

Handling research misconduct: employers and host organisations

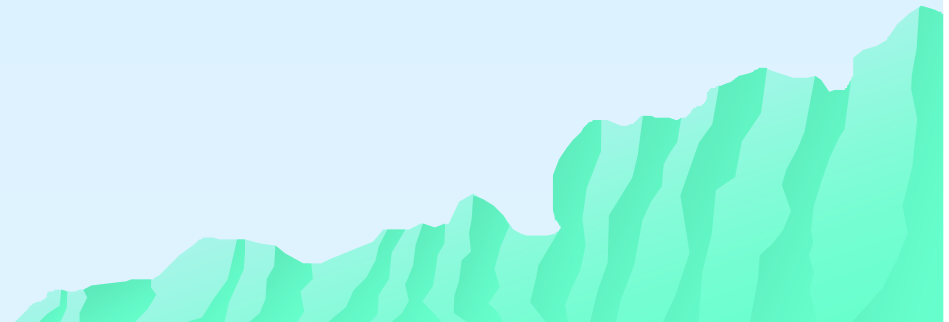
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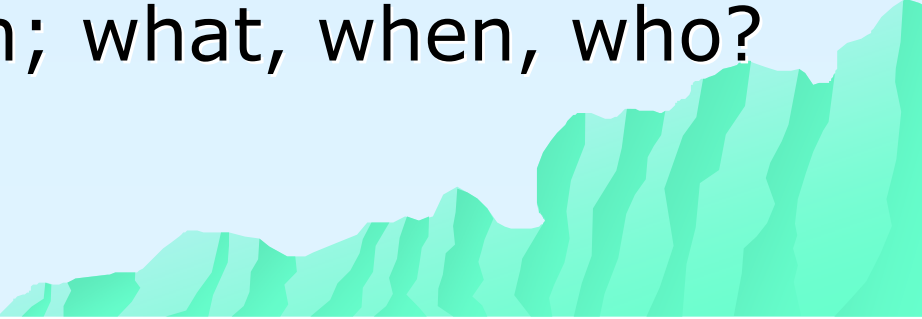


Handling research misconduct: employers and host organisations

- ◆ Examining how universities and NHS organisations need to work together to create a consistent and coordinated approach to handling research misconduct.



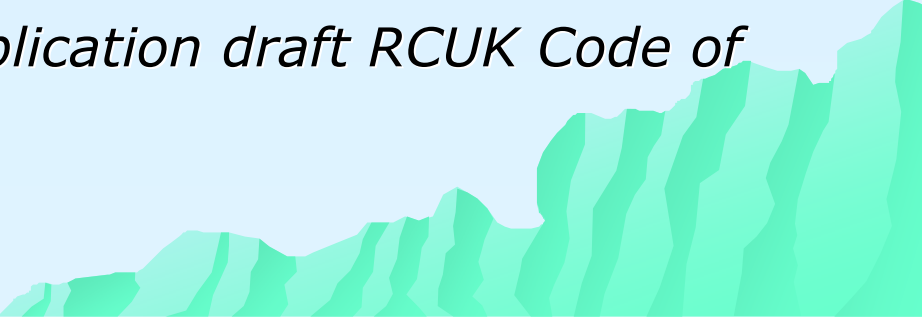
Today's workshop

- ◆ What is misconduct and what is not
 - ◆ Size of the problem
 - ◆ Causes
 - ◆ Impact and consequences
 - ◆ Examples
 - ◆ Current activity to address research misconduct
 - ◆ The way forward for the NHS? Discuss !
 - ◆ Action points for Forum; what, when, who?
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What is misconduct and what is not

- ◆ FFP
- ◆ QRP
- ◆ Misconduct is NOT
 - Genuine misinterpretation
 - Genuine difference of opinion
 - Genuine mistakes

In part drawn from a pre-publication draft RCUK Code of Conduct

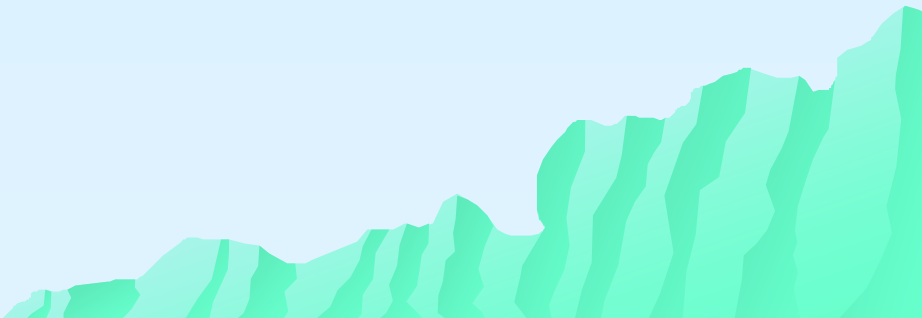


FFP

- ◆ Fabrication
 - Creation of fictitious data, research documentation, consent.
- ◆ Falsification
 - Inappropriate manipulation of data, images, consent or selective presentation of these
- ◆ Plagiarism
 - Use or misuse of ideas, intellectual property or work (in any medium) without appropriate acknowledgement or permission
 - citation plagiarism – willful or negligent failure to appropriately credit other or prior discoverers, so as to give an improper impression of priority

Questionable Research Practices

includes....

- ◆ Misrepresentation
 - ◆ Poor management of data & materials
 - ◆ Breach of duty of care
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Misrepresentation

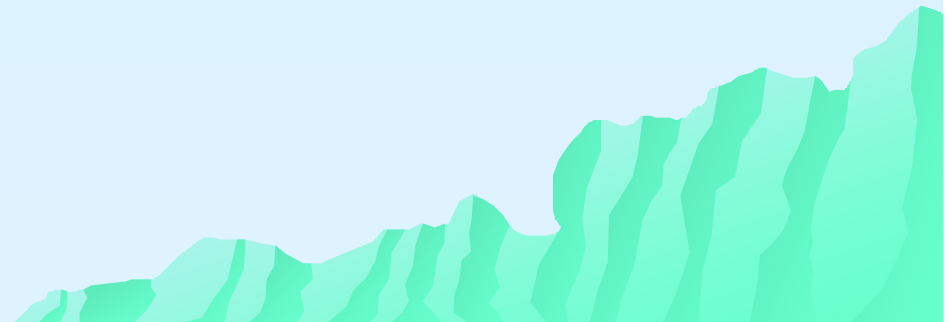
includes.....

- ◆ Undisclosed suppression of findings or data
- ◆ Knowingly or negligently presenting flawed interpretation of data
- ◆ Undisclosed duplication of publication (including duplicate submission)
- ◆ Failure to declare relevant interests of researcher or funder
- ◆ Claiming or implying qualifications/experience not held
- ◆ Inappropriate claim to authorship and/or attribution of work or denial of these to others
- ◆ ghostwriting – the phenomenon where someone other than the named author(s) makes a major contribution to the study
- ◆ suppression--the failure to publish significant findings due to the results being adverse to the interests of the researcher or his/her sponsor(s)--

Poor management of data & materials


includes.....

- ◆ Failing to preserve primary data and research evidence and make accessible to others for the appropriate time after the completion of the research
- ◆ Failure to secure the integrity of materials to ensure reliability of results



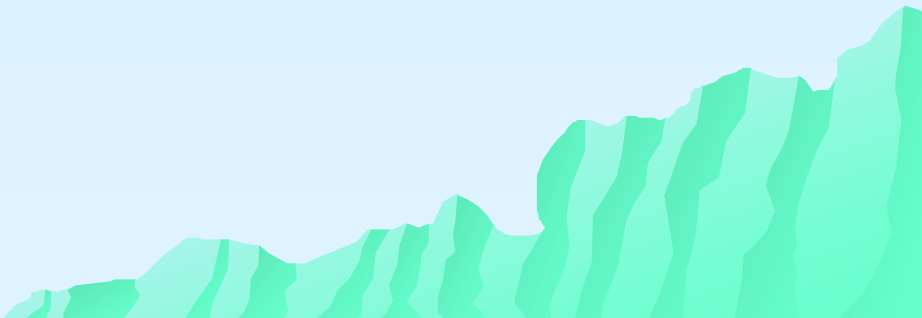
Breach of duty of care

includes.....

- ◆ Inappropriately disclosing the identity of individuals or groups without consent
 - ◆ Placing any person/organisation involved in danger without prior consent (including reputational danger)- even with consent must have appropriate safeguards
 - ◆ Failing to ensure that all risks and dangers, broad objectives and identity of research sponsors are known to the participants (or their legal representatives) to ensure informed consent obtained explicitly and transparently
 - ◆ Failing to comply with legal requirements in non-human subjects
 - ◆ Improper conduct in peer review of applications/publications eg. Misrepresentation of the contents, inadequate disclosure of limited competence, abuse of material provided in confidence
 - ◆ Failure to disclose evidence or suspicions of any misconduct to the appropriate authorities
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Questionable Research Practices


also includes....

- ◆ Poor research design and conduct
 - ◆ Failure to maintain skills and act with due care and skill
 - ◆ Inclusion of references to give arguments the appearance of widespread acceptance, which are fake, and/or do not support the argument
- 

Size of the problem

- ◆ Widely thought to be 'rare' – BUT
- ◆ Martinson (2005) peer-based list of major offences – surveyed 6000 PIs. 50% + response – self-admitted 0.3% major misconduct; 5 -15% QRP (over past 3 years)
- ◆ Gardner (2005) 5% reported fabrication/10 years
- ◆ Gess (2001) 305 new consultants, 50% observed Misconduct, 5.7% admitted involvement
- ◆ Rossner (2006) 1% serious misrepresentation of digital images
- ◆ Ranstern (2000) 51% 'knew' of misconduct, 26% involved in a study, est 0.08-0.69% personally offended
- ◆ Generally accepted that FFP 0.1-1%; QRP up to 50%

Causes

- ◆ Need to publish for career/RAE
 - ◆ Belief in right outcome
 - ◆ Embarrassment/fear of sanctions
 - ◆ Cover-up of previous poor or misconduct
 - ◆ Professional/personal rivalry
 - ◆ Personal gain, qualification/position/financial
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Tensions

- ◆ Transparency vs first to publish
- ◆ Continued sponsor income industry or non-commercial
- ◆ RAE priorities
- ◆ Challenging the status quo

Impact and consequences-FFP

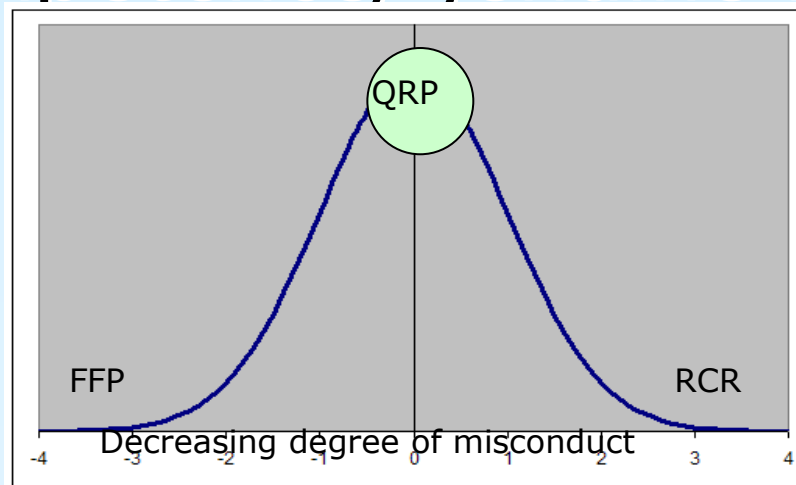
- ◆ short term significant
 - Damages public perception of scientific integrity and confidence in science; may reduce financial donations
 - Wastes research funding and time directly and in further studies
 - Undermines validity of results
 - ◆ Misleading conclusions
 - ◆ Clinical risk
 - ◆ Wasted health resources on ineffective interventions
 - ◆ May skew research agenda

Impacts - FFP

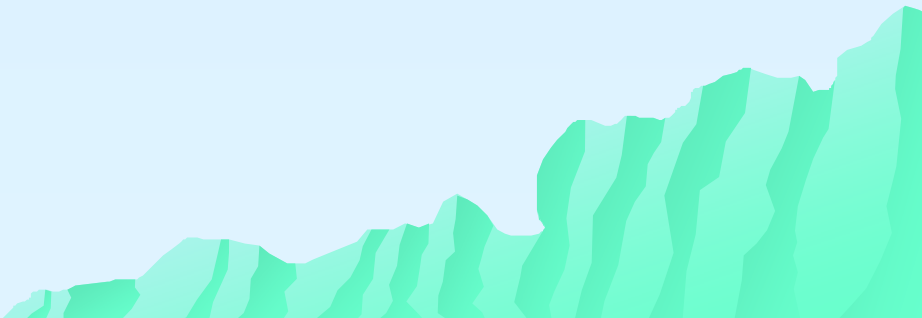
- ◆ Long term less significant
 - Esp if detected and dealt with appropriately
 - Science copes with bad data over time
 - Often most significant impact is on whistle-blowers

Impact and consequences QRP

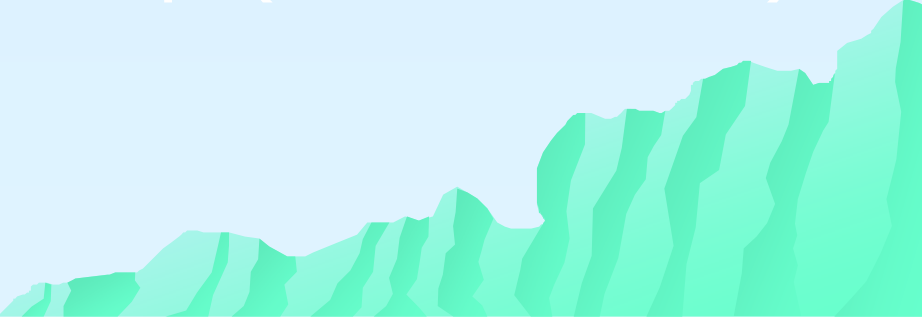
- ◆ Much more common and insidious
- ◆ Can affect whole groups or departments
- ◆ Often more difficult to prove vs incompetence/genuine mistakes



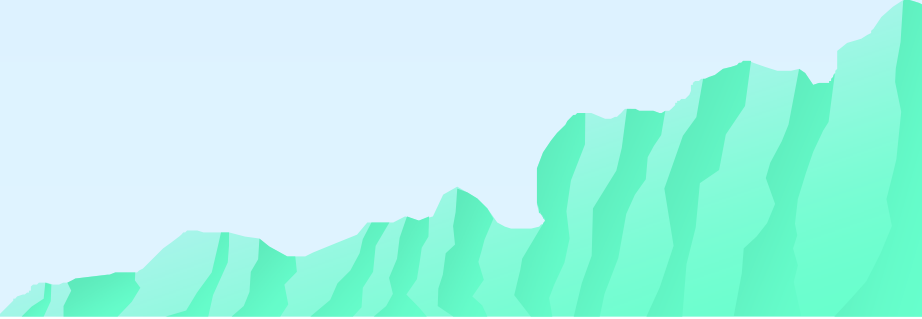
Examples

- ◆ Cornell Univ NEJM (2006) CT vs X-ray
 - ◆ Gelsinger
 - ◆ Roche
 - ◆ Summerlin
 - ◆ Sudbo
 - ◆ Poehlman
 - ◆ Hwang Woo-Suk
 - ◆ Darsee
 - ◆ Alsabti
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Current activity to address research misconduct

- ◆ Scientific journals – vigilance, plagiarism and multiple publication software, review of digital images, transparency and reporting.
 - ◆ UUK – RIO
 - ◆ USA – legislation
 - ◆ Recent policy workshop (Keele 2008)
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The Governance of good research conduct in the UK


- ◆ RCUK, UKRIO, WT, UUK, (DH, other Govt depts, NHS R&D Forum)
 - ◆ Reviewed types of misconduct, their impact, likely extent and causes, potential solutions and identification of where action is needed.
 - ◆ Do we need legislation in the UK?
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Policy Workshop feedback

◆ Problems


- Peer review
 - ◆ CoI, Bias, anonymity, lack of transparency, lack of training, failure to declare competency
- Independence
 - ◆ Academia failure to recognise CoI, Institutional CoI, funder motives
- Informed consent
 - ◆ Lack of standardisation, lack of understanding of subjects expectations, lack of training
- Management
 - ◆ Internal controls on grants and papers
 - ◆ Effective rewards for good conduct
 - ◆ Audit of materials and data
 - ◆ Audit of policies
 - ◆ Training, Training, Training

Policy Workshop feedback

- ◆ Potential solutions
 - Training & education
 - Transparency
 - Institutional Codes
 - Foster individual champions and good practice
 - Need more research on links between funder and outcome
 - Need balance between standardisation and evolving good practice
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The way forward for the NHS?

Discuss

- ◆ Education & training – all stages of career
 - ◆ Peer support and oversight
 - ◆ Supervision & appraisal
 - ◆ Systems and monitoring
 - ◆ Clear protocol & policies
 - ◆ Fair sanctions seen to be applied
 - ◆ Proactive detection
 - ◆ Collaboration across organisations
 - NHS, HEIs, Prof Bodies, Funders
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NHS R&D Forum – actions ?

- ◆ Training
- ◆ Sharing good practice
- ◆ Independent review and assessment
- ◆ Independent advice
- ◆
- ◆
- ◆
- ◆