Research Misconduct

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Learning Outcomes

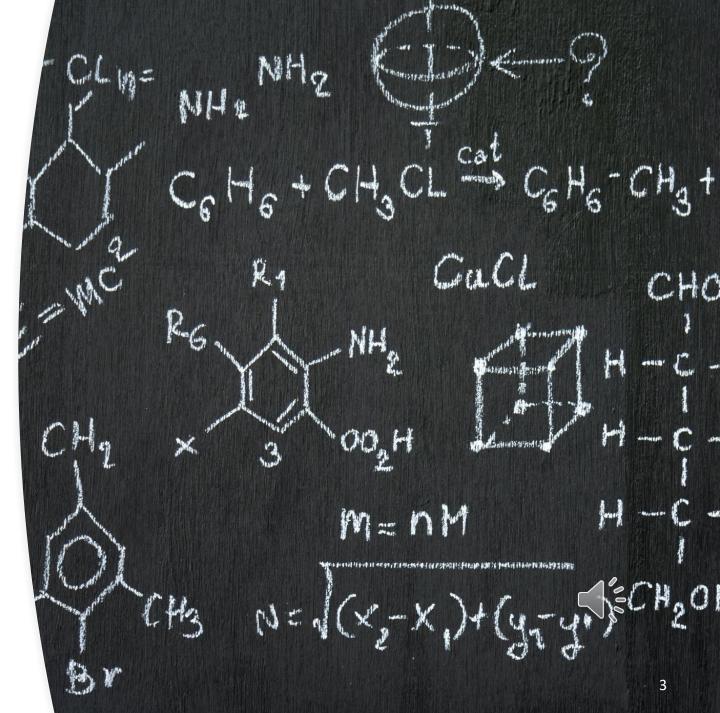
By the end of this module the learner should be able to

- Identify types of Research Misconduct
- Give examples of Questionable Research Practice
- Recognize Authorship Guidelines



Research Misconduct

- In 1830 the mathematician and inventor Charles Babbage (1791-1871) wrote about unethical practices that he had observed in British Science. He discussed Hoaxing, Forging, Trimming and Cooking of Data.
- Hoaxing and Forging occurs when one makes up data.
- Trimming occurs when one clips off pieces of data that do not agree with one's hypothesis
- Cooking occurs when one manipulates data in order to make them appear to be more accurate than they really are. (1)



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)



Definition of Research Misconduct

White House Office of Science and Technology Policy (OSTP) in 2002 develops a federal definition that was adopted by all federal agencies. The policy was implemented in 2005.

Research Misconduct is:

"Fabrication, Falsification or Plagiarism in proposing, performing or reviewing research or in reporting research results."



Wellcome Trust Definition

Misconduct includes "**Deliberate**, **Dangerous**, or **Negligent** <u>**Deviations**</u> from accepted practices in carrying out research" and "**Failure** to follow established protocols if this failure results in **unreasonable** risk or harm to humans, other invertebrates, or the environment. ⁽¹⁾



Definition of Research Misconduct

- 1. <u>Fabrication</u> is making up data or results and recording or reporting them.
- 2. <u>Falsification</u> 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. تزوير
- 3. <u>Plagiarism</u> 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.

(OSTP)

Research Misconduct (European)

European make a broader definition and add

- 4. Authorship problems...Guest, Honorary, Ghost, Gift, Reciprocal, duplicate publishing
- سوء إدارة Funds mismanagement and abuse الأموال وإساءة استخدامها
- 6. Any act; which is, in accordance with the established academic norms, is considered as an act of research integrity misconduct; such as piracy قرصنة, defamation التشهير, misinterpretation قرصنة, sabotage تخريب, professional misconduct السلوك المهني.

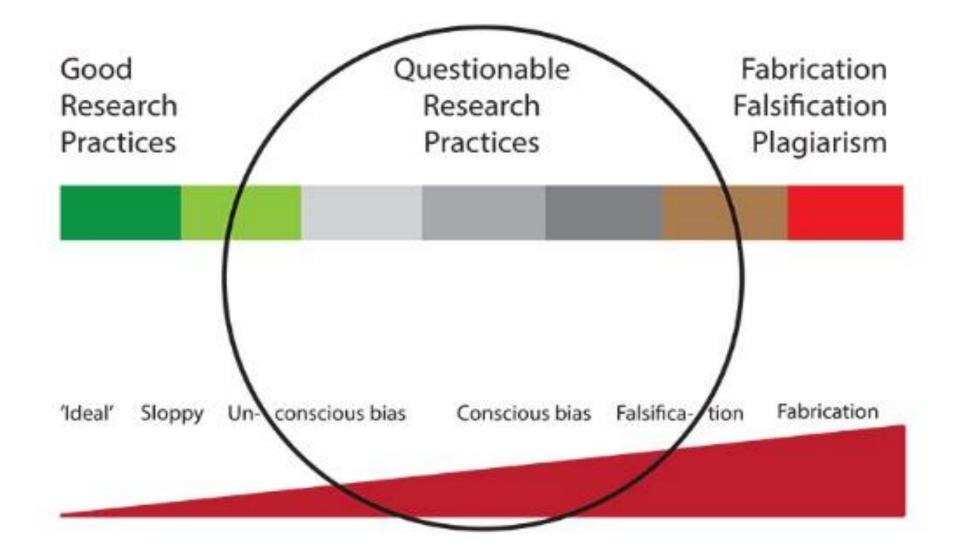


Scientific Misconduct

- Data Falsification تزوير البيانات
- Data Fabrication تصنيع البيانات
- Unethical research عير اخلاقي
- Defective data description
- Image manipulation
- Inadequate authorship
- 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).





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



Respond to research misconduct?

- A recognition of the problem by scientific 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



US Regulatory Response

- The United States was the first country to introduce legislation and federal laws to deal with research misconduct
- The Office of Scientific Integrity (OSI) in the National Institutes of Health (NIH) and the Office of Scientific Integrity Review (OSIR) in the Office of the Assistant Secretary of Health were established in 1989.
- These two offices were later merged in <u>1992</u> to form the <u>Office of</u> Research Integrity (ORI).
- In 1993, ORI became an independent body that introduced policies to manage research misconduct
- ORI oversees research activities and investigate allegations of research misconduct.



US Regulatory Response

 In 1989 NIH instructed institutions to conduct structured training in Responsible Conduct of Research (RCR)

• In **2000 ORI** mandated researchers receiving Public Health Service (PHS) funds to receive instruction in *Nine Core Topics* in **RCR**.

 These are: Data management, Authorship and Publications, Peer Review, Mentoring, Collaboration, Research Misconduct, Conflict of Interest, Research Animals and Research with Humans.

Committee on Publication Ethics (COPE)

- A group of prominent journal editors realized the scale of research misconduct and founded the Committee on Publication Ethics (COPE) in July 1997.
- The committee assumed an advisory role initially but by 2008, COPE was a founded as charity with a code of conduct and constitution.
- Several similar bodies were established; the UK Research Integrity Office (UKRIO) was establishes in 2006.
- Unlike the OSI, it is an advisory body with no legal or legislative arm.
- Similar bodies were founded in Europe but with no legal or status.



ICMJE Authorship Recommendations

Substantial Contributions to

- 1. Conception or design, or acquisition, analysis or interpretation of data; AND
- 2. Drafting the article, or Revising it critically for important intellectual content; **AND**
- 3. Final Approval of the version to be published; **AND**
- 4. Agreement to be Accountable for Accuracy and Integrity of all aspects of the work.

(International Committee of Medical Journal Editors, 2004) (Uniform Requirements of the International Committee of Medical Journal Editors, 8/2013)



NOT Qualifications for Authorship

- Acquisition of funding
- Providing and caring for study patients
- Providing materials (cell lines, patients, datasets)
- Collection of data;
- Writing, technical, or language editing of paper

- Helping someone with data analysis or collection
- Famous dissertation committee chair of third author
- General supervision of the research group
- Someone to whom you owe a favor

These contributions should be listed in the **Acknowledgements**

ICMJE website: www.icmje.org/index.html



Authorship

- GUEST authors are those who DO <u>NOT MEET accepted</u> authorship criteria but are listed because of their Seniority, Reputation or Supposed Influence
- GIFT (Honorary) authors are those who DO <u>NOT MEET</u> accepted authorship criteria but are listed as a personal favour or in return for payment
- GHOST authors are those <u>WHO MEET</u> authorship criteria but are not listed e.g. <u>employees of</u> <u>pharmaceutical</u> or device companies, <u>medical writers</u>, <u>marketing and public relations writers</u>, and <u>junior staff</u> <u>writing for elected or appointed officials</u>.



Authorship

Anonymous Authorship :

 authorship should be transparent but when the author can make a credible claim that attaching his or her name to the document could cause serious hardship (e.g., threat to personal safety or loss of employment

Group Authorship

- when a group of researchers has collaborated on a project, such as a multicenter trial, a consensus document, or an expert panel.
- Deceased or Incapacitated Authors.
- For cases in which a coauthor dies or is incapacitated during the writing, submission, or peer-review process, coauthors should obtain disclosure and copyright documentation from a familial or legal proxy.

Authorship Abuse

Coercion Authorship

Use of intimidation tactics to gain authorship

 Typically involves threat of seniority over subordinates or junior investigators to gain authorship

Not limited to senior vs. junior investigators



Tactics of Authorship Abuse

"Ghost journal"??



Merck published fake journal

- The drug company paid Elsevier to produce several volumes of a publication made to look like a peer-reviewed medical journal, with no disclosure of company sponsorship
- Contained only reprinted or summarized articles
- Most presented data favourable to Merck products

By Bob Grant April 30, 2009

flicker/linkurl:meviola;http://www.flickr.com/photos/69659670@N00/

Thank you!!