#### Over Two Decades of RCR Programs: What's changed, and does it resonate within the international context?

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The views expressed in this presentation are solely that of the author and not of any Institution or Organization.

# **Declarations**



I have no Conflicts of Interest to declare in association with this presentation.

## A look back

- RCR "legislation" in the US sprang up in the late 80s/early 90s
- Prior to 1989 National Institutes of Health (NIH) legislation: The apprentice model for RCR wasn't enough. Several institutions established courses in research ethics and scientific integrity because students appeared to have not learned fundamental issues important to the conduct of science. Two of the early examples were the University of Texas Health Science Center at Houston in 1984 and Virginia Commonwealth University in 1986. <u>In</u> <u>both cases, the premise was that mentoring was not sufficient and that it was necessary to supplement with</u> <u>formal courses</u>. (Kalichman, 2013)
- NIH requirement (1989) for programs on the responsible conduct of research in national research service award institutional training programs. Called out "core topics."
- The National Science Foundation (NSF) issued an RCR training requirement for NSF-funded students and postdoctoral scholars in 2009
- The United States Department of Agriculture National Institute of Food and Agriculture (USDA NIFA) issued a requirement for all personnel supported by the grant in 2013.
- The NIH has updated their guidance twice (2011, 2022), and the NSF updated their requirement once (2023), in response to the CHIPS and Science Act (2022).

# However, has mandating formal courses on "core" topics ever been an effective means to ensure research integrity?

#### **Current State – US Regulatory Requirements**

- NIH Revised list of core topics in February 2022 to cover issues of Conflict of Commitment, Data Security, Confidentiality in Peer Review and Creating Safe Research Environments – all to support US efforts to protect R&D investments in conjunction with Non-US engagements.
- NSPM-33: Focus on research security
- NSF updated RECR requirements in Summer 2023 to include faculty and senior personnel in training
  as participants with an emphasis on Effective Mentoring. Further, faculty are now required to submit
  a one-page plan describing how they will mentor graduate students and postdoctoral researchers as
  part of their application. Previously such a document was required only for postdocs. Investigators
  who receive NSF funding will also be required to certify annually that graduate students and postdoccs
  who work on their grant have an active individual development plan, which lays out their career
  goals.

#### APPE's National Dialogue\* on the State of Research Integrity Education – November 2023

Practices in the research environment which can erode the integrity of research include:

- toxic supervision
- abuse of power
- inattention to trainee wellbeing (hence the need for safe research environments)
- lack of effective institutional leadership and research support

"When the informal aspects of research environments and cultures run counter to the goals of RCR, formal RCR education is an insufficient tool and should be supplemented with more comprehensive institutional support."

Acknowledgments: Association for Practical and Professional Ethics (APPE) \*Improving Research Integrity: The Role of Accountability Across the Research Enterprise

### **Research Integrity vs. Preventing Misconduct**

- As referenced by the APPE National Dialogue report, it has become apparent that RCR should be more than a check the box exercise in the hope of preventing research misconduct.
- Institutional acknowledgement of culture realities, support, and values messaging are essential.
- The community of stakeholders is vast across the globe:
  - Students, Postdocs
  - Investigators, Faculty
  - Institutional Officials and Administrators
  - Government Regulatory and Sponsoring Agencies
  - Industry Sponsors, Non-profit Sponsors, Philanthropy
  - Journals
  - The Public i.e., the consumers of science



# **International Context**

- How does the US's hyper-vigilance on identifying and reporting foreign engagements/support affect multi-national collaboration?
- Do all cultures embrace "creating safe research environments" – free of harassment/discrimination of any kind based on how you present to the world? (e.g., gender, gender identity, sexual identity, age, ethnicity, race, religion, able-bodiness, etc.)?
- Use of Human Subjects and privacy laws increasingly countries have their own regulations for using PII and PHI.

PII Laws Around the World	
United States	HIPAA, COPPA, Privacy Act, State Laws, etc.
Europe	General Data Protection Regulation (GPDR)
Australia	Privacy Act of 1988
India	Digital Personal Data Protection Bill
Brazil	General Data Protection Law (LGDP)
Canada	Personal Information Protection and Electronic Documents Act (PIPEDA)
China	Personal Information Protection Law (PIPL)
Switzerland	Federal Act on Data Protection (FADP)
Saudi Arabia	Personal Data Protection Law (PDPL)
South Korea	Personal Information Protection Act (PIPA)
Singapore	Personal Data Protection Act (PDPA)
New Zealand	Privacy Act

Source: <u>https://piwik.pro/privacy-laws-around-globe/</u>

### **Ongoing Considerations**

- Is there a US/Western-centric bias when it comes to "regulating" RCR that helps or hinders international collaboration?
- Are the global efforts of WCRI (e.g., Singapore and Montreal Statements) and others making an impact when it comes to international collaboration?
- Should regulators world-wide consider other means than research misconduct policies and seek to reward exemplars vs. solely punishing bad actors?

#### Always looking to continue the conversation...

#### **Questions? Comments?**

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