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Research Misconduct

Neelain University
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Definition of research misconduct

- "Behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standards."

*proposed by a British consensus panel (1999)*
Andrew Jeremy Wakefield (born c. 1957)

• Is a British former surgeon and medical researcher, (1998) published a research paper supporting a link between the administration of the measles, mumps and rubella (MMR) vaccine, and the appearance of AUTISM and bowel disease

• Other Researchers were unable to reproduce Wakefield's findings or confirm an association between the MMR vaccine and autism, or autism and GIT disease.

• 2004 Sunday Times identified undisclosed Financial Interest

• The British GMC conducted an inquiry into allegations of misconduct against Wakefield and two former colleagues.

• Findings: children with autism were subjected to unnecessary invasive medical procedures, such as colonoscopy and lumbar puncture, and that Wakefield acted without ethical approval from an IRB. (1,2)
Yoshitaka Fujii

• a Japanese researcher in Anesthesiology, who in 2012 was found to have fabricated data in at least 172 scientific papers. [1]

• 23 Scientific Journals made a public request for an investigation of Fujii's research by the seven Japanese institutions named as affiliations in his published papers. [1]

• A committee, undertook an examination of 212 of the 249 papers credited to Fujii.

• On 29 June 2012, the committee reported finding that a total of 172 papers contained fabricated data. (126 papers "totally fabricated"). Only 3 of the 212 papers were valid.

• The report stated: "It is as if someone sat at a desk and wrote a novel about a research idea." [1]

[1]Normile, Dennis (2 July 2012), "A New Record for Retractions?", Science Insider (American Association for the Advancement of Science)
Definition of Research Misconduct

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

1. **Fabrication** is making up data or results and recording or reporting them.

2. **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.

3. **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research misconduct does not include honest error or differences of opinion.
Scientific Misconduct
Scientific Misconduct

• Data Falsification/Fabrication
• Unethical research
• Defective data description
• Image manipulation
• Inadequate author
• Undeclared conflict of interest.
• Redundant publication
• Plagiarism
• There is a continuum from truly correct to truly deceptive scientific research.
• The grey area in between is often referred to as ‘Questionable Research Practices’ (QRP).

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Examples of Questionable Research Practices’ (QRP).

- Neglecting negative outcomes
- Using inappropriate statistics to support one’s hypothesis
- Inappropriate research design
- Leaving out relevant controls
- Inappropriate re-use of controls
- Conscious bias
- Unethical experimentation
- Peer review abuse
Does Medicine have a Culture that Turns a Blind Eye to Research Misconduct?

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Vijay Soman and Philip Felig 1978; Yale, exposed 1980

- NEJM sent Felig a paper for review.
- Felig passed paper to Soman, his junior colleague.
- They rejected paper.
- A few months later, Am J Medicine sent original author a manuscript for Review, authored by Soman.
- Clearly copied from hers.
- Additional data had been made up by Soman.
- Felig resigned but stayed on at Yale.

Peer-review violation
Plagiarism
Fabrication
Robert Slutsky, Cardiological Radiologist, University of California

• Published 137 papers between 1978 and 1985--sometimes one every 10 days

• A Reviewer raised anxieties about some of Slutsky’s work.

• An investigation decided that 12 of Slutsky’s studies were definitely fraudulent and 49 questionable

• Many were retracted

Peer Review
Fabrication
Britain’s most dramatic case of fraud
August 1996: a Major Breakthrough

• Worldwide media coverage of doctors in London reimplanting an ectopic pregnancy and a baby being born
• Doctors had been trying to do this for a century. It was a huge achievement

Two Papers:
1. Successful transplant of ectopic pregnancy to uterus healthy baby;
2. Double-blind randomised trial on improving pregnancy success for women with polycystic ovary syndrome.
What had happened?

• A **Young Doctor** at St George’s Hospital Medical School had raised questions about the two papers

• An investigation was promptly started and showed:
  
  ➢ The patient did not exist
  
  ➢ The patients supposedly in the randomised trial could not be found

  ➢ Among studies investigated back to 1989 - three others fraudulent papers, two of them in the BMJ.
Obstetrician at St George’s London. Published 2 key papers
(1) successful transplant of ectopic pregnancy to uterus
healthy baby;
(2) double-blind randomised trial on improving pregnancy
success for women with polycystic ovary syndrome.
Patients were made up.
Among studies investigated back to 1989 - three others
fraudulent, two of them in the BMJ.
Attempted to hack computer to alter medical records.  
Fabrication
Struck off by the GMC
World renowned ultrasound Expert
Pearce’s boss, accepted gift authorship on ectopic pregnancy paper.
Reprimanded by GMC;
He was forced to resign both as Editor-in-chief of BJOG and as President of the Royal College of Obstetrics & Gynaecology.
Hwang Woo-suk (born January 29, 1953) is a South Korean veterinarian and researcher. He was a professor of biotechnology at Seoul National University.

In February 1999, he announced that he successfully created a cloned dairy cow, Yeongrong-i.

In February 2004, declared the successful creation of an embryonic stem cell with the SCNT method, and published their paper in the March 12 issue of Science.

Data turned out fabricated or falsified.

Also obtained human eggs for research by unethical means, including requiring female researchers to superovulate.
What does a country need to respond to research misconduct?

- A recognition of the problem by the medical community and its leaders
- An independent body to lead with investigations, prevention, teaching and research
- An agreement on what misconduct is
- Protection for whistle-blowers
- A body to investigate allegations
- A fair system for reaching judgements
- A code of good practice
- Systems for teaching good practice

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THANK YOU
Conflict of Interest

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Ethics of Research Workshop
Neelain University
25th May 2016
Interest: Definition

An interest may be defined as a **Commitment, Goal, or Value** held by an individual or an institution.

Examples include:

- **A Research Project** to be completed,
- **Gaining Status Through Promotion or Recognition,**
- **Protecting The Environment.**

Interests are pursued in the setting of social interactions.
Definition: Conflict of Interest

• A situation in which a person has a **Private or Personal Interest** sufficient to appear to **Influence the Objective Exercise** of his or her **Official Duties** as, say, a public official, an employee, or a professional.  
  (MacDonald, McDonald and Norman 2002)

• Any factor that might tend to **Undermine** a competent **Researcher’s** ability to make scientifically reliable judgments concerning research strategy, evidence or conclusions.  
  (Davis 1999)

• A set of circumstances that creates a risk that **Professional Judgment** or actions regarding a primary interest will be **Unduly Influenced by a Secondary Interest**.  
  (Institute of Medicine 2009)
What comprises COI?
Financial Interests

- Recruiting patients
- Research grants
- Stock options
Non-financial Interests

“If there’s no money, there’s no conflict...”

Tendency to focus on what’s measurable ($$$)

- Non-financial interests often ignored completely
- Given much less attention in policies

Not considered very harmful

- Less problematic than financial interests

Recognizing these threatens professional identity

- Objectivity, neutrality, independence

Non-financial interests can be especially problematic, because they are less recognized and less understood.
What comprises COI?

• Stock ownership
• Paid employment Board membership
• Patent applications (pending or actual)
• Research grants (from whatever source)
• Travel grants and honoraria for speaking or participation at meetings
• Gifts Membership of lobbying organizations
• Relationship with the National Research Ethics Review Committee, or with possible reviewers of the paper
• Relationship with organizations and funding bodies Membership of a government advisory board
Levels of COI
Levels of COI

• Researchers
• Conflicts of Interest by IRB Members
  \textbf{Individual Level}
  \textbf{Institutional Level}
• Institutional Conflicts of Interest
Levels of COI

Researchers
the researcher’s judgement may be influenced, or appear to be influenced:
• By Private or Personal Interests,

The IRB should assess:
• the likelihood and the seriousness of any harm that may result from such influence or from the mere appearance of undue influence
Levels of COI

Conflicts of Interest by IRB Members

- when their own research projects are under review by their IRB

- when they have been in direct academic conflict or collaboration with the researcher whose proposal is under review.
COI at the Institutional Review Board (IRB) Level

**Individual Level**
- Member is an investigator on research under review
- Members or staff hold significant financial interest in sponsor of research
- Loyalty to colleagues submitting for review
- Members closely tied to area of research under review
  - If familiar = too lenient
  - If competitor = too critical
- Possible impact of decisions on member's own work (e.g., policy changes)
- Personal agendas, deeply held beliefs
COI at the Institutional Review Board (IRB) Level

**Institutional Level**

- Pressure or desire to protect institution
- Concern for institutions reputation or prestige
- Promoting research vs. protecting subjects
- Undervaluation of IRB service
- Potential liability
- Institutional or community values
- Pressure for speedy reviews
- Institutional equity or ownership
- Review fees
Levels of COI

Institutional Conflicts of Interest

• Situations may arise where the parent organization has a strong interest in seeing a project approved before all ethical questions are resolved.

• The IRB must act independently from the parent organization.

• Institutions: respect the autonomy of the IRB; and ensure appropriate financial and administrative independence.
The Conflicts of Interest Policy provides for a three-fold approach:

- Disclose always
- Manage the conflict in most cases
- Prohibit the activity when necessary to protect the public interest or the interest of the University.
Managing COI in Practice

Being in a COI is not unethical ...the issue is how to handle it.

Guidance:
1. Identify COI, avoid *when possible*
2. Discuss with all concerned
3. Remove person from sensitive decisions

Sometimes 1 and 3 are impossible.
So 2 (*transparency & dialogue*) becomes crucial.
Thank you!!
Malcolm Pearce (1994-95)

- Obstetrician at St George’s, London
- Reported transplant of ectopic pregnancy to uterus and live birth
- Colleagues at same hospital said no knowledge of case
- Pearce tried to hack computer to alter notes
- Also found to have invented patients in study on polycystic ovary syndrome
- Struck off by GMC

Fabrication

http://tinyurl.com/pearce11
Geoffrey Chamberlain (1995)

- Linked to Malcolm Pearce case
- World reknowned ultrasound expert
- Chamberlain was Pearce’s Head of Dept, and Editor of British Journal of Obstetrics and Gynaecology where both fraudulent papers were published
- Accepted “gift authorship” for ectopic pregnancy paper
- Reprimanded by GMC
- “A considerable error of judgement” (Wells, 2008)

Gift authorship