

Promoting Human Research through Ethical Research Practices

Ivor Pritchard

Office for Human Research Protections

Ivor.Pritchard@hhs.gov

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Ethics

The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
The Associated Press

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

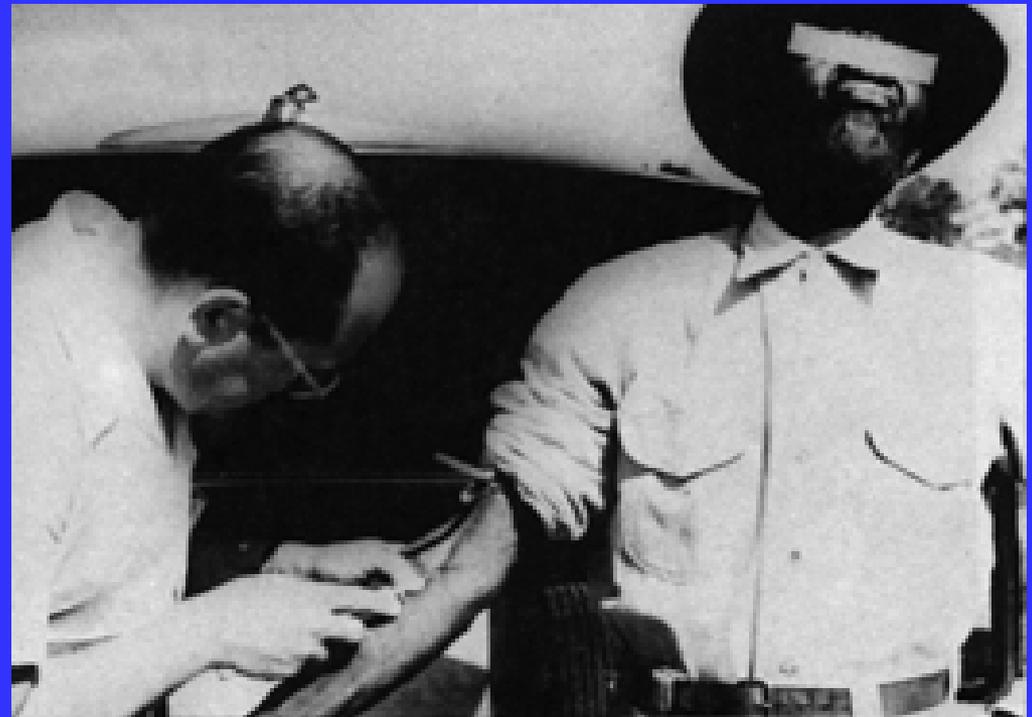
Officials of the health service who initiated the experiment have long since retired. Current officials, who say they

have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,



National Research Act (1974)

“The Commission shall ... conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects...”

The Ethical Principles of The Belmont Report

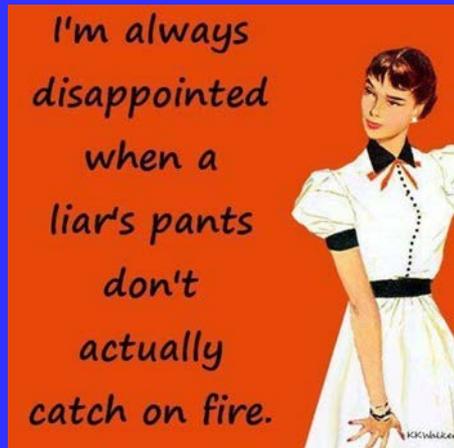
- Respect for Persons
- Beneficence
- Justice

Respect for Persons (1785)

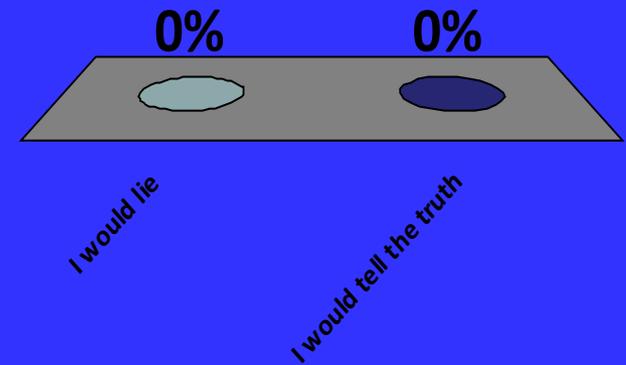


Immanuel Kant,
leading philosopher of
Deontology and the
categorical imperative of
treating every rational
being (person) as a free
rational agent, and as ends
in themselves.

A Classic Problem: Would You Lie If.....?



- A. I would lie
- B. I would tell the truth



Respect for Persons

Principle:

- Subjects as Autonomous Beings
- Protection of Subjects with Limited Autonomy

Applications:

- Informed Consent as Informed, Competent, and Voluntary
- Subjects' Assent and Third Party Consent

Beneficence (1789)

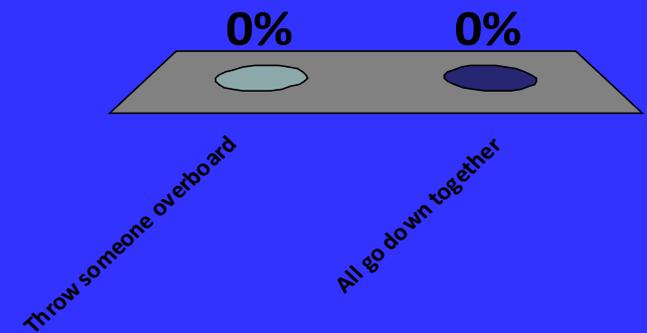


Jeremy Bentham,
leading philosopher of
Utilitarianism and the
*Principle of Utility of the
Greatest Happiness of
the Greatest Number*

A Classic Problem: Sacrificing the Few?



- A. Throw someone overboard
- B. All go down together



Beneficence

Principle:

- Do No Harm
- Maximize Benefits and Minimize Possible Harms

Applications:

- Favorable Risk/Benefit Assessment
- Systematic Analysis and Minimization of Acceptable Risks of Harm

Justice (350 BCE)

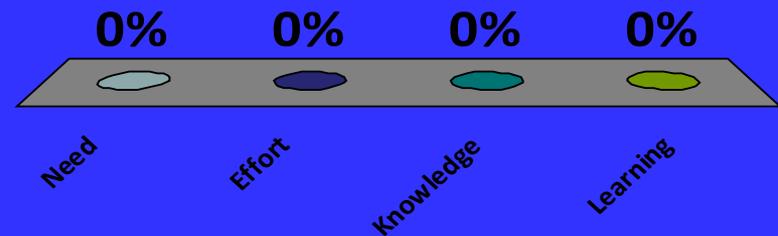


Aristotle,
leading philosopher of
Aristotelian Philosophy
and of the principle of
distributive justice,
distributing goods, rights, ,
burdens, etc., according to
what people deserve.

A Classic Problem: Who Deserves the Award?



- A. Need
- B. Effort
- C. Knowledge
- D. Learning



Justice

Principle:

- Distribute Burdens and Benefits Equitably
- Don't Exploit Vulnerable Populations

Applications:

- Select Individuals and Classes of Subjects Equitably
- Link Burdens to Benefits

Media and Research

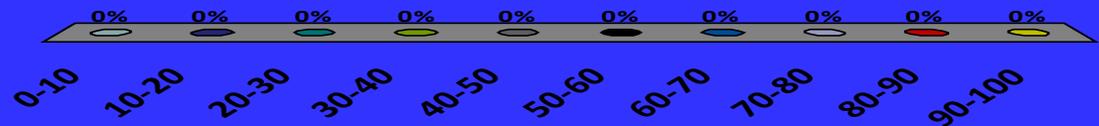
“[Obama] also altered the hospital’s research agenda.

When the human papillomavirus vaccine, which can prevent cervical cancer, became available, researchers proposed approaching local school principals about enlisting black teenage girls as research subjects. Obama stopped that. The prospect of white doctors performing a trial with black teenage girls summoned the specter of the Tuskegee syphilis experiment of the mid-20th century, when white doctors let hundreds of black men go untreated to study the disease.” (International Herald Tribune, 6/18/08)

A short side-trip: Compared to the other people here, how safe a driver are you?

{Estimated Position in Sample (Percentiles)}

- A. 0-10
- B. 10-20
- C. 20-30
- D. 30-40
- E. 40-50
- F. 50-60
- G. 60-70
- H. 70-80
- I. 80-90
- J. 90-100



****Low Percentiles: LESS SAFE DRIVING**
****High Percentiles: MORE SAFE DRIVING**

How safe a driver are you?

88% of US respondents and 77% of Swedish respondents believed themselves to be safer than the average driver.

(Svenson, 1981)

Troubling Biomedical Research

- Trial to Assess Chelation Therapy (TACT)
- Thiazolidinedione Intervention With Vitamin D Evaluation (TIDE)
- Phase 1 study of TGN1412 in Britain
- Red Cell Storage Duration Study in cardiac surgery patients (RECESS)
- Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT)
- Phase 1 Study of an FAAH inhibitor in France

Troubling Behavioral Research Activity

- Facebook Study of Emotional Contagion
- OkCupid Study of Mismatched Match-making
- CIA Experimental Interrogation Research
- Study of Canvassers' Effect on Opinions about Same Sex Marriage Equality
- Montana Study of Election Guide and Voting
- 'Ban' on Gun Violence Research by the Centers for Disease Control

Questions or Comments?