Research Ethics

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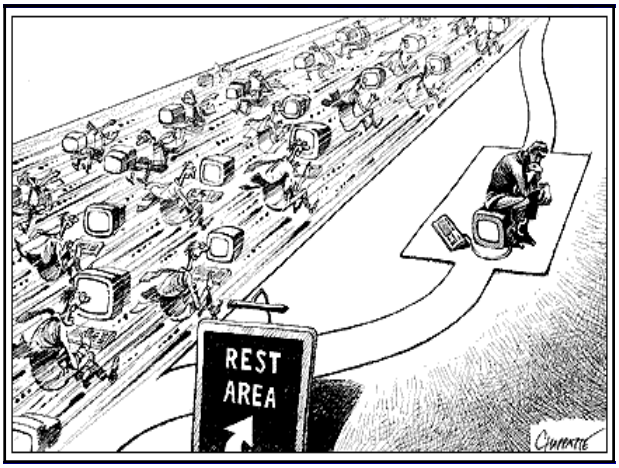
DCU

- 'Knowledge societies can be sustainable, coherent, innovative and integrative if they are based not only on pragmatic opportunities or political or financial interests, but on ethical values.'
  - World Summit on the Information Society http://InternetSociety.org

What is ethics?

- Ethics examines issues of right and wrong, should and shouldn't, fair and unfair, etc.
- Overlaps with values, rights, worldview, philosophy, religion
- Ethics assesses arguments, actions and character qualities.
- Ethics is the systematic study of concepts, principles and theories addressing right and wrong.



'If you are faced with a dilemma on what is the right thing to do, moral philosophy [ethics] will not find a decision for you. What it can do is remove some confusions and clarify some obscurities, so that the options stand out more plainly.'

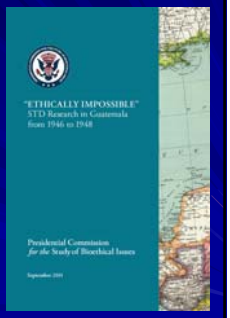
DD Raphael, *Moral Philosophy*, 2nd ed. Oxford University Press, 1994, p.10.

History of research regulation

- Nuremberg Code (1947)

Reaction to crisis and criticism

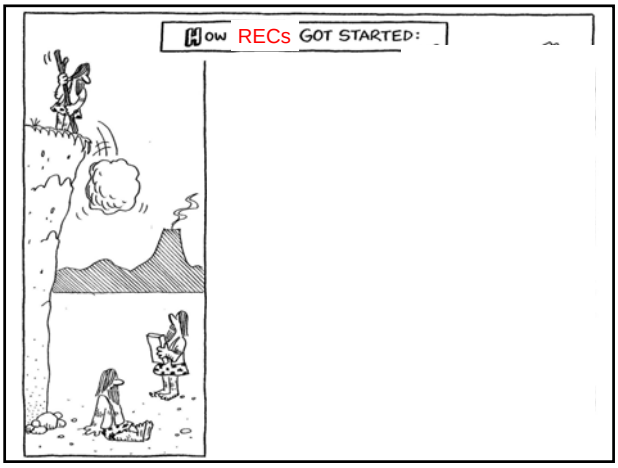
- e.g. Guatemala 1946-1948
- 'reprehensible'
- 'a dark chapter in the history of medicine'
- 'unconscionable'



Dónal P. O'Mathúna, "Moral Science: Ensuring Human Subjects Research is Ethical," *Research Practitioner* 13.3 (May-June 2012): 88-98.

Social science too

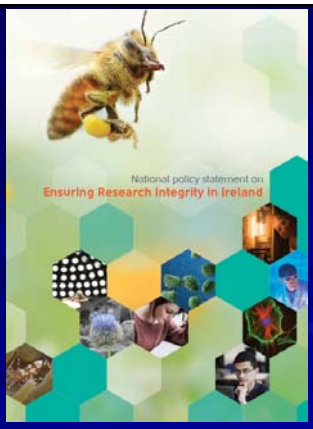
www.stanfordlawreview.org/online/privilege-belfast-project



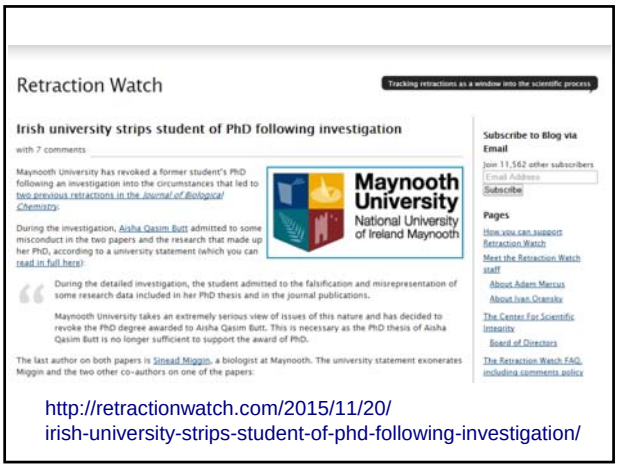
Relevant regulation

- EU Clinical Trials Directive 2001/20/EC (2001) – Irish regs S.I No 190 of 2004 → No. 536/2014
- Children's Research and Ethical Review – Department of Children & Youth Affairs 2012: www.dcya.gov.ie; also: http://childethics.com/
- HIQA Report 2012: http://www.higa.ie/publications/international-review-research-ethics-structures
- Health Information Bill 2014 → 2016
- Professional guidelines, e.g.
  - Association of Internet Researchers: (2012) http://aoir.org/documents/ethics-guide/

- "the virtuous researcher"
  - 'a focus on the internal ethical motivation of individual investigators, not only the rules and regulations that externally motivate investigators toward compliance' (p. 32)



http://www.iua.ie/research-innovation/research-integrity/


Retraction Watch

Tracking retractions as a window into the scientific process

Irish university strips student of PhD following investigation

with 7 comments

Maynooth University has revoked a former student's PhD following an investigation into the circumstances that led to two previous retractions in the Journal of Biological Chemistry.

During the investigation, Aisha Qasim Butt admitted to some misconduct in the two papers and the research that made up her PhD, according to a university statement (which you can read in full here):

> During the detailed investigation, the student admitted to the falsification and misrepresentation of some research data included in her PhD thesis and in the journal publications.
>
> Maynooth University takes an extremely serious view of issues of this nature and has decided to revoke the PhD degree awarded to Aisha Qasim Butt. This is necessary as the PhD thesis of Aisha Qasim Butt is no longer sufficient to support the award of PhD.

The last author on both papers is Sinead Miggin, a biologist at Maynooth. The university statement exonerates Miggin and the two other co-authors on one of the papers:

Maynooth University
National University of Ireland Maynooth

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How you can support Retraction Watch

Meet the Retraction Watch staff

About Adam Marcus

About Ivan Oransky

The Center For Scientific Integrity

Board of Directors

The Retraction Watch FAQ, including comments policy

http://retractionwatch.com/2015/11/20/irish-university-strips-student-of-phd-following-investigation/

Research ethics

- Formal approval
- Regulatory compliance
- Personal integrity
- Competency skills

General ethical principles

- Value
- Scientific validity
- Subject selection
- Risk-benefit ratio
- Independent review
- Informed consent
- Respect for potential and enrolled subjects
  - Emanuel et al. What makes clinical research ethical? *JAMA: The Journal of the American Medical Association*, 2000;283(20):2701-2711

Research ethics

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Value
Subject selection
Independent review
Informed consent

Scientific validity
Risk-benefit ratio
Respect for participants

1. Value

1. Research should be valuable
2. Could the results lead to benefits, improvements or useful information?
3. Has the question already been adequately answered, or is it a trifling topic?

- Responsible use of finite resources
- Avoidance of exploitation, especially of small populations
- No harms are justified if there is no social or scientific benefit.

- New knowledge balanced with research training
- Importance of adequate literature review.
- Role of the supervisor.

2. Scientific validity

- Is the study design appropriate to the research question?
- Is it feasible?
- Does the study have sufficient power and plan appropriate analysis for the methods?
  - 'Invalid research is unethical because it is a waste of resources as well: of the investigator, the funding agency, and anyone who attends to the research.'
    - Vanderpool, *Ethics of Research Involving Human Subjects* (1996)

3. Subject selection

- Ought to be fair/just.
- Participants should be chosen because of the study goals, not because of privilege, access, vulnerability, convenience, etc.
- Does the study need to be done with this group of participants? Why?
- Are all appropriate groups included?
- Those who bear the risks should benefit from the fruit.

- Contact information must be properly obtained.
- Data Protection Act must be adhered to.
- Guiding principle: personal information can only be released if directly related to why the data was collected.
- Local policies must be adhered to.

4. Risk-benefit ratio

- Risks relate to:
  - participant group
  - research methods, and
  - research topic
- Risk 'calculation' is complex, challenging and variable
- Methods of risk minimisation are also somewhat variable

Risks to researchers

- Does the research put the researcher at risk?
  - Not just physical, but psychological, social, cultural, religious?
- Is the researcher's conscience bothered or violated?
  - Violating conscience is a serious ethical issue.
- Is there undue pressure, overt or subtle?

5. Independent review

- Financial interests, but a lot more
- Have researchers conflicting roles or interests?
  - What if the researcher is also a teacher/colleague/relative of the participants?
- Independent review addresses potential conflicts of interest.
  - Reviewers with a range of backgrounds.

6. Informed consent

A. Competence
B. Information – plain language statement
C. Understanding
D. Lack of coercion
E. Authorisation

Explicit written informed consent may not always be necessary.

7. Respect for potential and enrolled participants

- Allowing subjects to change their minds
- Updating subjects on new data
- Monitoring of participants' welfare
- Providing results and findings
- Handling of all data, especially privacy and confidentiality

Respect cont.

- How will privacy & confidentiality be protected? Participants have claimed researchers 'stole our stories.'
- Is any deception involved? Does it need to be? How will it be perceived later?
- How can the research benefit (future) people? How will this be communicated?
- How are cultural, gender, family, religious aspects protected within the research?

Summary

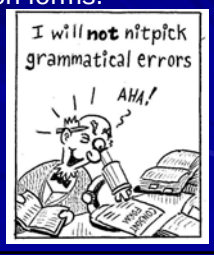
- Value
- Scientific validity
- Subject selection
- Risk-benefit ratio
- Independent review
- Informed consent
- Respect for potential and enrolled subjects

Research Ethics Committees

- Find the guidelines for the University, hospital, organisation, institution, etc.
- https://www4.dcu.ie/researchsupport/research_integrity_ethics.shtml
- Read the guidelines!
- Do you need to apply?
- How should you apply?
- When should you apply?
- Develop a schedule with your supervisor.

In general

- Ethics should infuse your research.
- Plan the research first; then fill out the research ethics application forms.
- Check your English

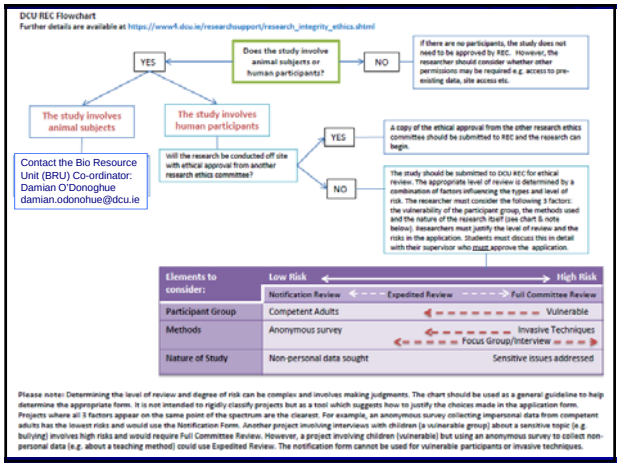


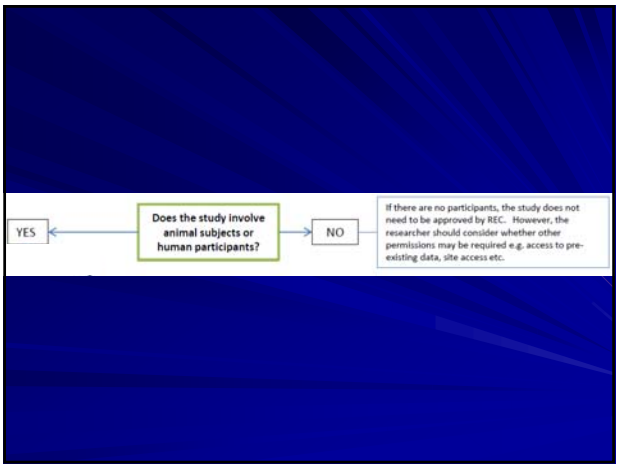
In general

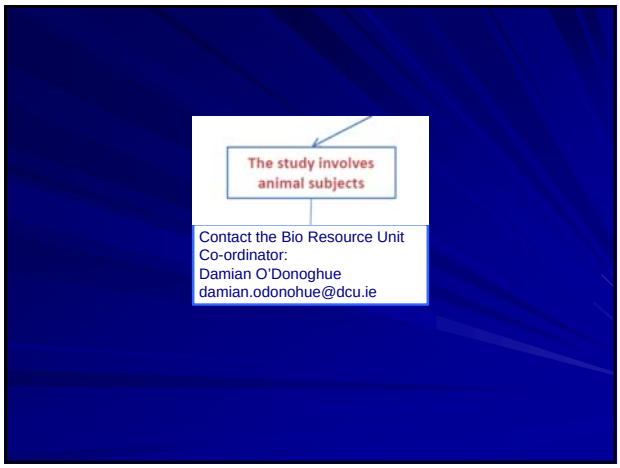
- Ethic
- Plan
- Chec
- Chec

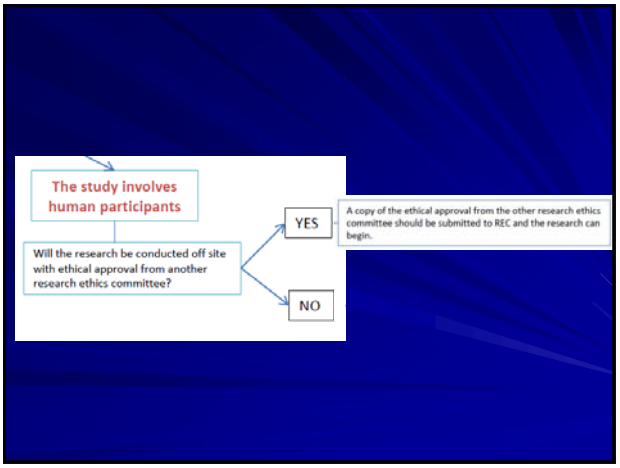
DCU REC

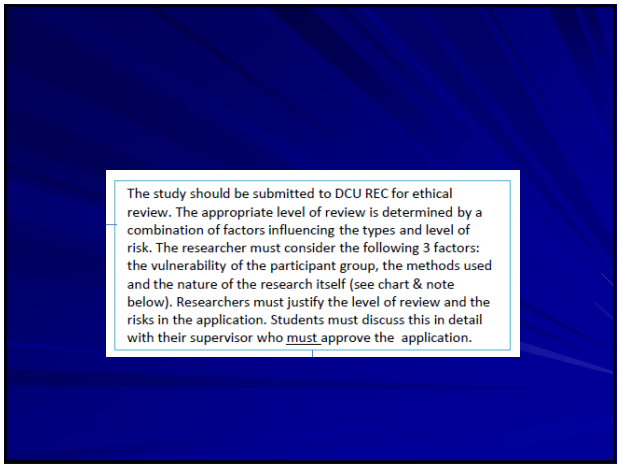
- Different types of applications
  - Biological safety committee
    http://www.dcu.ie/science_and_health/safety_info.shtml
  - Animal research
  - Full committee review
  - Expedited review
  - Notification
  - (Research projects for taught Masters degrees and undergraduates)

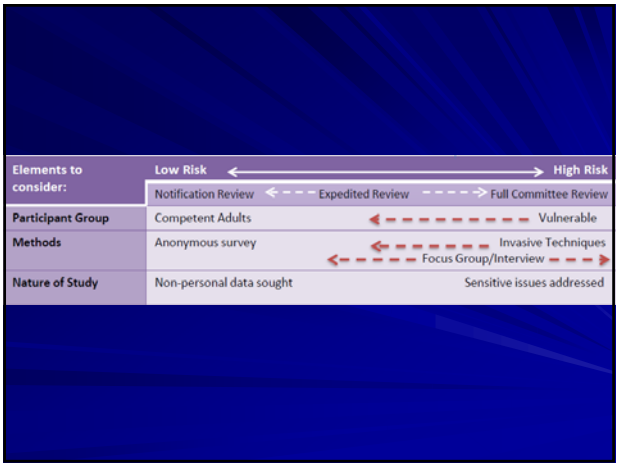


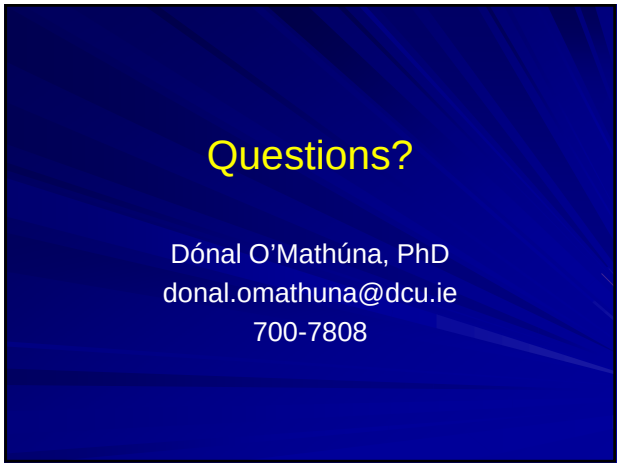

YES
Does the study involve animal subjects or human participants?
NO
If there are no participants, the study does not need to be approved by REC. However, the researcher should consider whether other permissions may be required e.g. access to pre-existing data, site access etc.


The study involves animal subjects
Contact the Bio Resource Unit Co-ordinator:
Damian O'Donoghue
damian.odonohue@dcu.ie


The study involves human participants
Will the research be conducted off site with ethical approval from another research ethics committee?
YES
A copy of the ethical approval from the other research ethics committee should be submitted to REC and the research can begin.
NO


The study should be submitted to DCU REC for ethical review. The appropriate level of review is determined by a combination of factors influencing the types and level of risk. The researcher must consider the following 3 factors: the vulnerability of the participant group, the methods used and the nature of the research itself (see chart & note below). Researchers must justify the level of review and the risks in the application. Students must discuss this in detail with their supervisor who must approve the application.


Elements to consider:
Low Risk
High Risk
Notification Review
Expedited Review
Full Committee Review
Participant Group
Competent Adults
Vulnerable
Methods
Anonymous survey
Invasive Techniques
Focus Group/Interview
Nature of Study
Non-personal data sought
Sensitive issues addressed


Questions?
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