US Model for Responsible Conduct of Research (RCR) / Research Misconduct

Time for an Overhaul?

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AGENDA

• Current U.S. Model Re Research Misconduct Allegations
• Legislative History of U.S. Model
• The Canadian System – An Alternative Approach
• Discussion: Are Changes to the U.S. System Warranted?
Current U.S. Model for Addressing “Research Misconduct” Allegations Under HHS Regulations

Became law in 2005 and are implemented and enforced by the Office of Research Integrity (ORI). NSF has similar rules.

**STEP ONE:** Does the allegation meet the “Definition” of Research Misconduct (RM)?

42 CFR 93.103: “Research misconduct means *fabrication, falsification* or *plagiarism* in proposing, performing or reviewing research or in reporting research results.”

[“FFP’”]

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Section 93.103(d): “Research misconduct does not include *honest error* or differences of opinion.”
Regulatory Definitions of FFP

Section 93.103(a) **Fabrication:** “making up data or results and recording or reporting them”

Section 93.103(b) **Falsification:** “manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record”

Section 93.103(c) **Plagiarism:** “the appropriation of other person’s ideas, processes, results, or words without giving appropriate credit”
STEP TWO: Are the Elements present for a “Finding” of RM (Section 93.104)

- A significant departure from accepted practices of the relevant community; AND
- The misconduct was committed either
  - intentionally
  - knowingly
  - recklessly; AND
- The allegation was proved by a preponderance of the evidence
- Note: The majority of U.S. Institutions of Higher Education have adopted the FFP definition of RM, including the concept that RM does not include honest error, and can be “found” only when the requisite mental state is present.
Administrative Actions Available to ORI

42 CFR 93.441: “When a final HHS action results in a settlement or research misconduct findings, ORI may... identify publications which require correction or retraction and prepare and send a notice to the relevant journal.” (emphasis added).

Thus, ORI’s ability to require correction or retraction of a false research record is limited to instances where there is a finding that:

- FFP was committed; AND
- The perpetrator’s mental state was at least “reckless”
- i.e. The government cannot order correction or retraction with the FFP is due to honest error, or innocent/negligent conduct.
What About at the Institutional Policy Level?

Review of several U.S. Institutions of Higher Learning found that most institutional RM policies are patterned very closely on the HHS rules and do not (on their face) give the VCR, President, or any other Senior Administrator broader authority to require retraction or correction.

E.g. “Other institutional actions that may be appropriate include, but are not limited to, withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found . . . .” “In addition, in cases where research misconduct is found, the school dean and/or the Dean of Research may take all other appropriate actions (including the correction of the public record) as deemed necessary and advisable to address the consequences of the research misconduct.”
Who are the “Victims” of Research Misconduct?

- The research record
  - ...when false or misleading data or results are presented in publications.

- Other researchers
  - ...when they rely on the accuracy of data or results to support current research or to plan future research.

- The public
  - ...when research funds and expertise are diverted due to a false or inaccurate research record.

And isn’t the “harm” to these “victims” the same whether the conduct was intentional or accidental?
ORI Yearly Statistics

Research Misconduct Case Outcomes by Year, 2006 - 2015

- No Findings of Research Misconduct, 17
- Misconduct Finding, 14

Cases Closed by ORI (Count)

Year

- 2006
  - 15
  - 20
- 2007
  - 10
  - 18
- 2008
  - 13
  - 4
- 2009
  - 11
  - 32
- 2010
  - 9
  - 22
- 2011
  - 13
  - 16
- 2012
  - 14
  - 21
- 2013
  - 12
  - 28
- 2014
  - 14
  - 27
- 2015
  - 27
  - 17

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How Did We Get Here?

Why is the U.S. model, and the U.S. government’s ability to impose sanctions and redress harm to the research record limited to instances where the researcher(s) involved acted intentionally, or at least recklessly?


Page 13: “Scientists and lawyers also recognize that a scientist should not be penalized for unintended and unforeseeable outcomes if that person acted as an ordinarily prudent person would, and with an acceptable level of care; this issue is also addressed in the "intent" part of the definition. Both lawyers and scientists recognize, further, that the scientific process inherently involves making mistakes. Errors are not research misconduct and should not be punished as such; the Commission’s research misconduct definition makes that clear.”
The Federal Office of Science and Technology Policy proposed for public comment the first government-wide definition of RM along with guidelines for handling allegations.

The introductory comments outlined the importance of an accurate research record:

Vol. 64 Federal Register No. 198, 55723: “Advances in science and engineering depend on the reliability of the research record, as do the benefits associated with them in areas such as health and national security. Sustained public trust in the scientific enterprise also requires confidence in the research record and in the processes involved in its ongoing development.”

“The proposed policy defines the scope of the Federal government’s interest in the accuracy and reliability of the research record and the processes involved in its development.”
Yet, the draft rules proposed the definition we use today: “Honest error” does not constitute FFP, and a finding of FFP requires at least a reckless state of mind. And, did not include correction of the research record as one of the “administrative actions” available to agencies.

**Comment to Draft Rules:** Publications based on false or fabricated data, or including such data, should be **required** to be officially withdrawn.

**Response:** Correction of the research record has been added to the list of possible actions to be taken **if a researcher is found** to have engaged in research misconduct. [emphasis added](Vol. 65 Federal Register, No. 235, 76261)
Take away:

- Strong historical emphasis on ensuring that the “punishment” imposed is appropriate.

But given an important “purpose” of our FFP rules is to protect “the reliability and accuracy of the research record,” is it time to consider a different approach?
Responsible Conduct of Research: The Canadian approach

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Responsible Conduct of Research (RCR)

An umbrella term that covers all aspects of the life cycle of research project

- Application for funding
- Conduct and analysis of research
- Management of research funds
- Dissemination of research results

RCR is about encouraging and promoting a positive research environment.
RCR guidance in Canada

- Guidance document: *Tri-Agency Framework: Responsible Conduct of Research*
- Developed by federal research funding agencies in 2011
- Covers all research disciplines
- Applies to all researchers and institutions who are eligible to receive federal funding
RCR Framework

- Describes responsibilities of researchers, institutions and Agencies
- Defines breaches of the RCR Framework
- Sets out the minimum requirements that must be included in institutional RCR policies regarding allegations
- Sets out the process that the Agencies follow for addressing allegations of breaches of Agency policies
Breach of the RCR Framework

Failure to comply with any Agency policy throughout the life cycle of a research project – from application for funding, to the conduct of the research and the dissemination of research results.

In determining whether an individual has breached an Agency policy, it is not relevant to consider whether a breach was intentional or a result of honest error. However, intent is a consideration in deciding on the severity of the recourse that may be imposed.

Article 3.1, RCR Framework
Intentionality

- The intention of an act is not relevant to the determination of a breach of the RCR Framework.
- Any contravention of the RCR Framework is a breach (even honest error).
- Objective of RCR is responsible research.
- Any breach, regardless of the reason, can negatively impact the integrity of the research and the integrity of the research record.
- Intent is a consideration when deciding on the severity of the recourse that may be imposed.
Scope of breaches

- Broader than fabrication, falsification and plagiarism (FFP)

- In addition to FFP, breaches may include:
  - Mismanagement of grant or award funds
  - Invalid authorship or inadequate acknowledgment
  - Destruction of research records
  - Self-plagiarism
  - Mismanagement of conflict of interest
  - Inaccurate or misleading information in funding applications
  - Conducting research involving human participants without ethics approval
Rectifying a breach

Researchers in breach of an Agency policy are expected to be proactive in rectifying a breach, for example, by correcting the research record, providing a letter of apology to those impacted by the breach, or repaying funds.

*Article 3.1, RCR Framework*
Recourse

- Letter of awareness/education
- Letter of admonishment
- Correction of the research record
- Termination of a grant or award
- Reimbursement of funds
- Ineligibility to participate in peer review committees
- Ineligibility to hold/apply for Agency funding for a period of time or permanently
- Public disclosure
Similarities in U.S. & Canadian approaches

- Process for addressing allegations (institutions; inquiries; investigations)
- Definitions of FFP
- Factors considered re: seriousness of misbehavior (e.g., pattern; impact)
<table>
<thead>
<tr>
<th>Difference</th>
<th>Canada</th>
<th>United States</th>
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<tbody>
<tr>
<td>Terminology</td>
<td>Breach</td>
<td>Research misconduct (RM)</td>
</tr>
<tr>
<td>Scope</td>
<td>Any non-compliance throughout research continuum</td>
<td>FFP only</td>
</tr>
<tr>
<td>Intentionality / mens rea</td>
<td>Not relevant to the determination of a breach</td>
<td>Must be committed intentionally, knowingly or recklessly</td>
</tr>
<tr>
<td>Governance</td>
<td>RCR enforced through funding</td>
<td>RI enforced by federal regulation</td>
</tr>
<tr>
<td>Correction of research record</td>
<td>Expectation to correct record, regardless of reason for the breach</td>
<td>Maybe, but only in cases where there is a finding of RM</td>
</tr>
<tr>
<td>Public disclosure</td>
<td>Only for serious breaches; at discretion of Agency President</td>
<td>Voluntary Settlement Agreement reached between ORI and Respondent</td>
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Potential benefits to a broader approach

- Addresses the violation by focusing less on the intent and more on rectifying the situation (less stigma)

- Shift of emphasis from wrongdoing to responsible behaviour (more incentive for RCR training)

- Accurate research record

- Researchers can confidently on the results in the scientific literature when planning future research

- Increased public trust that public funds are being used responsibly
Let’s discuss....