

Cardinal Sin in Research: Research Misconduct

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Agenda

- Why Should We Care?
- Regulatory Context
- Inherent Challenges
 - Be Prepared
 - Whose Responsibility is it
 - Knowledge and Communication
 - Coordination of Investigation
 - Does the Misconduct Impact Subjects?
 - Timeline for Each
 - Conflicting Conclusions

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Why Should We Care?

- Because We Have To!!
 - The regulations require that we do
 - Avoid problematic newspaper stories
- Because We Should!!
 - ◆ In 1998, a study linking the measles, mumps and rubella (MMR) vaccine to autism in children appeared in a respected medical journal. For a decade, the study grabbed headlines worldwide. Worried parents rejected the life-saving vaccine for their children and those with autistic children agonized that they allowed an injection that caused the condition.
 - ◆ But the vaccine-autism research was a fraud. The paper was retracted 12 years later, denounced as an elaborate deception.

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Why Should We Care?

- Former physician and researcher at Duke falsified data related to decoding the genetic makeup of tumors. (Anil Potti, MD)
 - Claimed that he created genomic technology that would predict with up to 90 percent accuracy which lung cancer patients were likely to have a recurrence and therefore benefit from chemotherapy.
 - Designed and opened three clinical trials to match chemotherapy to tumor genetics.
 - Enrolled approximately 100 patients.
 - Multiple retracted papers (including NEJM, JAMA, Lancet, Nature).
 - In 2012, 60 Minutes called it “one of the biggest medical research frauds ever.”

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Regulatory Context

- Research Misconduct
 - Office of Science and Technology Policy
 - <https://ori.hhs.gov/federal-research-misconduct-policy>
 - DHHS: Public Health Service Policies on Research Misconduct
 - Office of Research Integrity
 - https://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_200_5.pdf
 - Other agencies

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Regulatory Context

- ◆ Research Misconduct
 - ◆ Definition
 - ◆ Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
 - ◆ And
 - ◆ 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 the evidence.

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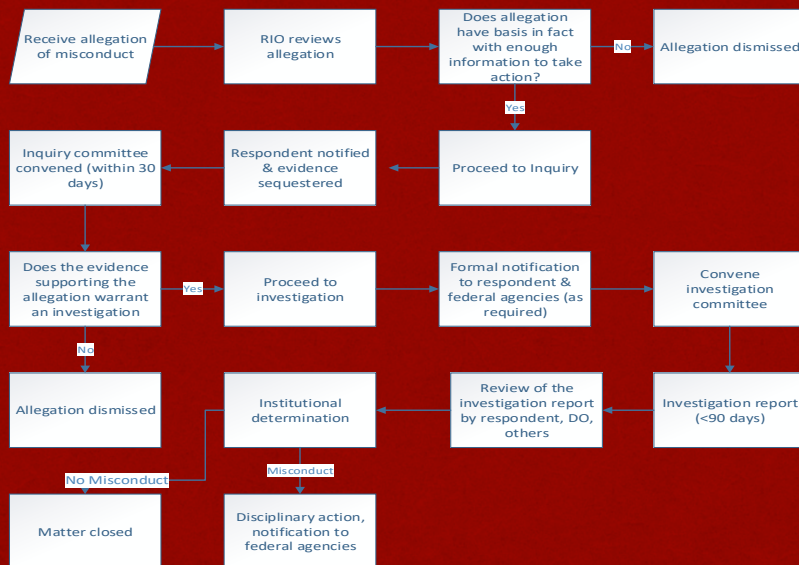
Discussion Points



“I always thought that my level of scientific misconduct was well within the community standards.”

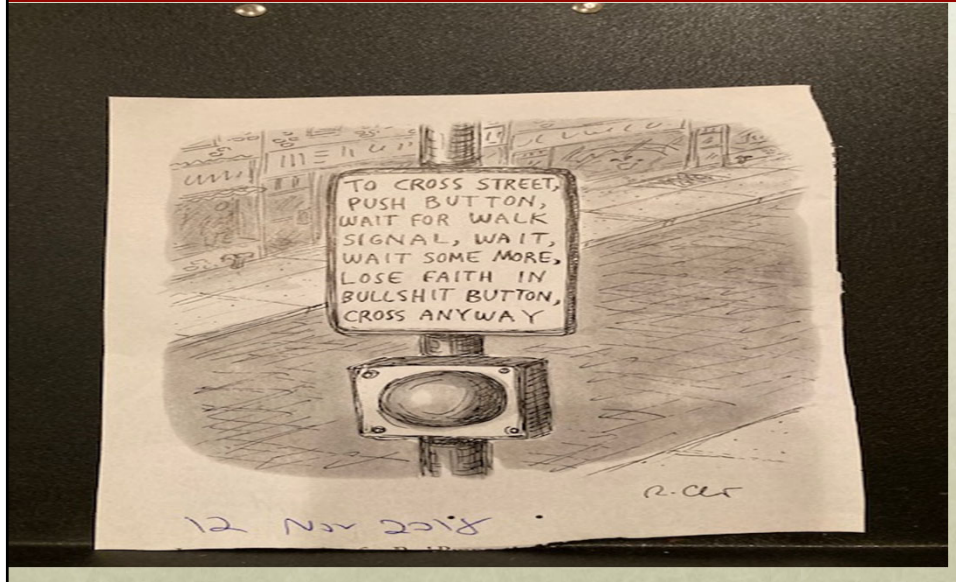
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Misconduct Process



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Regulatory Context



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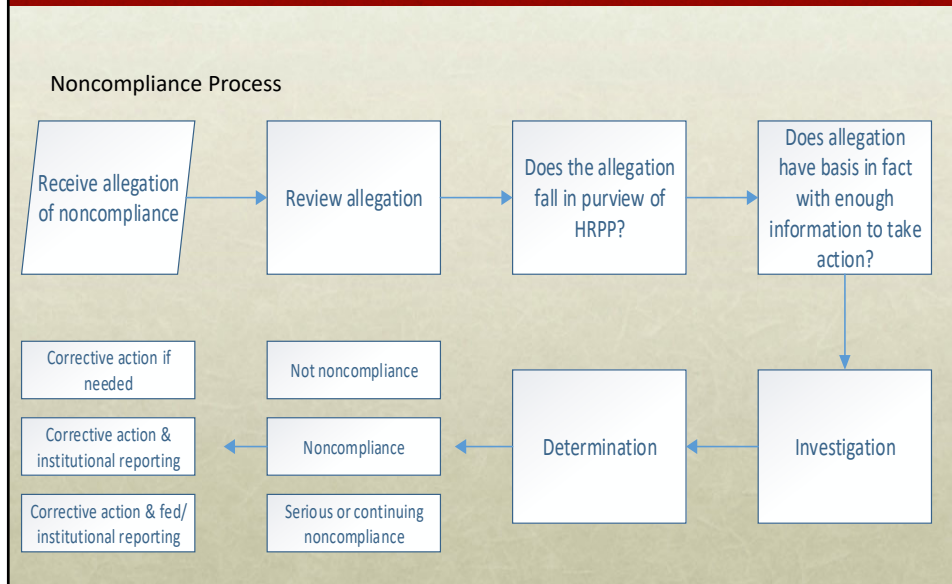
Twice as Bad: RM and Non-compliance

◆ Definition

- ◆ Any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with federal or state regulations, requirements of VHA Directive 1200.05, or institutional policies governing human subjects research or the requirements or determinations of the IRB. See also:
 - minor noncompliance
 - continuing noncompliance
 - serious noncompliance
 - <https://research.iu.edu/policies/human-subjects-irb/policy-definitions.html>
 - <https://research.iu.edu/policies/human-subjects-irb/reportable-events.html>

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Twice as Bad: RM and Non-compliance



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Twice as Bad: RM and Pay-back

- ◆ While relatively uncommon, not infrequently
 - ◆ Institution must return funds to sponsors
 - ◆ Mostly because of 'unallowable costs'
 - ◆ Generally happens because
 - ◆ Sponsor conducts an audit
 - ◆ Sponsor directs third party to conduct audit
 - ◆ Occasionally through self report (or at least less broadly known)
- ◆ Our Topic: Similar but Different
 - ◆ One the one hand
 - ◆ Matter of paying back due to 'unallowable costs'
 - ◆ But, on the other
 - ◆ Result of entirely different processes
 - ◆ Self report by in institution following
 - ◆ Finding of research misconduct

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Twice as Bad: RM and Pay-back

- ◆ After Determination of Research Misconduct
 - ◆ Report to sponsor and if federally funded, ORI
 - ◆ Detailed discussion of allegation(s) of misconduct
 - ◆ Detailed discussion of basis for determination of misconduct
 - ◆ Allegation by allegation
 - ◆ Detailed discussion of next steps
 - ◆ Sanctions
 - ◆ Correcting research record
 - ◆ Retractions
 - ◆ Consider if it may require payback
 - ◆ Sort of include this in report

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Twice as Bad: RM and Pay-back

- ◆ What Does Consider If Payback Is Required Mean
 - ◆ Requires interaction of research compliance and research administration, at the minimum
 - ◆ May also require (usually requires) involvement of:
 - ◆ Academic unit leadership
 - ◆ General Counsel's Office
 - ◆ Determine the extent to which, after misconduct determined
 - ◆ Did the research/researchers produced the research that they were funded to do
 - ◆ Sometimes a matter of when in the research process was it discovered and addressed
 - ◆ Research still under way
 - ◆ Research completed/published

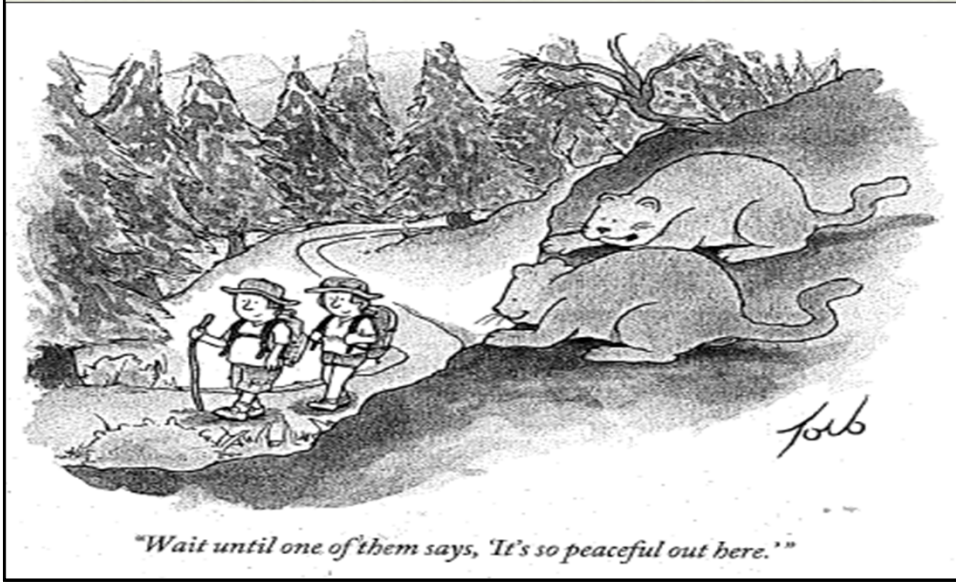
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Inherent challenges

- Be Prepared
- Whose Responsibility is it
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Inherent challenges: Be Prepared



Inherent challenges: Whose Responsibility

