

# 1947: Nuremberg Code

#### 10 key points

- Voluntary informed consent
- Experiment should be for the good of society, results not obtainable by other means
- Experiment should be based upon prior animal studies



Picture credit: U.S. Holocaust Memorial Museum, Washington, D.C. http://www.ushmm.org/researchidectors/charge/000 Columbia University

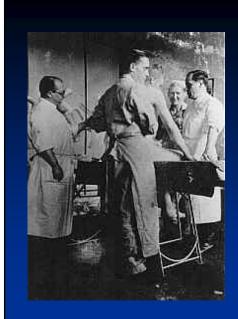


Photo credit: Main Commission for the Investigation of CrimesAagainst the Polish Nation-Institute of National Memory, Warsaw, Poland. http://www.ushmm.org/research/doctors/two.htm

- Physical and mental suffering and injury should be avoided
- There should be no expectation that death or disabling injury will occur from the experiment
- Risk vs. benefit
- Protect subjects against injury, disability, or death
- Only scientifically qualified individuals should conduct human experimentation
- Subject can terminate her/his involvement

## **Declaration of Helsinki**

**Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects** 

- •1953: World Medical Association
- •1964: Guide of ethical principles issued
- •Amended: 1975, 1983, 1989, 1996, 2000

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#### **Issues addressed:**

- Research w/humans should be based on laboratory and animal experimentation
- Experimental protocol should be reviewed by independent committee
- Informed consent
- Research conducted by medically/scientifically qualified individuals
- Risks/benefits
- Privacy of the subject
- Publication of research results

## 1966: Henry Beecher NEJM article

### "Ethics and Clinical Research"

- 22 human research investigations of dubious ethicity
- Discussed:
  - Study design
  - Informed consent
- Some subjects did not know that they were involved in an experiment
- Standard of care treatments withheld
- Patients were harmed by the studies

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# **1974: Congresses Passes the National Research Act**

- Informed consent
- IRBs
- Creates the <u>National Commission for the</u> <u>Protection of Human Subjects of</u> <u>Biomedical and Behavioral Research</u>
  - 1979: Ethical Principles and Guidelines for the Protection of Human Subjects in Research (<u>Belmont Report</u>)

## **1979: Belmont Report**

• Research vs. Practice

#### • Basic Ethical Principles

- Respect for persons
  - Individuals should be treated as autonomous agents
  - Those with diminished autonomy are entitled to protection
- Beneficence
  - Do no harm
  - Maximize possible benefits and minimize possible harms
- Justice
  - "Fairness in distribution"- Who ought to receive the benefits of research and bear its burdens? Copyright 2000 Columbia University

- Applications
  - Informed Consent
    - Information
    - Comprehension
    - Voluntariness
  - Assessment of Risks and Benefits
    - Many kinds of harms and benefits: physical, psychological, legal, social, economic
    - Justification of risk
    - Vulnerable populations
  - Selection of Subjects
    - Individual: Researchers exhibit fairness
    - Social: Distinction between classes able to bear the burden of research participation Copyright 2000 Columbia University

#### Council for the International Organization of Medical Sciences (CIOMS)

- 1982: Proposed International Guidelines for Biomedical Research Involving Human Subjects
- 1991: International Guidelines for Ethical Review of Epidemiological Studies
- 1993: Guidelines revised to address issues raised by vaccines and drugs trials, transnational research, and studies with vulnerable populations



- "Common Rule" -Federal Register (6/18/91); 56: 28002-28032

- 3 Basic Protective Mechanisms for Human Subjects

- (1) IRB Review of Research
- (2) Informed Consent by Subjects
- (3) Institutional Assurances of Compliance

"The most important continuing protection for human subjects is the presence of well-trained and sensitized investigators and IRB members"

> Protecting Human Subjects: Status of Recommendations OIG, DHHS (2000)

