

**Panel II: Optimal Personnel Characteristics  
Scientific and Professional Integrity and Compliance  
with Biosafety and Biosecurity Standards”**

**Education About the Responsible Conduct of Research**

**Nicholas H. Steneck, PhD**

**NSABB Public Consultation on Personnel Reliability Among  
Individuals with Access to Select Agents**

**Bethesda Marriott  
5151 Pooks Hill Rd., Bethesda, MD**

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# What are the hallmarks of scientific and professional integrity?

## ■ Responsible Conduct of Research

- Conducting research in ways that fulfill the professional responsibilities of researchers, as defined by their professional organizations, the institutions for which they work and, when relevant, the government and public.

## ■ Research Integrity

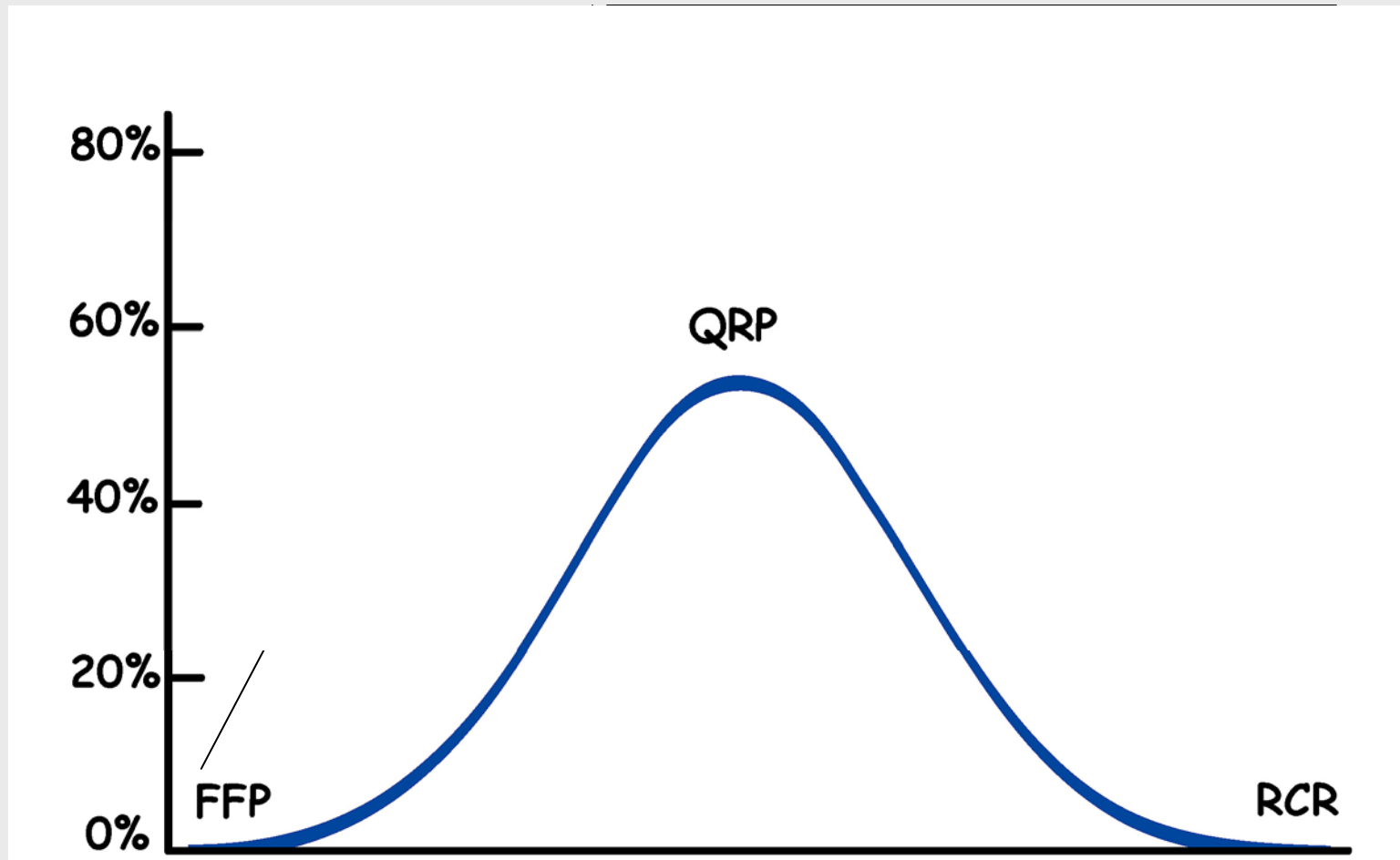
- The quality of possessing and steadfastly adhering to high moral principles and professional standards, as outlined by professional organizations, research institutions and, when relevant, the government and public.

Source: Steneck, *Science and Engineering Ethics*, Volume 12, Issue 1, 2006

# What behaviors involve breaches of scientific and professional integrity?

- Behaviors that fail to adhere to the “... high moral principles and professional standards...”
  - Research Misconduct
    - FFP ~ US Federal definition
    - US institutions and other countries have different definitions
  - QRP (Questionable Research Practices)

# How do researchers behave?



# Most misconduct is not reported

## ■ HHS

- \$30B, 350,000 researchers
- Predicted misconduct
  - 35 1/10,000
  - 350 1/1000
  - 3,500 1/100
- 15 cases/year confirmed

## ■ NSF

- \$5B, 75,000 researchers
- Average ca. 5 cases (2x HHS cases)
- Past, more P than FF

- **Conclusion: reporting is the weak link in current research misconduct policies in US**

## QRPs may be more important than FFP

- Al-Marsouki, *Contemporary Clinical Trials* 26(2005)

<b>Design</b>	<b>%</b>
Failure to use random allocation	92
Failure to specify in the protocol the main outcome measure	88
Inadequate allocation concealment	84
Different follow-up schedules in arms	80

<b>Conduct</b>	<b>%</b>
Tampering with treatment packs so as to un-blind allocation	95
Selective withdrawals on basis of knowledge of allocation	92
<b>Data falsification</b>	<b>92</b>
<b>Data fabrication</b>	<b>92</b>

## Al-Marsouki, continued....

<b>Analysis</b>	<b>%</b>
Altering analysis methods until finding a significant result	100
Use of battery of methods of comparison to get the right answer	100
Altering results in knowledge of allocation	100
Excluding patients to exaggerate effects or remove adverse events	99
Use of primary outcome measure that was not pre-specified	96
Selecting covariates to bias treatment effect in a particular direction	96
Selective exclusion of "protocol violation outliers"	88
Inappropriate subgroup analyses	88
Rely on biased comparisons as the primary analysis	87
Missing data ignored when informative	84
Using a different primary endpoint from that specified in the protocol	84
Post-hoc analysis not admitted	83

## What are hallmarks of a positive attitude toward safety and security?

- Knowledge of and respect for professional standards
- Belief in fairness of research process

## What are the indicators of a problematic attitude toward these matters?

- Willingness to compromise minor professional standards
- Situational thinker



# How can scientific and professional integrity be assessed in objective ways so as to be meaningful for assessing personnel reliability?

- Review record for meaningful RCR training
- Include general questions about professional responsibility in interviews:
  - Authorship and publication standards
  - Conflict of interest policy
  - Data and grant management
  - Collaboration and international research
- Researchers who are not aware of general professional standards cannot act with integrity

for more information

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[nsteneck@umich.edu](mailto:nsteneck@umich.edu)