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RESPONDING TO AGENCY INVESTIGATIONS IN THE NEW RISK LANDSCAPES

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Learning Objectives

By the end of this program, attendees will be able to:

- Understand new risk landscapes for research administration
- Identify procedural and substantive steps governing agency investigations and enforcement proceedings aimed at grant compliance issues
- Identify current trends in agency investigations of research grant compliance
- Understand different approaches and best practices when responding to agency investigations

“Why Is There So Much Fraud in Academia?”*

- More than 10,000 research articles retracted in 2022
- In 2015 study, less than half of findings from 100 research papers were successfully replicated
- Cheating is prominent feature in any human endeavor, including academia
 - Rewards Cycle (Publish – prominence – grants)
 - Fewer tenured positions available
- Ease of cheating in certain fields (i.e., social psychology v. economics)
 - nonpublic datasets
 - “probability hacking” (e.g., collecting 5 datasets, reporting 3)
 - third tier journals apply friendly scrutiny to research papers
- Financial incentives provided by adverse parties (i.e., hostile nations)
- Federal agency implementing new research integrity and security regimes
- Federal law enforcement stepping up enforcement against non-compliant institutions

* *Freakonomics Radio* podcast 1/10/24

Government Investigations: Types and Sources

Research institutions field inquiries in variety of ways:

- Informal Request
- Civil or Administrative Subpoenas
- Civil Investigative Demands
- Search Warrants

... and from a variety of sources:

- OIG (NSF, NIH, HHS, EPA, DOT, NASA, NEH, DOE, DoD, etc.)
- DOJ, FTC, USPI & other federal law enforcement
- State law enforcement and regulatory agencies
- GAO

Whistleblowers Incentivized to Report Fraud

Investigations frequently arise from internal whistleblowers.

- Whistleblower Protection Act protects “Relators” -- covered employees who disclose information that they reasonably believe evidences (i) violation of any law, rule, or regulation; (ii) gross mismanagement or waste of funds; (iii) abuse of authority including sexual harassment/hostile work environment; (iv) substantial and specific danger to public health or safety; or (v) agency policy decisions and/or censorship related to research, analysis, or technical information if the consequences result in the misconduct listed above.
- Whistleblowers entitled to protection against retaliation (taking, failing to take, threatening personnel action)
- Qui Tam cases under False Claims Act provide powerful incentive for whistleblowing

Qui Tam Litigation Mechanism

- Qui tam statutes enlist the public to sue those who defraud the government, and rewards those who sue in the government's name (called relators) with a portion of recovered proceeds.
- FCA proscribes presenting a false claim or making/using a false record or statement material to a false claim. FCA also reaches conspiracies to commit any such offense.
- Race to the courthouse: FCA features a first-to-file bar that precludes piggyback relator suits, and a public disclosure bar that precludes suits based on old news unless the relator is an original source. If agency initiates suit, others may not join. If agency has not sued, a relator may do so but must give government notice and afford it 60 days to decide whether to take over the litigation.
- If the government declines to intervene, a prevailing relator's share of any recovery is capped at 30%; if the government intervenes, the cap is lower and depends upon the circumstances.

Other Sources of Agency Investigations

- Periodic agency audits.
- Investigative press reports spawned by whistleblowers or counterintuitive findings.
- Independent reform entities such Center for Open Science (www.cos.io) and DataColada (www.datacolada.org).
- Incongruous findings.
- Internal investigations and reviews – best way possible to initiate agency investigation.

Inspector General Act of 1978

- Every agency's OIG tasked to "conduct, supervise, and coordinate audits and investigations relating to [the agency's] programs and operations."
- Nationwide document subpoena power
- Special powers of HHS OIG:
 - Temporarily or permanently exclude health care provider from participation in federal health care programs (42 CFR 1001, 42 CFR 1003.105)
 - Impose civil penalties and assessments (42 CFR 1003)

OIG Administrative Subpoenas

- Compulsory, nationwide process
- Limited to documents
 - “all information, documents, reports, answers, records, accounts, papers, and other data in any medium (including electronically stored information), as well as any tangible thing and documentary evidence necessary in the performance of the functions assigned by this Act, which subpoena . . . shall be enforceable by order of any appropriate United States district court.” 5a U.S.C. § 6(a)(4)
- Some agency OIG's subpoena authority extends to testimony, but most rely on interview requests

Civil Investigative Demands

31 U.S.C. §3733

- Compulsory pre-complaint process for production of documents, interrogatories, oral testimony
- Department of Justice or designee
- Preferred tool for False Claims Act investigations
- Nationwide jurisdiction
- Sworn certificates of completion for documents produced, interrogatory answers under oath
- Rule 45 subpoena discovery rules apply

SUBPOENA RESPONSE PROTOCOLS

- Employees immediately notify supervisor or in-house counsel if contacted by investigators
- Protect whistleblower rights – no retaliation
- Identify point person for working with agency and any outside counsel to handle response
- Preserve all documents and data upon learning of investigation – work with IT department to:
 - ❖ identify custodians of requested information
 - ❖ issue data retention letter
 - ❖ suspend auto-delete policies and mechanisms

SUBPOENA RESPONSE PROTOCOLS

- All document productions and interviews handled by counsel or compliance office
 - ❖ individuals not authorized to provide institution's materials
- Gather responsive materials, review, produce
- Do not impede or obstruct agency investigation
 - ❖ *negotiate* limits, no self-help measures
 - ❖ interview request quandary
 - ❖ third parties with responsive materials
 - ❖ *no* retaliation against suspected relators
- Limit email communications about investigation

SEARCH WARRANT RESPONSE PROTOCOLS

Time is of the essence when law enforcement enters premises:

1. check agent's credentials
2. immediately call in-house counsel
3. accompany and monitor agents if and as possible
4. attempt to protect privileged materials
5. request copy of affidavit filed in support of warrant
6. inventory seized records and devices
7. identify persons of interest
8. patrol bounds of warrant
9. prevent outright seizure of essential records and items if possible.

SEARCH WARRANT RESPONSE PROTOCOLS

10. limit dialogue with investigators to what is necessary to cooperate w exercise of warrant.
11. ask to have ESI and other data placed under seal pending further privilege review
12. de-brief with impacted staff
13. rule of thumb: **object**, but do not **resist**.
14. make written, contemporaneous record of all objections and requests to investigators executing the warrant, and convey to appropriate agency leads immediately

EFFECTIVE NEGOTIATION & COMPLIANCE

- Counsel in contact with investigators and negotiating timing and substantive parameters
- Identify and discuss production of electronically stored information (“ESI”), including:
 - ❖ custodial departments and personnel
 - ❖ relevant time period
 - ❖ key search terms
 - ❖ likely privilege and HIPAA issues
 - ❖ protect metadata
 - ❖ work with reputable and competent vendors
- Avoid “cold productions”

CONFLICT-OF-INTEREST ISSUES

Investigations and enforcement proceedings may present different conflict-of-interest issues:

- Unity of interest between institution - research staff
 - delivering *Upjohn* advisement to staff
 - receiving informed consent
- Allegations of criminal conduct, gross negligence, or personal wrongdoing (i.e., sexual harassment) may disrupt unity of interest, introducing potential conflicts
- Timing and severity of agency action impacts analysis

JOINT REPRESENTATION

Can institution's counsel also represent individual research staff throughout investigation/enforcement?

- ABA Model Rule 1.7 states that conflict exists if there is a *significant risk* that representation will be materially limited by lawyer's responsibilities to other client
 - risk assessment requires identifying potential conflicts that may arise over course of matter
 - common interests prevail unless substantial allegations of gross negligence/criminality
- Life cycle of investigation and severity of issues impact analysis.

MAINTAINING COMMON INTERESTS

- Role of Indemnification
- Informed Consent at outset requires a discussion:
 - possible effects of joint representation on lawyer's duty of loyalty, confidentiality, and A/C privilege
 - **no secrets viz. one another**
 - possibility that joint representation will fail and planning for that contingency
 - advance waiver of *identified* future conflicts
 - authorize use of confidential info of former client

Joint Representation Checklist

- Identify implicated research staff
- Assess potential conflicts given investigation stage; severity of investigation issues; nature of grant and contractual duties involved (including indemnity), personnel issues, etc.
- Discuss w/ clients possibility of potential conflicts and costs/benefits of joint representation
- Obtain written consent/waiver
- Promptly address conflicts as they arise

Preserving Indemnity Rights

- Broad indemnity extended to research faculty and staff comports with corporate unity doctrine
- Recognizing duty to defend promotes unity of interest and preserves legal privileges
- Providing indemnity promotes institution's control of investigation response and associated costs
- In absence of *proof* to contrary, assume good faith conduct and extend defense costs with claw-back rights against gross negligence or criminal conduct

When Bad Things Happen to Good People

Richard, "The Psychology of Ethical Decision-making"

- Common "mind tricks" leading to ethical lapses:
 1. Moral Licensing – how folks cheat on diets
 2. Gradual Change – goes unnoticed
 3. Fading -- more important matters push ethics into background
 4. Personalities > principles
- Getting leaders to listen is half the battle

When Bad Things Happen to Good People

Getting leaders to listen to your compliance program:

- Voice of the Client
- Peer Pressure
- Role Play
- Create Sense of Urgency
- Link Compliance to Profitability or other Goals
- Link Compliance to Better Investigation Outcomes

Key Take-Aways

Navigating between Scylla & Charybdis:

- Develop **compliance protocol**, train on it
- **Principles** before personalities
- Respond to investigation with **sense of urgency**
- **Capture** all the records, interview all the people
- **Negotiate** limits, but do *not* just help yourself
- Maintain **unity of interest** w/ research staff
- Navigate **whistleblower issues** carefully
- Good outcomes based on **record of compliance**
- Heroics based on **record of cooperation**
- **Advocate** at every opportunity.