Science, Research Ethics and Policy The Roles and Responsibilities of Key Actors

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Parsing terms

"Research ethics," "research integrity" and "responsible conduct of research (RCR)."

All three require intellectual honesty in designing, conducting, evaluating, and reporting research.

Research ethics is identifying, understanding and applying relevant moral rules, ethical principles, and professional norms to research.

Research integrity refers to accepting responsibility for ones actions and an affirmative commitment to ensuring trustworthiness of the scientific record—accuracy and reliability.

RCR calls for following ethical and scientific standards and legal and institutional rules in the conduct of research.

Research misconduct refers to research behaviors inconsistent with what ethics and the law require, recognizing that those behaviors falling under this definition very within and across countries.



Two Sides of the Same Coin

The importance of ethics to research "derives from a premise fundamental to doing science: the responsible conduct of research is not distinct from research, on the contrary, competency in research entails responsible conduct and the capacity for ethical decision making."

Institute of Medicine, Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct, 2002

"One of the basic responsibilities of scientists is to maintain the quality and integrity of the work of the scientific community."

Report of the AAAS Committee on Scientific Freedom & Responsibility, 1975

Science as a public policy priority

- Enormous sums of public monies invested in scientific research- return on investment
- Recognition that science is vital to a country's development and position in the global community
- Value of grounding policy decisions in scientific knowledge
- Social relevance of science--promised benefits; risks of harm; clash with ethical/religious values

Misconduct in research

Alan I. Leshner CEO, AAAS

"[W]idely publicized examples of scientific dishonesty,...or unacceptable scientific practice,...or repeated unverified claims of [scientific advancement], are not only misleading but seriously erode the public's trust in science."

SCIENCE February 2003

Why be concerned about misconduct in scientific research?

Betray public trust and that of one's colleagues

Immediate and long-term detrimental impact on research

Waste scarce resources, human and financial

Lead to inappropriate, or even harmful, treatment or policy decisions

Key actors in the research system

Researchers—individuals and groups Government–funder, regulator, source of policy Research Institutions (e.g., universities, industry)—institutional policies & procedures, education and training (faculty, students and staff/employees), funding Professional Societies—disciplinary norms and practices (e.g., ethics codes, practice guidelines), training materials and sessions (e.g., case studies, videos, meeting workshops), recognition of role models Professional Journals—peer review, instructions to authors, policies (e.g., data sharing, retractions) Private Funders (e.g., Foundations) Media—professional, trade and popular press Public (consumers of research)—return on investment, accountability

The researcher

All scientists are should be expected to practice intellectual honesty and accept personal responsibility for their behavior as researchers.

Whether for enhancing one's reputation among peers, financial greed, or keeping the grant funding from running dry, some scientists may be driven to undermine the work of others or use other devious means to "win the competition" for publishing in the top tier journals, securing grant funds, recruiting the best graduate students, and all the prestige those bring.

For those scientists who are well intentioned, they, like everyone else, are subject to moral blindness, poor reasoning, or carelessness.

Substantial consensus that the problem is more systemic to science than simply a reflection of a few bad apples.

The research system/environment

The research environment affects the governance of science in ways that create incentives to cut ethical corners.

More scientists, rising costs of doing research, and shrinking research budgets; race for the best graduate students; prestige and search for donors; social relevance of science; promotion and tenure policies.

"It is. . .incumbent on all scientists and scientific institutions to create and nurture a research environment that promotes high ethical standards, contributes to ongoing professional development, and preserves public confidence in the scientific enterprise."

Institute of Medicine, Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct, 2002

What steps are being taken?

National misconduct policies

Address research misconduct through law/regulation; originate with and are legally enforceable by government. Institutions cannot receive government funding without having in place a local policy to implement the national policy. This "local policy" requirement reflects decision by countries to make the institutions where research is conducted primarily responsible for implementing research misconduct policies and procedures, with provision for national review by governments.

National policies are important to ensure consistent coverage and enforcement of the most egregious forms of misconduct.

Institutions may have more inclusive and restrictive policies in place.

6 basic components: What is covered (definition); who is responsible for what; procedures; findings; appeals; sanctions.

What is covered?

It depends. Scope of coverage varies across the globe.

Accountability in Research, 2015

"An International Study of Research Misconduct Policies" David B. Resnik, Lisa M. Rasmussen, and Grace E. Kissling

Surveyed 40 countries that were the top funders of R&D; Mexico was listed as #23 based on 2014 data. 22 had a national misconduct in research policy.

Distinguished among seventeen different types of behaviors that policies classified as misconduct and included the category "other" for behaviors that did not fit these categories.

Findings

All twenty-two countries with national policies included fabrication, falsification, and plagiarism in the definition of misconduct, but beyond that, there was considerable diversity.

Unethical authorship was mentioned in 54.6% of the misconduct definitions, followed by unethical publication practices (36.4%), conflict of interest mismanagement (36.4%), unethical peer review (31.8%), misconduct related to misconduct investigations (27.3%), poor record keeping (27.3%), other deception (27.3%), serious deviations (22.7%), violating confidentiality (22.7%), and human or animal research violations (22.7%).

Brazil

Misconduct is understood as any conduct by a researcher that intentionally or by negligence transgresses the values and principles that define the ethical integrity of scientific research and relationships among researchers,....The most typical and frequent forms of serious misconduct are as follows:

a. Fabrication: The claim that data, procedures, or results were obtained or conducted when in fact they were not.

b. Falsification: The presentation of data, procedures, or results in such a modified, inaccurate, or incomplete way as to interfere in the evaluation of the true scientific merit of the research findings.

c. Plagiarism or the use of another's ideas or verbal formulations, in an oral or written format, without express and clear credit to the authors, in a way that may reasonably generate the perception that the ideas or formulations are one's own.

Canada

<u>Fabrication</u>: Making up data, source material, methodologies, or findings, including graphs and images.

<u>Falsification</u>: Manipulating, changing, or omitting data, source material, methodologies, or findings, including graphs and images, without acknowledgement and which results in inaccurate findings or conclusions.

<u>Destruction of research records</u>: The destruction of one's own or another's research data or records to specifically avoid the detection of wrongdoing or in contravention of the applicable funding agreement, institutional policy, and/or laws, regulations, and professional or disciplinary standards. <u>Plagiarism</u>: Presenting and using another's published or unpublished work, including theories, concepts, data, source material, methodologies, or findings, including graphs and images, as one's own, without appropriate referencing and, if required, without permission.

<u>Redundant publications</u>: The republication of one's own previously published work or part thereof, or data, in the same or another language, without adequate acknowledgment of the source, or justification.

<u>Invalid authorship</u>: Inaccurate attribution of authorship, including attribution of authorship to persons other than those who have contributed sufficiently to take responsibility for the intellectual content, or agreeing to be listed as author to a publication for which one made little or no material contribution. <u>Inadequate acknowledgement</u>: Failure to appropriately recognize contributions of others in a manner consistent with their respective contributions and authorship policies of relevant publications. <u>Mismanagement of Conflict of Interest</u>: Failure to appropriately manage any real, potential, or perceived conflict of interest, in accordance with the Institution's policy on conflict of interest in research, preventing one or more of the objectives of the Framework from being met.

China

Research misconduct includes the following 13 categories: (1) Plagiarism; (2) Fabrication; (3) Falsification; (4) Multiple submissions, under the same or different languages; (5) Improper and exaggerated authorship; (6) Conflict of interests biasing reviews, evaluations, or grant assessments; (7) Lobbying officials for government grants and sending messages to influence review panels, promising to return favors; (8) Using academic prestige to dominate the field and suppress potential challengers; (9) Unfair or honorary authorships, and selling and buying research papers; (10) Deliberately neglecting to cite earlier or the most related works; (11) Fabricated citation of a bogus author or journal; (12) The creation of "trash" or "fake journals," which collect submission fees from authors, conduct no formal review, and then only print enough copies to send to the authors; and (13) Inappropriate use of statistics.

USA

Research misconduct is "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or reporting research results."

U.S. Office of Science and Technology Policy, 2000

Are policies properly focused?

Ranking major and minor research misbehaviors: results from a survey among participants of four World Conferences on Research Integrity

Lex M. Bouter, Joeri Tijdink, Nils Axelsen, Brian C. Martinson and Gerben ter Riet *Research Integrity and Peer Review*, November 2016

Results

The rankings suggest that selective reporting, selective citing, and flaws in quality assurance and mentoring are viewed as the major problems of modern research. The "deadly sins" of fabrication and falsification ranked highest on the impact on truth but low to moderate on aggregate level impact on truth, due to their low estimated frequency. Plagiarism is thought to be common but to have little impact on truth although it ranked high on aggregate level impact on trust.

Conclusions

Our respondents were much more concerned over sloppy science [questionable research practices] than about...FFP. In the fostering of responsible conduct of research, we recommend to develop interventions that actively discourage the high ranking misbehaviors from our study.

Characteristics of a "good" policy

Consistent with goals/objectives

Effectiveness-does what it's supposed to do

Proportionality-benefits outweigh costs

Flexible and adaptable

Promotes public confidence

Clear requirements and sanctions for violations

Enforceable and fairly enforced

Transparent and accountable

From floor to ceiling

Although legally enforceable policies are a necessary function of government in "guiding" the behavior of its citizens, it will never be a fail-safe deterrence to bad behavior. As with any implementation of a law, some "bad guys/gals" will find a way to avoid its grasp.

Research community has come to recognize that any long-term effort to promote the responsible conduct of research must include a range of actors and interventions.

"As members of the professional research community, we should strive to develop and uphold standards that are broader than those addressed by the governmental regulatory framework for dealing with misconduct in science."

National Academy of Engineering Institute of Medicine February 2, 1994

Role of professional societies

Members of a scientific discipline are bound together by similar aspirations, values, and training....A scientist is defined [in part] by his or her relationship to the discipline....The scientific and engineering societies are visible, stable, and enduring entities, and act as the custodian of the discipline's core values, distinct knowledge and traditions, and professional norms and practices.

They can play an important role in influencing the moral tone and ethical climate in which research is conducted.

Mark S. Frankel, "Professional Societies and Responsible Conduct," in *Responsible Science: Ensuring the Integrity of the Research Process*, Vol. II, National Academy of Sciences, 1993.

Ethics guidance

Codes of Ethics/Codes of Conduct

Other Ethics Activities: ethics committees; workshops; major meeting sessions; articles in society journals/newsletters; resource materials, including case studies and curriculum guides; recognition of outstanding mentors and role models.

AAAS Conference on the Role and Activities of Scientific Societies in Promoting Research Integrity, 2000.



The role of professional journals

Science cannot advance without communication, which is vetted for its accuracy, reliability and interpretation. Throughout history, journals have served as the repositories for the "official" research record, certified by the relevant research community.

Journals remain quite influential because publication is the currency of advancement in the sciences—"publish or perish."

Instructions to Authors—what is expected of authors related to responsible conduct—access to data by other scientists; proper credit and citation to others; documentation that all authors are knowingly signing on to the manuscript; ethics review of research involving humans and animals.

Peer Review—clarity about what reviewers are entitled to examine when doing their review; reviewers' responsibility to report to the journal possible misconduct.

Policies—retractions; conflict of interest by authors and reviewers.

Enforcement—banning authors from publishing in the journal for a designated period of time; referring possible misconduct to the funder of the research and/or the institution that employs the researchers.

We cannot "escape from the darkness outside and within by dreaming of systems so perfect that no one will need to be good."

T.S. Eliot Choruses from The Rock 1934

Bridging the technical and normative through education

Research has consequences; some anticipated, others not. Education must go beyond technical competence.

The IOM perhaps reflected this view best, when it declared that "education on the ethical conduct of research [RCR] is the path most likely to have the desired results with the least level of intrusion and the greatest direct impact on overall norms."

Institute of Medicine, Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct, 2002

Education and training for integrity in research

Global explosion of RCR instruction since the mid-1990's

Primary responsibility of research institutions, but governments play a role

Focus on content and approach (what, who, how, and context)

Evaluation—does such instruction make a difference?

What to Teach?

Like the definition of research misconduct, there is variation across countries and even within a single country

USA way ahead of other countries in focusing on RCR education and training

Since the 1990's, a set of topics has emerged as "core topics" in teaching RCR. These include:

- Data Acquisition, Management, Sharing and Ownership
- Conflict of Interest
- Human Subjects
- Animal Welfare
- Research Misconduct (FFP)
- Publication Practices and Responsible Authorship
- Mentor / Trainee Responsibilities
- Peer Review
- Collaborative Science

Not required, but most have found their way into RCR education in USA

Other topics: ethical issues related to the impact of new lines of research/technology on society, including the environment; the effect of implicit bias on research; communicating science to non-scientists; advocacy in science; and the responsibilities of scientists to the larger society.

Approaches to Teaching—Who, How, and Context

Once again, diversity rules. There is no single notion of what background and skills are needed for instructors of RCR. How critical is knowledge of the science as well as of ethics? One instructor or multiple? Train-the-Trainers?

The target audiences are also diverse; do you focus on all active researchers, only young scientists, post-docs, graduate students, undergraduate students, laboratory staff?????

Context: a full course; component of existing courses; specially designated workshops/meetings; in-class and/or online instruction; designated classes for international students?????

Accountability

"Fostering an environment that promotes integrity in the conduct of research is an important part of...accountability."

Institute of Medicine, Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct, 2002

A central purpose of policies and education is to hold people accountable. To do that, researchers must know what are or are not acceptable practices and some mechanism of oversight must be in place.

Accountability goes hand-in-hand with assessment, that is, evaluating whether the education and oversight are accomplishing their stated purposes. In that regard, progress has been modest, at best.

There is "no solid evidence" to show what is or is not effective at fostering a research environment that is conducive to nurturing ethical research practices.

Institute of Medicine, Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct, 2002

What about RCR Education/Training?

Same is true for RCR education and training.

"The lack of data on what works, what doesn't work, and what has had mixed results has impeded the development of programs that build on prior successes and avoid prior failures."

R. Hollander and C.R. Arenberg, *Ethics education and scientific and engineering research: what's been learned? What should be done?* National Academies Press, 2009

Better tools and strategies for evaluating educational and training initiatives are sorely needed, as is greater clarity on the goals of research integrity education and training, so that whatever approaches are employed can be measured against those goals.

Assessing efforts to reduce misconduct, promote the responsible conduct of research and enhance research integrity is the 800 pound gorilla in the room.

Some Meta Questions?

Research Misconduct—What Should be Included?

A national policy must do at least two things well: (1) make clear the types of behavior covered and (2) generate confidence the policy will reduce threats to the integrity of science and protect the public interest.

Some behaviors are high impact, but may not be very prevalent (e.g., fabrication, falsification), while others (e.g., plagiarism, redundant publication) are low impact independently, but when aggregated can have a substantial impact.

Where to draw the line?

Global Implementation

The evidence is quite clear about the increasing internationalization of science.

"the generation of knowledge...takes place in a dynamic, complex and competitive international environment...[and] that today's research requires globally-engaged investigators working collaboratively across agencies and international organizations...."

National Science Foundation, Investing in America's Future. Strategic Plan FY 2006-2011, 2006

If science is global, so are the ethical and policy issues. The confluence of multiple cultures, regulatory systems, national laws, and diverse research institutions create the potential for tensions among the values, norms, and legal frameworks represented by international collaborators, even though the methods of science are universal. Questions of authority and applicability can surface when misconduct allegations arise in a research team from multiple countries. Is greater harmonization the answer? Is it realistic?

How much transparency?

Transparency is integral to accountability. Yet, it competes with privacy, and perhaps fairness as well, when dealing with cases that have implications for the integrity of science and the careers and reputation of scientists.

How best to build a balancing of those values into a national policy?

In the USA, our two largest funders of basic research—PHS and NSF—approach the issue differently. PHS publishes the names of those found guilty of research misconduct, while NSF does not.

Assess efforts to reduce/prevent research misconduct

Accountability without assessment is not accountability, at least not in any meaningful sense. Assessment is a global challenge that nobody has done well. What needs to be done?

Show me the data. Goals Process evaluation Performance and outcome measures Impact Funding

Warning! The results may not be well received by others. They should, however, give us some direction of where we should allocate resources.

"Self-assessment is never comfortable. But if the scientific community is to live up to its responsibilities to maintain the quality and integrity of science, then one has no choice but to do so, and to do it with the same rigor that scientists apply in the laboratory or in the field."

Mark S. Frankel, "Developing a knowledge base on integrity in research and scholarship," *Phi Kappa Phi Forum*, 2003.