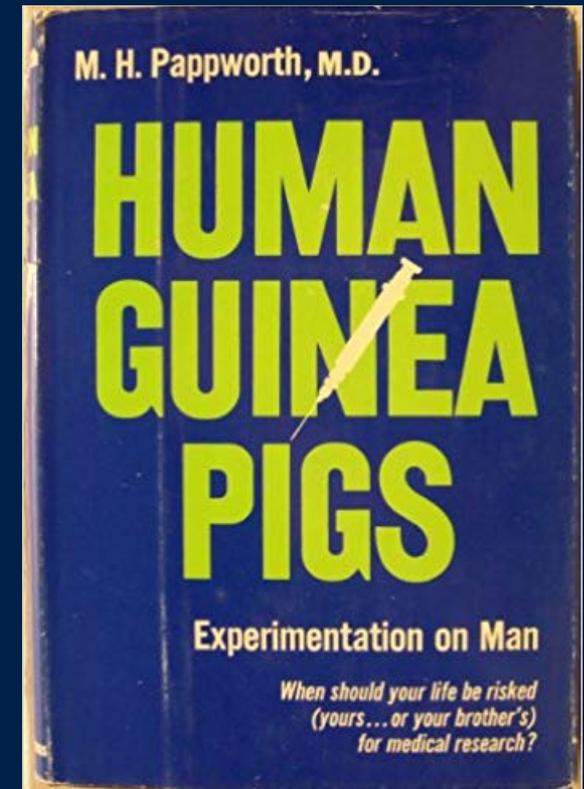


Medical Research Ethics

(Not: how to navigate IRAS and get REC approval)

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Ground Rules for applied ethics discussion

- Chatham House Rule (talk about the ideas but respect each-other's anonymity when sharing personal narratives)
- Please respect each other, we are talking about right and wrong, good and bad, professional and unprofessional
- *This does not mean that you need to agree with each-other, and there are **no** stupid questions or opinions.*

Aims:

- To introduce key ethical concerns when conducting medical and human research
- To introduce some theoretical background to research ethics
- To get you *thinking* about ethics when you plan and perform your research

What do we mean by 'research'?

- Research
 - Lab research
 - Clinical trials
 - Qualitative research
 - Observational research
 - Database/Biobank use
 - Theoretical research
 - Evidence synthesis
 - Audit (evaluating current practices)
 - Experiments for teaching and learning
- Research - A particularly worthy activity, why?



Ethics is not the same as rules and laws

But what is it?

Deontology: Things are right or wrong regardless of consequence: things that are right should be always right and wrong always wrong. People should always be an ends in themselves and never purely a means to an end.

Utilitarianism: we should aim to maximise pleasure and minimise pain (or maximise other forms of good and minimise other forms of harm). The predicted ends can justify the means.

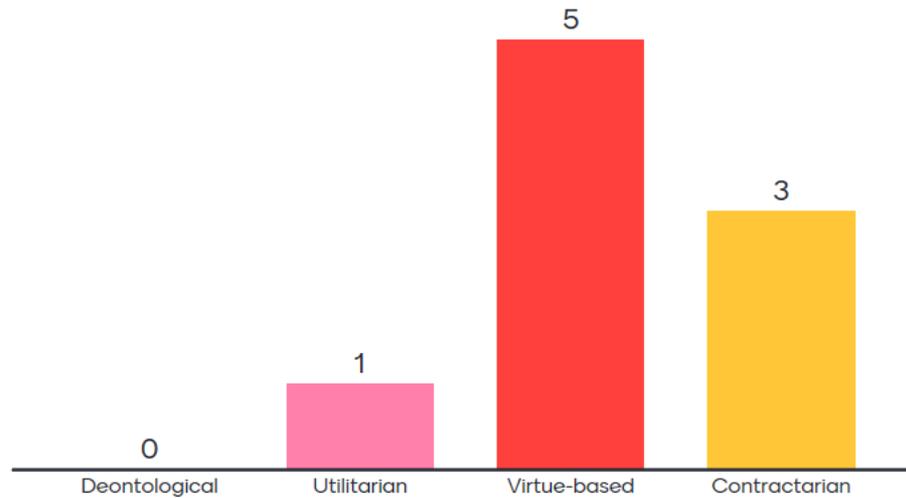
Virtues: right and wrong can be determined by thinking about what it is to live a good life, and the virtues that are necessary for this. We should aspire to excellence of character.

Contractarianism: without laws, life would be nasty brutish and short and therefore we need laws, rights and duties for the good of all.

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Which theory do you like best?

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These aren't 'just theories'!

- These positions give us guidance on how to act ethically
- They provide us with principles that impact how we should plan and conduct research
- You don't have to slavishly adhere to one...
- ...but you should bear them all in mind when considering the ethics of your research.

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What are the virtues of a good researcher?

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Intellectual vs. ethical virtues

Is the most 'true' way of finding an answer the most ethical?

Would you do a randomised controlled trial to determine the effectiveness of:

- The Heimlich manoeuvre
- Defibrillation for ventricular fibrillation
- Parachutes vs placebo for prevention of injury from high altitude falls?

Why not? What do you think would make an ethics committee allow an RCT on the above questions?

A long tradition of inhumanity?

- Herophilus (335-280 BC) and Erasistratus (304–250 BC) *may have* vivisected Egyptian Prisoners in Alexandria
- 1916 Chemical weapon tests on 25,000 servicemen at Porton Down
- Tuskegee study in Alabama from 1932 to 1972
- Nazi Germany – experiments in concentration camps
- 78 experiments without consent documented in NHS hospitals 1950s and 60s (Pappworth)
- More recent examples?
- ***What makes us condemn these historical examples?***

The Nuremberg Tribunals

- Harmful/lethal experiments conducted on captive human subjects

German doctors involved argued:

- Others had conducted harmful research on humans
- The interests of the state in a time of war
- There were no universally agreed standards for human research



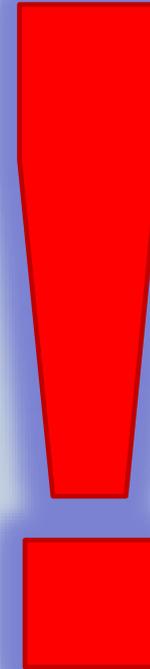
What do you think of these arguments?

A legislative journey to the present

- 1949 Nuremberg Code: 1) consent 2) justification 3) design 4) avoiding harm 5) qualified scientists 6) end experiment if causing harm or consent withdrawn
- National Research Act Public Law of 1974 (IRBs in the USA)
- 1964...2008 WMA Declaration of Helsinki revised
- 1968 Informal RECs in the UK
- **1984 and 1990** Principal guidelines covering research in UK issued by the Royal College of Physicians: require ethical review prior to research being carried out.
- 1991 Statutory Provisions for LRECs and MRECs
- 2009 IRAS (All UK human research in a *public* Health and Social Care Setting)

Broad principles (after Nuremberg)

- Equipoise
- A clear purpose
- Principle of Benefit/least harm
- Consent
- Confidentiality
- Justice
- Other issues?





The point of these rules? Protecting the vulnerable

- Children
- Incapacitous adults
- People who are not at liberty
- People in lower-income countries
- The human foetus
- Animals (3 Rs – Replace, Reduce and Refine)
- You?
- Are there any other vulnerable groups?
- **How might vulnerability lead to injustice?**



Consider:

- A family in a rural area of a lower-income country are informed that their child, who is gravely ill, will only be treated if the parents enrol her in a study to compare standard medication against placebo.
- A postdoctoral embryology researcher is informed by her head of department that she is much more likely to be promoted if she donates some of her own ova. He offers to fund her leave of absence for the egg-harvesting procedure.
- A research team (in a country with the death penalty) are seeking an appropriate human volunteer to receive a mechanical heart, they receive offers from several convicted criminals awaiting execution.

Question:

- So research without the guidance of ethics can go awry
- But can research have 'too much' ethics?
- Can research ethics be problematic?

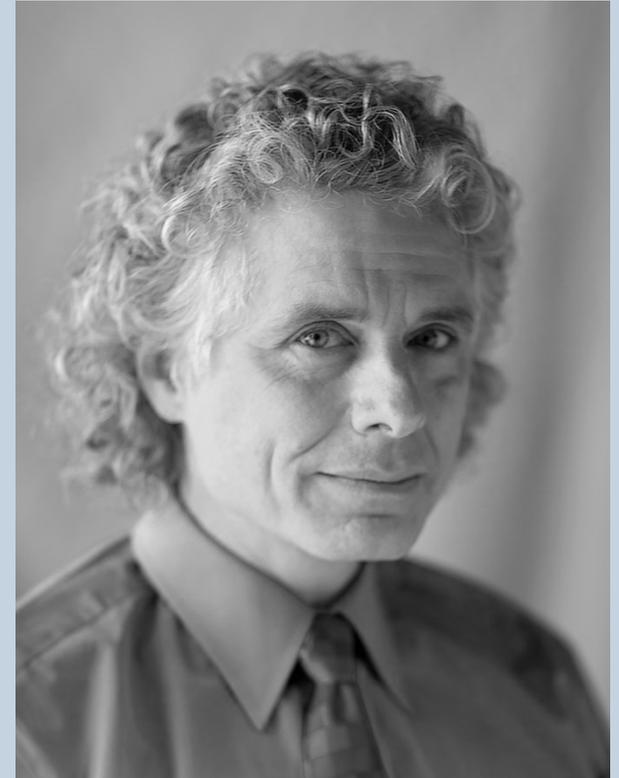


Stephen Pinker, Boston Globe Op Ed August 01 2015

Biomedical research, then, promises vast increases in life, health, and flourishing. Just imagine how much happier you would be if a prematurely deceased loved one were alive, or a debilitated one were vigorous — and multiply that good by several billion, in perpetuity. Given this potential bonanza, the primary moral goal for today's bioethics can be summarized in a single sentence.

Get out of the way.

A truly ethical bioethics should not bog down research in red tape, moratoria, or threats of prosecution based on nebulous but sweeping principles such as “dignity,” “sacredness,” or “social justice.”



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What do you think of Pinker's position?

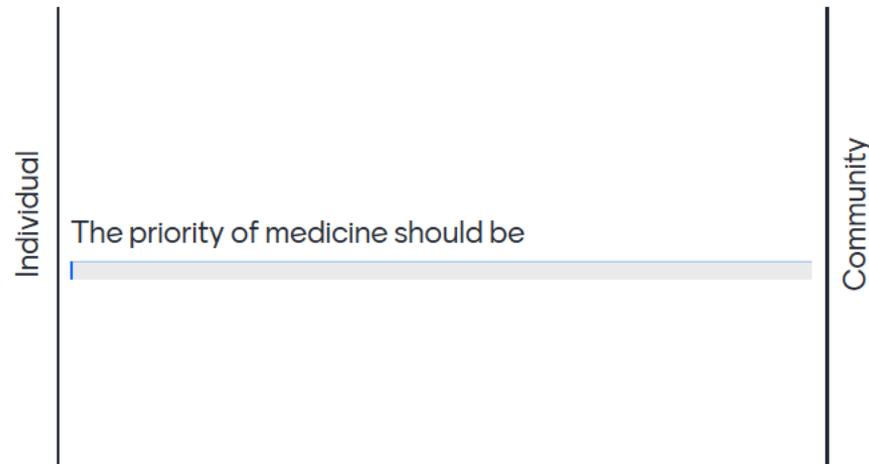
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Whose interests should medical research serve?

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Publication Ethics

What are the ways that published work can be criticised on ethical grounds? Why could they be unethical?

- Fraud
- Gift or Ghost authorship
- Plagiarism (and self plagiarism)
- Multiple submission
- Conflicts of interest
- Any others? What about ethical issues relating to professional conduct? Or the funding of research?

- Food for thought: A paper has just been discovered by historians. It describes pioneering surgical techniques developed by scientists in the 1950s from experiments on innocent non-consenting people. The technique has the potential to be lifesaving. Do you a) publish the paper or b) ban the paper? **Why?**

Add a slide about research funding and related ethical issues

- Conflicted funding
- Unfunded research
- Conflicted funding vs research not happening
- Mitigating conflicts
- etc

In Summary

- Ethics is something you *think* about, not just rules you follow
- Ethical research is as much about experimental design as it is about how you treat people
- Research ethics is largely based on simple principles: Clear rationale, Appropriate design, Consent, Harm minimization *but also fairness*.
- *A reasonable review of literature is increasingly mandatory*
- These principles apply to *any* research involving humans (and animals)
- The principles form the basis of preparation for ethical review by a REC
- Reflect on the virtues and principles we discussed today – do any of them help you to conduct better research?

Some Further Reading

- Resnik D, *The Ethics of Science: an introduction*, Routledge, New York, 1998
- Slowther A, Boynton P, Shaw S, *Research governance: ethical issues*, *JRSM*, 2006; 99: 65-72
- Wilson S, Draper H and Ives J, Ethical issues regarding recruitment to research studies within the primary care consultation, *Family Practice*, 2008; 25: 56-461
- Hope T, Savulescu J, and Hendrick J, Research, Chapter 14, pages 217-234 in *Medical Ethics and Law: the core curriculum* (2nd Edn), Elsevier 2008
- Glaziou and Chalmers on research waste
<https://www.bmj.com/content/bmj/363/bmj.k4645.full.pdf> Chalmers I. Regulation of therapeutic research is compromising the interests of patients. *International Journal of Pharmaceutical Medicine* 2007;21: 395-404.
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