

SCAW Annual Conference

**The Intersection of Noncompliance
and Research Misconduct**

Going from Bad to Worse

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HANDOUT

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Trust in Science

“Fostering a world where we build trust in science together is the kind of world we want to live in and a world we want to leave for future generations.”

Shella Garrity, Director of ORI
September 17, 2023

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Outline

- The meaning of research integrity (RI)
- Characteristics of investigators
- Noncompliance (NC)
- Dealing with allegations of NC
- Research misconduct (RM)
- Sloppy science (SS)
- The slippery slope
- Factors leading to breaches in RI
- Consequences of breaches

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What is Research Integrity?

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Research Integrity (RI)

Honesty
Design, conduct, and then report research results (both positive and negative) with verifiable, reproducible, unbiased accuracy without COI

Compliance
Comply with applicable federal requirements: the PHS Policy; NOT-ODs; AWAR; 21 CFR 58, 312, 812, 50, 56; 45 CFR 46; Biosafety; COI

Ethics
Follow guiding ethical principles: USGP, CIOMS-ICLAS; authorship (ICMJE); and applicable scientific society guidelines, (e.g., APS, SOT,)

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Characteristics of Investigators

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The “Good” Scientist

- Is concerned about the welfare and well-being of *animal subjects*
- Recognizes that using animals in research is a privilege granted by society
- Wants to follow the rules even when they disagree with some of the rules
- Wants to be both a productive and an ethical scientist
- Occasionally, and *unintentionally*, violates the rules
- Feels overburdened by ever escalating requirements

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The “Not So Good” Scientist

- Is concerned about animal welfare and well-being
- Fails to fully recognize that using animals is a privilege
- Seeks recognition even at the expense of compromising ethics
- Views many rules as an undue burden in the pursuit of science
- Occasionally, and sometimes intentionally, violates the rules

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The “Not So Good” Scientist (Cont.)

- Engages in sloppy science (SS) to expedite article submission with little concern about a lack of reproducibility of research results
- Occasionally, and intentionally, crosses the line from NC to committing research misconduct (RM)
- Knows that the probability of detecting a breach of research integrity is not very high

See: Richard Harris, *Rigor Mortis*,
Basic Books, N.Y., 2017

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What is Noncompliance (NC)?

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NC with the PHS Policy

- Any serious noncompliance (SNC) with the Policy
- Any continuing noncompliance (CNC) with the Policy
- Any serious deviation from the provisions of The Guide

Note: The PHS Policy at 1V.F.3. does not define SNC,
CNC or Serious deviations.
Refer to NOT-OD-05-034 for reportable examples of NC.
Refer to NOT-OD-12-148 for information on deviations.

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Examples of Reportable NC

- Conducting research without IACUC review and approval
- Conducting research beyond the expiration date established by the IACUC
- Implementation of a significant change without prior IACUC review and approval
- Failure to maintain appropriate animal-related records (e.g., health records)

Guidance on Prompt Reporting to OLAW under the PHS Policy,
NOT-OD-05-034, February 24, 2005

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Examples of Reportable NC *(cont.)*

- Failure to administer pain relieving agents per the protocol
- Failure to monitor animals post-procedurally, as required
- Failure to ensure death of animals after euthanasia procedures
- Failure to maintain aseptic technique during survival surgery
- Deviation from a “must” statement in The Guide without IACUC approval
- ...

*Guidance on Prompt Reporting to OLAW under the PHS Policy,
NOT-OD-05-034; NOT-OD-12-148*

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NC with AWA Regulations

- USDA classifies noncompliance incidents as follows:
 - Repeat
 - Reoccurring (Chronic)
 - Critical
 - Direct
 - Veterinary care direct

*Note: 9 CFR 2.31 (C)(4) does not define NC;
The USDA Animal Welfare Inspection Guide provides examples of NCIs
(Revised March 2024, Sections 2.41-2.46);
USDA Tech Note, May 2018*

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Dealing with Allegations of NC

An Outline

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Allegations of NC – Inquiry

- The IACUC Noncompliance Committee (NCC) should notify the IO and promptly assess the allegation to determine if there is:
 - Sufficient cause to believe the alleged NC warrants an investigation
 - A time urgency exists to immediately initiate an investigation
- The accused should be notified in writing of the allegation, records sequestered, and confidentiality maintained
- Whistleblower protection should be in place

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Allegations of NC – Inquiry *(cont.)*

- If animal welfare is found to be jeopardized, immediate action should be taken by the IACUC, AV, or IO as necessary
- If the inquiry finds an investigation is warranted, the accused should be notified in writing
- The IO should officially charge the NCC with conducting the required investigation

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Allegations of NC – Investigation

- The investigation should adhere to due process, be efficient, maintain confidentiality, and ensure full documentation
- The NCC should determine if the NC was committed intentionally
 - Intentionality is not a factor in finding NC, but is in determining an appropriate corrective action plan
- If possible, evidence of RM is identified, the matter should be referred to the RMC

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Allegations of NC – Investigation (cont.)

- Upon conclusion of the investigation by the NCC, a finding of NC requires it be proven by a “preponderance of the evidence”
- The NCC should present findings of NC to the full IACUC for a final determination
- The accused has the right to appeal a finding of NC to the full IACUC at a convened meeting
- The IO should be notified of the IACUC’s final decision regarding NC

Note: Neither OLAW nor USDA prescribe methods to investigate allegations of noncompliance.

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Allegations of NC – Investigation (cont.)

- The IACUC should develop an appropriate corrective action plan, with input from the investigator prior to implementation
- A finding of NC must be fully reported to OLAW in accordance with the PHS Policy at IV.F. 3. and NOT-OD-05-034
- Reporting NC to USDA is optional except for failure to correct a significant deficiency per 9 CFR 2.31(C)(3)

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What is Research Misconduct (RM)?

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The 2024 Final PHS Rule on RM

- 42 CFR 93 issued September 17, 2024
 - Amended October 2, 2024
- Effective January 1, 2025
- Institutional compliance required by January 1, 2026

*Federal Register vol. 89, NO 120,
Tuesday, September 17, 2024, pg 76296-76309*

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Research Misconduct (RM)

“Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”

*42 CFR 93.103, 234;
See also: ORI Case Summaries*

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Fabrication

“Fabrication means making up data or results and recording or reporting them.”

42 CFR 93.211

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Falsification

“Falsification means 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.”

42 CFR 93.212

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Plagiarism

“Plagiarism means the appropriation of another person’s ideas, processes, results or words without giving appropriate credit.”

42 CFR 93.227

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Requirements for Finding RM

- “There be a significant departure from accepted practices of the relevant research community.”
- “The misconduct be committed intentionally, knowingly, or recklessly.”
 - Intentionally: Act with the aim of carrying out the RM
 - Knowingly: Act with full awareness of committing RM
 - Recklessly: Act with indifference to a known risk of the RM

42 CFR 93.103, 221, 223, 231

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Requirements for Finding RM *(cont.)*

- “The allegation be proven by a preponderance of the evidence.”*

**Just enough evidence to make it “more probably true than not” that the allegation is true (i.e., a 51% or greater likelihood that the allegation is true).*

42 CFR 93.103, 105, 210, 228

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Not Research Misconduct

RM does not *technically* include:

- Self-plagiarism
- Authorship disputes
- Honest differences of opinion
- Honest errors
- Innocent ignorance
- Sloppy science (SS)

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Sloppy Science (SS)?

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“Sloppy science is a larger evil than research misconduct”

J. Tiidink
5th World Conference on Research Integrity (2017)

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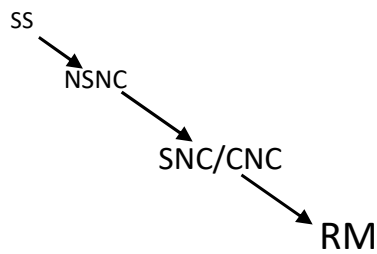
Sloppy Science (SS)

- Poor experimental design
- Misuse of statistics
- Accidentally mislabeling images
- “Cherry picking” data
- Ignoring data not in conformance with the underlying hypotheses
- Premature halting of data collection in order to support a conclusion
- Declining to use negative results
- Poor quality control in laboratory procedures
- ...

Based on J. D. Sternwedel
Scientific American Blog, 6/26/13

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The Slippery Slope



Intentional

- *Falsification*
- *Fabrication*
- *Plagiarism*

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What Factors Lead to Breaches in RI?

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Factors

- Poor mentoring
- The power differential
- Publish or perish
- Greed corrupts science
- The race for fame

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What are Possible Consequences of RM?

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Possible Consequences

- The public's trust in research is undermined.
- The institution's local and national reputation is impacted.
- The reputation of the investigator is damaged, and career ended.
- The careers of the research staff are negatively impacted.
- Graduate students encounter delays in completion of their research.
- Publications are required to be retracted.
- Animal rights activists may target the institution.

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Animal Activists File Federal Complaint Against Dana-Farber

Jina H. Choe, Veronica H. Paulus, Akshaya Ravi;
The Harvard Crimson,
February 13, 2024

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Possible Consequences (cont.)

- NIH requires payback of grant funds.
- The investigator is barred from receiving PHS grant funds.
- PHS-funded research can be conducted only under supervision.
- Patients sue the investigator and the institution.
- The investigator files suit against the institution.
- The investigator is required to pay a financial penalty.
- The investigator is sentenced to time in prison.

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Possible Consequences (cont.)

- Prison sentences:
 - 2005: Paul Kornak (Albany VA)
 - 71 months, \$688,735
 - 2015: Dong-Pyou-Han (Iowa State U)
 - 57 months, \$7,216,980.12
 - 2017: Darion Kinion (Lawrence Livermore NL)
 - 18 months, \$3,300,000
 - 2021: Song Guo Zheng (Ohio State)
 - 37 months, \$3,813,000
 - 2022: Simon Saw Teong Ang (U of Arkansas)
 - 12 months, \$5,500

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Conclusion

Responsible conduct of research is an absolute imperative. The best way to promote research integrity is to:

- Establish an institutional culture of good conscience and compliance.
- Provide in-person education and training to all research personnel.
- Understand and comply fully with all applicable federal requirements.
- Implement a proactive, adequately resourced PAM program.
- Deal with breaches of RI expeditiously, and with due process.

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Thank You!

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