliance office understaffed; no monitoring for a year
- Discussion: Risks? Control weaknesses? Audit approach?

Questions

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ACUA Baker Tilly 2025 – Higher education benchmarking survey

Why participate?

- Share your insights on current practices, challenges and trends
- Receive a complimentary report with aggregated results + data-driven guidance

Survey details

- ~15 minutes to complete
- Deadline: **Sept. 19, 2025**
- Answer as many or as few questions as you like
- Stay anonymous by entering "Anonymous" in demographics
- Results will be shared with all ACUA members

Designed for higher education internal auditors

Scan the QR code to take survey

Resources

- Research Misconduct News | UK Research
- Case Summaries | ORI - The Office of Research Integrity