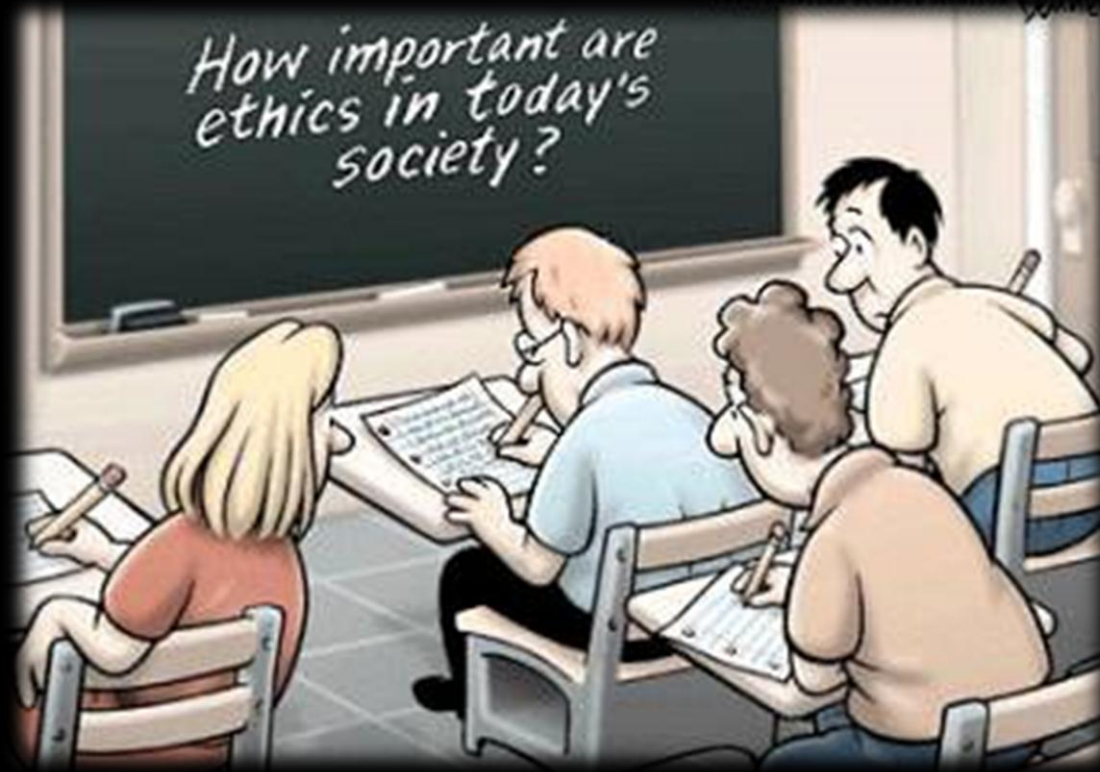


# Human Research Ethics & IRBs



# THE NEED FOR ETHICAL PRINCIPLES

## Medical atrocities of WWII

At Auschwitz *Professor Carl Clauberg* injected chemical substances into wombs of thousands of Jewish and Gypsy women. They were sterilized by the injections, producing horrible pain, inflamed ovaries, bursting spasms in the stomach, and bleeding. Men and women were positioned repeatedly for several minutes between two x-ray machines aimed at their sexual organs. Most subjects died or were gassed immediately because the radiation burns from which they suffered rendered them unfit for work. Men's testicles were removed and sent to Breslau for histopathological examination. (retrieved from <http://www.auschwitz.dk/doctors.htm>)



# **Tuskegee syphilis study 1932 - early 1970s**

**399 African American men  
No informed consent  
Not told what they had ... just “bad blood”  
Penicillin available in 1947 but men not told**

**1972 study terminated when leaked to the press**

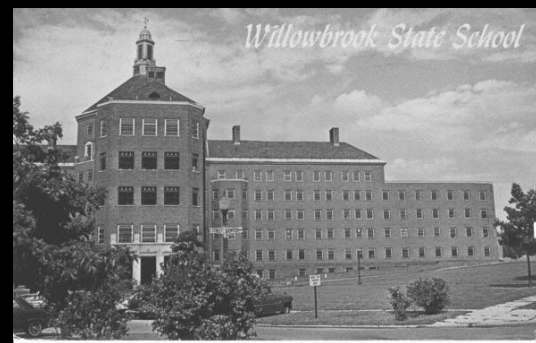
**28 died of syphilis  
100 died from medical complications related to syphilis  
40 wives of participants had been infected with syphilis  
19 children had contracted the disease at birth**



(Courtesy National Archives)

## Willowbrook hepatitis project 1956

**Willowbrook State School was a state-supported institution for children with mental retardation located in central Staten Island in New York City. The school gained notoriety in the 1960s for a medical study conducted there. The school was closed in 1987.**

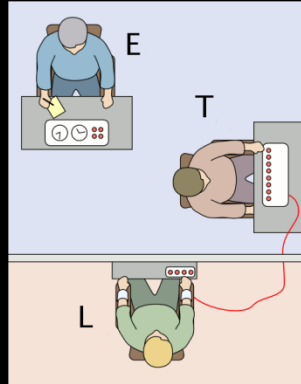
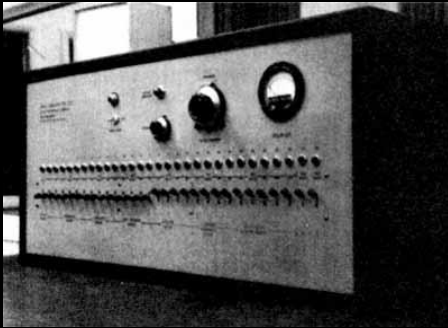


**Between 1963 and 1966, healthy children were intentionally inoculated, orally and by injection, with the virus that causes the disease, then monitored to gauge the effects of gamma globulin in combating it.**

**What made this study particularly unethical?**

# Stanley Milgram's obedience to authority 1963

<http://www.livevideo.com/video/7CB9CBD939C648519A52B18224199D3F/milgram-experiment.aspx>



# Zimbardo prison study 1971

<http://www.youtube.com/watch?v=rmwSC5fS40w>



# HUMAN ETHICS

## Institutional Review Board (IRB)

**Protects rights & well-being of participants & researchers**

**Need to be in compliance with the federal code 45 CFR 46**

**Principles of the Belmont Report**

**Respect for persons**

**Beneficence**

**Justice**

# **BELMONT REPORT**

## **Respect for persons**

**People are autonomous and must be respected**

**Extra protection for vulnerable populations**

## **Beneficence**

**Do no harm: maximize benefits & minimize risks**

## **Justice**

**Selection of participants is fair & justified by the research**

**The people who participate are among those who stand to benefit**

# IRB CONSIDERATIONS

## Minimal Risk

that which we can expect to encounter in everyday life

## Vulnerable Populations

cannot give legal consent

more susceptible to risks, pressure to participate, or coercion

## Informed Consent

What they need to know & when deception is acceptable