Misconduct and Other Sins

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With assistance from
Richard Smith Editor, BMJ
NORMS

- Norms are general statements implying obligations and/or evaluations
- Norms are shared by members of a certain group
- A belief held by a single individual is not a norm.
Norms Of Scientists

- Intellectual integrity and objectivity
- Tolerance for disputes
- Doubt of certitude
- Recognition of error
- Unselfish engagement
- Communal spirit

Personal Experiences

Famous case of misconduct

Were shown an unpublished paper

Suspect the work of others

Know an unethical scientist
## Personal Experiences

<table>
<thead>
<tr>
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<th>Faculty</th>
<th>Trainees</th>
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<tbody>
<tr>
<td>Famous case of misconduct</td>
<td>43.5</td>
<td>23.5</td>
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<tr>
<td>Was shown an unpublished paper</td>
<td>65.7</td>
<td>66.0</td>
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<td>29.7</td>
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<tr>
<td>Knows an unethical scientist</td>
<td>50.0</td>
<td>26.3</td>
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When Norms Beget Regulations

- Your university is mandated by the Federal government to:
  - Manage federal assurance to conduct research ethically.
  - Ensure that research does not violate rules, (e.g. Unauthorized stem cell research or research using anthrax).
  - Mandates disclosure and management of financial interests and conflicts of interest.
  - Handle allegations of misconduct properly
Why Research Misconduct Matters

- It’s like child abuse: we didn’t recognise it, now, sadly, we identify a lot more of it.
- Recent evidence shows that most identified cases are deliberate.
- Misconduct undermines public trust.
- It corrupts the scientific record and leads to false conclusions that may be perpetuated and hard to reverse.
Sins Are Everywhere as are Sinners
Institutional (University) Sins

- Fostering a survivalist mentality in researchers.
- Favoritism.
- Coercing students to be research subjects.
- Failure to firewall financial ties.
- Poor treatment of whistleblowers
- Whitewashing misconduct investigations
- Failure to properly sanction the convicted and restore reputation of the innocent
UCLA IRB Reporting Requirements

UCLA personnel, including investigators, research team, faculty, staff, administration or students are responsible for the protection of the rights and welfare of human research subjects. To this end,

all parties are responsible for reporting serious or continuing noncompliance with applicable human research regulations or requirements, determinations, or policies of the IRB.

Investigators must report immediately upon discovery and no later than ten days from the occurrence.
Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is 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.
(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

New rules can be found at:
Sec 93.104 Requirements for findings of research misconduct

- There be a significant departure from the norms of the relevant research community; and
- The misconduct be committed intentionally, knowingly, or recklessly; and
- The allegation be proven by a preponderance of the evidence.

Burden of proof. The institution or HHS has the burden of proof for making a finding of research misconduct.
Sec 93.106 Evidentiary Standards

- The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct.
Affirmative Defense

(2) The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised, as well as any mitigating factors that are relevant to a decision to impose administrative actions following a positive finding of research misconduct.

In determining whether HHS or the institution has carried its burden of proof, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.
Sec. 93.210 Good faith

- **Good faith**, ..., means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have, based on what they knew at the time.

- **Good faith of a committee member** means carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.
Suspicion of Wrongdoing

Informal Communication
- Lab Chief
- Department Chair
- Ombudsman

Nature of Complaint
- Possible Scientific Misconduct
  - YES: Scientific Integrity Officer
    - YES: Sequester Data
    - NO: Initiate Formal Inquiry
  - NO:-initiate formal inquiry
- Misunderstanding, Disagreement, Breach of Manners, Larceny
  - YES: Mediation or other remedy
  - NO: Sequester Data
    - YES: Initiate Formal Inquiry
Formal Inquiry

Possible Misconduct

**Formal Investigation**
- Expert Committee
- Determine nature & extent of misconduct
- Quasi-legal procedure
- Legal representation
- Data sequestered
- ORI notified

**Committee Report**

Adjudication

**Sanctions:**
- Institutional, Governmental

**Office of Research Integrity Institute**

Not Misconduct

Mediation

Restore Reputation
Our Response to Whistleblowers

Pepper... and Salt

THE WALL STREET JOURNAL

“I wasn’t tattling ... I was whistleblowing.”
Whistleblowing

- Practical issues:
  
  Consider it an inquiry rather than an accusation

  Talk it over with friends

  Is there another side to the story?

  Write it down. Focus on the science and exact details

  Try to develop support

  You shouldn’t illegally examine someone’s data

Whistleblowing 2

- You may **not** have a right to know what’s going on. Is that okay for you?
- What kind of satisfaction do you want?
- If it’s your boss, you may have to move. Is that okay for you?
- Is there a way to achieve your goals without going to the “authorities”?
- Are you prepared for the long haul and for a bad outcome?
ORI : Ten Years of Reporting

- 703 Individual cases filed
- 602 inquiries
- 221 investigations
- 110 findings of misconduct (from 76 institutions)
New Defendants

- Now suing everyone including
  - The university
  - The teaching hospital
  - The PI
  - The sponsor
  - Top university officials
  - Individual IRB members
  - The hospital’s patient advocate (Abiomed)
New Defendants

- Grimes v. Kennedy-Krieger Institute of Johns Hopkins - lead exposure study. Controls were allowed to continue to be exposed to lead.
  - Maryland’s highest court faulted the judgement of the IRB and determined that its ruling constituted negligence

- With many individuals subject to the same conditions - ripe setting for class action suits. Much more lucrative for the attorneys
Why does misconduct happen?

- Why not?. It happens in all other human activities. Everyone lies pretty consistently.
- Pressure to publish, survivalist mentality.
- Defective ethical sensitivity (sociopath).
- Inadequate training. Not taught good practices. Indeed, sometimes encouraged in the opposite.
- Does sloppy behaviour spill over to fraud?
- You can often get away with it. The system works on trust.
Trust

- Research on humans is based on trust:
- That the truth is told about the study
- That COIs are revealed
- That the institution is fulfilling its responsibilities to the participants.
- That those conducting the study have the best interests of the participants at the top of their agenda.