

## Handling Multi-Faceted Investigations Related to Research

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1

## Presenter



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Executive Director of the Office of Research Integrity & Compliance  
University of New Mexico

**Attorney** 2002 - 2015

*Helped secure the largest jury verdict in the U.S. in 2013*

*In Re: Urethane Antitrust Litigation, U.S. District Court, District of Kansas, 04-md-01616*

**Consultant and Executive** engagements since 2015

**Adjunct Law Professor** at UNM School of Law since 2005

*taught: International Law, Intellectual Property Law, & Immigration Law courses*

**Legal areas:** international law,  
antitrust (competition) law,  
contract law,  
intellectual property law,  
scientific research & commercialization rules <sup>2</sup>



2

Go Lobos!

"Unexpected on Purpose"  
UNM Promotional (YouTube) Video

<https://www.youtube.com/watch?v=PioOO8vfii4>



Founded in  
1889

3

3

## UNM & Its Research at a Glance

**Public \* Carnegie Classification => R1 \* New Mexico's flagship university**

**TOTAL BUDGET (2021): > \$ 3 billion**

**POPULATION (2021):**

**RESEARCH BUDGET (2021): => \$ 308.5 million**

**22,000 students**

**3,000 faculty**

**4,300 staff**

- Incredible **diversity**:
  - => **Leads R1 universities in Native American student enrollment**
  - => **The only flagship state university that is also a Hispanic Serving Institution**
  - => **One of four R1 universities that are also Minority Institutions**
- Trauma 1 **teaching hospital** & an NCI-designated **Comprehensive Cancer Center**
- Proximity to **2 National Labs (DOE), AFRL, and a spaceport**



4

4



## Handling Multi-Faceted Investigations Related to Research

### Agenda

1. Slippery slopes and tips for dealing with them
2. How to anticipate/expect the unexpected
3. Preparing for public scrutiny caused by the investigation

[ Intermediate level session ]



5

5

## Complexities of Research Investigations



1. **Legally and procedurally rich;**
2. Misconduct usually **spans over years** and involves **multiple regulatory and policy regimes**, invoking **different investigatory processes;**
3. **Extraordinarily smart respondents**, most versed in an **uber sub-specialty** under scrutiny, who can afford **excellent legal counsel;**
4. **Avoiding claims** of breach of privacy/confidentiality, defamation, interference with business relations ...while **correcting scientific literature** or providing mandatory **reports;**
5. Findings can lead to **criminal penalties**, permanent **disbarment**, **treble damages** up to 3x actual or compensatory damages...;

=> **Verdicts and settlements** against an institution can be **> 100 million / investigation**

*Example: Duke University settled with federal government for 112.5 million for research data fraud in 2019 (the case involved \$ 200M in federal research funding)*



6

6

## Complexities of Research Investigations



6. Investigations can involve **many sponsors and many subject matter areas**;

*Hypothetical Example:*

**1 set of allegations =**

6 federal agencies,

federal contractors with energy and defense agencies,

**6 different investigatory regimes for just one issue** (falsification and fabrication of research results),

+ **other issues:** hostile behavior, physical attacks, authorship disputes, intellectual property ownership, intellectual property licensing, undue foreign influence, conflict of interest...

=> **One area of allegations alone**

[for example, conflict of interest (COI)]

**can invoke multiple compliance areas and investigatory processes**

[based on purchasing & procurement laws, contractual obligations, COI in research, COI in academics, COI in start ups... ].



7

7

## Complexities of Research Investigations



7. **Multiple institutions** may be investigating, respondents may hold **joint appointments** among the institutions with **competing jurisdictions**, and spaces to **sequester** may be dispersed **across institutions** with **mutually exclusive investigation teams and competing missions** (internal-facing vs. public-facing).

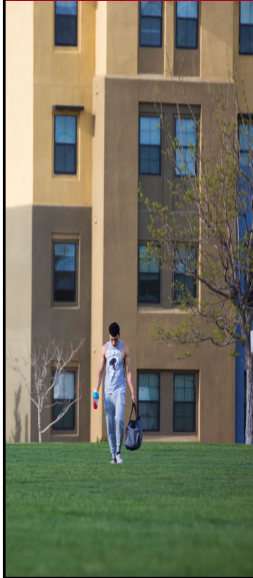
8. **Multiple decision makers** within each institution which may include **committees and panels as decision makers**.



8

8

## 1. Legal and procedural complexity



### ➤ YOU ARE NOT ALONE!

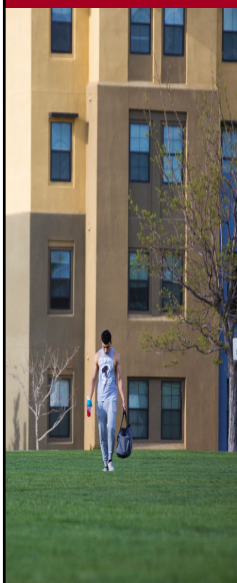
- Ensure **support by and access to** in-house legal counsel as well as all appropriate co-investigators within the institution
  - If legal expertise is lacking in-house, **advocate for acquisition &/or development of legal expertise** specific to research-related issues
  - **Build relationships with all relevant legal counsel** (in-house and outside if have designated outside counsel for research)
  - **Help with retention of legal counsel who is working out well** and has expertise in research **since training is long** and **practice an artform** rather than science
- **Engage your attorney** in discussions **with attorneys representing parties** in the investigation
- Ensure **ongoing and timely access, both verbal and in-writing**, to your **in-house counsel**



9

9

## 1. Legal and procedural complexity



### ➤ DO NOT LET PARTIES WANDER (ALONE), SEARCHING FOR PROCEDURAL RULES OF YOUR INSTITUTION!

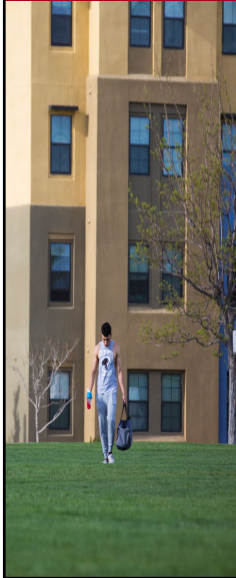
- Make sure your institutional policies and procedures provide for **adequate opportunities for respondent/s to defend and appeal**, as procedure (lack thereof, failure to follow, etc.) is the common ground for legal challenges
- Ensure that **rules governing procedures are clearly stated and easily accessible**
  - **At the minimum, provide copies** (in PDFs or another program that will resist the test of time and technological upgrades) of applicable rules and procedures **to the respondent (and the complainant/s, if your policies so require)** and **save those communications on the record**
- **Check all applicable institutional policies for notice requirements** as institutional policies may mandate them and **make their enforcement part of your internal office procedures and SOPs**
- **Do not forget notice requirements applicable to complainants and perhaps others** (sponsors, officials within your institution, etc.) as applicable



10

10

## 1. Legal and procedural complexity



- **PROCEDURALLY, EACH INVESTIGATION SHOULD NOT BE A LONE INCIDENT!**
- Apply **procedural rules as consistently as possible with proper factoring in of individualized aspects**
- **Maintain proper documentation** and ensure **adequate retention and disposal** for each investigation
- **Normally it is a bad idea to change or re-publish** rules or SOPs **amid an investigation**
- **Do not assume that more prescription is always a better choice** when drafting procedural (portions of) policies: **flexibility is sometimes needed** (especially for catch-all procedural policies)



11

11

## 2. Multiple regulatory and policy regimes, invoking different investigatory processes



- **FOR A SMOOTHER FLIGHT, HAVE THE RELEVANT CREWS BRING AND CONSOLIDATE THEIR TOOLS AND PUT THEM ALL IN THE SAME BASKET!**
- For **Intra-institutional situations**, it helps to have an **institutional catch-all investigatory policy** that proscribes procedure for when different investigatory mechanisms are involved or when there is not any procedure under violated policies
  - BUT ensure process (under the catch-all policy or one otherwise selected to harmonize across violated policies) is **sufficiently flexible and general**
    - *Example: sufficient level of leadership* be put in charge of **deputizing investigators** under the catch-all investigatory policy (Provost or above normally in university nomenclature)
- Do not forget to **factor in applicable aspects of specialty titles** that come with your role
  - *Example: Research Integrity Officer*



12

12

## 2. Multiple regulatory and policy regimes, invoking different investigatory processes



- **IF THERE IS NOT ANOTHER PILOT ON BOARD, START THE FLIGHT FOR THAT CREW!**
- If no one else more appropriate is taking the lead, **identify various pertinent enforcers of rules and policies at issue and convene the initial meeting in a timely manner** (if there is not anyone else better-suited)
- Ensure **everyone is in the room** [ BUT limit to the **need-to-know** ]:
  - Definitely your legal counsel and other co-investigators/policy enforcers
  - Public relations
  - Subject matter experts if needed (preferably one with an administrative/executive appointment in an office that enforces one of the polices alleged to have been violated)
  - Other institutional attorneys with specific subspecialties needed for matter at hand
  - ...



13

13

## 2. Multiple regulatory and policy regimes, invoking different investigatory processes



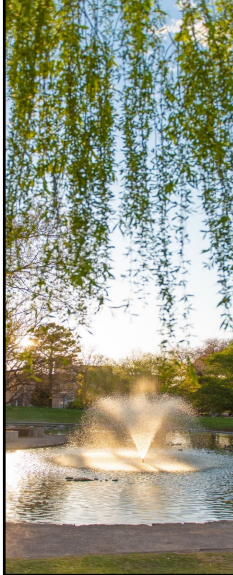
- **REMEMBER TO LET THE CREW ILLUMINATE THE PATH FORWARD TOGETHER, IN THE EARLY STAGES BEFORE THE SUNRISE!**
- Once those relevant parties are “in the room”:
  - Jointly identify **which investigators need to proceed** and determine **how** (or at least who needs to decide how) to proceed, under what process/es, etc.
  - **Allot sufficient time** for initial redress of allegations as well as various assignments/deputization
  - **Carve out the path** for clear and proper redress of allegations and any *prima facie* or preliminary assessments
- Reach consensus on **who shall lead overall and for different things** (decisions, coordination, scheduling, etc.)
- Determine **how best to demark and handle confidential material and communications**
- Discuss, at least conceptually, **different needs of different investigation teams to access confidential information**
- **Meet early** and then meet as needed



14

14

### 3. Extraordinarily smart respondents, most versed in an uber sub-specialty under scrutiny, who can afford excellent legal counsel



- **FIND YOUR OWN FOUNTAIN/S OF KNOWLEDGE! AND CLOAK THE SCENE WITH YOUR LEGAL COUNSEL'S ADVICE – AS LONG AS IT WILL NOT CAUSE YOU TO WEEP LATER!**
- Engage formally **experts in the relevant science or scientific evidence interpretation**, when needed (consider carefully external vs. internal)
- Develop a strategy with your institutional counsel on **the best method to communicate with the opposing counsel** (and stick to that strategy to the extent possible)
- If your in-house counsel lacks in skill, resources, or time to adequately advise you, **engage outside counsel if the stakes merit** additional legal support



15

15

### 4. Avoiding lawsuits while correcting scientific literature or providing mandatory reports



- **IT'S A BALANCING ACT ON A STEEP HILL FILLED WITH OBSTACLES!**
- **Challenges unique to corrective actions in research investigations:**
  - **Correcting scientific literature** can lead to either overt or inadvertent revelation of who is at fault
  - **Thesis and degree rescissions** directly impact **livelihood** which **makes it imperative to give proper due process under institutional investigatory procedure throughout the research-related investigation**
- **Common pitfalls while correcting scientific literature or providing mandatory reports:**
  - breach of privacy/confidentiality,
  - defamation,
  - interference with business and/or contractual relations, etc.



16

16



#### 4. Avoiding lawsuits while correcting scientific literature or providing mandatory reports



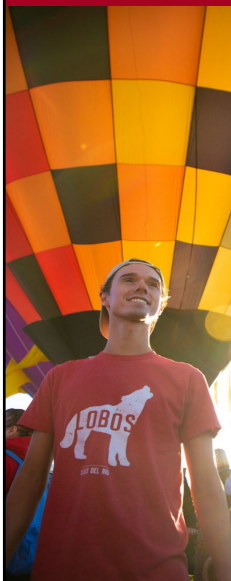
- **BUT REMEMBER THAT YOU CAN STILL CONTROL THAT BIKE!**
- Do not notice or report to any external institutions until **your language and approach has been vetted** by capable institutional **counsel**
- **Then run language by public relations**
- **Notify the relevant leadership** of the impending notices and consult them about the plan and the impending notice and report actions
- Do not let anyone interfere with your ability to carry out **your unequivocal duty in implementing the mandatory portion of notices and reports** that are **within your purview**
  - **Refrain from using external email addresses to reach respondents**
    - If a respondent does not have an email account issued by your institution, **use external emails as the last resort only, after establishing absence of better alternative**



17

17

#### 5. Findings can lead to **criminal penalties, permanent disbarment, treble damages** up to 3x actual or compensatory damages



- **ENGAGE A SPECIAL MEMBER OF THE CREW TO LEAD YOU THROUGH PROPER LANDING OF THE BALLOON!**
  - Same messages as in slide no. 9 on Legal and Procedural Complexities, re: attorney engagement and access...
- PLUS
- **Strategize with your in-house attorney/s**
    - If they cannot provide business or strategic advice, **read rules of professional conduct by the cognizant Bar Association/licensing authority with jurisdiction over your institution** to verify whether your legal counsel is so restricted
      - [Note: **attorneys could be ignorant of the fact** that the relevant licensing authority's rules encourage or even mandate that strategic and/or business counsel be a part of legal advice (this can be especially true of attorneys who are licensed in multiple jurisdictions).]



18

18

## 6. Many sponsors and many subject matter areas



- **ALTHOUGH ALL OFFICE SPACES OF THE BUILDING SEEM EQUALLY PRIORITIZED AND COMFORTABLE, THERE ARE ALSO COMMON SPACES THAT CAN USE MORE ATTENTION!**

### **PROBLEM:**

- Investigations can involve **many sponsors and many subject matter areas**;

*Hypothetical Example:*

**1 set of allegations** can invoke

**6 different investigatory regimes for just one issue** (falsification and fabrication of research results),

PLUS **there are usually additional issues** such as:

hostile behavior, physical attacks, authorship disputes, intellectual property ownership, intellectual property licensing, undue foreign influence, conflict of interest...

ON TOP OF WHICH

=> **One area of allegations alone**

[for example, conflict of interest (COI)]

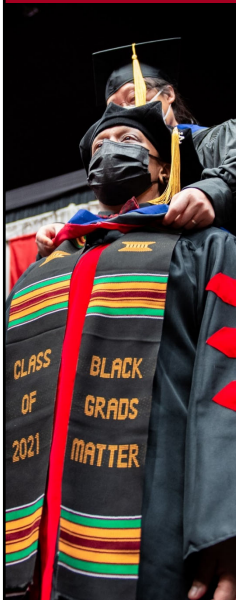
**can invoke multiple compliance areas and investigatory processes**

[based on purchasing & procurement laws, contractual obligations, COI in research, COI in academics, COI in start ups... ].



19

## 6. Many sponsors and many subject matter areas



- **THIS PHOTO SPEAKS FOR ITSELF AND I AM INCLUDING IT FOR ITS LITERAL/PLAIN TEXT MEANING!!**

### **SOLUTIONs to slippery slope no. 6:**

Same messages as in slides on Legal and Procedural Complexities

### **PLUS**

- Following conclusion of the investigation and appropriate institutional determinations, there is **additional need for some coordination** in addressing  
corrective measures,  
sanction implementation,  
literature correction,  
notices, etc.,

to **preclude diffusion of responsibility or other detrimental assumptions**, among other things.

- **For inter-institutional situations:** Although exchange or vetting of language is likely a stretch, there should be **at least discussions about the timing** to preclude surprises and inform appropriate parties within your institution and under your investigation process, **and to properly coordinate where needed.**



20

## 7. Complications associated multiple independent institutions doing simultaneous investigations



- **WAIVE YOUR (INSTITUTION'S) BANNER LIKE IT IS FOR THE PROUD, NOT THE SHROUD!**
- Common PROBLEMS:
  - **joint appointments** among the institutions with **competing jurisdictions and policies**,
  - **spaces to sequester across institutions** with mutually exclusive investigation processes
  - **competing missions...**

SOLUTIONS:  
Same tips as in previous slides  
**PLUS**

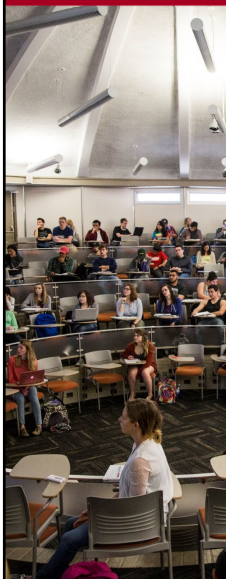
- When possible, **evaluate the best approach**: simultaneous investigations vs. consolidated investigation that accounts for unique institutional factors at appropriate trajectories (an important consideration to mention *albeit* an advanced one that needs much more time)
- **Factor in implications of public transparency laws** such as FOIA or IPRA



21

21

## 8. Multiple decision makers within each institution which may include committees and panels as decision makers



- **EVEN WHEN ALL EYES ARE SEEMINGLY ON YOU AND YOU ARE IN THE MAIN FOCUS, YOU CANNOT AND SHOULD NOT DO IT ALONE!**
- If **supporting the decision makers and/or committees**, ensure they understand adequately at the minimum: their **charge, elements and defenses, mitigating factors, availability and appropriateness of sanctions, and timelines for decisions and appeals**
- **Standardize** via templates **but always review through the prism of the specific situation** prior to deploying each correspondence that you are responsible for
- Although **committees** are hard to convene and run, they play a super **important role by objectifying the decision-making process** - if managed correctly, they **infuse additional integrity** into the research-related investigation
- If dealing **with different decision-making panels across institutions**, consider (upon your legal counsel's approval) **cross-appointing members** as appropriate



22

22

- 2. How to anticipate/expect the unexpected
- 3. Preparing for public scrutiny caused by the investigation



➤ **DISPERSED ACROSS COMMON THEMES, REFRAMED AND SUMMARIZED below:**

- Collaborate with appropriate parties and with your legal counsel (vital)
- Apply rules consistently to the extent possible
- Bring co-investigators into the picture if you must and share their expertise on their policies and processes
- Take charge if you must in order to properly coordinate and avoid pitfalls, within and across institutions
- But don't substitute for expertise of others
- Coordination is pivotal in early stages
- Don't let lawyered-up parties shake you up – be concerned with your own work and proper engagement of various stakeholders instead
- Keep in close contact with your attorney and extract adequate counsel if you must
- Find common denominators to simplify procedure, both intra- and inter-institutionally
- Coordinate and communicate and don't be afraid to take charge where appropriate!



23

23

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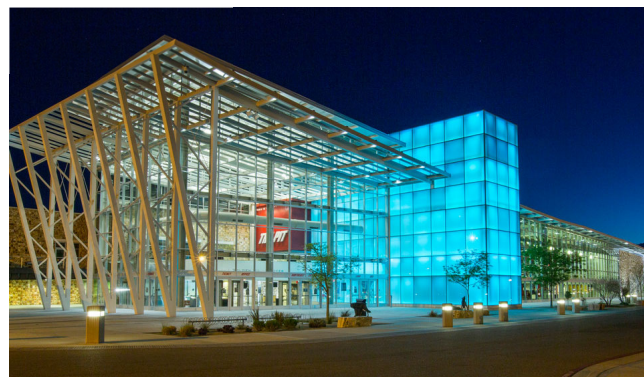
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Any Follow-up Questions?

Contact me!



24

24

NMI OFFICE OF RESEARCH  
INTEGRITY & COMPLIANCE

# THANK YOU!

Questions?

