M105: The Research Integrity Continuum and the Role of the Pre-award Administrator

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Welcome – who I am

Debra Schaller-Demers - NYC

Welcome – where are you from?

Where are you located?

- US Northeast Section
- US Midwest Section
- US Western Section
- US Southern Section
- Canadian Section
- International Section

More about the Group

Tell us what type of Institution

- University – PUI
- University – Graduate School
- Academic Medical Center
- Hospital
- Research Institute
- Non-profit
- Other

Tell us what role you play in RA

- Pre-award
- Post-award
- Both pre- and post-award
- Research Compliance
- Financial Compliance
- Tech transfer
- Legal counsel
- Other

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What is RCR?

Responsible Conduct of Research (RCR)

- The practice of scientific investigation with **integrity**.
- Awareness and application of established professional norms and **ethical** principles in the performance of ***all activities*** related to scientific research.

What is the difference between ethics, integrity, and compliance?

- Research *ethics*, research *integrity*, and research *compliance* are often used interchangeably.
- To be effective in their roles, it is important for members of the research community to understand the fundamental differences amongst these three concepts.
- Differences in how these words are used within an institution will determine how a research enterprise is structured and its approach to policies and procedures.

The more we know about why we must do something the more apt we are to do it and to do it correctly.

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Where is your institution on the ethics/compliance spectrum?

Opposing or Complementary?

Group Discussion:

- *Where does your organization fit?*
- *What carries more weight – ethics or compliance?*
- *Do they balance out in the end?*

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RCR = Research Ethics, Compliance, and Integrity

How does integrity fit between ethics and compliance?

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Research Obligations

Kalichman & Plemmons, 2014

How should researchers and staff who support them act?

- The choices are not always obvious or clear.
- It may be a matter of "right vs. right" rather than "right vs. wrong."

The obligation is not necessarily to make the right decisions, but to strive to make the best possible decisions.

- **Research:**
  How should research be conducted to meet our obligations to preserve and promote the integrity of research findings?
- **Researchers and Staff:**
  How should researchers and staff interact with one another to meet their obligations to others in their research community?
- **Society:**
  How should researchers and staff interact with the larger communities, academic and public, to meet their obligations to the society in which they live and work?
- **Asking Questions:**
  How, when, and where should researchers and staff be prepared to ask questions about the conduct of science to meet their obligations to the research, researchers, and society?

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Maintaining Objectivity - Confirmation Bias

To safeguard trust in scientific integrity we need objectivity – self-awareness is key!

- Charles Darwin discerned that he was more likely to remember **confirmatory evidence than findings that refuted his ideas.** This protected him against what we now call ***confirmation bias*** — **a tendency to favor evidence that validates one's preexisting beliefs.**
- Darwin was practicing ***intellectual humility***. He was aware of his cognitive biases and open to correction. This disposition is one of a suite of **epistemic virtues: traits that contribute to intellectual flourishing and accountable belief formation.**
- **The epistemic virtues have practical implications for research, teaching, uncovering pseudoscience, and reducing political tensions.**

Source: Satel, S. December 8, 2025 https://www.chronicle.com/article/are-bad-researchers-bad-people

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According to the NSF

The Responsible and Ethical Conduct of Research (RECR) is critical for excellence, as well as public trust, in science and engineering. It involves not only a responsibility to generate and disseminate knowledge with rigor and integrity, but also a responsibility to:

- **conduct peer review with the highest ethical standards**
- **diligently protect proprietary information and intellectual property from inappropriate disclosure**

RECR education is considered essential in the preparation of future scientists and engineers:

- ***treat students and colleagues fairly and with respect***

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Ethical Principles for Conducting Research

Principle	Behavior
Honesty	Honestly report data, results, methods and procedures, publication status, research contributions, and conflicts of interest. Do not fabricate, falsify, or misrepresent data in scientific communications, including grant proposals, reports, publications, and curriculum vitae.
Objectivity	Strive for objectivity and reproducibility in experimental design. data analysis, data interpretation, publication, peer review, personnel decisions, grant writing, expert testimony, and other aspects of research where objectivity is expected or required.
Carefulness	Avoid careless errors and negligence; carefully and critically examine your own work and the work of your peers. Keep good records of research activities, such as data collection, research design, consent forms, and correspondence with agencies or journals.
Credit	Allocate credit fairly on publications, patents, and other scientific and scholarly works. Do not plagiarize.
Openness	Share data, results, ideas, tools, materials, and resources. Be open to criticism and new ideas.

From: Shamoo, Adil E, and David B Resnik. 2022. *Responsible Conduct of Research*. 4th ed. New York: Oxford University Press.

Principle	Behavior
Transparency	Disclose materials, methods, experimental designs, conflicts of interest, and other types of information needed to understand and evaluate research.
Accountability	Take responsibility for your roles in research projects. Be prepared to answer questions about what you did and why and cooperate with audits and investigations of your research.
Confidentiality	Protect confidential communications, such as papers or grants submitted for publication, personal records, proprietary information, and records that identify individual research subjects or patients.
Respect for colleagues	Treat scientific colleagues (e.g., collaborators, peers, students, trainees, and research staff) with respect and professionalism. Do not physically or psychologically harm, threaten, abuse, or intimidate colleagues.
Non-discrimination	Do not practice favoritism; treat colleagues fairly. Do not discriminate against colleagues on the basis of sex, gender, sexual identity, race, ethnicity, religion, disability, or other characteristics not related to scientific qualifications.

From: Shamoo, Adil E, and David B Resnik. 2022. *Responsible Conduct of Research*. 4th ed. New York: Oxford University Press.

Principle	Behavior
Safety	Ensure that the research environment is safe. Take appropriate steps to prevent, minimize, or mitigate physical, chemical, biological, and psychosocial risks, including risks related to harassment or inappropriate conduct.
Respect for intellectual property	Honor patents, copyrights, and other forms of intellectual property. Do not use unpublished data, methods, or results without permission.
Intellectual freedom	Do not interfere with freedom of thought and inquiry and support the free expression of scientific information and ideas.
Protection for animals used in research	Protect the welfare of animals used in research. Do not conduct animal experiments that are scientifically unnecessary, poorly designed, or needlessly cruel and inhumane.
Protection of human research subjects	Protect the rights, dignity, and welfare of human research subjects. Obtain informed consent from competent, adult subjects; minimize research harms and risks and maximize benefits; take special precautions with vulnerable populations; and distribute the benefits and burdens of research fairly.

From: Shamoo, Adil E, and David B Resnik. 2022. *Responsible Conduct of Research*. 4th ed. New York: Oxford University Press.

RCR Core Topics

1. Conflict of commitment - in allocating time, effort, or other research resources
2. Conflict of interest - personal, professional, and financial
3. Policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
4. Mentor/mentee responsibilities and relationships
5. Safe research environments (e.g., those that promote inclusion and are free of sexual, racial, ethnic, disability and other forms of discriminatory harassment)
6. Collaborative research, including collaborations with industry and investigators and institutions in other countries
7. Peer review, including the responsibility for maintaining confidentiality and security in peer review

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Core RCR topics continued:

8. **Data acquisition and analysis;** laboratory tools (e.g., tools for analyzing data and creating or working with digital images); recordkeeping practices, including methods such as electronic laboratory notebooks
9. **Research data management**; curating, securing (confidentiality), storing, sharing, accessing, transmitting, ownership, and **Reproducibility**
10. **Research misconduct** and policies for handling misconduct
11. **Responsible authorship and publication**
12. **The scientist as a responsible member of society,** contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research
13. **Research asset management:** Export Controls, Dual Use Research of Concern, and Intellectual Property

Phases of Research

Research Planning	Human and Animal Subjects	Use of rsNA and Biohazards	Use of hESC and hPSC	Conflict of Commitment and Interest	Grant and Contract Proposals
Research Conduct	Lab Safety and Environment	Data Management	Collaboration and Mentoring	Social Responsibility	
Research Reporting	Authorship	Responsible Publication	Peer Review	Sponsored Award Management	

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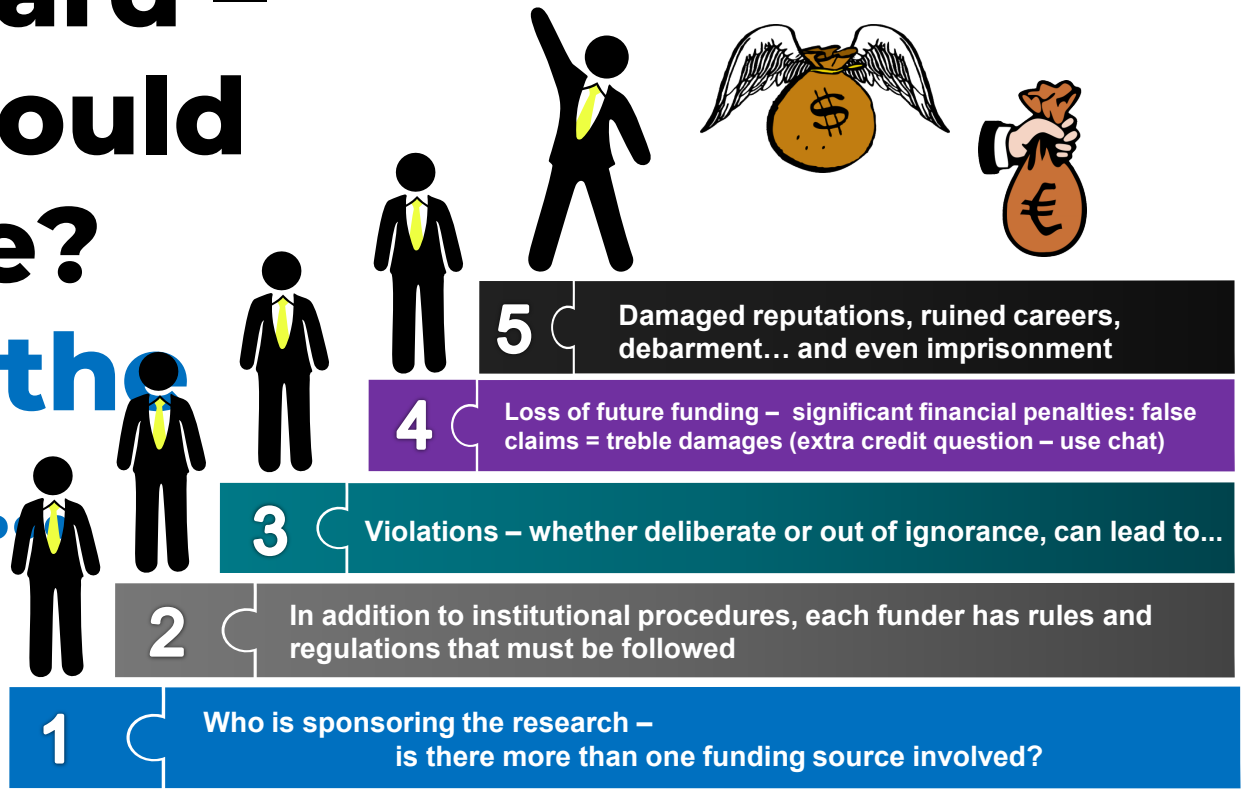
Gold Standard Science - NIH

- Reproducible
- Transparent
- Communicative of Error and Uncertainty
- Collaborative and Interdisciplinary
- Skeptical of Its Findings and Assumptions
- Structured for Falsifiability of Hypotheses
- Subject to Unbiased Peer Review
- Accepting of Negative Results as Positive Outcomes
- Without Conflicts of Interest

Published August 22, 2025: https://www.nih.gov/about-nih/nih-director/statements/nih-publishes-plan-drive-gold-standard-science

Pre-award – why should we care?

Follow the money.



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Grants Management & Compliance

- **Grant submissions and award acceptances are subject to compliance**

  Division of Grants Compliance and Oversight (DGCO) Ensures and evaluates the efficient and effective management of extramural resources.
- **Recipients of NIH grant funds must comply with all applicable Federal statutes (such as those included in appropriations acts), regulations, and policies in addition to complying with institutional requirements.**

http://grants.nih.gov/grants/compliance/compliance.htm#glance

To make a formal allegation about an NIH-funded grant or cooperative agreement, contact: **HHS OIG Hotline** Matters involving whistleblower complaints, or fraud, waste and mismanagement in any Department of Health and Human Services program(s), including NIH-funded grants or cooperative agreements, should be reported to the Office of Inspector General (OIG). **Contacting the HHS OIG Hotline:** Submit a Hotline Complaint

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Pre-award Concerns

- **Do you know the integrity/compliance touchpoints in the pre-award cycle?**
- **Does the study involve humans, animals, rsNA/rDNA, biohazards, embryonic stem cells, COI management, data management, and research security concerns (foreign components) ?**
    - **All of the above require ethical/compliance review, oversight, and adherence to funding and regulatory agency requirements**

What should we do?

- **We are often witness to questionable research practices, poor stewardship of research funds, and sometimes actual instances of misconduct.**
- **We are uniquely situated to be agents of intervention and problem solving but may not always feel equipped with the knowledge and ability to intervene.**
  - ***Administrators must feel empowered to question behavior if we are going to be agents to promote ethical conduct.***
- **Be familiar with institutional policies and tools (e.g., hotlines) that support raising concerns and protect those that do raise concerns, whether they are faculty, researchers, administrative staff, or students.**

Case Study

Prof. Whizkid, an Associate Professor of Neuroscience at a research intensive US University is submitting a big NIH R01 application to study Alzheimer's disease.

- **They also spend 8 hours per week as a scientific advisor with an equity interest in a startup company based on brain imaging technology their spouse invented.**
- **This technology will be used in the planned animal experiments.**
- **They are planning on doing some experiments with collaborators in Hong Kong in rodents and pigs.**
- **The animals will be shipped to Hong Kong and then tissue samples will be shipped back to the US.**

As a grants manager, what questions should you be asking and/or who should you be in contact with to ensure compliance

Can RCR education make a difference?

Let's discuss:

- *Can educational programs impact ethical decision making and behavior?*

- Key points:
  - Institutional Commitment
  - Awareness – Reflection
  - Expectations – open and safe environment
  - Consequences

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Questions?
Closing Comments?

ACKNOWLEDGMENTS:

Some material for this session was adapted from sessions/lectures done by this author for NYU, MSK, CUNY, and SRAI - including

The Research Integrity Toolkit,

(funded by the Office of Research Integrity Conference Grant: ORI IR160026-01-00 - "Supporting responsible research organizations: a framework for engaged research managers and administrators")

and by former SRAI colleagues:

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Thank You!