Research Ethics and Responsibility

Lecture

Course: Academic Integrity and Academic Writing, ZNU

Lecture Outline

- The problem
- Causes of misconduct
- Responsible conduct of research
- Linking back to research governance
- Questionable research practices
- Preventative measures
- Mini research misconduct case studies

The problem

- 2% - 14% of scientists have admitted to or observed fabricated or falsified data
- 33% - 72% have admitted to or observed "questionable research practices"

- *How do we solve this problem?*

Table 1. Results to a survey of extent of and response to research misconduct in low- and middle-income countries.

Country	National System	Institutional System	Cases	Discussed
China	Yes, China Ministry of Science and Technology has a regulation effective Jan 1, 2007 (for science and technology programs)	Yes	Some	Some discussion, mostly by media on publicized cases
Southern cone (Argentina, Chile, Uruguay)	No	No	Some	No
Nigeria	No	No	High profile cases involving drug company, no local cases	Discussed by Nigerian editors
Tunisia	Yes, includes sanctions	No	No public cases	Beginning
Costa Rica	No, law proposed	No	No public cases	Yes, hence law proposed
Guatemala	Partial	No	High profile case of abuse by US researcher in 40 s	Yes, because of high profile cases
India	No	Yes	"Whispers" and case reported in BMJ and WSJ	Some, nothing formal
Peru	Partial	Yes, because NIH grant	No public cases. 3/30 masters students guilty of plagiarism	"Barely"
South Africa	Yes, National Ethics Council	Yes	One very high profile case. People aware that it happens	"Not much"
Bangladesh	No	Yes	Some cases reported	No

NIH, National Institutes of Health.
doi:10.1371/journal.pmed.1001315.t001

Ana J, Koehlmoos T, Smith R, Yan LL (2013) Research Misconduct in Low- and Middle-Income Countries. PLoS Med 10(3): e1001315. doi:10.1371/journal.pmed.1001315
http://journals.plos.org/plosmedicine/article?id=info:doi/10.1371/journal.pmed.1001315

Causes of misconduct

- *Pressure to publish (contested)*
- *Unsupportive research environments*
- *Human frailty (temptation, rationalization, ambition, incrementalism, peer pressure etc.)*
- Lack of research integrity policies
- Cash reward for publication
- Cultures and situations were mutual criticism is hampered
- Early career researchers

Responsible Conduct of Research

- Comprehensive response to misconduct
  - prevention, investigation, punishment, correction
- Closely linked to session on research governance
  - Research ethics (moral standards)
  - Research integrity (professional standards)

Research Governance

Research Integrity & Ethics

Responsible Conduct of Research

- Broader than Research Ethics
  - *How we conduct research*
  - *How we interact with other researchers*
  - *How we interact with society*
- Absence of FFP
  - Falsification of data; Fabrication of results; Plagiarism
- Absence of Questionable Research Practices (QRP)

Questionable Research Practices

- Focus is often on FFP but often the real damage is done by QRP
  - Misrepresentation
  - Poor data management
  - Poor record keeping
  - Inaccuracy
  - Bias/conflicts of interest
  - Duplicate publication
  - Selective reporting
  - Miss-use of authorship (gift authorship/guest authorship)

Why have an integrity policy?

- Compliance
- Reputational risk
  - http://ori.hhs.gov/case_summary
- Decrease disputes and misunderstandings
- Provide a platform for conversations about ‘sticky’ issues
- Improve moral and ethical decision-making skills
- Protect the interests and welfare of subjects of research

Preventative Measures

- Code of Conduct
- Clear policies and procedures for research approval and research misconduct
- Consultation service
- Checklists
- Training
  - Integrate research ethics training into all research methods training (inc. undergraduate)
  - Using Cases for teaching research ethics

Guidance on Good Research Practice

- 'Singapore Statement' on Research Integrity
  - http://www.singaporestatement.org/statement.html
- UK Research Integrity Office: Code of good practice for research
  - http://www.ukrio.org/wp-content/uploads/UKRIO-Code-of-Practice-for-Research.pdf
- US Office of Research Integrity
  - http://ori.hhs.gov

Code of Conduct

- Research design
- Collaborative working
- Conflicts of interest
- Research involving human participants, human material or personal data
- Research involving animals
- Health and safety
- Intellectual property
- Finance
- Collection and retention of data
- Monitoring and audit
- Peer review
- Publication and authorship

Research Ethics Checklist

Example research ethics initial checklist

An ethics checklist should be completed for every research project. It is used to identify whether a full application for ethics approval needs to be submitted. Below is an example of a checklist that could be used in a UK research organisation to initially determine the potential level of risk or harm within a proposed study (research organisations may have their own checklist that should be used for submitting proposals to their institutional research ethics committee).

This checklist is only an example. Please refer to your research organisations' code of practice on ethical standards for research involving human participants. The principal investigator or, where the principal investigator is a student, the supervisor, is responsible for exercising appropriate professional judgment in this review.

An appropriate checklist must be completed before potential participants are approached to take part in any research.

Project details			
Project title			
Applicant details			
Name of researcher (applicant)			
Role			
Contact address			
Email			
Telephone			
For students only			
Module name and number or MA/MPhil course and department			
Supervisor's or module leader's name			
Research ethics initial checklist			
Please answer each question by ticking the appropriate box:			
		Yes	No
Research that may need to be reviewed by National Research Ethics Committee or another external Ethics Committee (if yes, please give brief details as an annex)			
Will the study involve recruitment of patients or staff through the public health system or the use of public health data or premises and/or equipment?			
Does the study involve participants age 16 or over who are unable to give informed consent? (eg people with learning disabilities: see Mental Capacity Act 2005 / Adults with Incapacity (Scotland) Act 2000. All research that falls under the auspices MCA/AWI must be reviewed by NHS REC)			
Research that may need a full review			
Does the research involve potentially vulnerable groups: children, those with cognitive impairment, or those in unequal relationships? (eg your own students)			
Will the study require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited? (eg students at school, members of self- help group, residents of nursing home?)			
Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (eg covert observation of people in non-public places)			
Will the study involve discussion of sensitive topics? (eg sexual activity, drug use, politics)			
Are drugs, placebos or other substances (eg food substances, vitamins) to be administered to the study participants, or will the study involve invasive, intrusive or potentially harmful procedures of any kind?			
Will tissue samples (including blood) be obtained from participants?			
Is pain or more than mild discomfort likely to result from the study?			
Could the study induce psychological stress, discomfort, anxiety or cause harm or negative consequences beyond the risks encountered in normal life?			
Will the study involve prolonged or repetitive testing?			
Will the research involve administrative or secure data that requires permission from the appropriate authorities before use?			
Is there a possibility that the safety of the researcher may be in question? (eg in international research: locally employed research assistants)			
Does the research involve members of the public in a research capacity (participant research)?			
Will the research take place outside the UK?			
Will the research involve respondents to the internet or other visual/vocal methods where respondents may be identified?			
Will research involve the sharing of data or confidential information beyond the initial consent given?			
Will financial recompense be offered to participants?			

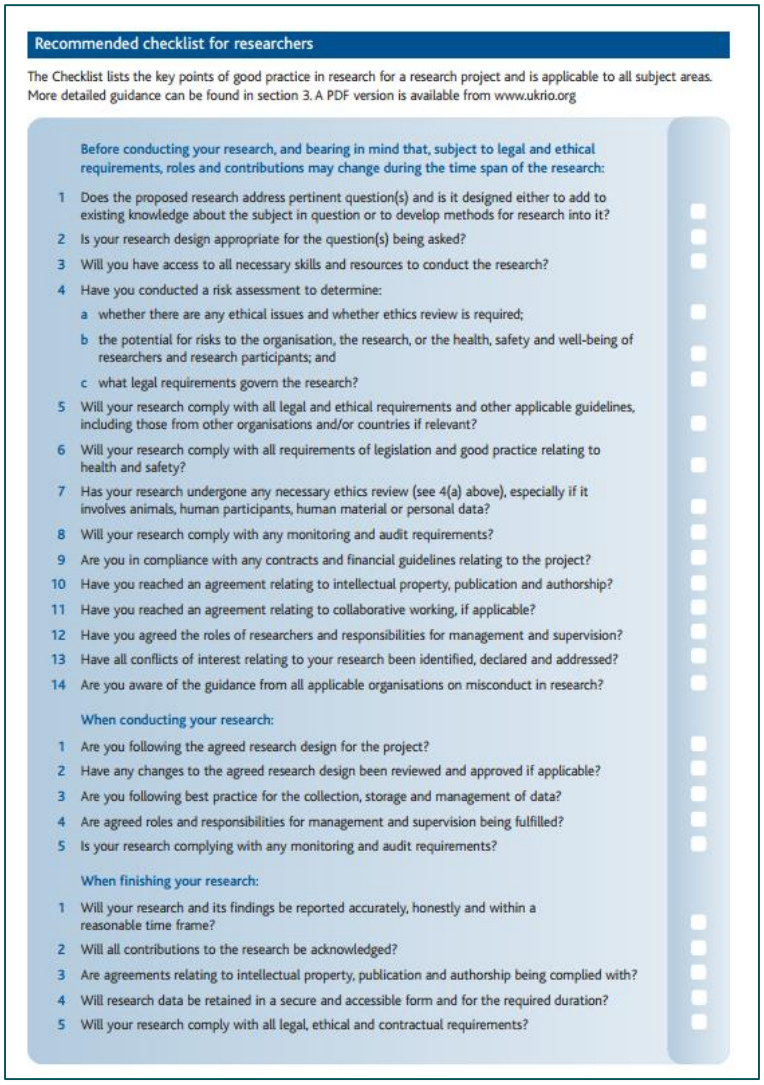
Principal Investigator		
Signed:	Date:	
Supervisor or module leader (where appropriate)		
Signed:	Date:	

It is a researcher's responsibility to follow the research organisation's code of practice on ethical standards, and any relevant academic or professional guidelines in the conduct of their study. This includes providing appropriate information sheets and consent forms, and ensuring confidentiality in the storage and use of data.

Any significant change in the question, design or conduct over the course of the research should be notified to the faculty or school research ethics officer and may require a new application for ethics approval.

Source: http://www.esrc.ac.uk/files/funding/guidance-for-applicants/ethics/example-research-ethics-initial-checklist

Research Integrity Checklist



Recommended checklist for researchers

The Checklist lists the key points of good practice in research for a research project and is applicable to all subject areas. More detailed guidance can be found in section 3. A PDF version is available from www.ukrio.org

Before conducting your research, and bearing in mind that, subject to legal and ethical requirements, roles and contributions may change during the time span of the research:

1. Does the proposed research address pertinent question(s) and is it designed either to add to existing knowledge about the subject in question or to develop methods for research into it?
2. Is your research design appropriate for the question(s) being asked?
3. Will you have access to all necessary skills and resources to conduct the research?
4. Have you conducted a risk assessment to determine:
   - a whether there are any ethical issues and whether ethics review is required;
   - b the potential for risks to the organisation, the research, or the health, safety and well-being of researchers and research participants; and
   - c what legal requirements govern the research?
5. Will your research comply with all legal and ethical requirements and other applicable guidelines, including those from other organisations and/or countries if relevant?
6. Will your research comply with all requirements of legislation and good practice relating to health and safety?
7. Has your research undergone any necessary ethics review (see 4(a) above), especially if it involves animals, human participants, human material or personal data?
8. Will your research comply with any monitoring and audit requirements?
9. Are you in compliance with any contracts and financial guidelines relating to the project?
10. Have you reached an agreement relating to intellectual property, publication and authorship?
11. Have you reached an agreement relating to collaborative working, if applicable?
12. Have you agreed the roles of researchers and responsibilities for management and supervision?
13. Have all conflicts of interest relating to your research been identified, declared and addressed?
14. Are you aware of the guidance from all applicable organisations on misconduct in research?

When conducting your research:

1. Are you following the agreed research design for the project?
2. Have any changes to the agreed research design been reviewed and approved if applicable?
3. Are you following best practice for the collection, storage and management of data?
4. Are agreed roles and responsibilities for management and supervision being fulfilled?
5. Is your research complying with any monitoring and audit requirements?

When finishing your research:

1. Will your research and its findings be reported accurately, honestly and within a reasonable time frame?
2. Will all contributions to the research be acknowledged?
3. Are agreements relating to intellectual property, publication and authorship being complied with?
4. Will research data be retained in a secure and accessible form and for the required duration?
5. Will your research comply with all legal, ethical and contractual requirements?

- http://www.ukrio.org/wp-content/uploads/UKRIO-Code-of-Practice-for-Research.pdf

Embedding Discourse into Research Environment

- Values established in research groups
- ‘Training’ must be embedded and continuous
  - Mentoring (with clear checklist of responsibilities)
  - Ad hoc conversations
  - Research group / lab meetings
  - Clubs
  - Research lectures or seminar series

Response

- Mechanisms for reporting misconduct?
  - Online reporting, hotline, mentor
  - https://johnshopkinsspeak2us.tnwreports.com/
- Clear disciplinary procedure (including appeals)
  - http://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/research_misconduct.html
- Learning from mistakes

Case Study Exercise

- In your group, read your case study and discuss the following questions
  - What are the research integrity issues arising?
  - What should the researcher do?
  - What systems, processes and resources do you have at your institution to guide their behavior?
  - Do you identify any gaps in your institution?

Disclaimer: