Wish I Had Known That a Year Ago:

Lessons Learned in the Midst of Conducting a Research Misconduct Inquiry and Investigation

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Session Objectives

- Provide regulatory guidance on misconduct proceedings and information related to conducting inquiries and investigations of research misconduct.
- Discuss mistakes to avoid and best practices to become more prepared to take on a Research Misconduct Inquiry and Investigation.
- Review steps to be prepared before getting the dreaded "I think we have a problem" call.
- Outline tips for encouraging a culture of integrity and compliance at your institution.

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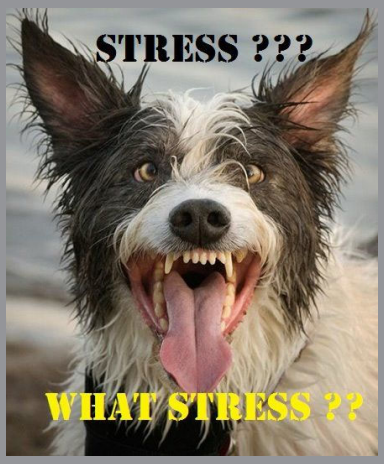
Our story….

- It was a sunny day in January…



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Poll

- Have you ever been involved in a research misconduct inquiry or investigation?
  - Yes
  - No

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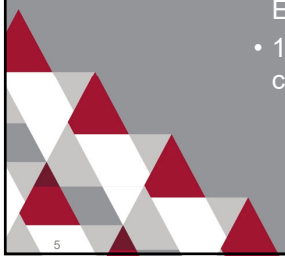
Federal Regulations on Research Misconduct

- **42 CFR Part 93 - Public Health Service Policies on Research Misconduct**
- **45 CFR Part 689 – National Science Foundation Policies on Research Misconduct**
- Federal Policy on Research Misconduct at 65 Federal Register (FR) 76260 (December 6, 2000) – applies to other federal agencies including the Office of Science and Technology Policy, the Environmental Protection Agency, Veteran's Health Administration
- 14 CFR Part 1275 – National Aeronautics Space Administration's codification of the Federal Policy on Research Misconduct



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Parties in a Research Misconduct Case

- The Complainant is the person who makes an allegation of Research Misconduct.
- The Respondent is the person against whom an allegation of Research Misconduct is directed.

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Parties in a Research Misconduct Case

- The Research Integrity Officer (RIO) is the institutional official who is responsible for handling allegations of research misconduct.
- The Deciding Official (DO) is the institutional official who makes final determinations on allegations of research misconduct and any institutional actions. The DO will not be the same individual as the RIO and should have no direct prior involvement in the institution's misconduct proceeding.

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What Is Research Misconduct?

As defined by the Office of Research Integrity:

Research Misconduct is Fabrication, Falsification, or Plagiarism in proposing, conducting, or reviewing research, or in reporting research results

42 CFR 93.103

(Honest error or honest differences in opinion are not research misconduct)

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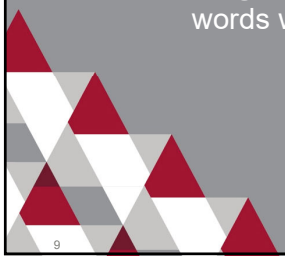
FFP Definitions

- **Fabrication** – Making up data or results and recording or reporting them.
- **Falsification** – Manipulating research materials, equipment, or processes, or changing or omitting data or 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.



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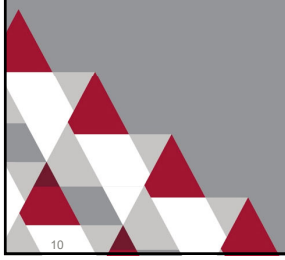
Research Misconduct Findings

A finding of research misconduct requires that:

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



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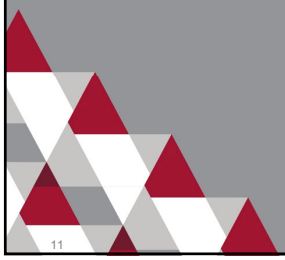
Significant Departure from Accepted Practices

Consider the practices within the discipline or field of the Respondent and also the experience of the Respondent. Should he/she have known what the standards and practices of his/her field are, and did he/she deviate from those standards and practices?



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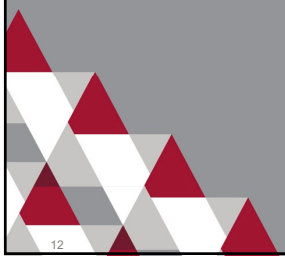
Assessment of Intent

Remember that in order for there to be a finding of misconduct, there must be a determination that the act was done intentionally, knowingly, and/or recklessly.

This can be one of the most challenging aspects of a misconduct proceeding. Be sure to review these points with your Investigation Committee for every allegation, and document those assessments.



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Assessment of Intent

Reckless: The person did not exercise the care a reasonable person in the same situation would have exercised, and he/she did so with a conscious awareness of, or indifference to, the risk of adverse consequences and potential resulting harm.

Knowing: The person had an awareness or understanding of his/her actions, or should have known. The person acted consciously or deliberately.

Intentional: The person acted with a specific purpose in mind; the person acted with the purpose of committing the misconduct.

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Steps for Handling Allegations of Research Misconduct

- Assessment of Allegations
- Inquiry
- Investigation
- Institutional Decision
- Reporting to Federal Agencies

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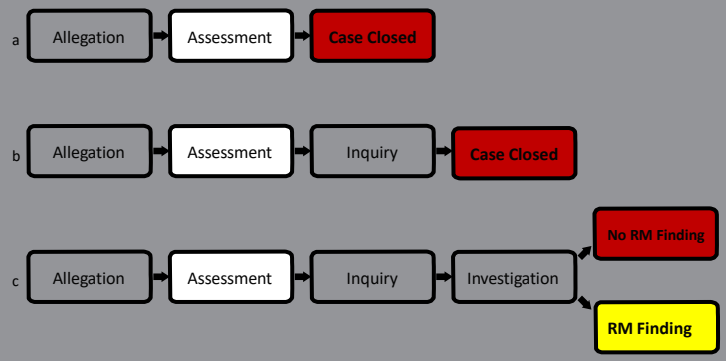
Possible Paths



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Do the Respondent's actions appear to constitute Fabrication, Falsification, or Plagiarism?

YES

NO → No misconduct finding

Do the actions represent a significant departure from accepted practices?

YES

NO → No misconduct finding

Did the Respondent commit the actions intentionally, knowingly or recklessly?

YES

NO → No misconduct finding

Are the actions proven by a preponderance of the evidence?

YES

NO → No misconduct finding

Research Misconduct Finding

Adapted from Tulane Policy provided by Lisa Wurtzel

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Prepare in Advance

- Policies should be in place long before you have an allegation.
- Do not wait until you have an allegation to mobilize.
- Review Office of Research Integrity website regularly - https://ori.hhs.gov/.
- Know your Research Integrity Officer and build a relationship with him/her.
- Delineate duties (if possible).

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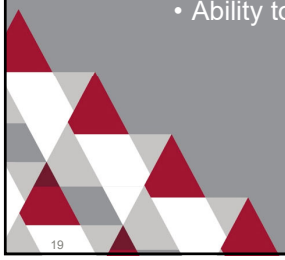
Policy Considerations

- Review ORI website for sample policies
- Involvement of your General Counsel – are they informed on misconduct regulations?
- Involvement of Respondent's Counsel
- Conflict of interest
- Confidentiality
- Sequestration of data and storage of sequestered data
- Timelines
- Ability to request and likelihood of receiving extensions



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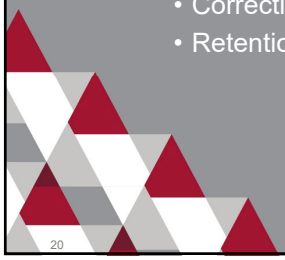
Policy Considerations Continued

- Responsiveness of Respondent – expected to respond to committee requests and be cooperative throughout inquiry and investigation
- Protection from retaliation for Complainant and all other parties
- Protection of public health, research subjects, state and federal resources, etc.
- Deciding Official
- Appeal Process
- Termination or Resignation of Respondent prior to resolution – proceeding continues
- Correction of scientific record if misconduct is found
- Retention of all relevant evidence and documentation from misconduct proceedings



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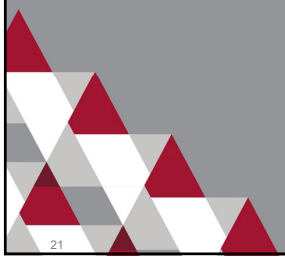
Create Checklists/SOPs

- Allegation procedures checklist
- Inquiry procedures checklist
- Investigation procedures checklist
- NOTE: Consult regulatory guidance and your institutional policies



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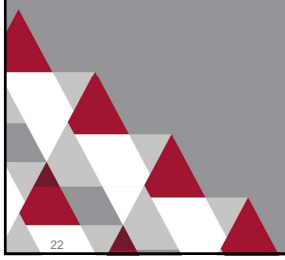
Mistakes to Avoid - Sequestration

- Sequestration of evidence/records after notification of allegations – risk evidence being destroyed or disappearing.
- Improper electronic sequestration – involve IT and ensure they can make forensic copies so that there is a proper trail of when the records were created and changed.
- Obvious sequestration which could violate confidentiality requirements – the process is confidential and therefore sequestration should also be confidential.



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Sequestration

- Create an SOP and follow it.
- Review process with interested parties (general counsel, campus police,…).
- Consider data storage and data ownership – make sure both are addressed in your policies.
- Start process early – complete sequestration before or at time of notification of allegations.
- Respondent should not know about the allegation(s) before sequestration happens.
- Remember that the process is confidential.
- ORI is developing guidelines – watch for these and incorporate them into your SOP.

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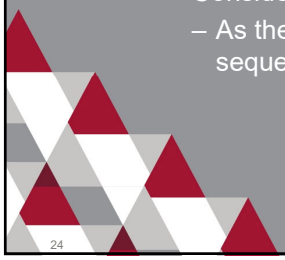
Sequestration: Go Early-Go Big

- All data and electronic files related to the allegation(s) should be sequestered before the inquiry begins.
- Work with IT department to sequester electronic files (emails, data files, images, statistical analyses, manuscripts, etc.) . Need a forensic image of electronic files that can be retained and sent to ORI at completion of the investigation.
- Respondent should not be aware of electronic sequestration.
- May have to involve/inform Respondent for hard copy data sequestration.
- Consider whether anyone else should be included in the sequestration.
  - As the case and interviews proceed, you may discover other records that need to be sequestered. Follow same process/procedure to the extent possible.



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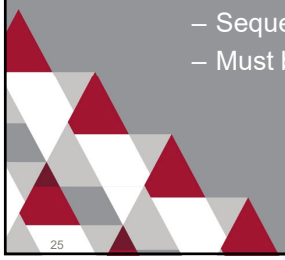
Sequestration: Go Early-Go Big

- Keep an inventory of all sequestered items.
- Get sign-off from person whose records were sequestered and give them a copy of signed inventory.
- Document well – whose, what, when
- Consider how you will store sequestered items
  - Large envelopes for storing documents and slides??
  - Dedicated file cabinet??
  - Sequestered items must be stored in a secure place with limited access.
  - Must be retained until process is complete with ORI – could take years!



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Who is on the team??

- Research Integrity Officer (RIO)
- RIO Support
- General Counsel
- Security/Campus Police
- Sponsored Programs Offices
- IRB or IACUC if applicable
- Conflict of Interest
- Human Resources
- Employee Assistance Program (EAP)
- Student Affairs/Registrar's Office (if students are involved be aware of FERPA)
- Respondent's Department Chair or Dean
- Deciding Official (DO) and Executive Management

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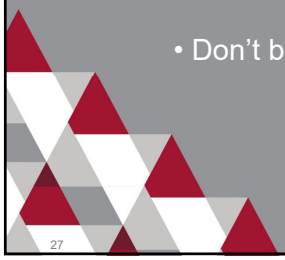
Building Relationships

- What is your relationship with your Research Integrity Officer (RIO)?
- Do you have a working relationship with your IT Security department?
- Do you have a working relationship with your Office of Sponsored Programs?
- Can you reach out to colleagues at other institutions?
- Are you involved in any professional organizations that have resources?
  Association of Research Integrity Officers -ARIO
  www.ariohq.org

- Don't be afraid to communicate with NIH, ORI, NSF….



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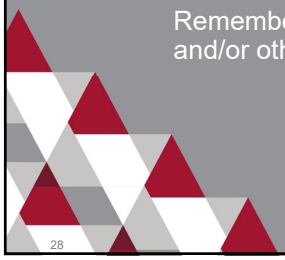
Other Relationships

- University Communications Department
- Export Control Officer
- Facility Manager and/or Security Officer
- Title IX Coordinator
- Dean of Students/Student Affairs
- Thesis Committee
- Postdoctoral Fellow Office

Remember that you may need to ensure support for the Complainant, Respondent, and/or other parties to the proceeding in addition to getting assistance with the process.



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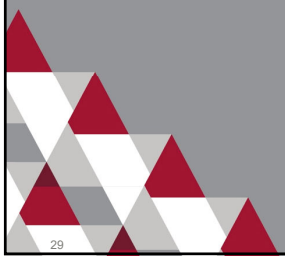
Committee: Who will serve?

- RIO convenes the committee.
- Committee members should have subject matter expertise.
- Be aware of the large time commitment.
- Training for committee members on federal regulations and campus policy.
- Will you have a standing committee or an ad hoc committee for each case?
- Will you use the same committee for both the inquiry and the investigation?



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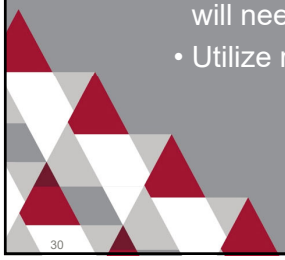
Committee Training

- Committee Charge
- Conflict of interest disclosures
  - Respondent must be given opportunity to review and approve potential committee members.
  - Committee members must declare any conflicts of interest.
- Confidentiality agreements
- Don't assume that committee members know and understand RM regs – they will need training and constant reminders to stay within the regulations/policies.
- Utilize resources on the ORI website.



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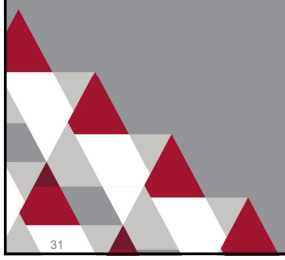
Evaluation of Evidence

- How will you organize and present the evidence to the committee?
- Keep confidentiality and FOIA in mind!
  - Limit use of email correspondence.
  - A dedicated Box Account and /or encrypted flash drives can help.
- Will you need subject matter experts or consultants?
- Will you need to purchase additional software for image analysis?



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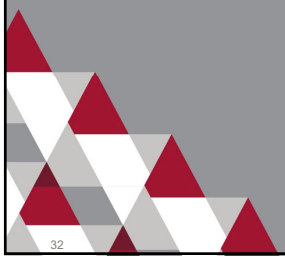
Confidentiality

- Confidentiality cannot be stressed enough.
- All committee members should sign a confidentiality agreement.
- Anyone involved in the inquiry or investigation process must sign a confidentiality agreement.
- **Reputations must be protected.**



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Points to Consider in Conducting Interviews

- Who needs to be interviewed? How will you communicate with them, keeping confidentiality in mind?
- Start scheduling early. This takes time and you have deadlines.
- All parties must sign confidentiality agreements.
- If students are involved, consider FERPA regulations.
- How will you record the interview proceedings?
- How will you create transcripts?
- Respondent must be allowed to review transcript of his/her interview.
- Can the respondent include their attorney in the interview?
  - What does your policy say?

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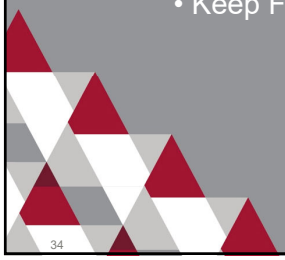
Tips for Conducting Meetings and Interviews

- Document committee meeting minutes and interviews as soon as possible.
  - Record all interviews and meetings or use a court reporter.
  - Review tapes as soon as possible after the fact to make transcription easier.
  - Be sure to send recordings and/or transcription from each interview to the interviewee for review and comment.
  - Be sure to send recordings and/or draft transcription from Respondent interviews to the Respondent for review and comment.
- Keep FOIA in mind.



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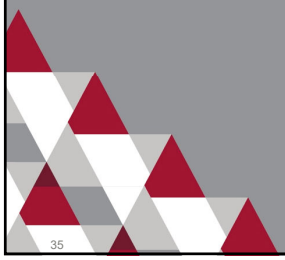
Mistakes to Avoid - Meeting Minutes

- Waiting too long to record committee meeting minutes
  - Tip: Record all committee meetings and transcribe as soon as possible following the meeting
  - Tip: Send draft minutes to all committee members for review
- Documenting too many details in minutes
  - Tip: Keep FOIA in mind
  - Tip: Make minutes concise and de-identified as much as possible



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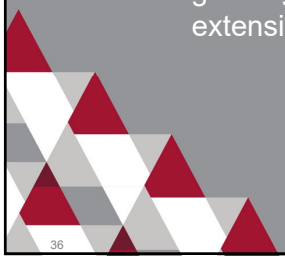
Deadlines and Timelines

- Always be aware of upcoming deadlines.
- Have a timeline with goals to ensure that you meet the deadlines.
- Remind committee of deadlines, but be prepared for committee frustrations.
- Don't be afraid to ask for extensions from regulatory agencies.
- Be sure that your policy allows for extensions.
- Document reasons for the extensions as well as agency correspondence granting these extensions – the Respondent is likely to take exception with extensions.



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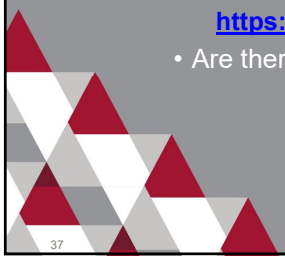
Other Things to Consider

- How far back does the review go? Regulations give a 6 year time frame, but there is an exception if the questioned work references earlier work (42 CFR §93.105).
- You must investigate fully to determine the extent of any misconduct (42 CFR §93.310(h)).
- Is the questioned work part of a current, federally funded grant or agreement?
- Should the federal funding agency be notified and when?
  - See NIH guidance NOT-19-020 "Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH" at **https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-020.html**.
- Are there False Claims Act considerations?



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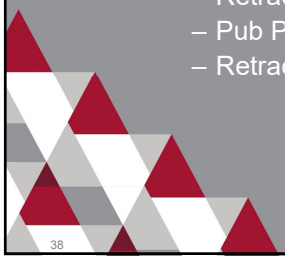
Publications: What to do?

- Determine which publications are impacted by the misconduct.
- Do publications need to be retracted or should an expression of concern be filed?
- How soon should journals be contacted in order to correct the scientific record? Keep confidentiality in mind – don't contact journals too soon.
- Who will contact journals if Respondent refuses to do so?
- Be aware of retraction related websites:
  - Retraction Watch
  - Pub Peer
  - Retractiondatabase.org



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Writing the Reports

- Engage all members of the Inquiry and Investigation Committees in writing those reports.
- Be sure that each allegation and the finding on each allegation is addressed in the Investigation report.
  - Each finding must include what the misconduct was (FFP), who committed the misconduct, whether the misconduct was committed intentionally, knowingly, and/or recklessly, and that the preponderance of the evidence proved the misconduct.
- Also be aware of timelines.
  - Allow time for committee member review.
  - Respondent to review draft Investigation report and submit comments.
  - DO to review and accept or require changes to the Investigation report.
- Keep FOIA in mind.

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Research Misconduct is not…

- Authorship disputes
- Misuse of grant funds
- Data management issues
- Failure to properly disclose conflicts of interest
- Lack of rigor or reproducibility in research
- 'Toxic culture' / Supervision issues
- IRB / IACUC / IBC non-compliance
- Sexual harassment
- HR issues

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It's Not Misconduct but It's Not Okay…

If an allegation is determined to not be research misconduct, it could be **Detrimental (or Questionable) Research Practices (DRPs or QRPs)** – these stray from the norms and appropriate practices of science and may need to be dealt with through the institution's faculty or employee disciplinary processes.

- Do you have policies that address behaviors that don't meet the definition of research misconduct?
- If not, how will you deal with these issues?

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Tips From Friends

- When possible, verify the information received from the Complainant, Respondent and witnesses.
- Misconduct cases can at first appear to be sloppiness, honest errors, discord between researchers, differences of opinion, etc. Look into the data anyway to confirm there is no clear sign of FFP at the beginning.
- If something looks too good to be true, it's probably not true. The corollary, if someone's research results look much better than anyone else working in the field (or that person is the only one who can "get things to work"), a review of their methods/data may be a good idea.
- If a lab or core service group depends on only one person to perform a special procedure, someone else should be reviewing the data. A single unsupervised person may do great work, but also would not be caught cutting corners.

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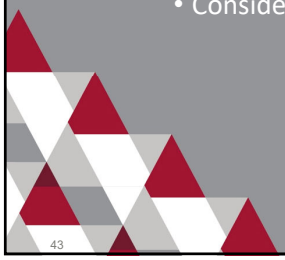
Tips From Friends

- It is not uncommon for misconduct cases to also involve non-compliance in another area (such as financial or COI) – the corollary of this also means that if a researcher is substantially non-compliant in one or more other areas, you may want to think about checking their research data.
- Document all steps in the review process, even calendar scheduling with committees, respondents, complainants. Print/save emails.
- Hire a court reporter to record interviews.
- Consider the impact of Faculty Bargaining Agreements.



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Tips from Friends

- Be aware of conflicts of interest and don't use faculty members from Respondent's department as committee members.
- Remember the NIH "statute of limitations" and make sure that your policy is in agreement with this statute, but also be aware of exceptions.
- Consider how you will deal with the media and FOIA requests.
- Avoid emails containing sensitive information.
- Work with counsel's office to identify things that are confidential/privileged and mark them as such.
- Reports should be written in a manner that makes them easily redacted.

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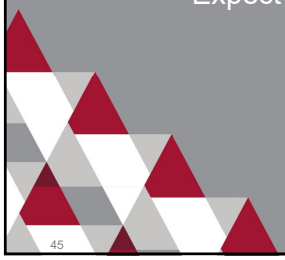
More Tips From Friends

- Review your policies often and make sure that you follow them.
- Consider RM education for HR and Title IX Coordinator.
- Create a general information sheet for the Respondent.
- Mental health of the individuals involved is something to keep in mind; everyone should be given information about the available resources if they may need to talk with someone or seek help.
- Expect lawsuits.



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Ensure Culture of Integrity

- Encourage a culture of integrity "Top to Bottom"
- Tone at the Top is very important – make sure it is shared often
- Increase RCR training
  - Try to make the training convenient to the audience
  - Attempt to meet/train department chairs and upper administration
  - Implement RCR training for all faculty
  - Ensure graduate students also receive RCR training

"Values first. Logic and data second." - Bruce A. McPheron, PhD, Executive Vice President and Provost, The Ohio State University

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Us at the end of the investigation….

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We'd Love to Hear From You!

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