

# Opportunities and challenges in research misconduct proceedings, an ORI's perspective

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**OASH**

Office of the  
Assistant Secretary  
for Health



# Disclosure

The opinions presented here are mine and does not reflect that of the Office of Research Integrity (ORI) and/or the Office of the Assistant Secretary of Health (OASH). I have no financial disclosures or incentives to declare. I have not actual or potential conflict of interest in relation to this program/presentation.

Established 1992

## MISSION

ORI's mission is to advance research integrity, protect taxpayer funds for Public Health Service-supported research, and support research integrity communities.



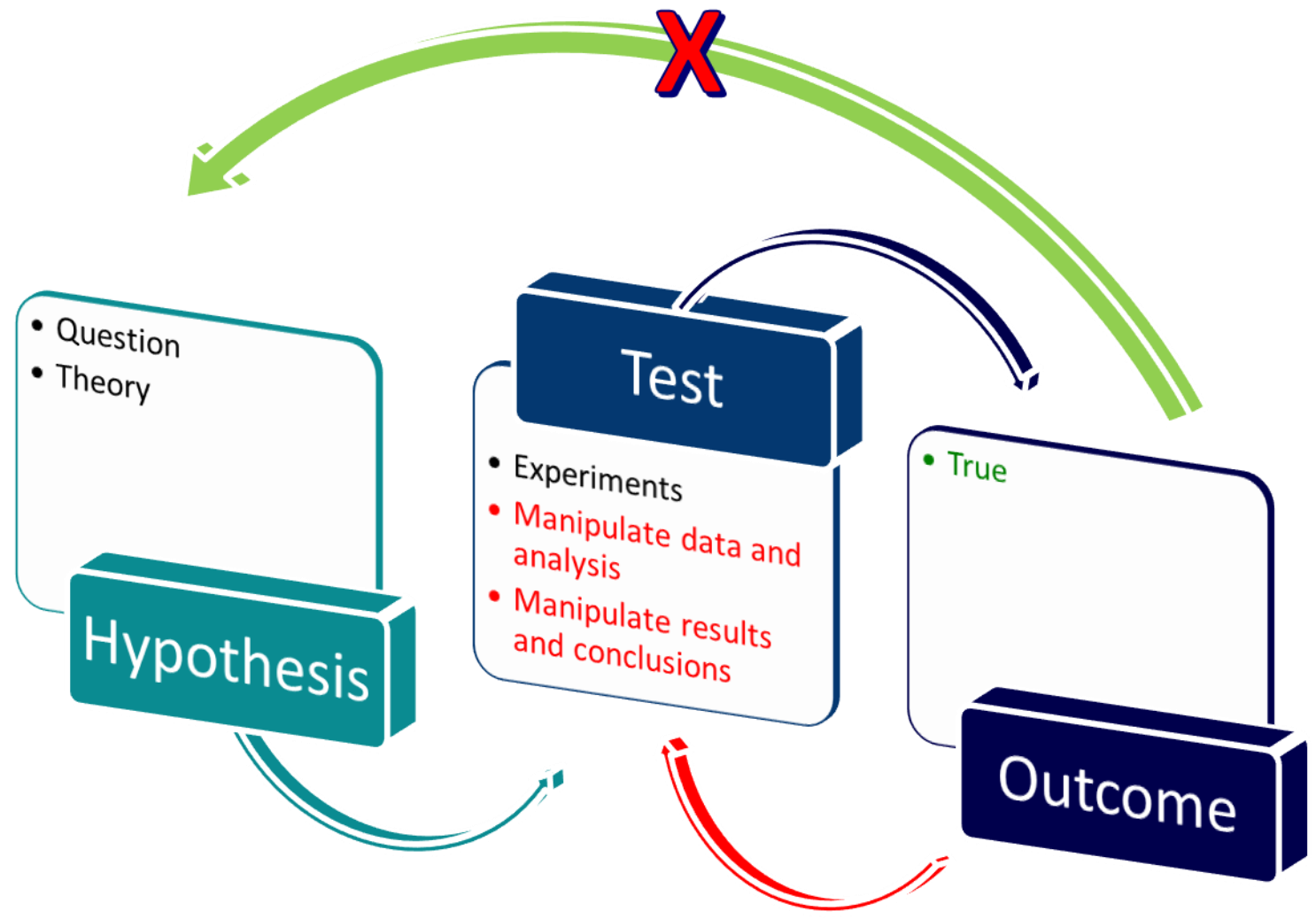
## Code of Federal Regulations

A point in time eCFR system



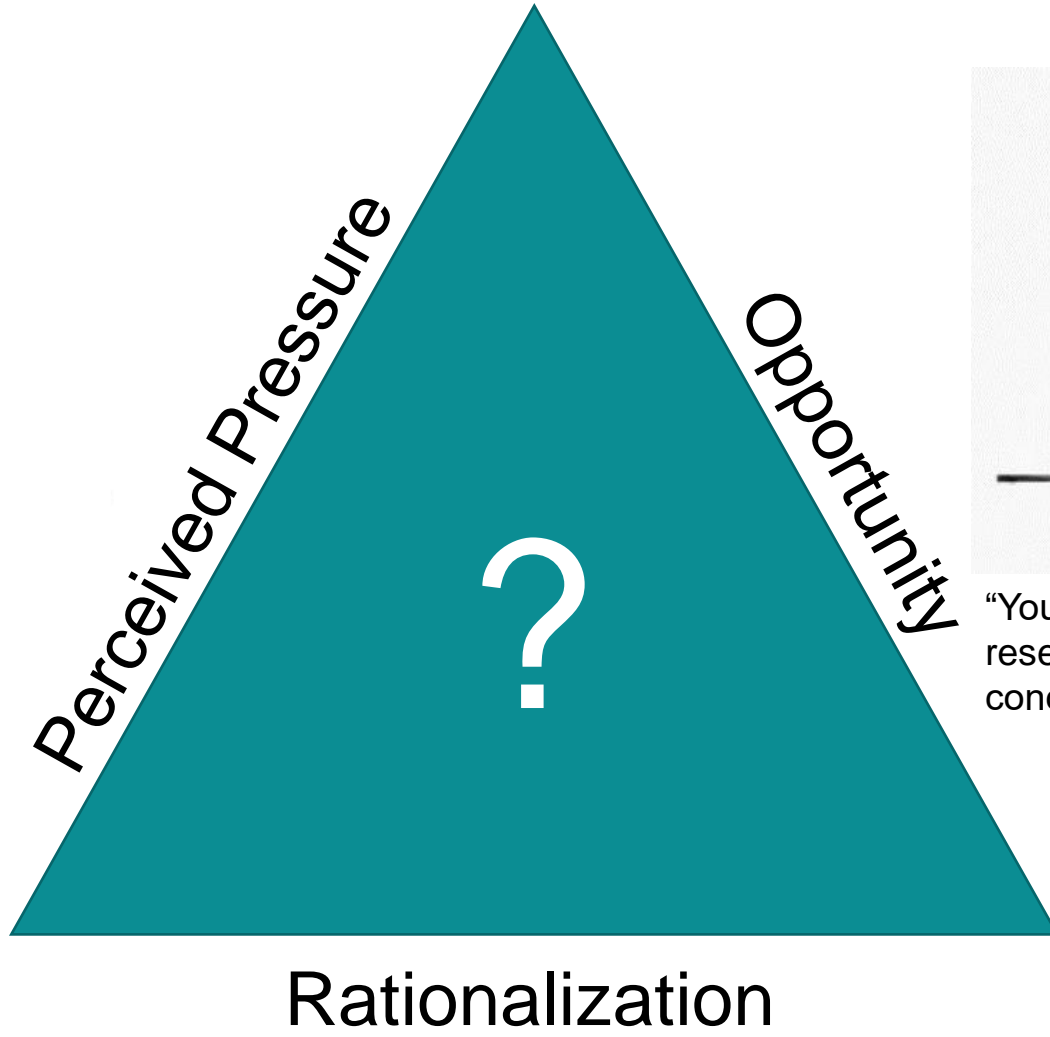
### **Title 42 Part 93: Public health service (PHS) policies on research misconduct**

Applicable to **PHS-supported biomedical or behavioral** extramural or intramural research, research training or activities related to that research or research training  
(§ 93.102)



Hypothesis...experiment...conclusion.  
Wow. This is so last century.

**Respondent:** Person alleged to have committed research misconduct



“You are completely free to carry out whatever research you want, so long as you come to these conclusions.”

<https://www.pinterest.com/pin/research-integrity--346003183841167710/>

*Adapted from Cressey's Fraud Triangle*

## 42 C.F.R. §93.103 and §93.104

**Fabrication**

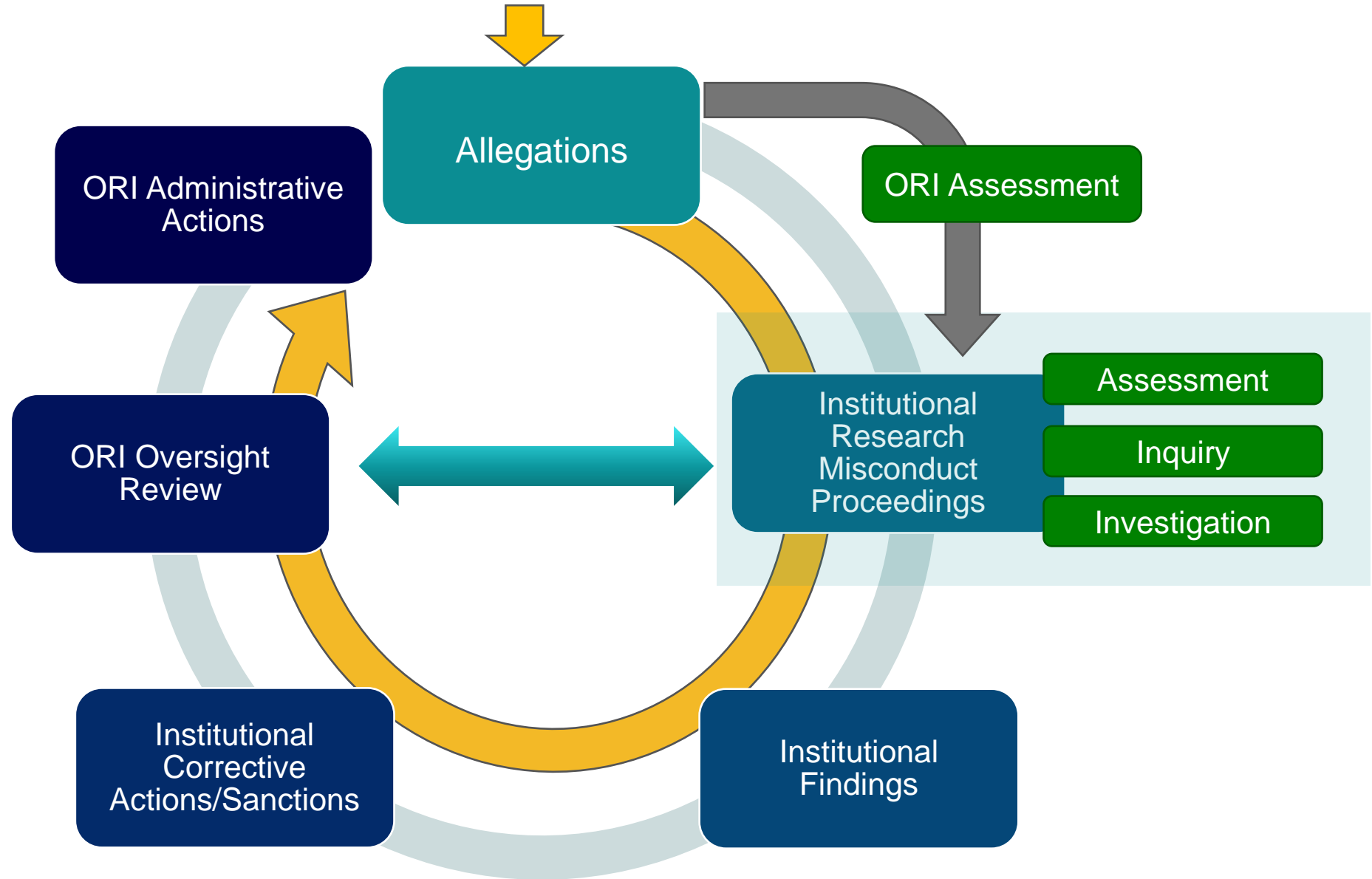
**Falsification**

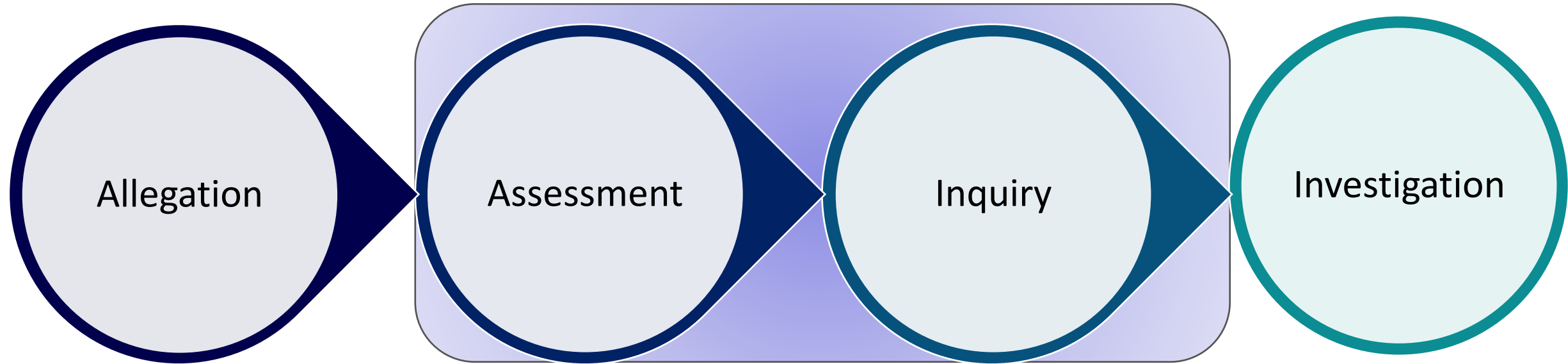
**Plagiarism**

...in proposing, performing, or reviewing research, or in reporting research results.

- ✓ Committed intentionally, knowingly, or recklessly
- ✓ A significant departure from accepted practices
- ✓ Proven by a preponderance of the evidence.
- ✗ Honest error
- ✗ Collaborator/Author dispute
- ✗ Protocol violations etc.

# After an Allegation is Submitted





Must be specific and in good faith: e.g., Figure X in Document Y is problematic because of reason Z

Determine if the allegation appears credible: e.g., indeed the two questioned figures appear identical

- notify the respondent
- **sequester evidence prior or at the time of notification to the respondent**
- committee of experts not required

- committee of experts
- competent, thorough and fair
- research misconduct or not
- by whom
- scope of research misconduct

Estimated Direct Cost: \$525,000

- Michalek *et al.* PLoS Med. 2010 Aug; 7(8): e1000318.



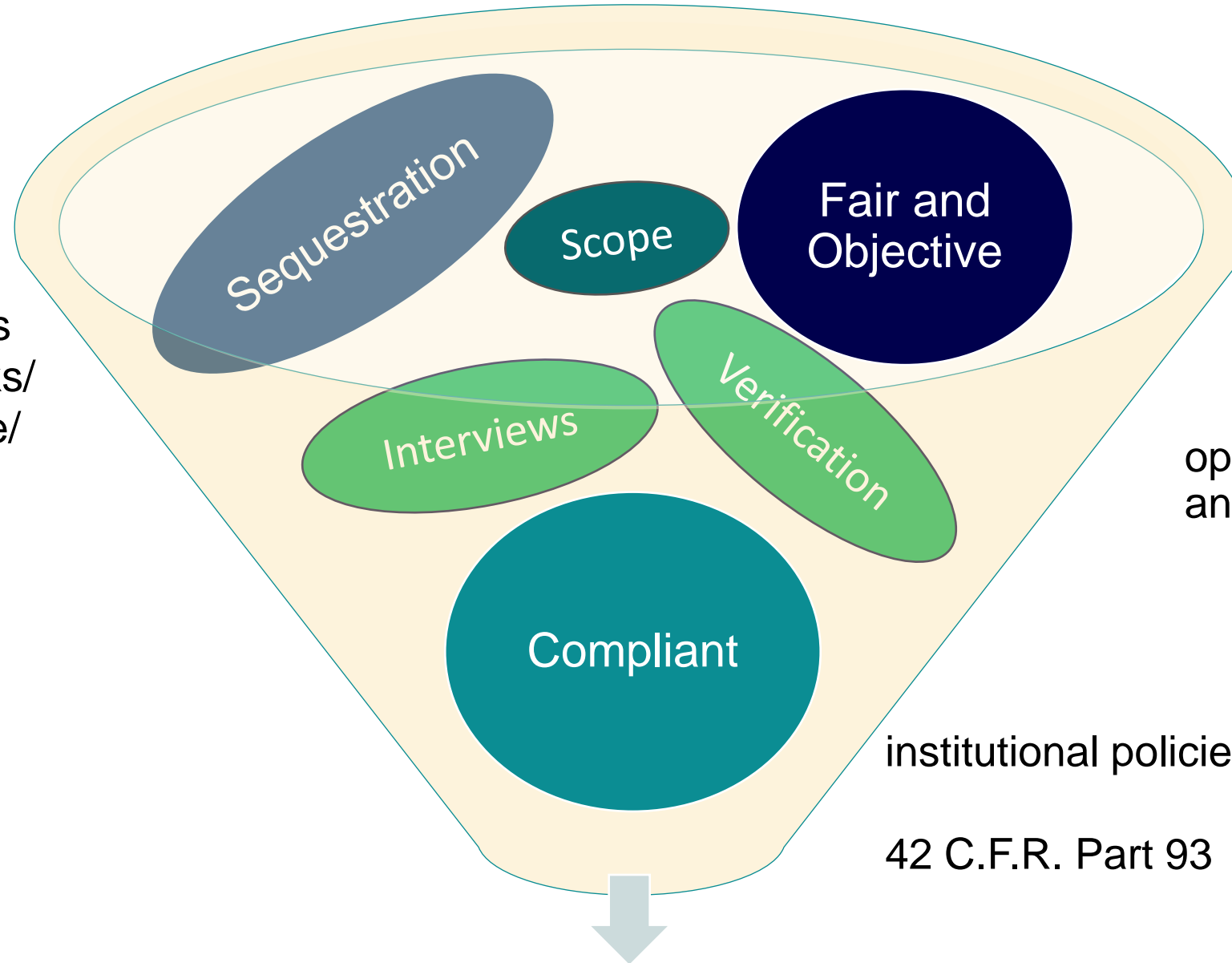
# Important Procedural Aspects

chain of custody

avoid evidence contamination

cover all aspects (Email/notebooks/instruments/core/computers)

often



conflict of Interest

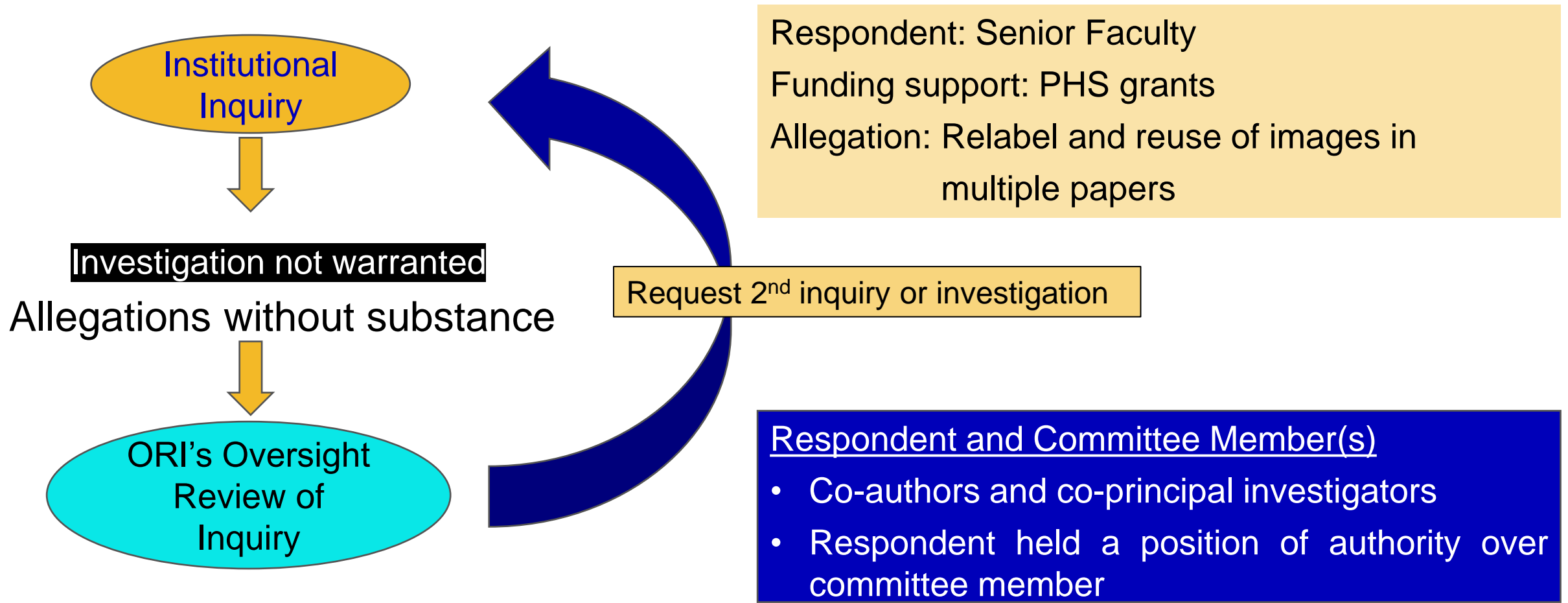
opportunity to comment and defend

institutional policies

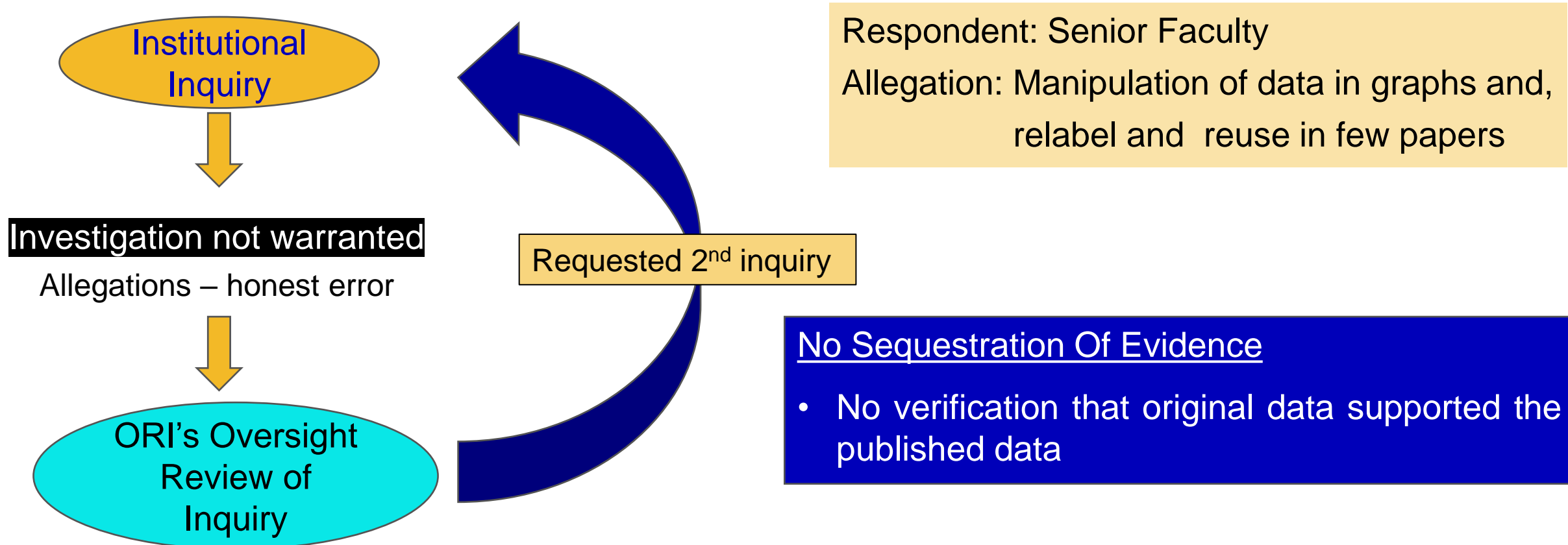
42 C.F.R. Part 93

Good Research Misconduct Proceedings

**42 C.F.R. § 93.300(b)** “ensure that **individuals** responsible for **carrying out** any part of the research **misconduct** proceeding do **not have** unresolved personal, professional or financial **conflicts of interest** with the complainant, respondent or witnesses”



42 C.F.R. § 93.305(a) “Either **before or when** the institution **notifies the respondent** of the allegation, inquiry or investigation, **promptly** take all reasonable and practical steps to **obtain custody** of all the research records ...”



42 C.F.R. § 93.300(b) “a thorough, **competent, objective and fair** ...”

42 C.F.R. § 93.312(b) “institution **must give the respondent** a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, **the evidence** on which the report is based”

Respondent: Post-doctoral Fellow  
Allegation: Image manipulations

- **Supervisor conveyed to the investigation committee that Respondent admitted to manipulation**
- **Committee did not confirm the admission with Respondent**
- **Institution did not share final report with Respondent**
- **No evidence to suggest Respondent created “original” manipulated files**

Institutional Investigation

**Research Misconduct**

Admission by the Respondent

- Most institutions conduct excellent research misconduct proceedings
- Impact of poor research misconduct proceedings is far reaching

Time

Resources

Cost

Fairness

- Avoid pitfalls
- When in doubt, reach out to ORI

“The best way to show that a stick is crooked is not to argue about it or to spend time denouncing it, but to lay a straight stick alongside it”

— D.L. Moody





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THANK YOU!

Questions?

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