

# **Issues in Protecting Human Research Participants**

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# Session Objectives

- **Review historical issues & their importance to present – day research**
- **Identify ethical issues underlying responsible research conduct**
- **Describe critical factors in the protection of research participants**



# Historical Issues

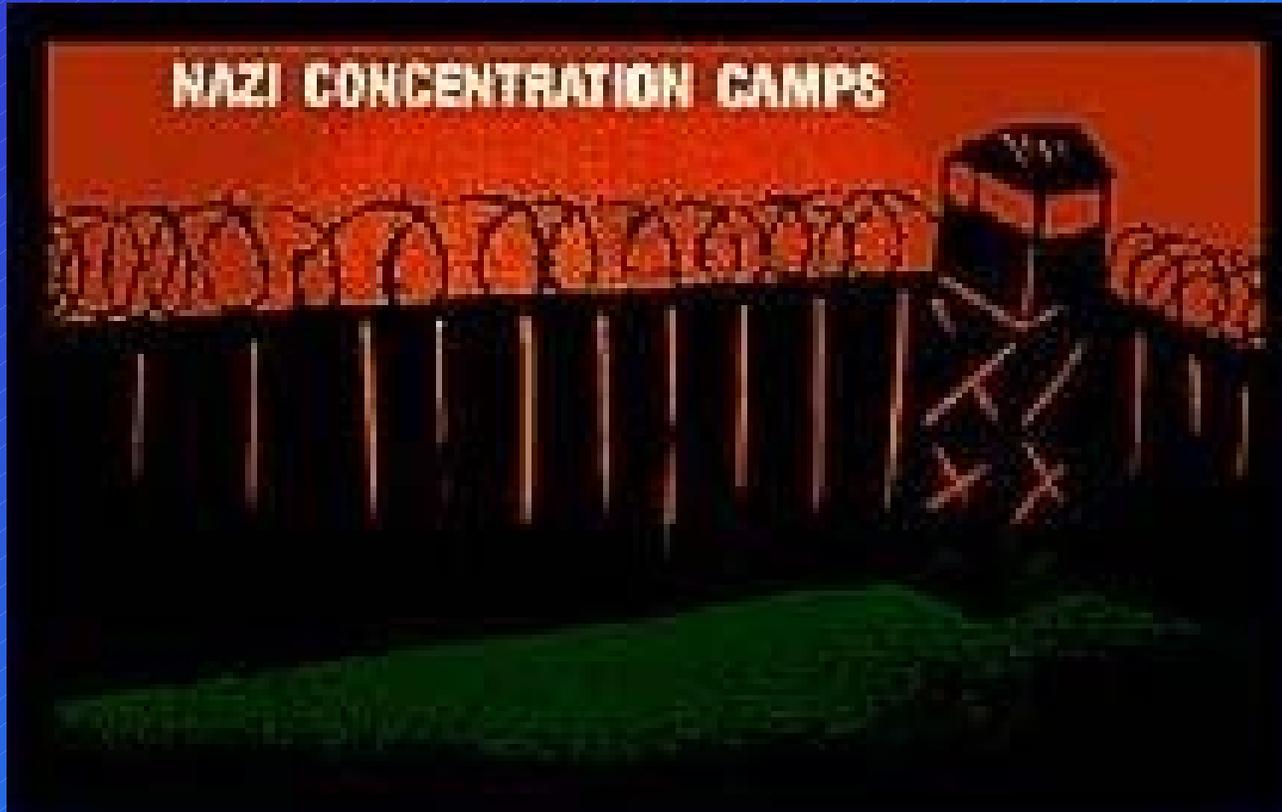


# **Chronology of Events**

**1900 – Prussian Directive Prohibits  
Non – therapeutic Research**

**1931 – Reich Health Council  
Regulations Require  
Participant Consent**

# World War II



**Experimentation**



# Nuremberg Trials



# **Chronology of Events**

**1946 – AMA Rules on Human Experimentation**

**1946 – 1948**

**Illinois State Prison  
Malaria Experiments**

**1959 – Nuremberg Re-evaluated**



# **Chronology of Events**

**1960s**

**Boston University LMRI Research**

**Brooklyn Jewish Hospital**

**Declaration of Helsinki**

**Willowbrook**



# Tuskegee Study 1972



# **Chronology of Events**

**1970s**

**National Research Act - 1974**

**National Commission for  
Protection of Human Subjects**

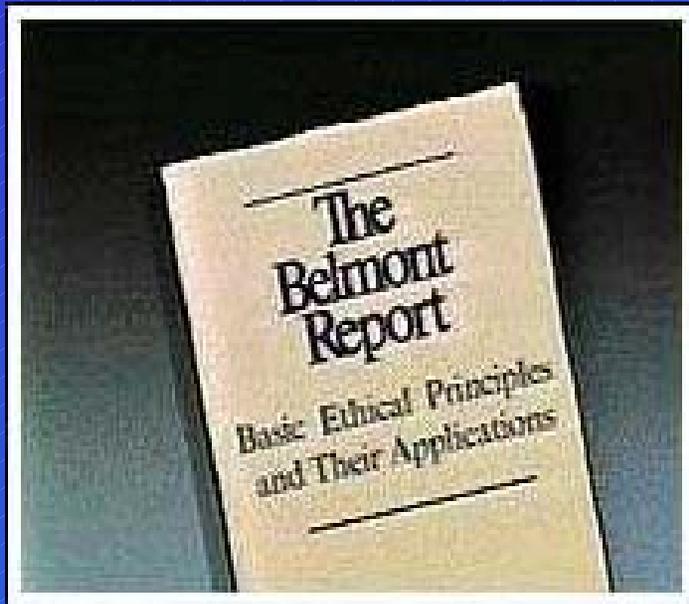
**Federal Regulations on Use of  
Human Research Subjects**



# **Chronology of Events**

**2001**

**Maternal Drug Tests  
South Carolina**



# Ethical Issues

# Respect for Persons

- **Choice, no undue pressure**
- **Protection of vulnerable populations**

# **Beneficence**

- **Maximize benefits**
- **Minimize risks, harm, discomfort**

# Justice

- **Equitable selection**
- **Fair treatment**



# Protecting Research Participants





# Institutional Review Boards



# Purpose of IRBs

- **Protection of participants who enroll in research studies**
- **Adequate protection from harm or basic rights violations**
- **Evaluation/resolution of ethical issues in research studies**



# Role of IRBs

- **Approve/disapprove research activities**
- **Request modifications in research**
- **Conduct continuing reviews**



# IRB Membership

**Mostly volunteers**

**Range of expertise & experience**

**Professional competence to review acceptability of research activities**



# **IRB Evolution in US**

## **National Institutes of Health Policy on Human Subject Protection 1953**

**Protection of adult  
research volunteers**

**Mechanism for  
prospective  
research review**



# IRB Evolution in US

**National Institutes of Health  
Public Health Service Policy  
1966**

**Prospective  
review of research required**



# IRB Evolution in US

**National Research Act 1974**

**Human subject protection policies  
became Federal Regulations**

**IRB review & approval required**

**Informed consent required**



# Review Areas

- **Risks minimized, no unnecessary exposure to harm**
- **Risks reasonable in relation to benefits**



# Review Areas

- **Adequate provisions for safety in research plan**
- **Additional protections for persons in vulnerable populations**



# **Review Areas**

- **Equitable selection of participants**
- **Informed consent procedures**
- **Confidentiality/privacy**



# Vignettes



- 1. Which ethical principle is involved?**
- 2. What risks exist for participants? What benefits exist?**
- 3. What protections should be included?**
- 4. Should this research study be conducted? Why? Why not?**

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