



RESEARCH METHODOLOGY

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NUREMBERG CODE

- Code for “permissible medical experimentation”
- Voluntary informed consent – duty and responsibility of the experimenter
- Must be fruitful results for society – not possible to obtain by any other means
- Designed using results of animal experimentation – justifying the human experiment
- Should avoid all unnecessary suffering and injury
- Should not be done if there is reason to expect death or disabling injury

NUREMBERG CODE

- Risk must not outweigh the humanitarian benefits
- Preparation against even remote possibilities of injury or worse
- Must be conducted by scientifically qualified people
- Subject may end the experiment if unable to continue due to physical or mental reasons
- Scientist may end the experiment if they believe it is likely to cause injury or death

NUREMBERG CODE

- One of the most important milestones in the history of medicine
- Not law, nor official code of ethics
- But deep influence on human rights
- Prototype for codes of medical ethics
- International Covenant on Civil and Political Rights 777
- Universal Declaration of Human Rights/IBHR
- Geneva Declaration; Helsinki Declaration
- Relevance to us: knowledge, precaution, prevention

UNETHICAL CLINICAL TRIALS

- Pharmaceutical corporations main culprit
- Developing countries main victims
- Usually the corporations are aware of ethics violations
- Violations “outsourced” to local agencies (CROs)
- Trials not following guidelines can escape detection if nothing goes wrong
- Academic people can be involved in such trials

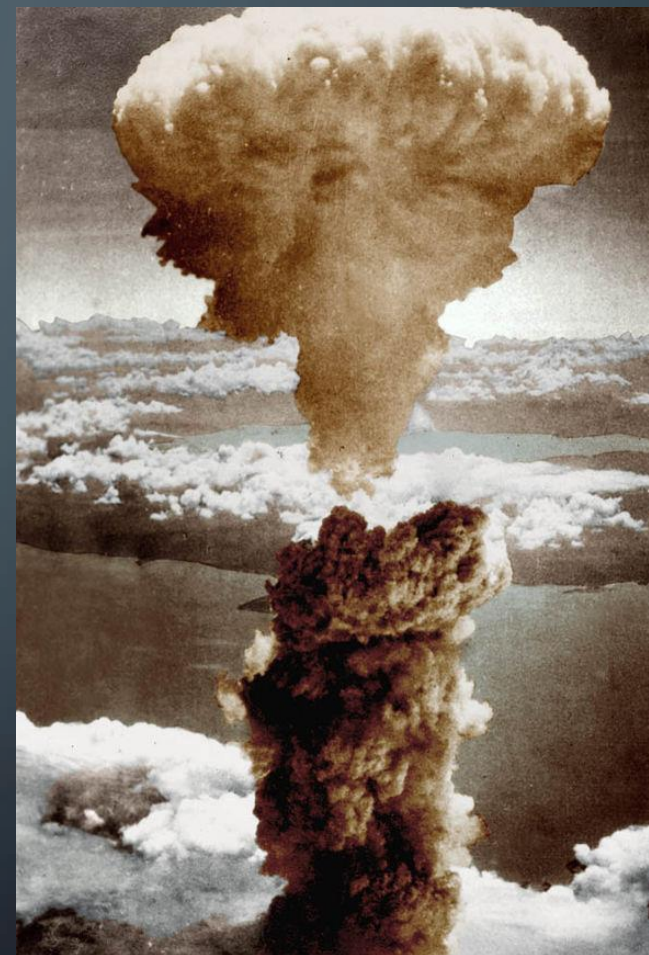
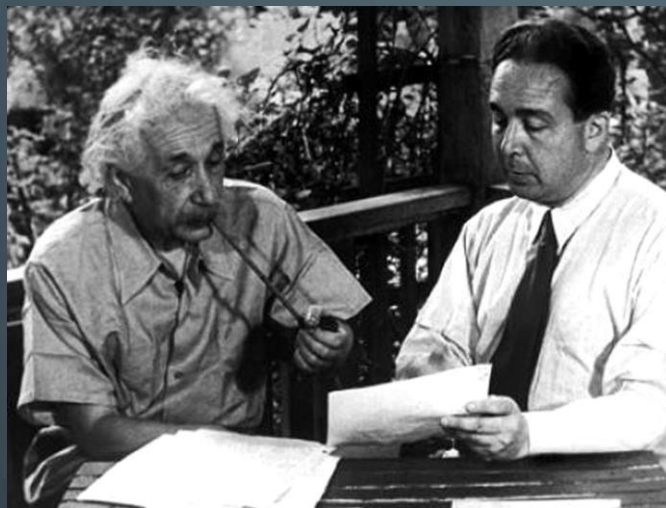
ROTAVIRUS VACCINE TRIALS

- India 2011-12 (Delhi, Pune, Vellore)
- More than 2000 infants (out of ~6800) given placebo (saline injection)
- Funded by private and government sources
- Bill and Melinda Gates foundation, DBT, NIH, Norway, UK, Bharat Biotech
- This would not have been permitted in the US
- This was published in Lancet (2020 JIF 79, rank 5)
- Points to a double standard of ethics (M. Carome, Public Citizen)

MORE EXAMPLES

- Mepacrine sterilization trials (India and Bangladesh, 1990s)
- Letrozole trials by Sun Pharma (2005-05)
- HPV vaccine trials (Andhra Pradesh, Gujarat, 2009-10)
- Net En case (Supreme Court 2000)
- Norplant trials (1992?)
- Streptokinase trials (2003)
- Many others

MANHATTAN PROJECT



[T]he line separating good and evil passes not through states, nor between classes, nor between political parties either—but right through every human heart—and through all human hearts ... If only there were evil people somewhere insidiously committing evil deeds, and it were necessary only to separate them from the rest of us and destroy them. But the line dividing good and evil cuts through the heart of every human being.

Aleksandr Solzhenitsyn
The Gulag Archipelago