



OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

The Principles of the Belmont Report and the Ethics of Human Research

Ivor A. Pritchard, Ph.D.

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Disclosure and Disclaimer: Ivor Pritchard

I have a relevant professional relationship with respect to this educational activity with the following organization:

*The Office for Human Research Protections (OHRP)
U.S. Department of Health and Human Services
(Senior Advisor to the Director of OHRP)*

The opinions expressed are those of the presenter and do not necessarily reflect the policy of the U.S. Department of Health and Human Services.



Who Am I?

- A Philosopher
- A Government Bureaucrat
- 71 years old
- Male
- Heterosexual
- White, Anglo-Saxon Protestant
- High Socio-Economic Status



Where Did the Belmont Principles Come From?

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.

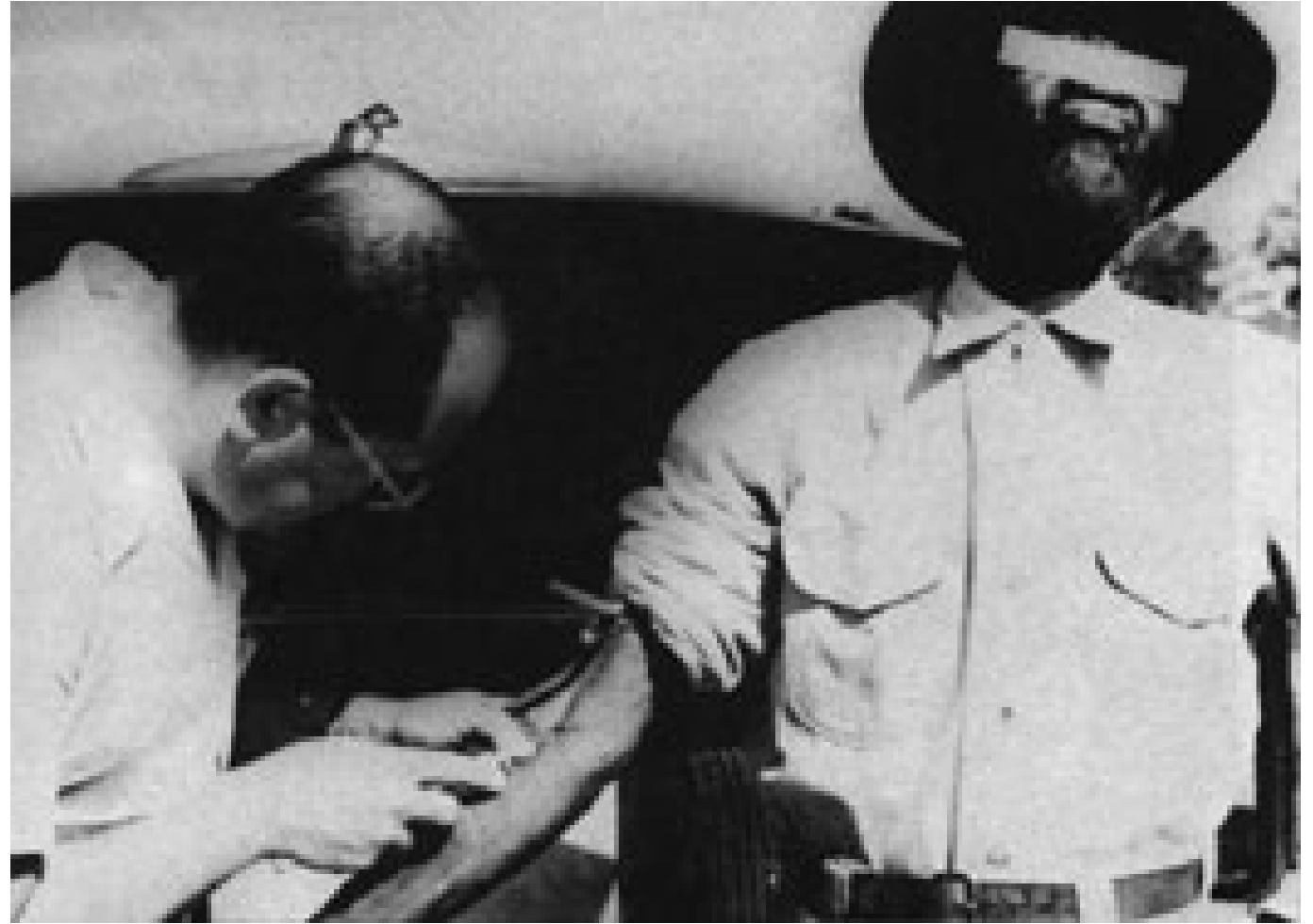
Officials of the health service who initiated the experiment have long since retired. Current officials, who say they

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,



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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...”



National Research Act (cont.)

“...the Commission shall consider at least the following:

(ii) The role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects.

(iii) Appropriate guidelines for the selection of human subjects for participation in biomedical and behavioral research.

(iv) The nature and definition of informed consent in various research settings.”



The Ethical Principles of The Belmont Report (1979)

- Respect for Persons
- Beneficence
- Justice



Respect for Persons (1785)

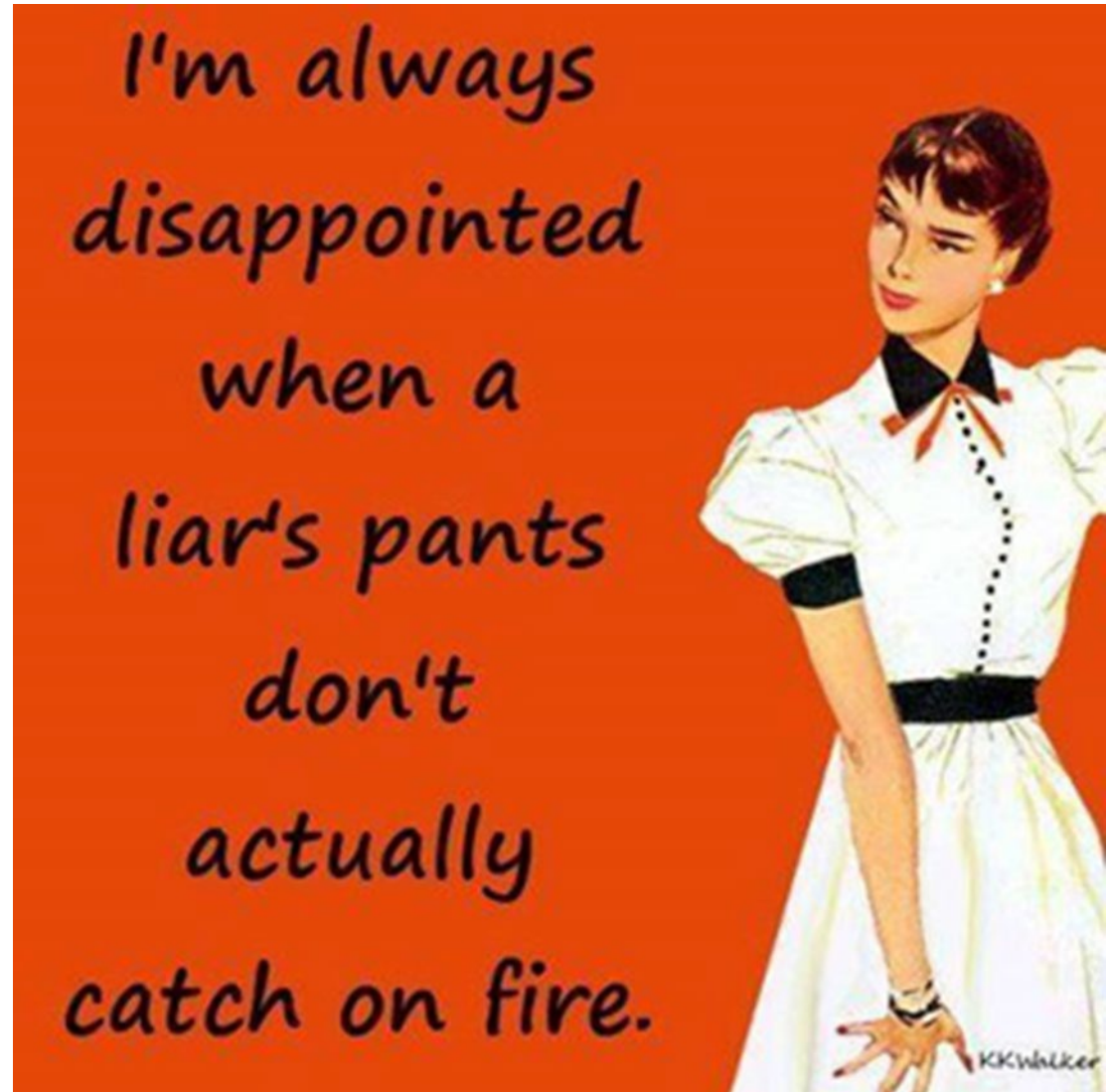


Immanuel Kant,
leading philosopher of
Deontology and the *categorical imperative* of treating every rational being (person) as a free rational agent, and as ends in themselves.



A Classic Ethical 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



The Regulatory Criterion Reflecting Respect for Persons

“Informed Consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by 46.116”
(.111(a)(4))



Beneficence (1789)



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

A Classic Ethical Problem: Sacrificing the Few?

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



Principal Issues for the Principle of Beneficence

- Are all kinds of benefits/harms of equal value, or are some kinds of benefits/harms preferable over others?
- Should future individuals or populations be counted, or only those of the present?



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



The Regulatory Criteria Reflecting Beneficence

“Risks to subjects are minimized: (i) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.” (.111(a)(1))

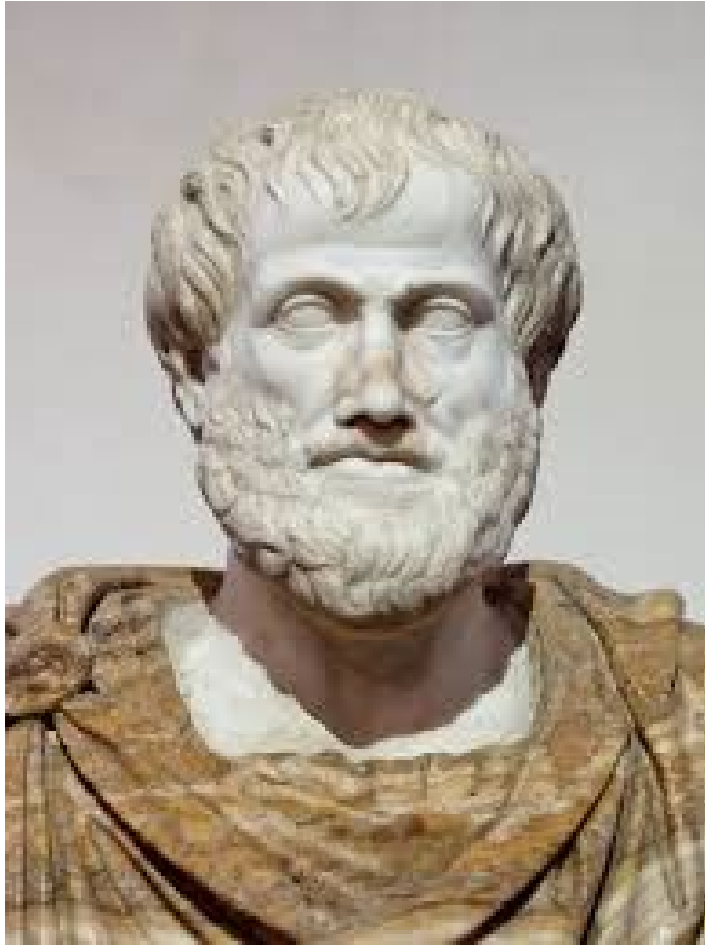


The Regulatory Criteria Reflecting Beneficence (II)

“Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result....” (.111(a)(2))



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 Ethical Problem: Who Deserves the Scarce Benefit?

- A. Equal Chance
- B. Need
- C. Effort
- D. Societal Contribution
- E. Merit



Justice

Principle:

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

Applications:

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



The Regulatory Criterion Reflecting Justice

“Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.” (.111(a)(3))



The Belmont Principles and the American Value System

"We hold these truths to be self-evident, that all men [!?] are created **equal**, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, **Liberty** and the **pursuit of Happiness**." (Declaration of Independence, 1776)

Equality, Liberty, and Happiness
Justice, Respect, and Beneficence



Do the Belmont Principles Solve All the Ethical Issues in Human Subjects Research?

- Sometimes
- Not completely, if the Belmont Principles imply opposing answers
- Not completely, if new or controversial questions about applications arise because of social change
- Not completely, if new or controversial questions about applications arise because of changes in the research landscape
- [But Don't Throw Them Out!]



If the Belmont Principles Suggest Opposing Answers

- Respect for Persons vs. Beneficence in Large Scale Standard of Care/Comparative Effectiveness Studies:
 - Raises the question of how much risk it is ethical to expose someone to without their consent.
 - Raises the question of whether people have an obligation to participate in research.
- Justice vs. Beneficence in research efforts to address health disparities.



Causes of Death (20-24) by Race & Sex (2020)

Sex/Race/ Ethnicity	Accidents: Rate/100,000	Suicide: Rate/100,000	Homicide: Rate/100,000
Hispanic Male	76	22	23
Hispanic Female	18	5	4
White Male	69	32	6
White Female	28	7	3
Black Male	82	29	140
Black Female	34	5	18
Asian Male	26	17	6
Asian Female	7	8	[Rank #8]
American Indian Male	123	77	29
American Indian Female	64	21	[Rank #3]



If Social Change Leads to New or Controversial Questions

- COVID 19 Pandemic
 - Can a disaster response create an obligation to participate in research?
 - Is there a limit to the level of risk exposure in research with informed consent?
- Black Lives Matter Movement
- Dobbs vs. Jackson Women's Health Organization
- LePage vs. Center for Reproductive Medicine



Should Individual Subjects from Different Social Groups Be Treated Differently in Research?

- Individuals from social groups that have been/are the objects of historical discrimination (e.g., by race, sex, gender identity, indigenous identity)
- Children
- Fetuses
- Embryos
- People with impaired decision-making
- Subjects engaged in criminal behavior (e.g., illegal drug use)
- Prisoners
- Members of the Military/Veterans
- Public Officials



Who Should Control the Direction of Research?

Procedural Justice

The Havasupai agreed to provide samples to enable a research study addressing the frequency of diabetes in the Tribe. Later secondary studies were proposed to examine questions related to mental disease in the Tribe and to study their geographical ancestry. Once they learned of these studies, the Havasupai objected that the studies were potentially stigmatizing and inconsistent with Havasupai traditional beliefs, and opposed them. (Harmon, 2010)



Should Research Contribute to Group Harm or Stigma?

Researchers analyzed data from two American national data sets, and found:

- Teachers and nonteachers hold pro-White implicit and explicit racial biases.
- Differences between teachers and nonteachers were negligible or insignificant.

“Teachers Are People Too: Examining the Racial Bias of Teachers Compared to Other American Adults” (*Educational Researcher*, May 2020)



If Changes in the Research Landscape Pose New Questions: Technology Is Changing the World



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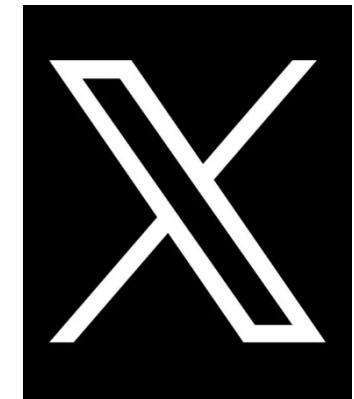
The Technological Ease of Violent Behavior



Technology Is Changing the Research Landscape: The Technological Ease of Sharing Information



The Virtual Marketplace of Information



The Technological Ease of Mining Data



And then There's AI and ChatGPT.....

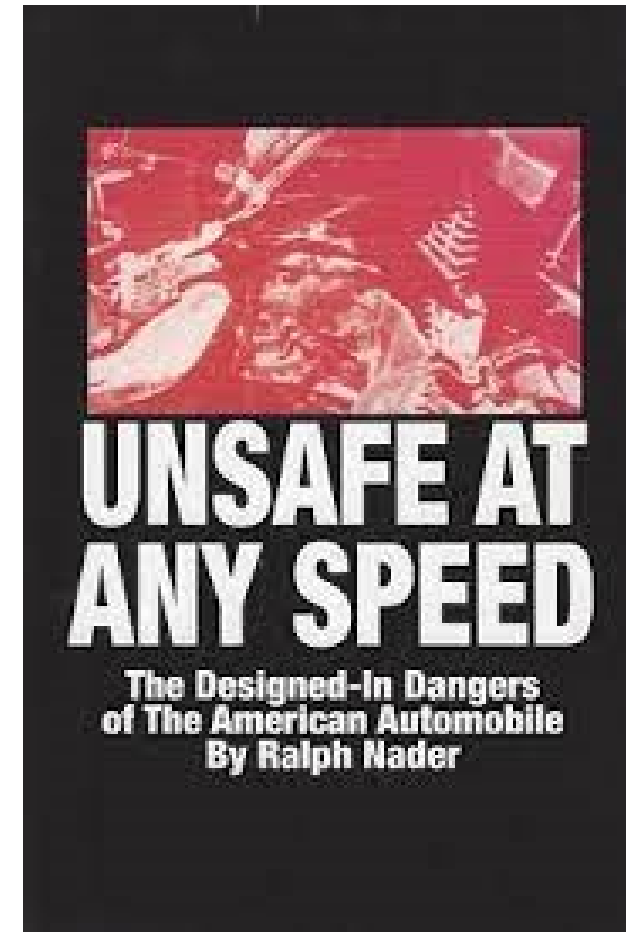
“AI’s potential depends on how it’s used, Califf said. “It could be used for tremendous gain, or it could be used for tremendous harm.”(5/31/23)

“Mitigating the risk of extinction from AI should be a global priority alongside other societal-scale risks such as pandemics and nuclear war.” (Center for AI Safety, 5/30/23)

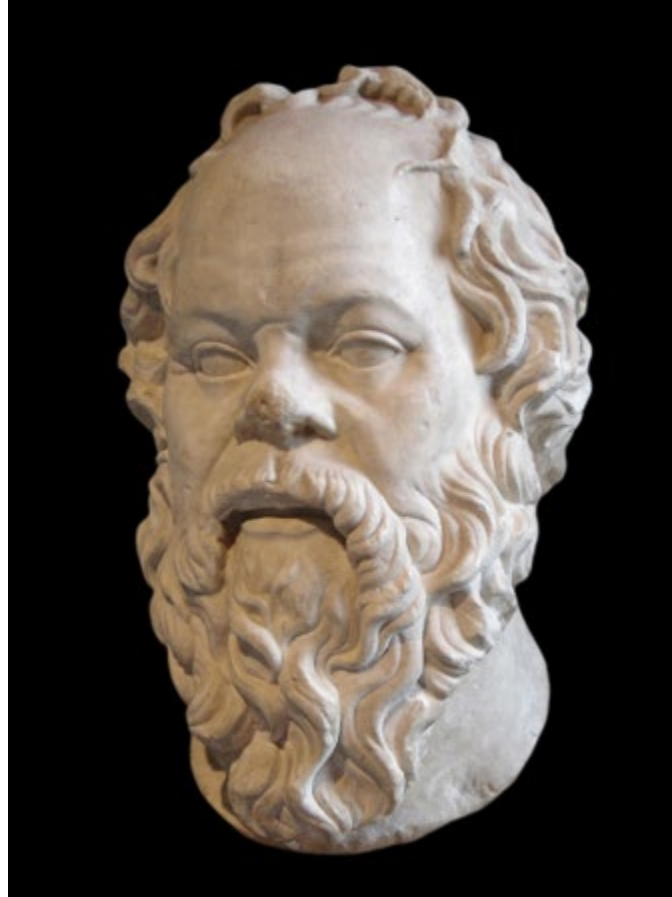


Who Is Responsible for the Consequences of the Technologies' Research Use?

- The Producer of the Technology?
- The User of the Technology?
- The Regulators of the Technology?
- The Society that Allows the Technology?



Questions?



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