Global PaedSurg Research Training Fellowship

Session 3:

Ethical considerations, gaining study approval and undertaking patient consent

Lars Hagander, Lund University, Sweden – Jan 25 2018

wellcome trust

KING'S HEALTH PARTNERS

Pioneering better health for all

wellcome trust

KING'S HEALTH PARTNERS

Pioneering better health for all

Overview

Ethical considerations

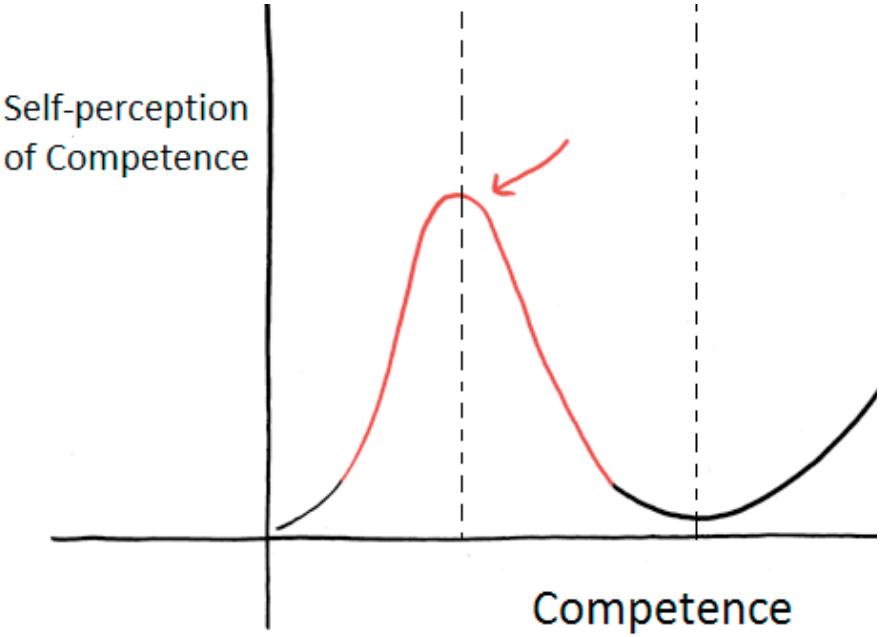
- Historical background
- Guiding resolutions
- Ethical principles

Study approval and consent

- Responsibility of researchers and ethics review boards
- Consent from parents and child

Learning Objectives

- Recognize issues
- Identify regulations
- Define principles
- Describe consent
- Pediatric angles
- Describe IRBs
- Internationality



Responsible conduct of research

Scientific freedom

- Historical abuses
- Researchers have cheated
- Humans exploited and hurt

Misconduct of research

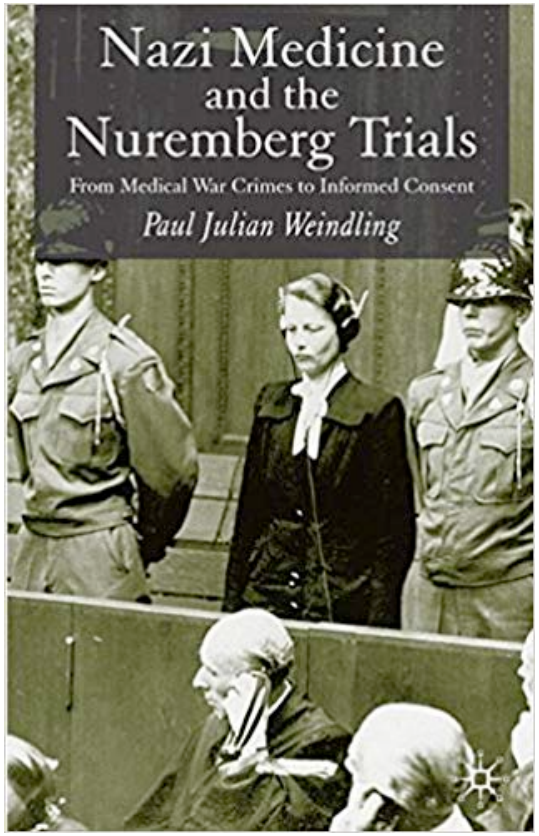
We are all at risk

- Career and incitement structure?
- Velocitation? Tunnel vision?
- Dehumanisation? Indifference?
- Ignorance?
- Lack of oversight and control?

The Nürnberg code

The 10 points:

- Voluntary at all time
- Informed consent
- Rationale and societal benefit
- No other way
- Proportionality
- Stop when dangerous
- Skilled personnel



The declaration of Helsinki

- 1964 – … – 2013 ..
- World Medical Association
- Conflict of Interest
- Ethics Review Boards
- Vulnerable populations
- International research
- Not legally binding

WORLD MEDICAL ASSOCIATION

wellcome trust

KING'S HEALTH PARTNERS

Pioneering better health for all

Convention on Human Rights and Biomedicine

- The Oviedo Convention
- The only International legally binding instrument
- The European treaty on patient's rights
- European Council: 1997 ➔ 2005
- Informed consent

wellcome trust

KING'S HEALTH PARTNERS
Pioneering better health for all

The Belmont Report

- National Research Act, 1974
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- Emphasized three ethical principles

Three ethical principles

1. Respect for Persons:
- Autonomy
- Informed consent

2. Beneficence:
- To do no harm
- Maximize the risk/benefit ratio

3. Justice:
- Selection of study subjects
- Fair share of benefits

The Common (and *Final*) Rule

Informed Consent:

- Purpose and choice
- Risks and benefits
- Rights
- Privacy
- Responsible

Institution Review Boards

- Human Subjects Research
- Ethical committee Review

What is research?

"Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

[US Common Rule, 2017]

What is then *not* research!?

- Audits

What is a human subject?

"A living individual about whom an investigator (whether professional or student) conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; *or*
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens"

[US Common Rule, 2017]

Sensitive personal identifiers?

- Race or ethnicity
- Political opinion
- Religion or philosophy
- Union
- Sexuality
- Heatlh (in the broadest sense)

Ethics review board

- **To approve**, require modification in research to secure approval, defer action, or disapprove all research activities, including proposed changes in ongoing, previously approved, human subject research.

- **To suspend** or terminate the approval of ongoing, previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected, serious harm to subjects.

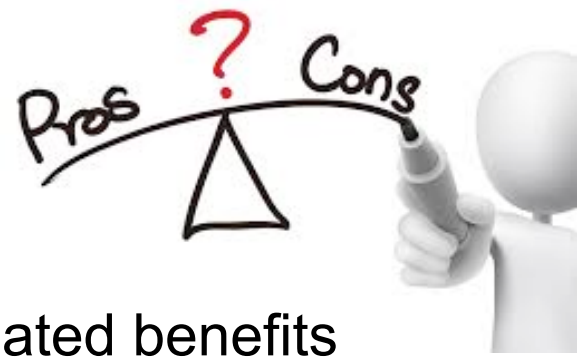
Do no harm

Protection from harm

- Physical harm
- Mental (at recruitment?)
- Integrity (universal?)
- Socially (stigma at presentation?)
- Financial and legal

Particular attention to when standard of care is changed

Full Review

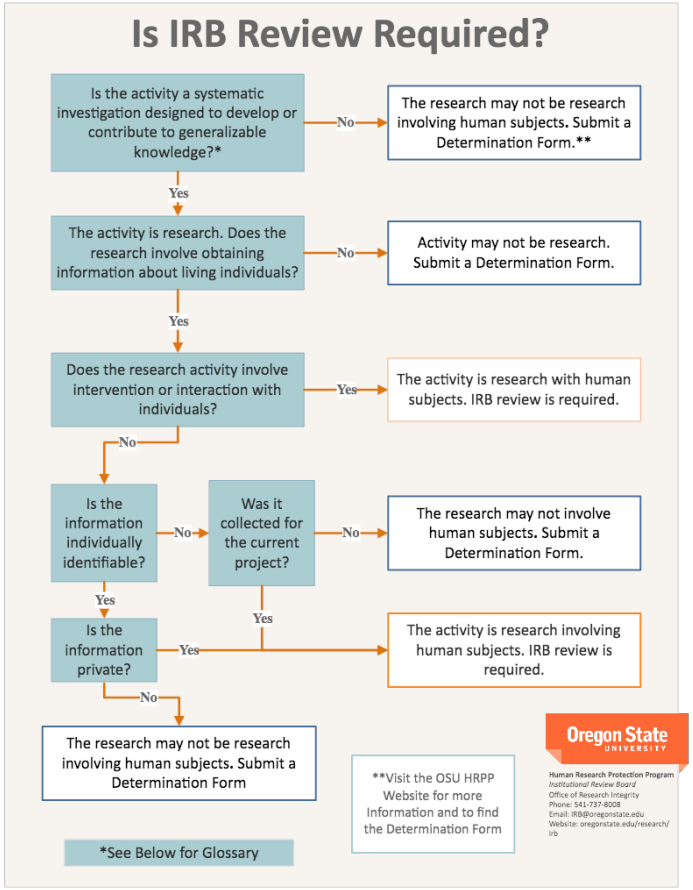


- Risks to subjects are minimized
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent is sought from each subject
- Informed consent is appropriately documented
- Data collection is monitored to ensure subject safety
- Privacy and confidentiality of subjects is protected
- Additional safeguards are included for vulnerable populations

Is review required?

- Human subjects research!
- Expedited review?
- Who can decide on exemption?
- Await scrutiny and decision

  (not possible retrospectively)



wellcome trust

KING'S HEALTH PARTNERS

Pioneering better health for all

Data safety

- Code the data
- Separate key
- Material locked up
- E-safety. RedCap
- GDPR. HIPAA..

Information to the study subjects

1. Background and Aim
2. Why we ask you
3. Details of the study
4. Standard of care
5. Risks
6. Benefits
7. Data handling
8. Study results information
9. Insurance
10. Voluntary and withdrawal
11. Responsibles
12. Consent form

Exempt from informed consent:

- When impossible
- When not feasible

Opt-out

- Advertisement in nation-wide newspapers

Competence

- cognitive impairment: unconciousness, dementia, age

Informed consent from the child?

- Child assent

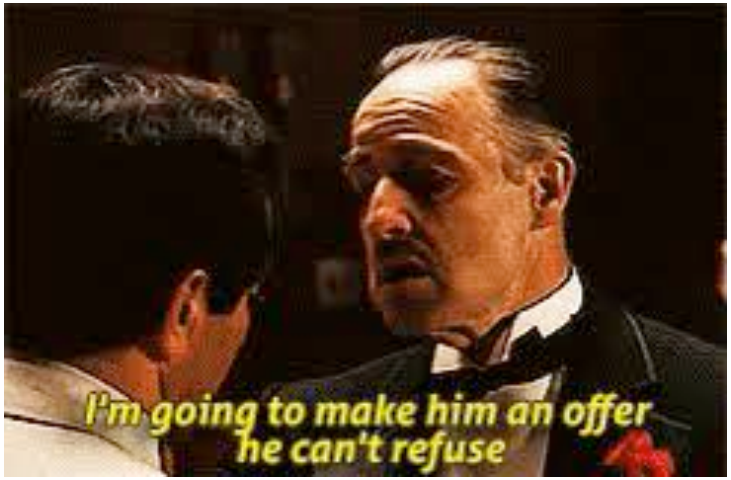
Informed consent

- Who should give consent?
- When to obtain informed consent?
- How should consent be obtained?
- How should consent be recorded?
- Are inducements acceptable?

Free will?

Volontary [of course] – but

- Persuation?
- Dependency?
- Reimbursements?
- Benefits?



Benefits

- Better care and follow-up?
- Preventive care?
- Interviews with therapeutic potential
- Remuneration

- Don’t exaggerate the benefits

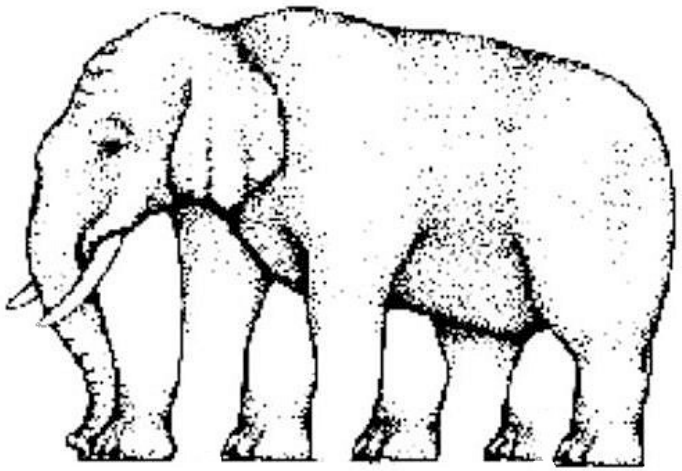
– to do no harm is of paramount importance


Equipoise
?

Equipoise – the control group treatment

What level of care for those in the control group?

- Non-universal standard of care: At least half get something?
- Or a non-inferiority approach?

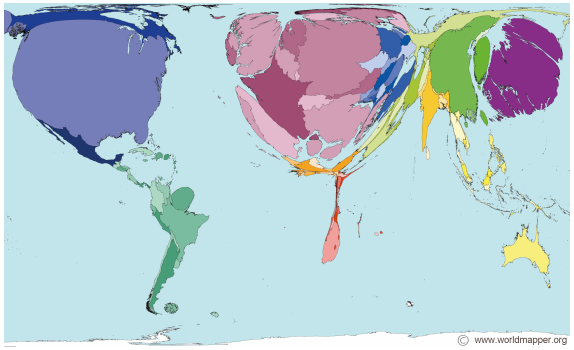


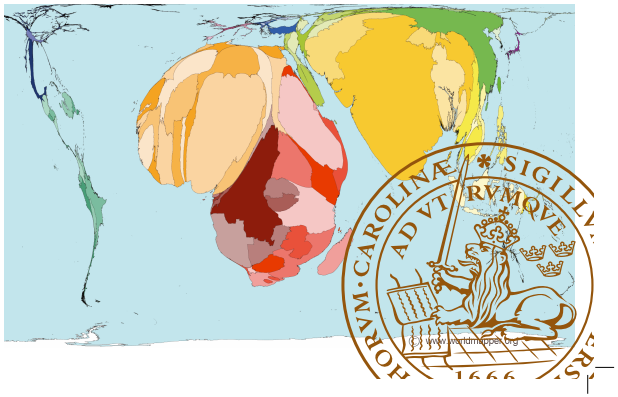
Other treatment considerations

- Provision of care after screening or diagnosis?
- Should an intervention be provided after the trial?
- Are the research outputs likely to lead to relevant and sustainable health benefits to people in the areas where the research is undertaken?

Final remarks

- Prohibitively complicated /costly?
- We are all at risk
- Ignorance
- Lack of oversight and control





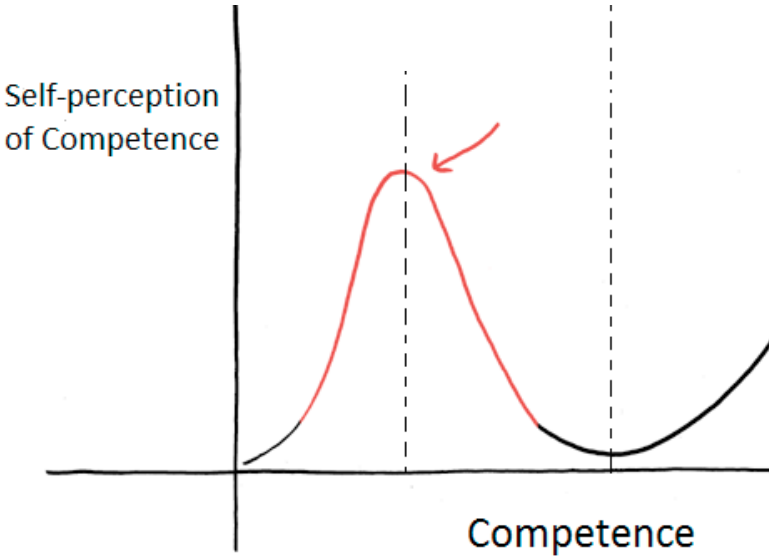
wellcome trust

KING'S HEALTH PARTNERS
Pioneering better health for all

Conclusion

Ethical considerations

- Historical background
- Guiding resolutions
- Ethical principles



Study approval and consent

- Responsibility of researchers and ethics review boards
- Consent from parents and child

- **Global PaedSurg Consent form templates:**
  https://www.dropbox.com/sh/hvhgzp1259hbn9o/AAChUe7RNZzpq6SYFyWZI_vga?dl=0
- **The Belmont Report:**
  https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
- **The Common Rule:**
  https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html
- **The Helsinki Declaration:**
  https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

Thank you for listening, any questions?

globalpaedsurg4@gmail.com

@PaedsSurgeon @GlobalPaedSurg #GlobalPaedSurg

www.globalpaedsurg.com

wellcome trust

KING'S HEALTH PARTNERS

Pioneering better health for all

Thank you for listening, any questions?

globalpaedsurg4@gmail.com

@PaedsSurgeon @GlobalPaedSurg #GlobalPaedSurg

www.globalpaedsurg.com

wellcome trust

KING'S HEALTH PARTNERS

Pioneering better health for all