

# Research, Renegades and Roos

*Exploring Integrity in Science Down Under*



Greg Koski, PhD, MD, CPI  
Harvard Medical School  
Boston, Massachusetts, USA

Former Director, Office for Human Research Protections  
U.S. Department of Health and Human Services  
Washington, D.C.



# Science, Truth and Trust

- Science seeks knowledge through research
- Knowledge is based on truth
- Truth is the foundation of trust
- Trust once violated is very difficult to restore



# Integrity and Responsibility

- Science is a human endeavor
- Integrity depends upon behavior
- Most scientists and institutions behave responsibly
- Some, perhaps many, do not
- A single act of irresponsible misconduct harms all of science



# Accountability in Science

- Public support for research is strong
  - The public's money is used to fund research
  - The public rightfully expects its money to be used wisely
- Mechanisms to ensure accountability must be part of the scientific enterprise
  - Responsible parties expect to be held accountable for their actions
  - Openness and transparency foster integrity and trust
  - Process is powerful--it promotes consistency, fairness, and acceptance of the outcome

# Does Australia Need a Better System?




For what?



# Does Australia Need a Better System?


- For managing allegations of scientific misconduct?
- For ensuring public accountability in science?
- For promoting responsible conduct of research?
- For fostering professionalism in science?



# The Myth of the Scientific Method

--Bauer, H. 1992

- Scientists use many different methods and approaches
- Rarely does science follow a logical and ordered progression as portrayed in a typical scientific paper
- The 'classic' scientific method should be viewed as an ideal, not as a formula
- To suggest otherwise provides society with unrealistic expectations of science and scientists



# Medawar's Dilemma

*"Is the Scientific Paper a Fraud?" -- Sir Peter Medawar (1963)*

- There is no definable, universally agreed upon standard by which scientific research is actually conducted
- How, then, can there be a standard for either definition or prosecution of scientific misconduct?



# Deviations of the Moral Compass of Scientists

## ■ Misconduct

- *Falsification, fabrication, plagiarism and gross deviation from the norm*

## ■ Misbehavior

- *Noncompliance, coercion, harassment, intellectual theft, authorship, financial conflicts, misrepresentation and other misadventures*

## ■ Misdirection

- *Inadequate education and training, poor advice, failed mentorship, stepping on a “slippery slope”*



# The “Schwarz Syndrome”

- Misconduct in science is a “disease”
  - Roy Schwarz, MD
- We must work to better understand
  - *Predisposing factors*
  - *Enabling situations*
  - *Preventive measures*
  - *Treatment strategies*



# Values-Based Education

- Reaffirm the fundamental values of science as determinants of professional conduct
- Change the culture of science and scientists
  - *“Not a culture of compliance, but a culture of conscience and responsibility”*
  - *“Do it right because it is the right thing to do”*
- Emphasize values-based education from the earliest stages of training
  - *Ethics is intrinsic to science, not an addendum nor an administrative burden*
  - *“Science without conscience is lame, conscience without science is blind” (Albert Einstein)*



# Values-Based Oversight

- Oversight of professionals by professionals, for the integrity of the profession
- Robust, independent oversight builds confidence and trust in the profession while fostering responsible conduct of its practitioners



# A Values-Based Approach

- An effective system of education, training, independent oversight and objective validation of competency through certification and accreditation are hallmarks of professionalism
- All professional scientists should demonstrate mastery of the principles and practices of responsible conduct of science

What about Oversight?

Who is responsible, anyway?



# An Overview of Oversight

- Oversight of scientific conduct occurs at many levels
  - *Government*
  - *Institution*
  - *Professional Organizations*
  - *Legal System*
  - *Public*
  - *Individual*



# Regulation of Research in the US—A Legacy of Mistrust

- “to err is human... to cheat is downright American”
- “if you know what the result is going to be, why bother doing the experiment?”
- “there is no data like no data”
- “there is no room in America for dishonest scientists... we already have too many “



# Statutory Basis for Regulation of Research in the US

- National Research Act
- Public Health Service Act
- Food, Drug and Cosmetic Act
- Health Insurance Portability and Accountability Act
- (Human Subjects Protection Act?)



# Government Oversight

- Executive

- *Funding Agencies*

- *Regulatory Agencies and Offices*

- *Investigative Agencies*

- Legislative

- *Congressional Committees*

- *Investigations, hearings*

- Judicial



# Federal Oversight of Research

## ■ Primary Oversight

- *Office for Research Integrity*
- *Office for Human Research Protections*
- *Food and Drug Administration*
  - Office for Good Clinical Practice
  - Bioresearch Monitoring Program

## ■ Secondary Oversight

- *National Institutes of Health*
  - Office for Extramural Research
  - Office for Grants and Contracts
  - Office for Biotechnology Activities
  - Office for Laboratory Animal Welfare



# The Federal Assurance Process

- Federal support is granted to institutions, not individuals
- Institutions seeking federal support file an assurance of regulatory compliance
- Terms of assurance are defined by regulations and guidance
- Assurances may be approved, disapproved, revoked, suspended, or restricted
- Responsibility is delegated to the institution



# Implementation of Assurances

- The Assuring Institution develops and manages:
  - *Procedures for dealing with alleged falsification, fabrication or plagiarism*
  - *Procedures for disclosing and managing conflicts of interest*
  - *Programs for protection of human subjects in research, including Institutional Review Boards (IRBs), policies and procedures*
  - *Programs for responsible grants management*



# How Does It Work? (or not!)

- An allegation is made
- The institution gathers evidence
- If warranted, an investigation is initiated by the institution, which appoints an panel of inquiry
- The institution reports its findings and corrective actions to the government
- The government may require further action
- (Additional legal actions are common!)



# Oversight of Privately Funded Research

- Federal jurisdiction for research oversight is limited
  - Use of public funds
  - Involving or effecting interstate commerce
- Does not extend to some private research
- Applies to social, behavioral and biomedical sciences



# What about the FDA?

- Focuses on sponsors and investigators, rather than institutions—does not use an assurance process
- Receives monitoring reports from sponsors
- Conducts audits, for cause and not for cause
- Investigates allegations of non-compliance or fraud—to maintain validity and objectivity of data
- May withhold product approval or disqualify investigator or performance site
- Jurisdiction frequently overlaps other offices



# Key Features of the Federal Oversight Process in the US

- Decentralized and very complex
- Delegates authority to research institutions
- Compliance-focused approach, largely reactive
- Responds to allegations as they arise
- Follows the money




# Key Weaknesses of the Federal Oversight Process in the US

- Decentralized and very complex
- Delegates authority to research institutions
- Compliance-focused approach, largely reactive
- Responds to allegations as they arise
- Follows the money



# A System Plagued by Competing Interests and Commitments

- Federal agencies
- Institutions
  - Institutional review boards
- Investigators
- Whistle-blowers
- Sponsors



# The ABC's Approach to Managing Scientific Misconduct

- Assess
- Blame
- Criticize
- Sanction



# The “Death Spiral” in Research Misconduct and Regulation

- A growing number of allegations/revelations
- Declining public confidence in oversight process
- Failure of government to take effective action
- Erosion of public trust and calls for reform
- More stringent regulations and enforcement



# Characteristics of an Effective System for Research Oversight

- Proactive, Prevention-Focused
- Objectivity
- Consistency
- Authority
- Autonomy
- Transparency
- Accountability



# Protection of Human Subjects

## *An Outcome-Focused Systems Approach*

Education and Support

Investigation

Evaluation

Consultation

Accreditation

*Compliance Domain*

*Performance Domain*

*“Effectiveness of the system depends upon a partnership between the government and the private sector.”*



# “Lesson’s from the Hall Affair”

–*Martin Van Der Weyden, Editor MJA*

- External, independent inquiry of allegations from the start
- Statutory power to investigate and inquire
- Sufficient scientific expertise to ensure credibility
- Transparency and accessibility of final reports



# “Lesson’s from the Hall Affair”

–*Martin Van Der Weyden, Editor MJA*

- Establish uniform processes and procedures
- Shift the emphasis from managing scientific misconduct and fraud to prevention

***“If we can learn from this, it will have made a contribution to the pursuit of integrity in research.”***